

**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, 2022
or

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

For the transition period from _____ to _____
Commission File Number: **001-00100**



THERAPEUTICSMD, INC.

(Exact name of Registrant as specified in its Charter)

Nevada

(State or other jurisdiction
of incorporation or organization)

87-0233535

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

**951 Yamato Road, Suite 220
Boca Raton, Florida**

(Address of principal executive offices)

33431

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022, 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 \$87,323,238.

As of April 5, 2023, there were outstanding 9,953,290 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 2023 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, 2022.

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Part I

Item 1. Business

Overview

Throughout this Annual Report on Form 10-K ("2022 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"), and BocaGreenMD, Inc., a Nevada corporation ("BocaGreen").

TherapeuticsMD owns or has rights to trademarks, service marks, or trade names that were previously used in connection with the operation of its business, or are now licensed by another party, including TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, vitaCare™, BIJUVA®, and IMVEXXY®, which are protected under applicable intellectual property laws and are the property of the Company. This 2022 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 2022 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 2022 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 2022 10-K Report, this information could prove to be inaccurate as a result of a variety of matters.

Forward-looking statements

This 2022 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, and other plans and objectives for future operations, and assumptions and predictions about future demand, marketing, expenses and sales are all forward-looking statements. These statements may be found in the items of this 2022 10-K Report entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this 2022 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 2022 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, competition from other businesses, market and general economic factors, and the other risks discussed in Item 1A of this 2022 10-K Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this 2022 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 2022 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 2022 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 was previously 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.

In December 2022, we changed our business to become a pharmaceutical royalty company, primarily collecting royalties from our licensees. Our Company is no longer engaging in research and development or commercial operations and is transforming to a virtual company with limited infrastructure. On December 30, 2022 (the "Closing Date"), the Company completed a transaction (the "Mayne Transaction") with Mayne Pharma LLC, a Delaware limited liability company ("Mayne Pharma") and subsidiary of Mayne Pharma Group Limited, an Australian public company, pursuant to which the Company and its subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize the Company's IMVEXXY, BIJUVA and prescription prenatal vitamin products sold under the BocaGreenMD® and vitaMedMD® brands (collectively, the "Licensed Products") in the United States and its possessions and territories, (ii) assigned to Mayne Pharma the Company's exclusive license to commercialize ANNOVERA® (together with the Licensed Products, collectively, the "Products") in the United States and its possessions and territories, and (iii) sold certain other assets to Mayne Pharma in connection therewith.

Pursuant to a License Agreement, dated December 4, 2022, between the Company and Mayne Pharma (the "Mayne License Agreement"), the Company granted Mayne Pharma, on the Closing Date, (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain adjustments, for a period of 20 years following the Closing Date. The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimum annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below (the "Minimum Annual Royalty"). Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

Pursuant to a Transaction Agreement, dated December 4, 2022, between the Company and Mayne Pharma (the "Transaction Agreement"), the Company sold to Mayne Pharma, at closing, certain assets for Mayne Pharma to commercialize the Products in the United States, including the Company's exclusive license from the Population Council to commercialize ANNOVERA (the "Transferred Assets").

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the Mayne License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment (as defined below) and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended.

On the Closing Date, the Company and Mayne Pharma entered into Amendment No. 1 to the Mayne License Agreement (the "Mayne License Agreement Amendment"). Pursuant to the Mayne License Agreement Amendment, Mayne Pharma agreed to pay the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise be received pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition, the parties agreed that Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement, including the Company's minimum payment obligations thereunder.

This action represented a shift in our business and therefore, the related assets and liabilities associated with commercial operations are classified as discontinued operations on our consolidated balance sheets

and the results of operations have been presented as discontinued operations within our consolidated statements of operations and comprehensive income (loss) for all periods presented.

See Note 2 - Discontinued Operations to the consolidated financial statements included in this Annual Report on Form 10-K for further details.

The Company also has 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.

In connection with the Company's transformation into a pharmaceutical royalty company, the termination of our executive management team (except for Mr. Marlan Walker, our former General Counsel and current Chief Executive Officer) and all other employees was completed by December 31, 2022. Severance obligations for all employees other than executive officers were paid in full in the first quarter of 2023 and severance obligations for terminated executive officers will be paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022, we employed one full-time employee primarily engaged in an executive position. We have engaged external consultants, including certain former members of our management team, who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations.

vitaCare divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. ("vitaCare") with the sale of all vitaCare's issued and outstanding capital stock (the "vitaCare Divestiture"). We received net proceeds of \$142.6 million, net of transaction costs of \$7.2 million, and we recognized a gain on sale of business of \$143.4 million. Included in the net proceeds amount was \$11.3 million of customary holdbacks as provided in the stock purchase agreement (the "Purchase Agreement"), which is recorded as restricted cash in the consolidated balance sheets. The restricted cash was held by an escrow agent and was released to us in March 2023. Additionally, we may receive up to an additional \$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. We will record the contingent consideration at the settlement amount when the consideration is realized or realizable.

The Purchase Agreement contains customary representations and warranties, covenants, and indemnities of the parties thereto. The commitments under a long-term services agreement related to vitaCare was transferred to Mayne Pharma as part of the Mayne Transaction. In addition, under the Mayne License Agreement Amendment, Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to us by \$1.5 million in consideration of Mayne Pharma assuming our obligations under the long-term services agreement related to vitaCare.

The pre-divestiture operations of vitaCare were reclassified to discontinued operations in December 2022 when the Company transitioned to becoming a royalty company and licensing its products to Mayne Pharma.

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.

As of the date of the filing of this Annual Report, the future extent to which the COVID-19 pandemic may continue to materially impact our financial condition, liquidity, or results of operations remains uncertain and difficult to predict. 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.

Our business model

We changed our business in 2022, by out-licensing our products and collecting royalties, after granting an exclusive license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD® and vitaMedMD® brands in the United States and its possessions and territories and assigning the Company's exclusive license to commercialize ANNOVERA in the United States and its possessions and territories to Mayne Pharma.

The Company also has license agreements with strategic partners to commercialize IMVEXXY and BIJUVA outside of the U.S. In July 2018 we entered into the Knight License Agreement pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel. In June 2019, we entered into the Theramex License Agreement 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.

Currently, we collect royalties on sales of ANNOVERA, IMVEXXY, and BIJUVA under the TherapeuticsMD brand, prescription prenatal vitamins under our vitaMedMD brand name, and authorized generic formulations of our prescription prenatal vitamin products under BocaGreenMD brand name.

We expect that the primary source of our future revenue will be based on payments we may receive for milestones and royalties related to these products.

The Company no longer has research and development, commercial, manufacturing and finance infrastructure and operates as a virtual corporation with no material capital investment in fixed assets.

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 ethynodiol (EE). There are 10 different progestins that have been used in contraceptives sold in the U.S. The progestin component provides most of the contraceptive effect, while the estrogen component primarily provides cycle control, for example, minimizing bleeding or spotting between cycles. The progestin exerts its contraceptive effect by inhibiting ovulation, or release of an egg from the ovary, and by thickening cervical mucus. Thickening cervical mucus helps to prevent sperm entry into the upper genital tract. The estrogen component, in addition to providing cycle control, makes a small contribution to contraception by decreasing the maturation of the egg in the ovary. 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 reversible 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 vasomotor symptoms ("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 Licensed Menopause portfolio

/IMVEXXY

On December 30, 2022, we granted an exclusive license to commercialize the Company's IMVEXXY in the United States and its possessions and territories to Mayne Pharma. 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). We previously granted licenses to commercialize the Company's IMVEXXY product outside of the United States to Theramex and Knight.

As part of the FDA's approval of IMVEXXY, we 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 would have been required to provide progress reports to the FDA on an annual basis. The obligation to conduct this study was transferred to Mayne Pharma as part of the License Agreement.

BIJUVA

On December 30, 2022, we granted an exclusive license commercialize the Company's BIJUVA in the United States and its possessions and territories to Mayne Pharma. 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 previously granted licenses to commercialize the Company's BIJUVA product outside of the United States to Theramex and Knight.

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.

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.

Our licensed prenatal vitamin products

On December 30, 2022, we granted an exclusive license to commercialize, in the United States and its possessions and territories, 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 to Mayne Pharma.

License agreements

Mayne license agreement

Pursuant to the Mayne License Agreement, on the Closing Date the Company granted Mayne Pharma (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain adjustments, for a period of 20 years following the Closing Date. The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimum annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

Pursuant to the Transaction Agreement, the Company sold to Mayne Pharma, at closing, certain assets for Mayne Pharma to commercialize the Products in the United States, including the Company's exclusive

license from the Population Council to commercialize ANNOVERA.

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended.

On the Closing Date, the Company and Mayne Pharma entered into the Mayne License Agreement Amendment. Pursuant to the Mayne License Agreement Amendment, Mayne Pharma agreed to pay the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition, the parties agreed that Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement, including the Company's minimum payment obligations thereunder.

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.

ANNOVERA

On December 30, 2022, we assigned the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma. The segestrone 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 segestrone 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. We 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. 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 May 2022, the FDA approved the supplemental NDA for ANNOVERA. With the FDA approval of the supplemental NDA, we expect the third-party contract manufacturer will be able to supply sufficient ANNOVERA to better meet customer demand. Our obligations to perform the post-approval study have been transferred to Mayne Pharma as part of the Mayne License Agreement.

We believe that ANNOVERA competes across all the contraception options for women, especially for those women seeking a long-lasting option without a procedure.

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

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.

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 and amortized over the remaining useful life over which the license rights contributed directly or indirectly to our cash flows. On December 30, 2022, we assigned the ANNOVERA license to Mayne Pharma. The rights and obligations under the Population Council License Agreement have been transferred to Mayne Pharma and will revert back to us upon certain events. For additional information, see "Note 5. License rights and other intangible assets" to the consolidated financial statements included in this 2022 10-K Report.

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 had 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 was to be offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. 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. Our obligations to perform the post-approval study have been transferred to Mayne Pharma as part of the Mayne License Agreement. We believe, Mayne Pharma is 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 the NDA holder for ANNOVERA.

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 Mayne Pharma, or the date following such expiration that follows a continuous period of six months during which Mayne Pharma has 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 Mayne Pharma on 180 days' prior notice to the Population Council.

Sales concentration

Our business model is dependent on third parties achieving specified milestones and product sales. For information on the concentration of licenses of our products, see "Note 10. Revenue" to the consolidated financial statements included in this 2022 10-K Report. Currently, the Company collects license revenue from 3 licensees.

Seasonality

The pharmaceutical markets in which we license our products are not subject to seasonal sales fluctuations. However, our license 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 licensed products

As of December 30, 2022, we were no longer responsible for any manufacturing and have no manufacturing contracts. All manufacturing responsibility has been transferred to Mayne Pharma.

Mayne Pharma sources third-party contract manufacturing organizations ("CMOs"), for the commercial supply of the 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. The CMOs are responsible for the manufacture of licensed products in accordance with the product specifications and applicable regulatory requirements. There are 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. If Mayne Pharma is unable to obtain sufficient quantities of drugs or receive raw materials in a timely manner, it could be required to delay its 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 our licensees from, successfully commercializing, and marketing our products" below for further discussion related to our dependence on third-party CMOs.

Mayne Pharma uses third-party manufacturers to manufacture and package the vitamin and supplement products that we licensed to them, as well as meet applicable contract and regulatory requirements. They currently obtain all 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, Mayne Pharma is dependent on Lang and its subcontractors for the manufacture of our vitamin and supplement products. We believe that Lang maintains multiple supply and purchasing relationships throughout the raw materials marketplace to provide an uninterrupted supply of products to meet Mayne Pharma's manufacturing requirements.

While we used Lang for the manufacturing of our vitamins and supplements prior to licensing them to Mayne Pharma, we experienced no material difficulties in obtaining the vitamin and supplement products we needed in the amounts we required and do not anticipate those issues in the future. At present, we believe the relationship with Lang is established and reliable, and to the best of our knowledge, Mayne Pharma continues to use Lang as its third-party manufacturer for most of the licensed vitamins and supplements.

Quality control for our products

Our licensed products for the U.S. market are required to be manufactured in accordance with the FDA's current Good Manufacturing Practice, or cGMPs. The third-party suppliers and manufacturers of our licensed

products are also responsible for continued compliance with cGMP requirements. As of December 30, 2022, we are no longer involved in quality control activities, which have been transferred

to Mayne Pharma. To comply with these drug commercialization standards, we believe that Mayne Pharma has personnel with pharmaceutical development, manufacturing, and quality assurance experience who are responsible for the relationships with the suppliers of our licensed products. We assigned our commercial supply agreements with Catalent to Mayne Pharma, and to the best of our knowledge, Catalent continues to manufacture the commercial supply for both IMVEXXY and BIJUVA. We also assigned our commercial supply agreement with Sever Pharma Solutions to Mayne Pharma. To the best of our knowledge, Sever Pharma Solutions continues to manufacture the commercial supply for ANNOVERA. For the prenatal vitamins, we believe that Mayne Pharma continues to collaborate 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 licensed products.

Research and development

As of December 30, 2022, we no longer conduct any research and development activities. Historically, our product development programs have been concentrated in advanced hormone therapy pharmaceutical products.

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, 2022, we have 54 issued domestic patents and 47 issued foreign patents as well as 60 pending patent applications (47 foreign and 13 domestic), including:

- 22 issued domestic patents and 19 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, China, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- 22 issued domestic patents (20 utility and two design) and 25 foreign patents (16 utility and nine design) that relate to IMVEXXY. These patents establish an important intellectual property foundation for IMVEXXY and are owned by us. The domestic patents will expire between 2032 and 2034. 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 one issued foreign patent that relate to our transdermal-patch candidates, which are owned by us. The domestic utility patent will expire in 2032. The foreign patent will expire in 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 two 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.

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, including those licensed by Mayne Pharma, Knight and Theramex with our licensees to the extent permitted under their respective license agreements. 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 to that intellectual property.

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.

Mayne Pharma licensed US patents and trademarks for our commercial products. Under the terms of the Mayne License Agreement, Mayne Pharma exclusively took over prosecution of our US patent and trademark portfolio and enforcement of our licensed patents and trademarks.

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.

Post-Approval Regulation

Mayne Pharma is required to comply with several post-approval requirements for our currently approved drug products. We no longer have responsibility for any post-approval requirements. As the holder of an approved NDA, Mayne Pharma is 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 contracted for the commercial supply of the 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 the BIJUVA product was identified in Catalent's response to the Form FDA 483. 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.

Our licensees rely, and expect to continue to rely, on third parties to produce commercial quantities of our licensed drugs. Future FDA and state inspections may identify compliance issues at the facilities of the manufacturers of our licensed products 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.

Regulatory exclusivity

There are two types of NDAs available under Section 505(b) of 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 3 of this 2022 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 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.

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. Our licensees and the licensed products 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 licensees’ ability to operate and our ability to receive licensing revenues 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 the business activities of the entities with whom we do business 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. If our past 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, our licensees and the licensed products 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.

Employees

In connection with the Company's transformation into a pharmaceutical royalty company, the termination of our executive management team (except for Mr. Marlan Walker, our former General Counsel and current Chief Executive Officer) and all other employees was completed by December 31, 2022. Severance obligations for all employees other than executive officers were paid in full in the first quarter of 2023 and severance obligations for terminated executive officers will be paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022, we employed one full-time employee primarily engaged in an executive position. We have engaged external consultants, including certain former members of our management team, who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations.

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 2022 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 2022 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:

- We currently derive all of our revenues from royalties related to sales of our products, and the failure of our licensees 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 have incurred net losses in the past and there are no assurances we will be able to maintain or increase profitability in the future.
- There is substantial doubt about our ability to continue as a going concern.
- We could be affected by transitions in our senior management team.
- The dependence upon third parties for the manufacture and supply of our women's healthcare products may cause delays in, or prevent our licensees from, successfully commercializing and marketing our products.
- The commercial success of our products will depend upon gaining and retaining significant market acceptance of these products among physicians and payers.
- Coverage and reimbursement may not be available for our products, which could make it difficult for our licensees to sell our products profitably.
- Time and costs associated with winding down our general and administrative, commercial, and research and development activities may be significant.
- Our future success depends on our ability to attract and retain qualified personnel.

- Our financial condition and results of operations for 2021 and 2022 were, and our financial condition and results of operations for 2023 and beyond may be, adversely affected by the ongoing COVID-19 (coronavirus) pandemic and any future pandemics or epidemics.
- Licensing of intellectual property involves complex legal, business and scientific issues, and disputes could jeopardize our rights under such agreements.
- Our products and our licensees are subject to extensive government regulation.
- We must rely on Mayne Pharma to prosecute, file lawsuits or take other actions to protect or enforce our intellectual property and there can be no assurance they will be take such actions or be successful.
- 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 the distribution channels of our licensees.
- Any failure of our licensees to adequately maintain a sales force will impede our growth.
- Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Risks related to our business

We currently derive all revenue from royalties related to sales of our women's healthcare products, and the failure of our licensees to maintain or increase sales of these products could have an adverse effect on our business, financial condition, results of operations, and growth prospects.

Following the Mayne Transaction, we derive all revenue from royalties related to sales 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 our licensees will be able to sustain such sales or that such sales will grow. In addition to other risks described herein, the ability of our licensees 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 their 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 our licensees may implement in the future;
- changes to the licensed products' labels and labeling, including new safety warnings or changes to boxed warnings, that further restrict how our licensees market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

If revenue from royalties related to sales of our products does not increase, we may be required to seek to raise additional funds, which could have an adverse effect on our business, financial condition, results of operations, and growth prospects.

We have incurred net losses in the past and there are no assurances we will be able to maintain or increase profitability in the future.

In 2022, we recognized a net income of \$112.0 million due to the net proceeds from the Mayne Pharma Transaction and vitaCare divestiture exceeding our costs and expenses. We utilized a significant portion of net proceeds to repay borrowings and redeem our preferred stock. In the past, we have incurred recurring net losses, including net losses of \$172.4 million and \$183.5 million for 2021 and 2020, respectively. As of December 31, 2022, our stockholders' equity was \$35.1 million. 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 costs associated with the wind down of our historical business as well as the ongoing costs of being a public company. As a result, we may not maintain or increase profitability. 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, merge,

consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

There is substantial doubt about our ability to continue as a going concern.

Our current liquidity position raises substantial doubt about our ability to continue as a going concern and Grant Thornton LLP, our independent registered public accounting firm for the fiscal year ended December 31, 2022, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2022, indicating such. Our ability to continue as a going concern may depend on our ability to obtain additional capital as well as our ability to minimize operational expenses, including any potential net working capital adjustments relating to the Mayne Transaction. As substantial doubt about our ability to continue as a going concern exists, our ability to finance our operations through the sale and issuance of debt or equity securities or through bank or other financing could be impaired. Our ability to obtain financing on reasonable terms is subject to factors beyond the Company's control, including general economic, political, and financial market conditions. The capital markets have in the past experienced, are currently experiencing, and may in the future experience, periods of upheaval that could impact the availability and cost of equity and debt financing and there can be no assurance that such financing will be available on terms commercially acceptable to the Company, or at all. If we are unable to improve our liquidity position, we may not be able to continue as a going concern.

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. In December 2022, following the Mayne Transaction, all of our top executives, except for our former General Counsel, were terminated, and our former General Counsel was appointed as Chief Executive Officer.

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 may cause delays in, or prevent our licensees from, successfully 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 specifications and in compliance with applicable regulatory requirements, including the FDA's current Good Manufacturing Practice ("cGMPs"). We entered into long-term supply agreements with Catalent Pharma Solutions, LLC for the commercial supply of IMVEXXY and BIJUVA which have been assigned to Mayne Pharma. We also entered into a long-term supply contract with QPharma AB, now known as Sever Pharma Solutions, for ANNOVERA, which contract was also assigned to Mayne Pharma. We depended 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.

Regulatory requirements could pose barriers to the manufacture of our women's healthcare products. All of our existing products are manufactured by third-party contract manufacturing organizations ("CMOs"). These CMOs are required 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 the manufacturers of our product cannot successfully manufacture material that conforms to specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, regulatory submissions related to our products 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, our licensees may need to find alternative manufacturing facilities, which would result in substantial disruptions of sales of our products. In addition, manufacturers of our products 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 the manufacturers of our products to comply with applicable cGMP regulations or other applicable requirements could result in sanctions being imposed on us or our licensees, 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. Our licensees may be able to enter into long-term agreements with alternative manufacturers, or do so on commercially reasonable terms, and if they 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 to the delay or other detriment of our products, or otherwise do not satisfactorily perform according to the terms of their agreements. Finally, we could experience manufacturing delays or interruptions because of the ongoing COVID-19 pandemic.

We have also experienced a greater than expected amount of raw materials for ANNOVERA being out of specification. If any of the third-party CMOs of our products or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of their agreements, or do not devote sufficient time, energy, and care to providing our manufacturing needs, or if any manufacturing specification modifications that we or Mayne Pharma 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 licensees 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 experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of their agreement between, 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, which could impair our licensee’s ability to supply our products at the levels required for commercialization and prevent or delay their successful commercialization.

The commercial success of our existing products 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 licensee’s 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 our licensees 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 royalties related to sales of these products. In addition, the efforts of our licensees to educate the medical community and third-party payers on the benefits of our products may require significant resources and may never be successful.

Coverage and reimbursement may not be available for our products, which could make it difficult for our licensees to sell our products profitably.

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. The 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 our licensees 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 them, 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 licensees' 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 our licensees 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.

The ability of our licensees 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 Biden administration through an Executive Order or other policy or regulatory action. Further, despite our progress with commercial payers, there is no guarantee that our licensees will be able to retain our agreements or obtain new agreements or that they 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 licensees' 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.

We expect that our licensees will 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 our licensees fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, they could have difficulty achieving market acceptance of our products and our business, financial condition, results of operations, and prospects could be harmed.

Time and costs associated with winding down our general and administrative, commercial, and research and development activities may be significant.

There are significant costs associated with winding down our normal historic operations, such as separation of employees, termination of contracts and engagement of external consultants, all of which have and may in the future reduce our cash resources and take up large portions of our employees' and consultants' time.

Our future success depends on our ability to attract and retain qualified personnel.

We have one employee and use a limited number of external consultants for the operation of our company, any of whom may terminate their consultancy with us at any time. We may not be able to attract and retain consultants on acceptable terms given the competition for similar personnel. Some of our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We do not maintain "key person" insurance. If we are unable to continue to use our current consultants, or if we are unable to recruit new consultants, then our ability to operate our business will be negatively impacted and it could interfere with our ability to receive any potential royalties.

Our financial condition and results of operations for 2021 and 2022 were, and our financial condition and results of operations for 2023 and beyond may be, adversely affected by the ongoing COVID-19 pandemic and any future pandemics or epidemics.

Our business has been, and we anticipate that it will continue to be, impacted by the COVID-19 pandemic and any future pandemics or epidemics. 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 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. The sales force of our licensees may continue 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 their ordinary course sales and marketing programs.

Our future results of operations and liquidity could be adversely affected by extended billing and collection cycles at our company, our licensees, or otherwise; delays in payments of outstanding receivable amounts beyond normal payment terms, including royalty payments; supply chain disruptions; and uncertain demand.

Disruptions have occurred and may occur in the future that affect our licensees' 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 (and royalties) and damage to our reputation.

Our business may also be affected by negative impacts of the COVID-19 pandemic and any future pandemic or epidemic 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 or any future pandemics or epidemics that cannot be predicted. Accordingly, disruptions to our business as a result of COVID-19 and other pandemics or epidemics could continue to result in an adverse effect on our business, results of operations, financial condition and prospects in the near-term and beyond 2023.

Unfavorable global economic conditions could harm our business, financial condition or results of operations.

Our results of operations could be harmed by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, including the impact of increased interest rates and inflation (such as the recent rise in inflation in the United States), could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. The foregoing could harm our business and we cannot anticipate all of the ways in which unfavorable economic conditions and financial market conditions could harm our business.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the \$250,000 Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insurance limitations. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments.

Our products and our licensees are subject to extensive and costly government regulation.

Our products 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 ("OIG"), the U.S. Department of Justice ("DOJ"), 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 of our products are 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 and our licensees 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") is a criminal statute that prohibits anyone 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 government 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" has been broadly interpreted to include anything of value, including, for example, kickbacks, bribes, gifts, discounts, rebates, 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 under the AKS, 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 claims for 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 OIG 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 under the AKS.

- The FCA prohibits entities and individuals from knowing and willfully (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 for payment by Medicare, Medicaid, and other government healthcare programs, or improperly retaining known overpayments from government healthcare programs;

o 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 whether through judgment 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.

o 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 government healthcare 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;

o "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 government health care programs.

- The 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.
- 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. 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. State laws may also govern the privacy and security of health information or other personal information in certain circumstances.
- 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.

- 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 the Medicaid Program or other 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., payment is made by a private insurer or even a self-paying patient; 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 non compliance, including 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 through ballot referendum, 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 including our licensees, comply with applicable healthcare laws and regulations could be costly. 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, President Biden signed the Inflation Reduction Act of 2022 into law on August 16, 2022, which among other things, seeks to lower prescription drug costs for Medicare beneficiaries and reduce drug spending by the federal government. Specifically, the prescription drug provisions under the Inflation Reduction Act:

- Require that the federal government negotiate prices for certain drugs covered under Medicare Part B and Part D with the highest total spending, beginning in 2026;
- Require drug manufacturers to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries, beginning in 2023;
- Cap out of pocket spending for Medicare Part D enrollees and make other Part D benefit design changes, beginning in 2024;
- Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program, beginning in 2024; and
- Delay implementation of the Trump Administration's drug rebate rule, beginning in 2027.

The law that established the Part D benefit included a provision known as the "noninterference clause", which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP prescription drug plan sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Further, the Secretary does not currently negotiate prices for Part B drugs, rather, Medicare reimburses providers based on 106% of the average sales price (ASP), which is the average price paid to all non-federal buyers in the U.S., inclusive of rebates (other than Medicaid rebates). The Inflation Reduction Act amends the non-interference clause by adding an exception that requires the Secretary of HHS to negotiate prices with drug manufacturers for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). Under the new Drug Price Negotiation Program, the number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The total number of drugs with negotiated prices will increase over time. Part D drugs with negotiated maximum fair prices are required to be covered by all Part D plans. Additionally, an excise tax will be levied on drug manufacturers that do not comply with the negotiation process. The excise tax starts at 65% of a drug's sales in the U.S. and increases by 10% every quarter to a maximum of 95%. As an alternative to paying the tax, manufacturers can choose to withdraw all of their drugs from coverage under Medicare and Medicaid. In addition, manufacturers that refuse to offer an agreed-upon negotiated price for a selected drug to Medicare beneficiaries enrolled in Part B and/or Part D or to a provider of services to such individuals (such as a physician or hospital) will pay a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price of the drug.

Following passage of the Inflation Reduction Act, President Biden issued an Executive Order on October 14, 2022 titled "Lowering Prescription Drug Costs for Americans", calling for additional measures to complement the Inflation Reduction Act and further drive down prescription drug costs. Under the Executive Order, the HHS Secretary is directed to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries, including cost-sharing models and value-based payments. It is unclear what additional payment and delivery models the Innovation Center may propose and how those models may impact drug pricing, including the pricing and access to our products.

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 Patient Protection and Affordable Care Act ("ACA") and any further changes in the law or regulatory framework 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, the ability of our licensees to sell our products to government payers may be limited, thereby reducing anticipated revenues and profitability.

Even after the approval of IMVEXXY, BIJUVA, and ANNOVERA, the products and the holder of the marketing authorizations will still face extensive, ongoing regulatory requirements and review, and the 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 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 requirements.

As part of the FDA's approval of IMVEXXY, we 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, which study was assumed by Mayne Pharma as the holder of the new drug application ("NDA"). 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 penalties against the holder of the NDA, which could include withdrawal of the NDA approval and withdrawal of the product from the market. For ANNOVERA, post marketing studies are being performed by the Population Council and Mayne Pharma as the NDA holder. 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. To the extent that Mayne Pharma or the Population Council, as applicable, does not fulfil these studies to the FDA's satisfaction, the ability of our licensees to sell the applicable product may be limited and there may be an adverse impact on our revenue and results of operations.

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.

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. Facilities for the manufacturer of pharmaceutical products also undergo internal audits as well as external audits by third parties. If our licensees 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 our licensees, 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 additional clinical trials be conducted, imposing new monitoring requirements, or requiring the establishment of 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 licensees' promotional materials or messages, they may be required to modify or discontinue using them and may be required to provide corrective information.

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 repackagers, 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 and the activities of our licensees are also potentially subject to federal and state consumer protection and unfair competition laws. If we, our licensees 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 or our licensees’ practices and any alleged violation of law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend or impose restrictions on our licensees’ operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require our licensees to initiate a product recall; or
- exclude our licensees from providing our products to those participating in government healthcare programs, such as Medicare and Medicaid, and refuse to allow our licensees to enter into supply contracts, including government contracts.

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

The federal government has pursued actions against pharmaceutical companies for violations of the AKS, including relating to remuneration paid to physicians for attendance at speaker programs, consulting arrangements, and marketing, among others. As noted above, the OIG released a Special Fraud Alert in 2020 regarding manufacturer speaker programs and announced several settlements with manufacturers relating thereto. As noted above, violations of the AKS are also per se false claims for purposes of the FCA and as a result, have resulted in large settlements between manufacturers and the government. Separately, the government has pursued actions against manufacturers under the FCA for causing the submission of false claims arising from manufacturer off-label marketing. These and other enforcement efforts have resulted in large civil settlements and corporate integrity agreements between manufacturers and the government. We have adopted comprehensive compliance guidance and endeavor to structure our business arrangements and marketing efforts in compliance with all applicable law, including the AKS and the FCA; however, we cannot guarantee that the government, whistleblower or court will agree with our interpretations. 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 prescription drug products that are placed into interstate commerce in the United States. 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 monitoring promotional activities and 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 ours or our licensee's compliance controls, policies, and procedures will be sufficient to protect against acts of ours or their employees, business partners, licenses, 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. We believe that Mayne Pharma offers 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. Our co-pay assistance programs are intended to assist qualified patients with private insurance with any out-of-pocket financial obligations but exclude any government healthcare program beneficiaries. Several investigations into patient assistance practices have resulted in significant civil and criminal settlements. 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 patient assistance programs are structured incorrectly or support programs fail to comply with applicable law, Mayne Pharma risks becoming subject to government investigations, and potentially, facing penalties or other consequences for violations under fraud and abuse laws, which may inhibit revenues through royalties due to reduced sales volume. Although we believe that ours and our licensees business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that ours or our licensees 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 operations and our licensees current operations, including activities conducted by our former sales team or agents or our licensees current 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 or our licensees may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of ours or their 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 licensees, or our other contractors or agents receive or obtain individually identifiable health information from patients, healthcare professionals, pharmacies, or other individuals or entities, we or they could be subject to criminal penalties if we mishandle individually identifiable health information in a manner that is not authorized or permitted by HIPAA or other applicable privacy and security laws. 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.

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 licensee's ability to 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 or telehealth platform, 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 licensees' 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. Following the expiration of the COVID-19 public health emergency on May 11, 2023, prescribing of controlled substances via a virtual encounter will be more limited. 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.

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

- the scope of rights granted under the agreement and other interpretation-related issues;
- our or our licensees' obligations to make milestone, royalty, or other payments under those agreements;
- our or our licensees' obligations to prosecute existing and new patent applications;
- our or our licensees' obligations to enforce infringement of our intellectual property;
- whether and the extent to which the ANNOVERA technology and processes infringe on intellectual property of the Population Council that is not subject to the ANNOVERA license agreement;
- the ownership of inventions and know-how arising under the agreement or resulting from the joint creation or use of intellectual property by our licensees and us and our partners;
- our right, or the right of our licensees, to transfer or assign the license; and
- the effects of termination.

These or other disputes over our obligations, our licensees' 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, or, with respect to the ANNOVERA license agreement that we have assigned to Mayne Pharma, Mayne Pharma, fail to meet obligations under that 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 or Mayne Pharma 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 after an uncured, material breach of the agreement by us. Any uncured, material breach under a license agreement could result in our loss of exclusive rights and may lead to a complete termination of any commercialization efforts for the applicable product.

In July 2018, we entered into the Population Council License Agreement to obtain exclusive U.S. rights to commercialize ANNOVERA. The agreement required 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. The Company's license under the Population Council License Agreement was sold to Mayne Pharma as part of the Mayne Transaction.

In connection with the Mayne Transaction, we granted a license to Mayne Pharma (i) to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories. Any disputes arising under the agreements governing the Mayne Transaction may have a material adverse impact on our revenue, results of operations and financial position.

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 such sales 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 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 products will depend largely upon our licensee's success in increasing the consumer base for our products. 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 our licensees are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed. In addition, loss of exclusivity may provide opportunity for competing products, particularly generics, to erode 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 the efforts of our licensees 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 if approved, could result in significant decreases in the revenue derived from royalties 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 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, there will be 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 licensees' distribution channels.

Our revenue is dependent on our licensees' distribution through wholesale distributors and retail pharmacy distributors. Our business would be harmed if our licensees' customers refused to distribute our products and if our licensees were not able to replace such customers through their distribution channels.

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

As of December 31, 2022, we had federal net operating loss ("NOL") carryforwards of \$640.0 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.

Any failure of our licensees to adequately maintain a sales force or adequately promote our products will impede our growth.

We are substantially dependent on the sales forces of our licensees 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 growth in revenue in the future will depend, in large part, on our licensees' success in recruiting, training, and retaining direct sales personnel, and their decision to adequately promote our products. If our licensees are unable to hire, engage, and develop enough productive sales personnel or fails to adequately promote our products, our business prospects could suffer.

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 ours and our licensees' 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. 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 to that our licensees 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, the Population Council, or our licensees were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- we, the Population Council, or our licensees 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 or our licensees 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, the Population Council, our licensees, 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 or our licensees 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, the sales of IMVEXXY could be adversely affected and our license revenue could be significantly decreased. 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 must rely on Mayne Pharma to file lawsuits or take other actions to protect or enforce our patents and there can be no assurance they will be take such actions or be successful.

Competitors may infringe our patents or the patents of the ANNOVERA licensor. Following the Mayne Transaction, we no longer have the express right to enforce our intellectual property. To counter infringement or unauthorized use, we must rely on Mayne Pharma to file infringement claims, including with respect to Teva’s IMVEXXY Notice Letter. There can be no assurance that Mayne Pharma will have sufficient financial or other resources to file and pursue such infringement claims in the United States, 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 of the ANNOVERA licensor 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 the ANNOVERA licensor, 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 the ANNOVERA licensor, at risk of being invalidated, held unenforceable, or

interpreted narrowly. Moreover, we may not be able to prevent, alone or with our licensees, or the ANNOVERA licensor, 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 January 2023, we received a deficiency letter (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we were not in compliance with the rules for continued listing as set forth in Nasdaq Listing Rule 5620(a) (the "Annual Meeting Rule") due to our failure to hold an annual meeting of stockholders within 12 months after our fiscal year ended December 31, 2021. The Notice had no immediate effect on the listing of our Common Stock. We did not hold an annual meeting of stockholders during 2022 due to our then ongoing strategic processes.

The Notice stated that, under Nasdaq Listing Rule 5810(c)(2)(G), we had 45 calendar days, or until February 20, 2023, to submit a plan to regain compliance with the Annual Meeting Rule. We timely submitted such plan, and Nasdaq granted us an extension until June 29, 2023, to regain compliance. It our intent to hold an annual meeting of stockholders in 2023 prior to such deadline and to fully regain compliance with all applicable Nasdaq listing standards.

However, there can be no assurance that we will be able to regain compliance with the Annual Meeting Rule 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 stockholder owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2022, Rubric Capital Management LP ("Rubric") and its affiliates beneficially owned approximately 18.5% of our common stock. Rubric may be able to largely determine the outcome of all matters requiring stockholder approval. For example, Rubric 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 operation of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of 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 licensees may initiate product recalls or withdrawals or may be subject to regulatory enforcement actions that could negatively affect our business.

Our products may be subject to product recalls, withdrawals, or seizures if any of our products are believed to cause injury or illness or if our licensees 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, which 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. 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 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;
- 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
- the obligation to indemnify our licensees that would be a diversion of management's time and 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.

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

Our licensees' 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 our licensees from, successfully commercializing, and marketing our products" above. If the manufacturers of our products are unsuccessful in obtaining raw materials, if our licensees are unable to manufacture and release inventory on a timely and consistent basis, if our licensees fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our licensees' 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.

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 previously sold and the royalties we receive, 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 ("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. 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

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 our licensees or their partners will be free to manufacture or market our products as planned or that we or the ANNOVERA 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 products, the holders of any such patent may be able to block our ability to commercialize the applicable product 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 our licensees, 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 previously relied 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 former employees 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, prior to the Mayne Transaction we previously employed 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 former 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;
- unanticipated serious safety concerns related to the use of our products;
- the inability for our licensees 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 our competitors;
- the effectiveness of 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;

- 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 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 an 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 are in a process of subleasing our headquarters in Boca Raton as a result of shifting our business to become a pharmaceutical royalty company and terminating our employees.

Item 3. 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 the FDA by Teva Pharmaceuticals USA, Inc. (“Teva”). The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the IMVEXXY Notice Letter, Teva alleges that TherapeuticsMD patents listed in the FDA’s Orange Book that claim compositions and methods of IMVEXXY (the “IMVEXXY Patents”) are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the 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 the FDA from granting final approval of the ANDA for 30 months from the date of the IMVEXXY 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. As of December 31, 2022, 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 life of the patents. 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 an unsuccessful legal proceeding. As of December 30, 2022, and per the Mayne License Agreement, Mayne Pharma is responsible for all enforcement of our patents, including this litigation with 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 30, 2022, the closing price of our common stock on Nasdaq was \$5.59 per share. As of February 28, 2023, there were 40,366 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 for the operation 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.

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 2022 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 2022 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

TherapeuticsMD was previously 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.

In December 2022, we changed our business to become a pharmaceutical royalty company, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. On December 30, 2022, the Company completed the Mayne Transaction pursuant to which the Company and its subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize the Company's IMVEXXY, BIJUVA and prescription prenatal vitamin products sold under the BocaGreenMD® and vitaMedMD® brands in the United States and its possessions and territories, (ii) assigned to Mayne Pharma the Company's exclusive license to commercialize ANNOVERA in the United States and its possessions and territories, and (iii) sold certain other assets to Mayne Pharma in connection therewith.

Pursuant to a License Agreement, dated December 4, 2022, the Company granted Mayne Pharma, on the Closing Date, (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the

first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain adjustments, for a period of 20 years following the Closing Date.

The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

Pursuant to a Transaction Agreement, dated December 4, 2022, between the Company and Mayne Pharma, the Company sold to Mayne Pharma, at closing, certain assets for Mayne Pharma to commercialize the Products in the United States, including the Company's exclusive license from the Population Council to commercialize ANNOVERA.

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the Mayne License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended.

On the Closing Date, the Company and Mayne Pharma entered into Amendment No. 1 to the Mayne License Agreement. Pursuant to the Mayne License Agreement Amendment, Mayne Pharma agreed to pay the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition, the parties agreed that Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement, including the Company's minimum payment obligations thereunder.

As part of the transformation that included the Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2 Discontinued Operations to the consolidated financial statements included in this Annual Report.

The Company also has license agreements with strategic partners to commercialize IMVEXXY and BIJUVA outside of the U.S.

- In July 2018, we entered into a the Knight License Agreement with 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 the "Theramex License Agreement with 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.

In connection with the Company's transformation into a pharmaceutical royalty company, the termination of our executive management team (except for Mr. Marlan Walker, our former General Counsel and current Chief Executive Officer) and all other employees was completed by December 31, 2022. Severance obligations for all employees other than executive officers were paid in full in the first quarter of 2023 and severance obligations for terminated executive officers will be paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022, we employed one full-time employee primarily engaged in an executive position. We have engaged external consultants, including certain former members of our management team, who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations.

vitaCare divestiture

On April 14, 2022, we completed the divestiture of vitaCare with the sale of all vitaCare's issued and outstanding capital stock (the "vitaCare Divestiture"). We received net proceeds of \$142.6 million, net of transaction costs of \$7.2 million, and we recognized a gain on sale of business of \$143.4 million. Included in the net proceeds amount was \$11.3 million of customary holdbacks as provided in the Purchase Agreement, which is recorded as restricted cash in the consolidated balance sheets. The restricted cash was held by an escrow agent and was released to us in March 2023. Additionally, we may receive up to an additional \$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. We will record the contingent consideration at the settlement amount when the consideration is realized or realizable.

The Purchase Agreement contains customary representations and warranties, covenants, and indemnities of the parties thereto. The commitments under a long-term services agreement related to vitaCare was transferred to Mayne Pharma as part of the Mayne Transaction. In addition, under the Mayne License Agreement Amendment, Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to us by \$1.5 million in consideration of Mayne Pharma assuming our obligations under the long-term services agreement related to vitaCare.

The operations of vitaCare were classified as discontinued operations in December 2022, when the Company completed the change in its business by becoming a royalty company.

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.

As of the date of the filing of this Annual Report, the future extent to which the COVID-19 pandemic may continue to materially impact our financial condition, liquidity, or results of operations remains uncertain and difficult to predict. 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.

Portfolio of our licensed products

In December 2022, we changed our business to become a pharmaceutical royalty company, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. On December 30, 2022, we granted an exclusive license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD® and vitaMedMD® brands and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma.

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 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.

On December 30, 2022, we granted an exclusive license to commercialize the Company's IMVEXXY in the United States and its possessions and territories to Mayne Pharma. We also have entered into licensing agreements with third parties to market and sell IMVEXXY outside of the U.S. We entered into the Knight License Agreement, with Knight pursuant to which, we granted Knight an exclusive license to commercialize IMVEXXY in Canada and Israel. We entered into 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, 2022, no IMVEXXY sales had been made through these licensing agreements.

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 would have been required to provide progress reports to the FDA on an annual basis. The obligation to conduct this study was transferred to Mayne Pharma as part of the License Agreement.

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.

On December 30, 2022, we granted an exclusive license to commercialize the Company's BIJUVA in the United States and its possessions and territories to Mayne Pharma. We also 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 2022 and 2021, we had BIJUVA sales of \$1.4 million made through the Theramex License Agreement, and such sales were included as license revenue in the statements of operations. In addition, in 2021, we received 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.

ANNOVERA (segesterone acetate ("SA") and ethynodiol ("EE") vaginal system)

On December 30, 2022, we assigned the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma. 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 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 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. 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 May 2022, the FDA approved the supplemental NDA for ANNOVERA.

Prenatal vitamin products

On December 30, 2022, we granted an exclusive license to commercialize, in the United States and its possessions and territories, 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 to Mayne Pharma.

Results of operations

In December 2022, we granted an exclusive license to commercialize our IMVEXXY, BIJUVA, and prescription prenatal vitamin products and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma, which resulted in a business shift that had a major effect on our operations and financial results.

As part of the transformation that included the Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2 to the financial statements included in this Annual Report.

The discussion below, and the revenues and expenses discussed below, are based on and relate to the continuing operations of the company.

2022 compared to 2021

	Year ended December 31,	
	2022	2021
Revenue:		
Product revenue, net	\$ —	\$ —
License revenue	69,963	2,573
Total revenue, net	69,963	2,573
Cost of revenue	1,397	1,402
Gross profit	68,566	1,171
Operating expenses:		
Selling and marketing	—	—
General and administrative	57,903	80,748
Research and development	—	—
Restructuring expense	9,472	—
Total operating expenses	67,375	80,748
Income (loss) from operations	1,191	(79,577)
Other (expense) income:		
Other (expense) income, net	(117)	272
Total other (expense) income, net	(117)	272
Income (loss) from continuing operations before income taxes	1,074	(79,305)
Provision for income taxes	—	—
Net income (loss) from continuing operations	1,074	(79,305)
Income (loss) from discontinued operations, net of income taxes	110,923	(93,110)
Net income (loss)	\$ 111,997	\$ (172,415)

Revenue. As part of the transformation of our Company and the Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods presented.

Revenue from continuing operations is related to our license agreements. We recorded \$70.0 million in license revenue related to the allocation of the initial upfront payment and guaranteed minimum royalties from the Mayne License Agreement during the year ended December 31, 2022, and \$2.6 million in license revenue related to achieving previously established milestone payment targets and sales from other licensee during the year ended December 31, 2021.

Gross profit. Our gross profit for 2022 was \$68.6 million, an increase of \$67.4 million, compared to 2021. The increase in our gross profit was primarily a result of an increase in license revenue related to the initial upfront payment and guaranteed minimums from the Mayne Transaction.

Operating expenses. Total operating expenses for 2022 were \$67.4 million, a decrease of \$13.4 million, or 16.6%, compared to 2021. Total operating expenses decreased primarily due to lower general and administrative expenses described below during 2022, partially offset by \$9.5 million of restructuring expenses including severance, employee termination costs contract termination costs and write off of fixed assets related to restructuring activities following the Mayne Transaction.

Our general and administrative costs were \$57.9 million for 2022, a decrease of \$22.8 million, or 28.3%, compared to 2021. This decrease was primarily related to \$12.7 million in lower compensation and employee benefit costs, \$6.7 million in lower stock-based compensation expenses, and \$3.6 million in lower information technology expenses. These decreases were partially offset by \$3.2 million in higher expenditures attributable to various professional fees, such as legal, consulting, etc.

Income (loss) from operations. For 2022, we had an income from operations of \$1.2 million, as compared to a loss from operations of \$79.6 million for 2021. This change was attributable to \$13.4 million in lower operating expenses and \$67.4 million in higher gross profit.

Other income (expense), net. In 2022, we had non-operating expense of \$0.1 million compared to non-operating income of \$0.2 million in 2021.

Provision for income taxes. In 2022 or 2021, we recorded no provision for income taxes for continuing operations.

Net income (loss) from continuing operations. For 2022, we had a net income of \$1.1 million, or \$0.12 per basic and \$0.11 per diluted common share, compared to a loss of \$79.3 million, or \$9.96 per basic and diluted common share, for 2021.

Discontinued Operations—Revenues were \$80.7 million for 2022, a decrease of \$3.6 million, or 4.3%, as compared to the prior year. The decrease was driven by a decrease in IMVEXXY revenue of \$4.7 million, lower BIJUVA revenue of \$0.5 million and lower prenatal vitamins revenue of \$2.2 million, partially offset by higher revenue of ANNOVERA of \$3.8 million. Operating expenses were \$97.6 million for 2022, a decrease of \$35.7 million, as compared to the prior year. Operating expenses decreased due to lower selling and marketing expenses of \$33.0 million and lower research and development expenses of \$2.1 million as compared to the prior year, partially offset by restructuring charges of \$6.2 million recorded in 2022, which were recorded due to our business shift after granting an exclusive license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma. The decrease in operating expenses also reflected the reduction of vitaCare operating expenses in connection with its divestiture in April 2022 and the termination of employees on December 31, 2022 following the Mayne Transaction. Operating loss from discontinued operations was \$32.5 million, a decrease of \$27.7 million as compared to the prior year.

We reclassified certain expenses that were associated with debt that was required to be repaid as a result of transaction with Mayne Pharma and the vitaCare divestiture to discontinued operations, which included interest, amortization of deferred financing costs as well as expense for accretion of the Company's newly-designated Series A Preferred Stock, par value \$0.001 per share (the "Series A Preferred Stock") and loss on extinguishment of debt. Discontinued operations other income (expense) reflects a \$143.4 million gain on the sale of the vitaCare business and a \$62.0 million gain on sale of ANNOVERA, net of transaction costs partially offset by \$17.0 million in expense for accretion of Series A Preferred Stock in 2022, \$8.4 million in loss on extinguishment of debt in connection with amendments to the Financing Agreement (as defined below) during 2022 and \$3.1 million in higher interest expense and amortization of deferred financing costs as compared to 2021. For additional information, see Note 2 - Discontinued Operations, in the notes to the consolidated financial statements appearing elsewhere in this Annual Report.

Liquidity and capital resources

Our primary use of cash is to fund the continued operations of our company. 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, 2022, we had cash totaling \$38.1 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.

On April 14, 2022, we completed the vitaCare Divestiture and included \$11.3 million of customary holdbacks, as provided in the Purchase Agreement, which is recorded as restricted cash in the consolidated balance sheets. The restricted cash was held by an escrow agent and was released to us in March 2023. Additionally, we may receive up to an additional \$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. We utilized \$120.0 million of net proceeds from the vitaCare Divestiture to make a prepayment of the loans under the Financing Agreement under the terms of Amendment No. 9 of the Financing Agreement.

On December 30, 2022, we granted Mayne Pharma (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories. The total consideration from Mayne Pharma to us under the License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the transaction agreement dated December 4, 2022, and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the License Agreement, as amended.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain

adjustments, for a period of 20 years following the Closing Date. The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain

further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

See "Going Concern" below for further discussion related to our ability to generate and obtain adequate amounts of cash to meet our liquidity needs and our plans for to satisfy our such needs in the short-term and in the long-term.

Cash flows

The following table reflects the major categories of cash flows from continuing operations for each of the periods (in thousands).

Cash flow from continuing operations	2022	2021
Net cash provided by (used in) operating activities	\$ 9,359	\$ (55,133)
Net cash used in investing activities	(355)	(2,223)
Net cash (used in) provided by financing activities	(235,206)	129,552

2022 compared to 2021

Operating Activities from continuing operations. Net cash provided by operating activities in 2022 was \$9.4 million, compared to net cash used in operating activities of \$55.1 million for 2021. This decrease of \$64.5 million or 117%, was primarily due to a \$80.4 million decrease in our net loss from continuing operations resulting from allocated to day one license revenue from the Mayne Transaction, a \$8.7 million decrease in cash usage related to changes in operating assets and liabilities, and a \$7.2 million increase in non-cash expenditure adjustments as compared to 2021.

Investing Activities from continuing operations. Net cash used in investing activities for 2022 was \$0.4 million, compared to net cash used in investing activities of \$2.2 million for 2021. This change was due to lower fixed asset and patent related costs as compared to 2021.

Financing Activities from continuing operations. Net cash used in financing activities for 2022 was \$235.2 million, compared to net cash provided by financing activities of \$129.6 million for 2021. This change of \$364.8 million, or 281.6%, was primarily related to higher repayment of debt of \$169.4 million as compared to 2021, the redemption of our Series A Preferred Stock of \$38.7 million at liquidation preference, and the repayment of make-whole derivative of \$3.0 million as compared to 2021. This was partially offset by proceeds from Series A Preferred Stock of \$21.7 million, proceeds from make-whole payment of \$3.3 million, lower proceeds from sale of common stock of \$181.7 million, lower payment for financing fees of \$3.5 million and lower proceeds from sale of stock related to employee stock purchase plan of \$0.2 million as compared to 2021.

Operating Activities from discontinued operations. Net cash used in operating activities in 2022 was \$13.4 million as compared to net cash used in operating activities of \$87.6 million for 2021. This decrease relates to a decrease in net loss of \$204.0 million reflecting four months of vitaCare activities in 2022 as compared to a full year in 2021 and reductions in marketing expenses for the commercial business as well as lower research and development expenses to preserve cash in 2022, as well as increase in non-cash expenditure adjustments which included debt financing fees, non-cash interest expense, accretion of Series A Preferred Stock and make-whole payment accretion and the loss of extinguishment of debt as compared to 2021.

Investing Activities from discontinued operations. Net cash provided by investing activities for 2022 was \$223.8 million which included proceeds from divesture of vitaCare of \$142.6 million and proceeds from the sale of ANNOVERA of \$81.2 million in 2022.

For additional details, see the consolidated statements of cash flows included in this 2022 10-K Report.

Other liquidity measures

Receivable. On December 30, Mayne Pharma acquired our account receivable balance of approximately \$29.3 million which is subject to certain working capital adjustments. As of December 31, 2022, we had a royalty receivable of \$1.5 million relating to the short-term portion of receivable from Mayne Pharma and \$20.3 million relating to the long term portion of royalty receivable which includes royalties recognized from the Minimum Annual Royalty. See Note 1 Business, basis of presentation, new accounting standards and summary of significant accounting policies (L Revenue Recognition) to the consolidated financial statements included in this Annual Report.

Inventory. On December 30, Mayne Pharma acquired our inventory balance of approximately \$8.4 million, which is subject to certain net working capital adjustments.

Debt. On December 30, 2022, we repaid all obligations under the Financing Agreement and the Financing Agreement was terminated. See Note 7. Debt to the consolidated financial statements included in this Annual Report.

Going concern

On December 4, 2022, we entered into agreements with Mayne Pharma pursuant to which we (i) granted Mayne Pharma an exclusive license to commercialize IMVEXXY, BIJUVA, and prescription prenatal vitamin products (in the United States and its possessions and territories), (ii) assigned to Mayne Pharma the Company's exclusive license to commercialize ANNOVERA in the United States and its possessions and territories, and (iii) sold certain other assets to Mayne Pharma.

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the License Agreement, as amended.

On the Closing Date, we repaid all obligations under the Financing Agreement, dated as of April 24, 2019, as amended, with Sixth Street Specialty Lending, Inc., as administrative agent, the various lenders from time-to-time party thereto, and certain of the Company's subsidiaries party thereto from time to time as guarantors (the "Financing Agreement") and the Financing Agreement was terminated.

Following the transaction with Mayne Pharma, we changed our business to become a royalty company, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. We may need to raise additional capital to provide additional liquidity to fund our operations until we become cash flow positive. To address our capital needs, we are pursuing various equity and debt financing and other alternatives. 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 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 financing and other strategic alternatives, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses.

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.

If Mayne Pharma's sales of IMVEXXY, BIJUVA, or ANNOVERA are delayed, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than estimated, or if we are unsuccessful with future financings and or the continued impact of the COVID-19 pandemic or the supply chains related to the third-party contract manufacturers is worse than we anticipate, our existing cash reserves would be insufficient to satisfy our liquidity. 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 7. Debt" and "Note 8. Commitments and Contingencies" to the consolidated financial statements included in this 2022 10-K Report.

Contractual obligations

A summary of contractual obligations is as follows:

	Total	Year 1	Years 2-3	Years 4-5	> 5 years
Operating lease obligations	\$ 11,868	\$ 1,443	\$ 2,990	\$ 3,141	\$ 4,294
Total contractual obligations	\$ 11,868	\$ 1,443	\$ 2,990	\$ 3,141	\$ 4,294

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. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered 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, 2022 and 2021.

In the normal course of business, we may be confronted with issues or events that may result in 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 8. Commitments and contingencies" to the consolidated financial statements included in this 2022 10-K Report.

Employment agreements

Information regarding employment agreements is in "Note 8. Commitments and contingencies" to the consolidated financial statements included in this 2022 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 2022 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, 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 2022 10-K Report.

Discontinued Operations

Discontinued operations comprise activities that were disposed of at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, Presentation of Financial Statements. An adjustment has been made to the consolidated statements of operations for the twelve months ended December 31, 2022 and 2021 to reclassify commercial activities and vitaCare activities to discontinued operations as the cessation of these operations, in the aggregate, represented a business shift that will have a major effect on the Company's operations and financial results. For additional information, see Note 2 - Discontinued Operations, in the notes to the consolidated financial statements appearing elsewhere in this Report.

Segment reporting

We manage and operate as one business, which prior to December 2022 was focused on creating and commercializing products targeted exclusively for women and after we signed License Agreement with Mayne Pharma, it is focused on collecting royalties from licensing our products. Our business 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. Accordingly, we view our business as one reportable operating segment.

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.

On December 30, 2022, we closed a License Agreement with Mayne Pharma pursuant to which we sold to Mayne Pharma the exclusive license rights in our product ANNOVERA and granted an exclusive license in other products, including IMVEXXY and BIJUVA. Under the terms of the License Agreement, we received \$140 million at closing and we are eligible to receive additional payments in the aggregate of up to an additional \$30 million based on the achievement of sales milestones (collectively, the "Milestone Amounts"). The proceeds at closing were allocated between consideration for the sale of ANNOVERA and the initial license fee for the Licensed Products, as the sale of ANNOVERA was accounted for under ASC 610-20, Gains and Losses from Derecognition of Nonfinancial Assets in arriving at the gain on disposal (see Note 2 to the financial statements included in this Annual Report), while the license grant of the other products were recognized under the provisions of ASC 606, Revenue from Contracts with Customers, as a license of functional intellectual asset. The proceeds were allocated among the Licensed Products on the relative net present value of forecasted future product sales from those products. The Milestone Amounts will be recognized, as applicable, in subsequent periods based on actual product sales that exceed the respective net sales milestones as such variable consideration is constrained by the occurrence of the subsequent sales.

Our royalty revenue recognized in 2022 primarily related to royalties provided for under the Mayne License Agreement based on Mayne Pharma's sales of the Licensed Products subject to that agreement. Under the agreement, the Mayne License Agreement, the Company is entitled to earn royalties on net sales of all of the Licensed Products at a royalty rate of (i) 8% on the first \$80 million of net sales of the Licensed Products and (ii) 7.5% on net sales of all of the Licensed Products after the first \$80 million of net sales. The royalty rate is subject to a 2% reduction upon the earlier to occur of (i) the expiration or revocation of the last valid claim covering a Licensed Product, and (ii) a generic product launch (a "LOE"). We are entitled to minimum annual royalties beginning with the year ending December 31, 2023 (\$3 million annual minimum) and continuing with 3% annual increases through the year ending December 31, 2034 (the "Minimum Annual Royalty"). The Minimum Annual Royalty totaled \$42.6 million, and this total amount was allocated among the Licensed Products on the relative net present value of forecasted future product sales from those products. The portion allocated to consideration for the sale of ANNOVERA was attributed towards the gain on disposal of that asset. For the remaining portion allocated to the license grants for the other products, we determined that the minimum guarantee underlying the Minimum Annual Royalty should be treated as fixed consideration and recognized under ASC 606 at the point in time when the license was transferred. Since the Minimum Annual Royalty will be received in annual installments through 2034, we determined the transaction price allocated under ASC 606 contained a significant financing component, and we therefore determined the initial royalty revenue and corresponding receivable based on the present value of the allocated Minimum Annual Royalty. The present value was calculated using a discount rate of 10.45%, based on the credit characteristics of Mayne Pharma and the timing of future payments, and the value will be accreted to full value through the earlier of January 1, 2034 or a LOE. This royalty receivable is a contract asset as of December 31, 2022, and is further subject to offset by Mayne Pharma.

Royalty revenue earned in excess of the Minimum Annual Royalty will be recognized under ASC 606, which provides revenue recognition constraints by requiring the recognition of revenue at the later of the following: 1) when the subsequent sale occurs or 2) when the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied). We applied the royalty recognition constraint required under the guidance for sales-based royalties, which requires a sales-based royalty to be recorded no sooner than the underlying sale. Therefore, royalties on sales of products commercialized by Mayne Pharma will be recognized in the subsequent periods that the Licensed Products are sold.

For additional discussion on revenue, see "L. 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 2022 10-K Report.

During 2022 and 2021, we had BIJUVA sales of \$1.4 million made through the Theramex License Agreement, and such sales were included as license revenue in the statements of operations. In addition, in 2021, we received 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. We previously granted licenses to commercialize the Company's BIJUVA product outside of the United States to Theramex and Knight.

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.

Restructuring Costs.

Our restructuring costs consist primarily of severance, employee termination costs contract termination costs and write off of fixed assets related to restructuring activities.

Recent accounting pronouncements

Information regarding accounting standards adopted during 2022 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 report thereon, commencing on page F-1 of this 2022 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 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 2022 10-K Report. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) accumulated and communicated to our management, including our Principal Executive Officer and Principal 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 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, 2022. 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, 2022.

This 2022 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 2022 10-K Report.

Item 9B. Other information

None.

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 2023 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 2023 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 2023 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 2023 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 2023 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 2022 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.(33)
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(35)
3.4	Bylaws of the AMHN, Inc.(7)
3.5	First Amendment to Bylaws of the Company, dated December 17, 2015(8)
3.6	Second Amendment to Bylaws of the Company, adopted May 27, 2022(36)
3.7	Third Amendment to Bylaws of the Company, dated July 29, 2022(37)
3.8	Certificate of Change to Articles of Incorporation of the Company(38)
3.8	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (37)
4.1	Form of Certificate of Common Stock(9)
4.2†	Description of Securities of the Company
10.1	Form of Common Stock Purchase Warrant(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(27)
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	Form of Common Stock Purchase Warrant, dated February 24, 2012(17)
10.9	Common Stock Purchase Warrant, issued to Plato & Associates, LLC, dated January 31, 2013(18)
10.10	Form of Warrant to Purchase Common Stock, dated August 5, 2020(6)
10.11	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)

- 10.12 [Second Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020\(20\)](#)
- 10.13 [Warrant issued by the Company to Robert Finizio\(20\)](#)
- 10.14 [Amendment to Warrant issued by the Company to Robert Finizio\(20\)](#)
- 10.15* [Warrant issued by the Company to John C.K. Milligan, IV\(20\)](#)
- 10.16* [Amendment to Warrant issued by the Company to John C.K. Milligan, IV\(20\)](#)
- 10.17 [Subscription Agreement, dated August 5, 2020, by and among TherapeuticsMD, Inc. and the Subscribers identified on the Schedule of Subscribers attached thereto\(6\)](#)
- 10.18*** [License Agreement, dated July 30, 2018, by and between TherapeuticsMD, Inc. and The Population Council, Inc.\(22\)](#)
- 10.19*** [Lease, dated October 5, 2018, by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc.\(23\)](#)
- 10.20* [Executive Employment Agreement, dated as of August 3, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd\(28\)](#)
- 10.21* [TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated as of August 31, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd\(29\)](#)
- 10.22* [Employment Agreement, dated June 1, 2020, between the Company and James C. D'Arecca\(6\)](#)
- 10.23* [Amendment to Employment Agreement, dated October 15, 2021, between TherapeuticsMD, Inc. and James C. D'Arecca\(30\)](#)
- 10.24* [Executive Employment Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman\(31\)](#)
- 10.25* [TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman\(32\)](#)
- 10.26* [Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and Michael Donegan\(24\)](#)
- 10.27* [Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and Robert G. Finizio\(24\)](#)
- 10.28* [Amended and Restated Employment Agreement, dated November 24, 2020, between the Company and John C.K. Milligan, IV\(24\)](#)
- 10.29* [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\(26\)](#)
- 10.30* [Employment Agreement, October 30, 2019, between the Company and Edward J. Borkowski\(20\)](#)
- 10.31* [Amendment to Employment Agreement between the Company and Edward J. Borkowski\(20\)](#)
- 10.32*** [License and Supply Agreement, dated June 6, 2019, by and between TherapeuticsMD, Inc. and Theramex HQ UK Limited\(21\)](#)
- 10.33* [Form of Indemnification Agreement between TherapeuticsMD, Inc. and each of its executive officers and directors\(19\)](#)
- 10.34 [Controlled Equity OfferingSM Sales Agreement, dated November 27, 2020, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co.\(24\)](#)
- 10.35 [Controlled Equity OfferingSM Sales Agreement, dated March 3, 2021, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co.\(25\)](#)
- 10.36* [2022 Executive Retention and Performance Bonus Plan. \(ERB-Plan\)\(34\)](#)
- 10.37 [Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated July 29, 2022\(37\)](#)
- 10.38 [Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TOA Talents, LLC, dated July 29, 2022\(37\)](#)
- 10.39 [Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated September 30, 2022\(39\)](#)
- 10.40 [Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TAO Talents, LLC, dated September 30, 2022\(39\)](#)

10.41	Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated October 28, 2022(40)
10.42	Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TAO Talents, LLC, dated October 28, 2022(40)
10.43***+	License Agreement by and between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated December 4, 2022(41)
10.44***+	Transaction Agreement by and between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated December 4, 2022(41)
10.45**†	Amendment No. 1 to the License Agreement between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated as of December 30, 2022
10.46†	Amendment No. 1 to the Transaction Agreement between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated as of December 30, 2022
10.47*†	Amended and Restated Employment Agreement, dated as of December 18, 2018, by and between TherapeuticsMD, Inc. and Marlan Walker
10.48*†	Amendment, effective October 15, 2021, to the Employment Agreement, dated as of December 18, 2018, by and between TherapeuticsMD, Inc. and Marlan Walker
10.49*	Amendment, dated February 21, 2023, to the Employment Agreement, dated as of December 18, 2018, as extended effective October 15, 2021, by and between TherapeuticsMD, Inc. and Marlan Walker(16)
10.50*	General Consulting and Services Agreement by and between TherapeuticsMD, Inc. and MCD Consulting Management Services, LLC, dated February 21, 2023(16)
21.1†	Subsidiaries of the Company
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
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. 001-00100).
- (16) Filed as an exhibit to Form 8-K filed with the Commission on February 27, 2023 and incorporated herein by reference (SEC File No. 001-00100).
- (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. 001-00100).
- (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, 2018 filed with the Commission on November 8, 2018 and incorporated herein by reference (SEC File No. 001-00100).
- (23) Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2019 filed with the Commission on November 8, 2019 and incorporated herein by reference (SEC File No. 001-00100).
- (24) 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).
- (25) 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).
- (26) 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).
- (27) 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).
- (28) 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).

- (29) Filed as exhibit to Form S-8 filed with the Commission on August 31, 2021 and incorporated herein by reference (File No. 333-259221)
- (30) 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).
- (31) 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).
- (32) 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).
- (33) 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).
- (34) Filed as an exhibit to Form 10-K for the year ended December 31, 2021, filed with the Commission on March 23, 2022 and incorporated herein by reference (File No. 001-00100).
- (35) Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2022, filed with the Commission on May 16, 2022 and incorporated herein by reference (File No. 001-00100).
- (36) Filed as an exhibit to Form 8-K filed with the Commission on June 3, 2022 and incorporated herein by reference (File No. 001-00100).
- (37) Filed as an exhibit to Form 8-K filed with the Commission on August 1, 2022 and incorporated herein by reference (File No. 001-00100).
- (38) Filed as an exhibit to Form 8-K filed with the Commission on May 9, 2022 and incorporated herein by reference (File No. 001-00100).
- (39) Filed as an exhibit to Form 8-K filed with the Commission on October 3, 2022 and incorporated herein by reference (File No. 001-00100).
- (40) Filed as an exhibit to Form 8-K filed with the Commission on October 31, 2022 and incorporated herein by reference (File No. 001-00100).
- (41) Filed as an exhibit to Form 8-K filed with the Commission on December 5, 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 2022 10-K Report to be signed on its behalf by the undersigned, thereunto duly authorized, on April 7, 2023

THERAPEUTICSMD, INC.

/s/ Marlan D. Walker

Marlan D. Walker
Chief Executive Officer

/s/ Michael C. Donegan

Michael C. Donegan
Principal Financial and
Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this 2022 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 April 7, 2023.

Signature

Title

/s/ Marlan D. Walker

Marlan D. Walker

Chief Executive Officer

(Principal Executive Officer)

/s/ Michael C. Donegan

Michael C. Donegan

Principal Financial and Accounting Officer

/s/ Tommy G. Thompson

Tommy G. Thompson

Chairman

/s/ Cooper C. Collins

Cooper C. Collins

Director

/s/ Gail K. Naughton, Ph.D.

Gail K. Naughton, Ph.D.

Director

/s/ Justin Roberts

Justin Roberts

Director

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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, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recently changed its business strategy to become a royalty company. The Company has limited experience operating as a royalty company and may need to raise additional capital to fund its operations until the Company becomes cash flow positive. 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 matter

Critical audit matters 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. We determined that there are no critical audit matters.

/s/ GRANT THORNTON LLP

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

Miami, Florida
April 7, 2023

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

	As of December 31,	
	2022	2021
Assets:		
Current assets:		
Cash	\$ 38,067	\$ 64,907
Restricted cash	11,250	—
Prepaid and other current assets	6,034	5,859
Current assets of discontinued operations	—	48,702
Total current assets	55,351	119,468
Fixed assets, net	78	823
License rights and other intangible assets, net	6,943	7,144
Right of use assets	7,580	8,234
Royalty receivable, long term	20,253	—
Other non-current assets	253	253
Non-current assets of discontinued operations	—	33,550
Total assets	\$ 90,458	\$ 169,472
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	\$ —	\$ 188,269
Accounts payable	2,162	3,373
Accrued expenses and other current liabilities	18,846	13,338
Current liabilities of discontinued operations	25,831	47,911
Total current liabilities	46,839	252,891
Operating lease liabilities, non-current	7,369	8,063
Other non-current liabilities	1,107	2,139
Total liabilities	55,315	263,093
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001; 10,000 shares authorized	—	—
Common stock, par value \$0.001; 12,000 shares authorized, 9,498 and 8,598 (adjusted for the 50-for-1 reverse stock split) issued and outstanding as of December 31, 2022 and 2021, respectively	9	9
Additional paid-in capital	974,497	957,730
Accumulated deficit	(939,363)	(1,051,360)
Total stockholders' equity (deficit)	35,143	(93,621)
Total liabilities and stockholders' equity (deficit)	\$ 90,458	\$ 169,472

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,	
	2022	2021
Revenue:		
Product revenue, net	\$ —	\$ —
License revenue	69,963	2,573
Total revenue, net	69,963	2,573
Cost of revenue	1,397	1,402
Gross profit	68,566	1,171
Operating expenses:		
Selling and marketing	—	—
General and administrative	57,903	80,748
Research and development	—	—
Restructuring expense	9,472	—
Total operating expenses	67,375	80,748
Income (loss) from operations	1,191	(79,577)
Other (expense) income:		
Other (expense) income, net	(117)	272
Total other (expense) income, net	(117)	272
Income (loss) from continuing operations before income taxes	1,074	(79,305)
Provision for income taxes	—	—
Net income (loss) from continuing operations	1,074	(79,305)
Income (loss) from discontinued operations, net of income taxes	110,923	(93,110)
Net income (loss)	\$ 111,997	\$ (172,415)
Income (loss) per common share, basic:		
Continuing operations	\$ 0.12	\$ (9.96)
Discontinued operations, net	12.29	(11.70)
Net income (loss)	\$ 12.41	\$ (21.66)
Income (loss) per common share, diluted:		
Continuing operations	\$ 0.11	\$ (9.96)
Discontinued operations, net	11.84	(11.70)
Net income (loss)	\$ 11.96	\$ (21.66)
Weighted average common shares, basic	9,028	7,960
Weighted average common shares, diluted	9,366	7,960
Comprehensive income (loss):		
Net income (loss)	\$ 111,997	\$ (172,415)
Other comprehensive income	—	—
Comprehensive income (loss)	\$ 111,997	\$ (172,415)

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

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

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, December 31, 2020	5,995	\$ 6	\$ 754,938	\$ (878,945)	\$ (124,001)
Shares issued for sale of common stock, net of cost	2,435	3	184,112	—	184,115
Shares issued for exercise of warrants, net of cashless exercises	22	—	278	—	278
Shares issued for exercise of options	2	—	44	—	44
Shares issued for vested restricted and performance stock units	136	—	—	—	—
Shares issued for sale of common stock related to employee stock purchase plan	7	—	233	—	233
Share-based payment award compensation costs	—	—	18,125	—	18,125
Net loss	—	—	—	(172,415)	(172,415)
Balance, December 31, 2021	8,597	9	957,730	(1,051,360)	(93,621)
Shares issued for sale of common stock, net of cost	565	—	2,454	—	2,454
Lender warrants	—	—	2,727	—	2,727
Rounding for fractional shares in connection with the reverse stock split	142	—	—	—	—
Shares issued for vested restricted and performance stock units	189	—	—	—	—
Shares issued for sale of common stock related to employee stock purchase plan	5	—	14	—	14
Share-based payment award compensation costs	—	—	11,572	—	11,572
Net income	—	—	—	111,997	111,997
Balance, December 31, 2022	9,498	\$ 9	\$ 974,497	\$ (939,363)	\$ 35,143

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,	
	2022	2021
Cash flows from operating activities:		
Net income (loss)	\$ 111,997	\$ (172,415)
Less: Loss from discontinued operations, net of tax	110,923	(93,110)
Net income (loss) from continuing operations	1,074	(79,305)
Adjustments to reconcile net income (loss) to net cash used in continuing operating activities:		
Depreciation and amortization	1,193	736
Share-based payment compensation costs	11,572	18,125
Make-whole payment accretion	(354)	—
Other	(40)	720
Changes in operating assets and liabilities:		
Prepaid and other current assets	620	(1,125)
Other assets	(7,636)	—
Accounts payable	(1,211)	(1,062)
Accrued expenses and other current liabilities	4,262	4,639
Other non-current liabilities	(121)	2,139
Total adjustments	8,285	24,172
Net cash used in continuing operating activities	9,359	(55,133)
Cash flows from continuing investing activities:		
Payment for patent related costs	(355)	(2,189)
Purchase of fixed assets	—	(34)
Net cash provided by (used in) continuing investing activities	(355)	(2,223)
Cash flows from continuing financing activities:		
Proceeds from sale of common stock, net of costs	2,454	184,115
Proceeds from exercise of options and warrants	—	322
Proceeds from sale of common stock related to employee stock purchase plan	14	233
Repayments of debt	(219,432)	(50,000)
Proceeds from Series A Preferred Stock, net of transaction costs	21,684	—
Repurchase of Preferred Stock at liquidation preference	(38,657)	—
Proceeds from make-whole derivative	3,322	—
Repayment of make-whole derivative	(2,969)	—
Payment of debt financing fees	(1,622)	(5,118)
Net cash (used in) provided by continuing financing activities	(235,206)	129,552
Discontinued operations:		
Net cash used in operating activities	(13,437)	(87,560)
Net cash provided by investing activities	223,834	—
Net cash provided by financing activities	—	—
Net cash provided by (used in) discontinued operations	210,397	(87,560)
Net decrease in cash	(15,805)	(15,364)
Cash and restricted cash - continuing operations, beginning of period	64,907	79,019
Cash and restricted cash - discontinued operations, beginning of period	215	1,467
Total cash and restricted cash, end of period	\$ 49,317	\$ 65,122
Supplemental disclosure of cash flow information:		
Interest paid	\$ 13,545	\$ 25,068
Supplemental disclosure of noncash financing activities:		
Warrants issued in relation to debt financing agreement	\$ 2,727	\$ -

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

TherapeuticsMD, Inc. and Subsidiaries
Notes to the 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 (“2022 10-K Report”) as “TherapeuticsMD,” “we,” “our” and “us.” This 2022 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 2022 10-K Report may appear without the ®, TM 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.

TherapeuticsMD was previously 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. In December 2022, we changed our business to become a pharmaceutical royalty company, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. On December 30, 2022 (the “Closing Date”), the Company completed a transaction (the “Mayne Transaction”) with Mayne Pharma LLC, a Delaware limited liability company (“Mayne Pharma”) and subsidiary of Mayne Pharma Group Limited, an Australian public company, pursuant to which the Company and its subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize the Company’s IMVEXXY, BIJUVA and prescription prenatal vitamin products sold under the BocaGreenMD® and vitaMedMD® brands (collectively, the “Licensed Products”) in the United States and its possessions and territories, (ii) assigned to Mayne Pharma the Company’s exclusive license to commercialize ANNOVERA (together with the Licensed Products, collectively, the “Products”) in the United States and its possessions and territories, and (iii) sold certain other assets to Mayne Pharma in connection therewith.

Pursuant to a License Agreement, dated December 4, 2022, between the Company and Mayne Pharma (the “Mayne License Agreement”), the Company granted Mayne Pharma, on the Closing Date, (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain adjustments, for a period of 20 years following the Closing Date. The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

Pursuant to a Transaction Agreement, dated December 4, 2022, between the Company and Mayne Pharma (the “Transaction Agreement”), the Company sold to Mayne Pharma, at closing, certain assets for Mayne Pharma to commercialize the Products in the United States, including, with the Populations Council’s consent, the Company’s exclusive license from the Population Council to commercialize ANNOVERA (the “Transferred Assets”).

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the Mayne Transaction Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment (as defined below) and (iv) the right to receive the contingent consideration set forth in the

Mayne License Agreement, as amended. The acquisition of net working capital was determined in accordance with the Transaction Agreement and included significant estimates which could change materially for a period of up to two years following the Closing Date.

On the Closing Date, the Company and Mayne Pharma entered into Amendment No. 1 to the Mayne License Agreement (the "Mayne License Agreement Amendment"). Pursuant to the Mayne License Agreement Amendment, Mayne Pharma agreed to pay the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition, the parties agreed that Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement (see vitaCare divestiture below), including the Company's minimum payment obligations thereunder.

As part of the transformation that included Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2.

The Company also has 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.

In connection with the Company's transformation into a pharmaceutical royalty company, the termination of our executive management team (except for Mr. Marlan Walker, our former General Counsel and current Chief Executive Officer) and all other employees was completed by December 31, 2022. Severance obligations for all employees other than executive officers were paid in full in January 2023 and severance obligations for terminated executive officers will be paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022, we employed 1 full-time employee primarily engaged in an executive position. We have also entered into consulting agreements with certain former members of our management team who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations.

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. ("vitaCare") with the sale of all of vitaCare's issued and outstanding capital stock (the "vitaCare Divestiture"). We received net proceeds of \$142.6 million, net of transaction costs of \$7.2 million, and we recognized a gain on sale of business of \$143.4 million. Included in the net proceeds amount was \$11.3 million of customary holdbacks as provided in the stock purchase agreement (the "Purchase Agreement"), which is recorded as restricted cash in the consolidated balance sheets. The restricted cash was held by an escrow agent and was be released to us in March 2023. Additionally, we may receive up to an additional \$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. We will record the contingent consideration at the settlement amount when the consideration is realized or realizable.

The Purchase Agreement contains customary representations and warranties, covenants, and indemnities of the parties thereto. The commitments under a long-term services agreement related to vitaCare were transferred to Mayne Pharma as part of the Mayne Transaction. In addition, under the Mayne License Agreement Amendment, Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to us by \$1.5 million in consideration of Mayne Pharma assuming our obligations under the long-term services agreement related to vitaCare.

The divestiture of vitaCare was determined to be a component of discontinued operations in December 2022, when the Company changed its business by becoming a royalty company and as a result vitaCare activities were reclassified to discontinued operations for 2022 and 2021.

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.

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 and difficult to predict. 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.

Going Concern

On December 4, 2022, we entered into agreements with Mayne Pharma pursuant to which we granted Mayne Pharma an exclusive license to commercialize IMVEXXY, BIJUVA, and prescription prenatal vitamin products (in the United States and its possessions and territories), (ii) assign to Mayne Pharma the Company's exclusive license to commercialize ANNOVERA in the United States and its possessions and territories, and (iii) sell certain other assets to Mayne Pharma.

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the License Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the License Agreement, as amended.

On the Closing Date, we repaid all obligations under the Financing Agreement, dated as of April 24, 2019, as amended, with Sixth Street Specialty Lending, Inc., as administrative agent, the various lenders from time-to-time party thereto, and certain of the Company's subsidiaries party thereto from time to time as guarantors (the "Financing Agreement") and the Financing Agreement was terminated.

Following the transaction with Mayne Pharma, our primary source of revenue will be from royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. We may need to raise additional capital to provide additional liquidity to fund our operations until we become cash flow positive. To address our capital needs, we may pursue various equity and debt financing and other alternatives. 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 our available authorized shares.

Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock 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.

If Mayne Pharma's sales of IMVEXXY, BIJUVA, or ANNOVERA are delayed, if the net working capital settlement with Mayne Pharma under the Transaction Agreement, or if we are unsuccessful with future financings and/or the continued impact of the COVID-19 pandemic or the supply chains related to the third-party contract manufacturers is worse than we anticipate, our existing cash reserves would be insufficient to satisfy our liquidity. 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.

As part of the transformation as a result of Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2.

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. 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. We paid off our debt as of December 30, 2022, and as a result the adoption of this guidance will not have an impact on our financial statements and, to the extent we enter into new debt agreements, we will apply such guidance to those contracts.

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. Discontinued Operations

Discontinued operations comprise activities that were disposed of at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, Presentation of Financial Statements. An adjustment has been made to the consolidated statements of operations for the twelve months ended December 31, 2022 and 2021 to reclassify commercial activities and vitaCare activities to discontinued operations as both components, in the aggregate, represented a business shift that will have a major effect on the Company's operations and financial results. No amounts for shared general and administrative operating support expense were allocated to discontinued operations. As required by the terms of our Financing Agreement, the proceeds from both transactions were used to fully repay our outstanding debt borrowings. As a result, interest expense and amortization of deferred financing costs as well as expense for accretion of Series A Preferred Stock and loss on extinguishment of debt are included within income (loss) from discontinued operations, net of tax. Additionally, the related assets and liabilities have been reported as assets and liabilities of discontinued operations in the Company's consolidated balance sheet as of December 31, 2022 and 2021. For additional information, see Note 2 - Discontinued Operations.

D. 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.

E. Cash and Restricted 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.

Restricted cash is comprised of escrowed funds deposited with a bank relating to the vitaCare Divestiture. All restrictions were lifted in March 2023 and it is no longer restricted, see Note 15.

F. Accounts receivable and allowance for doubtful accounts

Accounts receivable are customer obligations due under normal trade terms and are measured at amortized cost. We historically extended credit on an unsecured basis to most of our customers based on an evaluation of a customer's financial condition, and collateral was not required. Our accounts receivable concentration of credit risk is primarily limited to 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. On December 30, 2022, Mayne Pharma acquired our accounts receivable balance of approximately \$29.3 million which is subject to certain working capital adjustments.

G. Inventories

Inventories 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. On December 30, 2022, Mayne Pharma acquired our inventory balance of approximately \$8.4 million, which is subject to certain net working capital adjustments.

H. 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, restricted 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.



I. 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.

J. License rights and other intangibles assets

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

License rights cost related to ANNOVERA were amortized until December 30, 2022 over the useful life over which the license rights would contribute directly or indirectly to our cash flows. The cost was amortized using the straight-line method as the pattern of economic benefit could not be reliably determined. On December 30, 2022, we assigned our ANNOVERA license to Mayne Pharma and included the remaining ANNOVERA license cost of \$30.2 million in our calculation of the gain on sale of assets. In addition, amortization of license rights of \$3.0 million for years 2022 and 2021 was reclassified to discontinued operations.

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.

K. Segment reporting

We manage and operate as one business, which prior to December 2022 was focused on creating and commercializing products targeted exclusively for women and after we signed Mayne License Agreement, is focused on collecting royalties from licensing our products. Our business 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. Accordingly, we view our business as one reportable operating segment.

L. 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. 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

On December 30, 2022, we granted an exclusive license to commercialize our prescription products and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma, which resulted in a business shift that had a major effect on our operations and financial results. As part of the transformation that included the Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. As of December 31, 2022, we are no longer directly engaged in the sale of prescription products.

Prior to the business shift in December 2022, prescription products were sold at fixed wholesale acquisition cost, or WAC, determined based on our list price. However, the total transaction price was variable as it was calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. These estimates were based on the amounts earned or to be claimed on the related sales and were classified as reductions of accounts receivable (if the amount was payable to the customer) or a current liability (if the amount was payable to a party other than a customer). To determine the transaction price, we estimated 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 was included in the transaction price only to the extent that it was probable that a significant reversal in the amount of cumulative product revenue recognized would not occur when the uncertainty associated with the variable consideration was subsequently resolved. In determining amounts of variable consideration to include in a contract's transaction price, we relied on our historical experience and other evidence that supported our qualitative assessment of whether product revenue would be subject to a significant reversal. We considered 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 could differ from our estimates. If actual results in the future varied from our original estimates, we would adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

We accepted 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 can not 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 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 did not allow product returns for prescription products that have been dispensed to a patient. We estimated the amount of our product sales that could be returned by our customers and recorded this estimate as a reduction of product revenue in the period the related product revenue was recognized. Where historical rates of return existed, we used history as a basis to establish a returns reserve for products shipped to wholesalers. For newly launched products, for which the right of return existed but for which we did not have history of product returns, we estimated 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, sometimes we constrained product revenue, if necessary, for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of products being shipped, price changes of competitive products and any introductions of generic products. We recognized the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since our returns primarily consisted of expired and short dated products that would not be resold, we did 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 offered various rebate and discount programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimated the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which was reviewed and adjusted, if necessary, on a quarterly basis. We recorded distributor fees based on amounts stated in contracts. We estimated chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. We provided discounts to our customers for prompt payment. Consumer rebates and coupons costs, distribution fees, chargebacks and discounts were deducted from gross product revenue at the time the product revenue was recognized.

For our prescription products, we offered a co-pay assistance program for eligible enrolled patients whose out of pocket costs were reduced to a more affordable price. This allowed patients to access the product at a reasonable cost and was in line with our responsible pricing approach. We reimbursed pharmacies for this discount through third-party vendors. The variable consideration was estimated based on contract prices, the estimated percentage of patients that would 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 could 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 was susceptible to such changes in coverage levels, which was outside the influence of the Company. As a result, we constrained variable consideration for our prescription products to an amount that would not result in a significant product revenue reversal in future periods. Our ability to estimate the net transaction price for our prescription products was constrained by our estimates of the amount to be paid for the co-pay assistance program which was directly related to the level of prescriptions paid for by insurance. As such, we recorded 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-evaluated 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.

On December 30, 2022, we and closed the Mayne Transaction pursuant to which we sold to Mayne Pharma the exclusive license rights in our product ANNOVERA and granted an exclusive license in other products, including IMVEXXY and BIJUVA (together, the three products being the "Licensed Products" - see Note 1). Under the terms of the Mayne License Agreement, we received \$140 million at closing and we are eligible to receive additional payments in the aggregate of up to an additional \$30 million, based on the achievement of sales milestones (collectively, the "Milestone Amounts"). The proceeds at closing were allocated between consideration for the sale of ANNOVERA and the initial license fee for the Licensed Products, as the sale of ANNOVERA was accounted for under ASC 610-20, Gains and Losses from Derecognition of Nonfinancial Assets in arriving at the gain on disposal (see Note 2), while the license grant of the other products were recognized under the provisions of ASC 606, Revenue from Contracts with Customers, as a license of functional intellectual property. The proceeds were allocated among the Licensed Products on the relative net present value of forecasted future product sales from those products. The Milestone Amounts will be recognized, as applicable, in subsequent periods based on actual product sales that exceed the respective net sales milestones as such variable consideration is constrained by the occurrence of the subsequent sales.

Our royalty revenue in 2022 related to royalties provided for under the Mayne License Agreement based on Mayne Pharma's sales of the licensed products subject to that agreement. Under the Mayne License Agreement, the Company is entitled to earn royalties on net sales of all of the Licensed Products at a royalty rate of (i) 8% on the first \$80 million of net sales of the Licensed Products and (ii) 7.5% on net sales of all of the Licensed Products after the first \$80 million of net sales. The royalty rate is subject to a 2% reduction upon the earlier to occur of (i) the expiration or revocation of the last valid claim covering a Licensed Product, and (ii) a generic product launch (a "LOE"). We are entitled to minimum annual royalties beginning with the year ending December 31, 2023 (\$3 million annual minimum) and continuing with 3% annual increases through the year ending December 31, 2034 (the "Minimum Annual Royalty"). The total Minimum Annual Royalty we are entitled to is \$42.6 million, and this total amount was allocated among the Licensed Products on the relative net present value of forecasted future product sales from those products. The portion allocated to consideration for the sale of ANNOVERA was attributed towards the gain on disposal of that asset. For the remaining portion allocated to the license grants for the other products, we determined that the minimum guarantee underlying the Minimum Annual Royalty should be treated as fixed consideration and recognized under ASC 606 at the point in time when the license was transferred. Since the Minimum Annual Royalty will be received in annual installments through 2034, we determined the transaction price allocated under ASC 606 contained a significant financing component, and we therefore determined the initial royalty revenue and corresponding receivable based on the present value of the allocated Minimum Annual Royalty. The present value was calculated using a discount rate of 10.45%, based on the credit characteristics of Mayne Pharma and the timing of future payments, and the value will be accreted to full value through the earlier of January 1, 2034 or a LOE. This royalty receivable is a contract asset as of December 31, 2022, and is further subject to offset by Mayne Pharma (see N. Contract Assets and Liabilities below).

Royalty revenue earned in excess of the Minimum Annual Royalty will be recognized under ASC 606, which provides revenue recognition constraints by requiring the recognition of revenue at the later of the following: 1) when the subsequent sale occurs or 2) when the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied). We applied the royalty recognition constraint required under the guidance for sales-based royalties, which requires a sales-based royalty to be recorded no sooner than the underlying sale. Therefore, royalties on sales of products commercialized by Mayne Pharma will be recognized in the subsequent periods that the Licensed Products are sold.

In 2021, we received 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. In 2022 and 2021, we recorded BIJUVA sales of \$1.4 million made through the Theramex License Agreement which was recorded as license revenue.

M. Cost of revenue

Cost of revenue includes the cost of inventory, manufacturing, manufacturing overhead and supply chain costs and product shipping and handling costs. Costs related to the Population Council License Agreement, which were based on our net sales of ANNOVERA, and amortization of license rights were reclassified to discontinued operations for 2022 and 2021 as a result of the transaction with Mayne Pharma.

N. Contract Assets and Liabilities

Contract assets as of December 31, 2022, include royalties recognized from the Minimum Annual Royalty (see L. Revenue Recognition above). Pursuant to the Mayne License Agreement, this asset was reduced in December 2022 by \$1.5 million in consideration for Mayne Pharma assuming an obligation payable to vitaCare, and will be further reduced, other than from future payments on receivables from Mayne Pharma, for \$1.0 million in prepaid royalties that we received from Mayne Pharma on the closing date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable to us under the Minimum Annual Royalty by an amount equal to \$257,250 per quarter plus interest calculated at 19% per annum.

O. Research and development

Research and development expenses included 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 included laboratory supplies, salaries, benefits, and share-based payment award compensation costs. CRO activity expenses included preclinical laboratory experiments and clinical trial studies. Other activity expenses included regulatory consulting and other costs. These consulting expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs which were reclassified to discontinued operations for 2022 and 2021 as a result of the transaction with Mayne Pharma. As of December 31, 2022, we do not have any ongoing research and development activities.

P. 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.

Q. Common stock reverse stock split

On May 6, 2022, we completed a reverse stock split of our Common Stock. As a result, outstanding shares of our Common Stock were split at a ratio of 50- for-1 (the "Reverse Stock Split") with any fractional shares resulting from the Reserve Stock Split rounded up to the next whole share of Common Stock. The number of authorized shares of Common Stock was also correspondingly reduced from 600.0 million shares to 12.0 million shares to give effect to the Reverse Stock Split. Additionally, all rights to receive shares of Common Stock under outstanding warrants, options, restricted stock units ("RSUs") and performance stock units ("PSUs") were adjusted to give effect of the Reverse Stock Split. Furthermore, remaining shares of Common Stock available for future issuance under share-based payment award plans and our employee stock purchase plan were adjusted to give effect of the Reverse Stock Split. Pursuant to Section 78.209 of the Nevada Revised Statutes, the approval of our stockholders was not required for our Board of Directors (the "Board") to effectuate the Reverse Stock Split.

All historical number of shares of Common Stock and per share data have been adjusted to give effect to the Reverse Stock Split. Additionally, since the Common Stock par value was unchanged, historical amounts for Common Stock and additional paid-in capital have been adjusted to give effect to the Reverse Stock Split.

R. 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.

S. 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.

T. Leases

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.

U. 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.

V. Restructuring charges

During the year ended December 31, 2022, the Company initiated and completed a restructuring plan that resulted in a reduction of its workforce to one employee. One-time termination benefits include severance, continuation of health insurance coverage, and other benefits for a specified period of time, as well as contract terminations and fixed assets write-downs, which resulted in \$15.7 million of restructuring costs for the year ended December 31, 2022. These costs have been recognized in the accompanying consolidated statement of operations as follows (in thousands):

	Year ended December 31, 2022
Executive termination benefits	\$ 3,897
Consulting and legal expenses	3,060
Other contract termination costs	2,515
Total restructuring expenses - general and administrative expenses	<u>\$ 9,472</u>
Employee termination benefits	\$ 4,813
Other contract termination costs	1,367
Total restructuring expenses - discontinued operations	<u>\$ 6,180</u>

At December 31, 2022, \$9.3 million related to restructuring costs was included in accrued expenses and other current liabilities and \$6.2 million was included in current liabilities of discontinued operations in the accompanying consolidated balance sheets.

W. Reclassification of prior year presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. An adjustment has been made to the consolidated statements of operations for 2022 and 2021 to reclassify commercial operations and vitaCare operations to discontinued operations as both components, in the aggregate, represented a business shift that will have a major effect on the Company's operations and financial results.

2. Discontinued Operations

We changed our business in 2022, by out-licensing our products to receive royalties and future sales related milestone payments, after granting an exclusive license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD and vitaMedMD brands in the United States and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma.

This plan represented a strategic shift having a major effect on the Company's operations and financial results. Upon the completion of the Company's restructuring and ultimate conversion from a commercial pharmaceutical company to a licensing only company with the consummation of the Mayne Transaction, the Company classified all direct revenues, costs and expenses related to commercial operations, within income (loss) from discontinued operations, net of tax, in the consolidated statements of operations for all periods presented. No amounts for shared general and administrative operating support expense were allocated to discontinued operations. As required by the terms of our Financing Agreement, the proceeds from both transactions were used to fully repay our outstanding debt borrowings, and as a result interest expense and amortization of deferred financing costs as well as expense for accretion of Series A Preferred Stock and loss on extinguishment of debt are included within income (loss) from discontinued operations, net of tax (as disclosed below).

Additionally, the related assets and liabilities have been reported as assets and liabilities of discontinued operations in the Company's consolidated balance sheet as of December 31, 2022 and 2021.

The total consideration from Mayne Pharma was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of \$12.1 million for the acquisition of net working capital subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million for prepaid royalties in connection with the License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the License Agreement, as amended.

The Company's estimate of net working capital at closing was determined in accordance with the Transaction Agreement which establishes the process for the determination of final net working capital. The determination of net working capital includes significant estimates which could change materially for a period of up to two years following the Closing Date. On March 29, 2023, the Company received Mayne Pharma's closing net working capital calculation which differed significantly from the Company's estimate of closing net working capital. The Company believes that its estimate of net working capital is reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's calculation and the nature of the estimates involved, the outcome of this matter is uncertain at this point. As a result, the Company cannot reasonably estimate a range of loss, and accordingly, the Company has not accrued any additional liability associated with Mayne Pharma's calculation.

The proceeds at closing were allocated separately to the sale of ANNOVERA and the license grant related to the other products, as the sale of ANNOVERA was accounted for under ASC 610-20, Gains and Losses from Derecognition of Nonfinancial Assets in arriving at the gain on disposal. We recognized \$70.0 million in revenue from transaction with Mayne Pharma, which represented license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products as well as present value of future minimum royalty payments (as discussed in Note 1).

The Company classified the \$143.4 million gain on the sale of the vitaCare business and \$62.0 gain on sale of ANNOVERA, net of transaction costs in discontinued operations.

The Company recorded a restructuring expense of \$15.7 million, for the year ended December 31, 2022 for contract terminations, severance, and fixed asset write-downs, of which \$6.2 million was recorded in discontinued operations.

The following table presents results of discontinued operations (in thousands):

	Year ended December 31,	
	2022	2021
Product revenue, net	\$ 80,749	\$ 84,378
Cost of goods sold	15,640	17,436
Gross profit	65,109	66,942
Operating expenses:		
Selling and marketing	75,208	108,195
General and administrative	11,301	11,854
Research and development	4,942	7,086
Restructuring charges	6,180	—
Total operating expenses	97,631	127,135
Loss from discontinued operations	(32,522)	(60,193)
Other (expense) income:		
Gain on sale of vitaCare	143,384	—
Gain on ANNOVERA sale	62,031	—
Loss on the extinguishment of debt	(8,380)	—
Interest expense and other financing costs	(36,065)	(32,917)
Expense for accretion of Series A Preferred Stock	(16,973)	—
Other income, net	—	—
Total other income (expense), net	143,997	(32,917)
Loss before from income taxes	111,475	(93,110)
Provision for income taxes	(552)	—
Net income (loss) from discontinued operations	\$ 110,923	\$ (93,110)

The following table presents the carrying amounts of the classes of assets and liabilities of discontinued operations as of December 31, 2022 and December 31, 2021 (in thousands):

	As of December 31,	
	2022	2021
Assets:		
Current assets:		
Cash	\$ —	\$ 215
Accounts receivable	—	36,176
Inventory	—	7,622
Prepaid and other current assets	—	4,689
Total current assets	—	48,702
Fixed assets, net	—	376
License rights and other intangible assets, net	—	33,174
Total assets	\$ —	\$ 82,252
Liabilities:		
Current liabilities:		
Accounts payable	\$ 12,243	\$ 16,945
Accrued expenses and other current liabilities	13,588	30,966
Total current liabilities	\$ 25,831	\$ 47,911

3. Prepaid and other current assets

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

	As of December 31,	
	2022	2021
Insurance	\$ 1,167	\$ 2,731
Paragraph IV legal proceeding costs	2,334	2,304
Other	2,533	824
Prepaid and other current assets	\$ 6,034	\$ 5,859

4. Fixed assets

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

	As of December 31,	
	2022	2021
Furniture and fixtures	\$ 931	\$ 891
Computer and office equipment	1,168	1,448
Computer software	375	375
Leasehold improvements	49	80
Fixed assets	2,523	2,794
Less: accumulated depreciation and amortization	2,445	1,971
Fixed assets, net	\$ 78	\$ 823

We recorded depreciation expense of \$0.6 million for 2022 and \$0.4 million for 2021.

5. 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, 2022			As of December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Hormone therapy drug patents	\$ 6,225	\$ 1,598	\$ 4,627	\$ 5,834	\$ 1,042	\$ 4,792
Hormone therapy drug patents applied and pending approval	1,995	—	1,995	2,020	—	2,020
Intangible assets subject to amortization	8,220	1,598	6,622	7,854	1,042	6,812
Intangible assets not subject to amortization:						
Trademarks/trade name rights	321	—	321	332	—	332
Intangible assets, net	\$ 8,541	\$ 1,598	\$ 6,943	\$ 8,186	\$ 1,042	\$ 7,144

We recorded, in continuing operations, amortization expense related to patents of \$0.6 million for 2022 and \$0.3 million for 2021. We recorded amortization expense related to the exclusive license rights agreement with Population Council of \$3.0 million for 2022 and 2021, which was reclassified to discontinued operations after we completed transaction with Mayne Pharma in December 2022, which are excluded from the table above.

Our intangible assets subject to amortization are expected to be amortized as follows (in thousands):

Year ending December 31,	
2023	\$ 337
2024	439
2025	438
2026	438
2027	438
Thereafter	2,537
Total	\$ 4,627

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, 2022 or 2021, therefore, no write downs were recorded to our licensed rights and other intangible assets.

6. Accrued expenses and other current liabilities

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

	As of December 31,	
	2022	2021
Payroll and related costs	\$ 8,748	\$ 6,549
Accrued contract termination costs	4,700	-
Research and development expenses	978	-
Professional fees	415	2,571
Operating lease liabilities	1,390	1,361
Prepaid royalty	1,011	-
Other	1,604	2,857
Accrued expenses and other current liabilities	\$ 18,846	\$ 13,338

We expense advertising costs when incurred, which amounted to \$13.2 million and \$39.7 million for 2022 and 2021, respectively, which was reclassified to discontinued operations as a result of business shift following transaction with Mayne Pharma.

7. Debt

Our debt consisted of the following (in thousands):

	As of December 31,	
	2022	2021
Financing Agreement	\$ -	\$ 200,000
Less: deferred financing fees	-	11,731
Debt, net	-	188,269
Current maturities of long-term debt	-	188,269
Long-term debt	\$ -	-

Financing agreement

We were 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. On December 30, 2022, we repaid all obligations under the Financing Agreement and the Financing Agreement was terminated.

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 Agent terminated the undrawn \$50.0 million tranche under the Financing Agreement, therefore, such amount was no longer available to us to borrow.

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 accrued 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 30, 2022, our interest rate was 10.45%. Interest on amounts borrowed under the Financing Agreement was due and payable quarterly in arrears. In addition, we were required to pay an annual administrative fee, and other fees and expenses.

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 95,042 shares of our common stock with an exercise price of \$79 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 was 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 \$59.5 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 \$79 to \$59.5 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.

In March 2022, we entered into Amendment No. 9 to the Financing Agreement (“Amendment No. 9”) pursuant to which, among other amendments, (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 a 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 pay a paid in kind (“PIK”) amendment financing 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 was waivable in certain conditions; (iv) the maturity date of the Financing Agreement was amended to June 1, 2022; and (v) the Company agreed to pay to the Lenders as a prepayment of the loans under the Financing Agreement 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. Amendment No. 9 was accounted for as an extinguishment of debt modification in accordance with U.S. GAAP. Accordingly, in March 2022, we recorded an \$8.4 million loss on extinguishment of debt, which represented the unamortized deferred financing fees, net of previously accrued prepayment fees. Additionally, Amendment No. 9 PIK financing fee was recorded as deferred financing fees and was amortized over the remaining term of the Financing Agreement. In April 2022, we utilized \$120.0 million of net proceeds from the vitaCare Divestiture to make a prepayment of the loans under the Financing Agreement under the terms of Amendment No. 9. Additionally, with the prepayment on the debt, \$16.0 million of the PIK financing fee was waived in accordance with Amendment No. 9.

In May 2022, we entered into Amendment No. 10 to the Financing Agreement (“Amendment No. 10”) pursuant to which, among other amendments, (i) interest payments under the Financing Agreement were paused, such that interest on each term loan was payable in cash and in arrears (a) upon any prepayment of that term loan, whether voluntary or mandatory, to the extent accrued on the amount being prepaid and (b) on the maturity date, (ii) the minimum cash covenant was set at \$10.0 million, (iii) the maturity date of the Financing Agreement was amended to July 13, 2022, (iv) the termination of the Company’s merger agreement with an affiliate of EW Healthcare Partners was added as an event of default, and (v) we agreed to a PIK financing fee of \$1.8 million, which fee was added to the principal amount of the loans under the Financing Agreement. Amendment No. 10 was accounted for as a debt amendment in accordance with U.S. GAAP. Accordingly, in May 2022, Amendment No. 10 PIK financing fee was recorded as deferred financing fees and was amortized over the remaining term of the Financing Agreement.

Also in May 2022, we entered into Amendment No. 11 (“Amendment No. 11”) to the Financing Agreement. Amendment No. 11 contains amendments to the Financing Agreement that would have gone into effect upon the satisfaction of certain conditions on or before July 13, 2022 (the “Amendment Effective Date”), including (i) the consummation of the merger with an affiliate of EW Healthcare Partners (the “Merger”), (ii) the payment in cash of (a) all accrued and unpaid interest under the Financing Agreement through and including the Amendment Effective Date and (b) all fees, costs, expenses and taxes then payable pursuant to Section 2.7 or 10.2 of the Financing Agreement, and (iii) the delivery to the administrative agent of certain customary documents with respect to the pledge of 100% of the capital stock of the Company. Since the consummation of the Merger did not occur, Amendment No. 11 never became effective.

On July 13, 2022, we entered into Amendment No. 12 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 24, 2022, and we agreed to pay the Lenders a PIK amendment fee in the amount of \$1.2 million. On July 24, 2022, we entered into Amendment No. 13 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 27, 2022, we agreed to pay the Lenders a payment of accrued and unpaid interest of \$2.9 million, and we agreed to retain Jeffrey Varsalone from G2 Capital Advisors as our chief restructuring officer. On July 27, 2022, we entered into Amendment No. 14 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 28, 2022. On July 28, 2022, we entered into

Amendment No. 15 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 29, 2022.

On July 29, 2022, we entered into Amendment No. 16 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to September 30, 2022, with the option for us to further extend the maturity date to October 31, 2022, and November 30, 2022, in each case if we receive not less than \$7.0 million in cash proceeds from an equity issuance, which, if preferred equity, is on substantially the same terms as the Preferred Stock. In lieu of a cash amendment fee, to induce the Lenders to enter into Amendment No. 16, on July 29, 2022, we issued Lender Warrants to purchase an aggregate of 185,000 shares of Common Stock, pursuant to a subscription agreement by and among the Company and the Lenders (the "July Lender Subscription Agreement"). The Lender Warrants to purchase 185,000 shares of our Common Stock issued pursuant to the July Lender Subscription Agreement have an exercise price of \$0.01 per warrant, subject to certain adjustment as provided therein, and an expiration date of July 29, 2032, and may be exercised via cashless exercise pursuant to the terms thereof. These Lender Warrants were initially valued at \$1.2 million based on the market price of our Common Stock on July 29, 2022 and entirely expensed as financing costs.

In connection with the closing of a private placement offering with Rubric Capital Management LP ("the Preferred Stock Investor") on September 30, 2022, and in accordance with Amendment No. 16 to the Financing Agreement, on September 30, 2022, we issued Lender Warrants to purchase an aggregate of 125,000 shares of Common Stock, pursuant to a subscription agreement by and among the Company and the Lenders (the "September Lender Subscription Agreement"), and the maturity date of the Financing Agreement was extended to October 31, 2022. These Lender Warrants have an exercise price of \$0.01 per share of Common Stock, subject to certain adjustment as provided therein, and an expiration date of September 30, 2032 and may be exercised via cashless exercise pursuant to the terms thereof. These Lender Warrants were initially valued at \$0.8 million based on the market price of our Common Stock on September 30, 2022 and recorded as deferred financing fees, which were expensed with maturity of the Financing Agreement on October 31, 2022. Additionally, in September 2022, we and the Lenders agreed to PIK interest of \$2.5 million related to the outstanding debt balance.

In connection with the closing of the private placement offering with the Preferred Stock Investor on October 28, 2022, and in accordance with Amendment No. 16 to the Financing Agreement, on October 28, 2022, we issued Lender Warrants to purchase an aggregate of 125,000 shares of Common Stock, pursuant to a subscription agreement by and among the Company and the Lenders, and the maturity date of the Financing Agreement was extended to November 30, 2022. These Lender Warrants have an exercise price of \$0.01 per share of Common Stock, subject to certain adjustment as provided therein, and an expiration date of October 28, 2032 and may be exercised via cashless exercise pursuant to the terms thereof. These Lender Warrants were initially valued at \$0.7 million based on the market price of our Common Stock on October 28, 2022 and recorded as financing costs.

The fair value of the Lender Warrants was based on the date of grant using our Common Stock's closing price at measurement date and was recorded to "Additional paid-in-capital" in the consolidated balance sheets. See Note 9, Mandatory Redeemable Preferred Stock and Stockholders' Equity (Deficit) for additional information regarding the equity financing with the Preferred Stock Investor.

On November 30, 2022, we entered into Amendment No. 17 ("Amendment No. 17") to the Financing Agreement. Pursuant to Amendment No. 17, among other things, (i) the maturity date of the Financing Agreement was extended to December 31, 2022, subject to the achievement of certain milestones by the Company, (ii) the minimum cash covenant was set at \$7.5 million, (iii) the Company agreed to pay the Lenders an amendment fee in the amount of \$750,000 and (iv) the Company paid the Lenders all accrued and unpaid interest under the Financing Agreement as of the Amendment Date, in the amount of approximately \$4.2 million. On December 30, 2022, we repaid remaining obligations under the Financing Agreement of \$75.0 million, PIK financing fees of \$17.0 million and the remaining accrued interest, and the Financing Agreement was terminated.

Interest and financing costs

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

	2022	2021
Interest expense	\$ 13,545	\$ 22,568
Prepayment fees	-	4,660
Financing fees amortization	22,520	5,689
Total	<u>\$ 36,065</u>	<u>\$ 32,917</u>

8. 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. We are in the process of subleasing our headquarters as a result of shifting our business to become a license company and terminating our employees. We anticipate that sublease income will approximate the amounts due under our existing leases, therefore no impairment of the right of use asset was recorded in 2022.

For 2022, operating lease expense related to our real estate leases was \$1.4 million and variable lease expense was \$0.7 million. For 2021, operating lease expense related to our real estate leases was \$2.1 million and variable lease expense was \$0.7 million. In 2022, our rental income was \$0.4 million on sublease of our two suites which were subleased following vitaCare transaction.

As of December 31, 2022, our remaining lease payments were as follows (in thousands):

	Year ending December 31,
2023	\$ 1,443
2024	1,477
2025	1,513
2026	1,551
2027	1,590
Thereafter	4,294
Total undiscounted lease payments	11,868
Less: imputed interest	3,109
Present value of lease payments	\$ 8,759

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

	As of December 31,	
	2022	2021
Assets:		
Operating lease right-of-use assets	\$ 7,580	\$ 8,234
Liabilities:		
Operating lease liabilities current (included in accrued expenses and other current liabilities)	\$ 1,390	\$ 1,361
Operating lease liabilities, non-current	7,369	8,063
Total operating lease liabilities	\$ 8,759	\$ 9,424

The following table presents other information related to leases:

	2022	2021
Weighted average remaining term (years) - operating leases	7.7	8.7
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)	\$ 1,413	\$ 2,335
Right-of-use assets obtained in exchange for new operating lease obligations (non-cash in thousands)	\$ —	\$ —

Mayne Pharma Agreement

Mayne Pharma paid us approximately \$12.1 million at closing for the acquisition of net working capital, as determined in accordance with the Transaction Agreement, and is subject to certain adjustments for a period of up to two years following the Closing Date.

Pursuant to the Mayne License Agreement Amendment, Mayne Pharma also paid the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition,



Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement, including the Company's minimum payment obligations thereunder.

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. The Population Council was also eligible to receive future payments upon the achievement of certain commercial sales milestones of ANNOVERA. On December 30, 2022, we assigned the ANNOVERA license to Mayne Pharma. The rights and obligations under the Population Council License Agreement have been transferred to Mayne Pharma and will revert back to us upon certain events.

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 had 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 was to be offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. 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. Our obligations to perform the post-approval study have been transferred to Mayne Pharma as part of the Mayne License Agreement. We believe that Mayne Pharma is 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 the NDA holder for ANNOVERA.

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 Mayne Pharma, or the date following such expiration that follows a continuous period of six months during which Mayne Pharma has 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 Mayne Pharma on 180 days' prior notice to the Population Council.

Purchase commitments

We had manufacturing and supply agreements whereby we were 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 ended each April and July, respectively. If the minimum order quantities of BIJUVA or IMVEXXY were not met, we were 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.

Additionally, with another third-party manufacturer, we had a manufacturing and supply agreement, renewable annually, whereby we were required to purchase a minimum number of units of ANNOVERA during a contract year. The annual contract period for ANNOVERA ended each August. If the minimum order quantities of ANNOVERA were not met, we were 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.

On December 30, 2022, after granting an exclusive license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD and vitaMedMD brands and assigning the Company's exclusive license to commercialize ANNOVERA to Mayne Pharma, the rights and obligations under the Catalent minimum manufacturing and supply agreements and other supply agreements have been transferred to Mayne Pharma.

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 the FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the IMVEXXY

Notice Letter, Teva alleges that TherapeuticsMD patents listed in the FDA's Orange Book that claim compositions and methods of IMVEXXY (the "IMVEXXY Patents") are invalid, unenforceable, and/or will not be infringed by Teva's commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the 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 the FDA from granting final approval of the ANDA for 30 months from the date of the IMVEXXY 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. As of December 31, 2022, 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 life of the patents. 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 an unsuccessful legal proceeding.

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 30, 2022 and per the license agreement, Mayne Pharma is responsible for all enforcement of our patents, including this litigation with 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.

Compliance with Nasdaq's continued listing requirements

In January 2023, we received a deficiency letter (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we were not in compliance with the rules for continued listing as set forth in Nasdaq Listing Rule 5620(a) (the "Annual Meeting Rule") due to our failure to hold an annual meeting of stockholders within 12 months after our fiscal year ended December 31, 2021. The Notice had no immediate effect on the listing of our Common Stock. We did not hold an annual meeting of stockholders during 2022 due to our then ongoing strategic processes.

The Notice stated that, under Nasdaq Listing Rule 5810(c)(2)(G), we had 45 calendar days, or until February 20, 2023, to submit a plan to regain compliance with the Annual Meeting Rule. We timely submitted such plan, and Nasdaq granted us an extension until June 29, 2023, to regain compliance. It is our intent to hold an annual meeting of stockholders in 2023 prior to such deadline and to fully regain compliance with all applicable Nasdaq listing standards.

Off-balance sheet arrangements

As of December 31, 2022 and 2021 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

In connection with the Company's transformation into a pharmaceutical royalty company, the termination of our executive management team (except for Mr. Marlan Walker, our former General Counsel and current Chief Executive Officer) and all other employees was completed by December 31, 2022. Severance obligations for all employees other than executive officers were paid in full in the first quarter of 2023 and severance obligations for terminated executive officers will be paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022, we have employed one full-time employee primarily engaged in executive position. We have engaged external consultants, including certain former members of our management team, who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations. The separation of our former Interim Co-Chief Executive Officers, former Interim Chief Financial Officer and other executives from the Company was a termination without "Good Cause," as defined in their employment agreements. In the aggregate, in December 2022, we recorded severance expenses for executive termination obligations of \$6.0 million, of which \$1.1 million was related to share-based compensation recorded in connection with accelerated vesting of certain share-based payment awards.

On September 6, 2022, our Board appointed interim Co-Chief Executive Officers. The separation of our former chief executive officer from the Company was a termination without "Good Cause," as defined in his employment agreement. Accordingly, our former chief executive officer received the separation benefits provided therein, and we recorded executive officer severance expenses of \$4.8 million, of which \$3.2 million was related to share-based compensation recorded in connection with accelerated vesting of certain share-based payment awards for the former chief executive officer. In connection with our former chief executive officer's separation from the Company, he ceased to serve as a member of our Board.

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 a new 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 maintained a voluntary defined contribution 401(k) plan covering all eligible employees as defined in the plan documents. The plan provided 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 elected to participate in the plan were generally fully vested in any existing matching contribution after five years of service with the Company. As part of termination of employees, all contributions made by the Company to each participant became 100% vested.

Contributions by the Company under the plan amounted to \$0.5 million and \$0.6 million for 2022 and 2021, respectively.

9. Mandatory Redeemable Preferred Stock and Stockholders' Equity (Deficit)

Rubric Capital Management LP Subscription Agreements (Sale of Mandatory Redeemable Preferred Stock and Common Stock)

On July 29, 2022, we entered into a Subscription Agreement with the Preferred Stock Investor, pursuant to which we issued and sold, in a private placement offering, (i) 15,000 shares of the Company's newly-designated Series A Preferred Stock, par value \$0.001 per share (the "Series A Preferred Stock") for a purchase price per share of Series A Preferred Stock equal to \$822.21 and an aggregate purchase price of \$12.3 million, and (ii) 565,000 shares of the Company's Common Stock, for a purchase price per share of Common Stock equal to \$4.72 and an aggregate purchase price of \$2.7 million. This offering closed on July 29, 2022, and we received aggregate gross proceeds of \$15.0 million, before expenses.

On September 30, 2022, we entered into a Subscription Agreement with the Preferred Stock Investor, pursuant to which we issued and sold, in a private placement offering, 7,000 shares of the Company's Series A Preferred Stock for an aggregate offering price of \$7.0 million. In addition, in lieu of issuing, selling and delivering 263,666 shares of the Company's Common Stock to the Preferred Stock Investor, we agreed to pay the Preferred Stock Investor, on the later of (i) the Maturity Date (as defined in the Certificate of Designation, Preferences and Rights of Series A Preferred Stock, establishing the powers, designations, preferences and privileges and the

qualifications, limitations or restrictions of the Series A Preferred Stock (the "Certificate of Designation")) or (ii) the date our obligations under the Financing Agreement were paid in full, a make-whole payment equal to 263,666 multiplied by the closing price of our Common Stock on the principal securities exchange or securities market on which the Common Stock is then traded, on the day prior to the date of payment of the make-whole payment. This offering closed on September 30, 2022, and we received gross proceeds of \$7.0 million, before expenses.

On October 28, 2022, we entered into a Subscription Agreement with the Preferred Stock Investor, pursuant to which we issued and sold, in a private placement offering, 7,000 shares of the Company's Series A Preferred Stock for an aggregate offering price of \$7.0 million. In addition, in lieu of issuing, selling and delivering 263,666 shares of the Company's Common Stock to the Preferred Stock Investor, we agreed to pay the Preferred Stock Investor, on the later of (i) Maturity Date or (ii) the date our obligations under the Financing Agreement were paid in full, a make-whole payment equal to 263,666 multiplied by the closing price of our Common Stock on the principal securities exchange or securities market on which the Common Stock is then traded, on the day prior to the date of payment of the make-whole payment. This offering closed on October 28, 2022, and we received gross proceeds of \$7.0 million, before expenses. The Company received gross proceeds of \$7 million from the Offering, before expenses.

The Series A Preferred Stock was not convertible into Common Stock and ranked senior to Common Stock, with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the Series A Preferred Stock had a liquidation preference equal to \$1,333 per share. The Series A Preferred Stock did not have any voting rights other than as required by applicable law. The holders of Series A Preferred Stock were entitled to dividends equal to 25% of cash dividends actually paid, if any, on shares of Common Stock, paid pro rata on the outstanding shares of Series A Preferred Stock. Upon the occurrence of change of control, the holders of Series A Preferred Stock could have required the Company to redeem all or part of such holder's Series A Preferred Stock at a redemption price per share of Series A Preferred Stock, payable in cash, equal to the liquidation preference of \$1,333 per share of Series A Preferred Stock.

We also had the option to redeem all the outstanding shares of Series A Preferred Stock on such terms if we consummated a change of control transaction. Each holder of Series A Preferred Stock also had the right to cause the Company to redeem all, but not less than all, of their shares of the Series A Preferred Stock upon the occurrence of certain events, including, without limitation, the Company's failure to comply with any covenants under the Certificate of Designation or if the Company commenced a bankruptcy proceeding, subject to certain conditions. Under such circumstances, the Company was required to redeem all, but not less than all, of the holder's outstanding shares of Series A Preferred Stock at a redemption price per share of Series A Preferred Stock, payable in cash, equal to the liquidation preference of \$1,333 per share.

We were required to redeem from each holder of Series A Preferred Stock all outstanding shares of Series A Preferred Stock held by such holder, at a redemption price per share of Series A Preferred Stock, payable in cash, equal to the liquidation preference of \$1,333 per share of Series A Preferred Stock, upon the earlier to occur of (i) the Maturity Date and (ii) the incurrence of Permitted Refinancing Indebtedness (as defined in the Certificate of Designation). The Company accreted the Series A Preferred Stock from its fair value on the date of issuance to its redemption value using the effective interest rate method.

On December 30, 2022, and in accordance with the terms of the Certificate of Designation, the Company mandatorily redeemed all 29,000 outstanding shares of Series A Preferred Stock at a purchase price of \$1,333 per share. The Company also paid certain affiliates of the Preferred Stock Investor approximately \$3.0 million as a make-whole payment pursuant to the subscription agreements previously entered into between the Company and the Preferred Stock Investor.

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 permitted 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 could 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 was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. The sales agent was not required to sell any specific number or dollar amounts of securities but acted as sales agent and used 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 sold a total of 674,106 shares of our common stock under the 2021 ATM Program at an average sale price of \$60.5 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 2022 10-K Report, we have not sold any additional shares of our common stock under the 2021 ATM Program. The Company does not currently have an effective shelf registration statement in place and therefore, the 2021 ATM program has been suspended. 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 1,189,189 shares of our common stock at an offering price of \$92.5 per share, and we received net proceeds of \$96.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

Warrants

As disclosed in Note 7. Debt, in 2022 we issued to the Administrative Agent and the lenders under the Financing Agreement Lender Warrants to purchase an aggregate of 435,000 shares of common stock in relation to Amendment No.16 to the Financing Agreement. In 2020, we issued to the Administrative Agent and the lenders under the Financing Agreement warrants to purchase an aggregate of 95,042 shares of our common stock.

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, December 31, 2020	131	\$ 77.50	\$ 1,041	7.3	
Exercised	(23)	\$ 15.50	\$ 1,146		
Expired	(5)	\$ 395.00			
Balance, December 31, 2021	103	\$ 76.19	\$ -	-	8.3
Granted	436	\$ 0.14			
Expired	(3)	\$ 341.50			
Balance, December 31, 2022	536	\$ 13.10	\$ 2,427		9.3

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 2022 was \$0.13 per warrant and the assumptions used to determine such fair value were as follows: expected term of 10 years, volatility of 69.4%, dividend yields of 0% and risk-free interest rates of 2.9%. The fair value of the Lender Warrants was based on the date of grant using our Common Stock’s closing price at measurement date and was recorded to “Additional paid-in-capital” in the consolidated balance sheets. There were no warrant grants in 2021.

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, 749,500 shares of common stock are authorized for issuance, which includes 449,500 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 55,000 RSUs (designated as “Time-Based Units”) and 55,000 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 13,200 RSUs (designated as “Time-Based Units”) and 5,200 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 part of the termination agreement with our CEO, 55,000 Performance Units were cancelled and 55,000 RSUs vested in 2022. As part of the termination agreements with our Chief Business Officer, 3,900 Performance Units and 11,466 RSUs vested in 2022.

As of December 31, 2022, 518,074 shares of common stock were subject to outstanding awards under our share-based payment award plans and inducement grants including outstanding PSUs that were vested at 100% as a result of termination of employees.

The following table summarizes the outstanding awards issued pursuant to our share-based payment award plans and inducement grants as of December 31, 2022 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)	47	198	96	352
2012 Plan (4)	11	—	—	—
2009 Plan (5)	114	—	—	—
2021 Inducement Grants	—	48	4	—

(1) The number of PSUs represents the number of PSUs that will vest.

(2) The number of remaining shares of common stock available for future issuance is based on the number of PSUs that will vest.

(3) As of December 31, 2022, outstanding options have exercise prices ranging from \$53.5 to \$136.5 and will expire on March 30, 2023, due to termination of employees except for awards for one employee and several consultants. Unvested RSUs will vest until July 2024. The unvested PSUs will vest until April 2025.

(4) As of December 31, 2022, outstanding options have exercise prices ranging from \$221.5 to \$446 and will expire on March 30, 2023, due to termination of employees except for awards for one employee and several consultants.

(5) As of December 31, 2022, outstanding options have exercise prices ranging from \$90 to \$446 and will expire on March 30, 2023 due to termination of employees except for awards for one employee and several consultants.

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 \$250.5 (“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 89,860 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 14,005 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 weighted 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, December 31, 2020	476	\$ 240.00	\$ 152	5.2	397	\$ 253.00	\$ 117	4.6
Granted	1	\$ 60.50						
Exercised	(2)	\$ 1.50	\$ 61					
Cancelled/Forfeited	(101)	\$ 300.50						
Expired	(21)	\$ 201.00						
Balance, December 31, 2021	353	\$ 225.98	\$ -	3.8	336	\$ 230.93	\$ -	3.6
Granted	-	\$ -						
Exercised	-	\$ -	\$ -					
Cancelled/Forfeited	(4)	\$ 94.99						
Expired	(177)	\$ 226.56						
Balance, December 31, 2022	172	\$ 228.28	\$ -	3.6	170	\$ 229.43	\$ -	3.6

We used the Black Scholes option pricing model to estimate the fair value of options granted. There were no option grants in 2022. 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%.

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, December 31, 2020	141	\$ 88.00	\$ 8,544	—	\$ -	\$ -	\$ -	\$ -
Granted	260	\$ 52.50						
Vested and settled	(103)	\$ 78.50	\$ 4,021					
Cancelled/Forfeited	(27)	\$ 73.50						
Balance, December 31, 2021	272	\$ 58.00	\$ 4,890	31	\$ 105.00	\$ 566		
Granted	170	\$ 16.05						
Vested and settled	(138)	\$ 67.50	\$ 1,343					
Cancelled/Forfeited	(58)	\$ 37.49						
Balance, December 31, 2022	246	\$ 29.64	\$ 1,376	189	\$ 26.28	\$ 1,059		

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, 2020	48	\$ 54.00	\$ 2,909	—	\$ —	\$ —	\$ —	\$ —
Granted	152	\$ 52.00						
Vested and settled	(34)	\$ 58.00	\$ 1,057					
Cancelled/Forfeited	(2)	\$ 53.50						
Balance, December 31, 2021	164	\$ 51.50	\$ 2,953	39	\$ 59.00	\$ 709		
Granted	63	\$ 34.50						
Vested and settled	(52)	\$ 58.26	\$ 108					
Cancelled/Forfeited	(75)	\$ 44.85						
Balance, December 31, 2022	100 (1)	\$ 42.30	\$ 558	81	\$ 39.95	\$ 450		

(1) The number of PSUs represents the number of PSUs that will vest.

Employee stock purchase plan

In June 2020, our stockholders approved the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan ("ESPP"), which reserved 108,000 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 2022, 5,229 shares were sold under the ESPP at the average price of \$2.6 per share and we received proceeds of approximately \$14,000. In 2021, 6,721 shares were sold under the ESPP at an average sale price of \$34.5 per share and we received proceeds of \$0.2 million. In the second quarter of 2022, the ESPP Plan was suspended.

Share-based payment compensation cost

Share-based payment compensation expense for PSUs is based on 100% vesting which was a part of termination of benefits for all employees who were terminated in 2022. 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 \$11.6 million for 2022 and \$18.1 million for 2021.

As of December 31, 2022, we had \$0.7 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 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, 2022, is expected to be recognized as share-based payment award compensation over a weighted average period of 1.4 years.

10.Revenue

Disaggregated revenue

The following table provides information about disaggregated revenue (in thousands) recognized in continuing operations:

	2022	2021
License revenue:		
Mayne Pharma	\$ 68,561	\$ -
Theramex	1,402	2,573
Total revenue, net	<u>\$ 69,963</u>	<u>\$ 2,573</u>

License agreements

Mayne license agreement

Pursuant to a License Agreement, dated December 4, 2022, between the Company and Mayne Pharma (the "Mayne License Agreement"), the Company granted Mayne Pharma, on the Closing Date, (i) an exclusive, sublicensable, perpetual, irrevocable license to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Licensed Products in the United States and its possessions and territories and (ii) an exclusive, sublicensable, perpetual, irrevocable license to manufacture, have manufactured, import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.

Pursuant to the Mayne License Agreement, Mayne Pharma will make one-time, milestone payments to the Company of each of (i) \$5.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$100.0 million, (ii) \$10.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$200.0 million and (iii) \$15.0 million if aggregate net sales of all Products in the United States during a calendar year reach \$300.0 million. Further, Mayne Pharma will pay to the Company royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first \$80 million in annual net sales and 7.5% on annual net sales above \$80.0 million, subject to certain adjustments, for a period of 20 years following the Closing Date. The royalty rate will decrease to 2.0% on a Product-by-Product basis upon the earlier to occur of (i) the expiration or revocation of the last patent covering a Product and (ii) a generic version of a Product launching in the United States. Mayne Pharma will pay to the Company minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

The total consideration from Mayne Pharma to the Company for the purchase of the Transferred Assets and the grant of the licenses under the Mayne Transaction Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended.

The proceeds at closing were allocated separately to the sale of ANNOVERA and the license grant related to the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products, as the sale of ANNOVERA was accounted for under ASC 610-20, Gains and Losses from Derecognition of Nonfinancial Assets in arriving at the gain on disposal of approximately \$62.0 million. We also recognized approximately \$70.0 million in revenue from transaction with Mayne Pharma which represented license to commercialize the Company's IMVEXXY, BIJUVA, and prescription prenatal vitamin products as well as present value of future minimum royalty payments (as discussed in Note 1).

On the Closing Date, the Company and Mayne Pharma entered into Amendment No. 1 to the Mayne License Agreement (the "Mayne License Agreement Amendment"). Pursuant to the Mayne License Agreement Amendment, Mayne Pharma agreed to pay the Company approximately \$1.0 million in prepaid royalties on the Closing Date. The prepaid royalties will reduce the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to \$257,250 per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment is paid to the Company. In addition, the parties agreed that Mayne Pharma will reduce one quarterly royalty payment (other than the first quarterly royalty payment) otherwise payable to the Company by \$1.5 million in consideration of Mayne Pharma assuming the Company's obligations under a long-term services agreement, including the Company's minimum payment obligations thereunder.



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, 2022, 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 both 2022 and 2021, we recorded BIJUVA sales of \$1.4 million made through the Theramex License Agreement. In addition, in 2021, we received 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. As of December 31, 2022, no IMVEXXY sales have been made through the either of the licensing agreements.

11. Income taxes

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

	2022	2021
United States	\$ 1,074	\$ (79,305)

For the year ended December 31, 2022, there was 0% and 0.5% provision for income taxes in continuing and discontinued operations, respectively, current or deferred. For the year ended December 31, 2021, there was no provision for income taxes in continuing and discontinued operations, current or deferred.

As of December 31, 2022, we had a federal net operating loss ("NOL") carryforwards of \$640.0 million, which is available to offset future taxable income. Approximately \$92.8 million of the federal NOLs can be carried forward for 20 years and will begin to expire in 2031. The remaining \$547.2 million can be carried forward indefinitely. In the event of future income, the NOL deduction arising from NOLs generated in taxable years beginning in 2021 will be limited to 80% of the excess taxable income. The Company experienced an ownership change pursuant to IRC Sec. 382. As a result, our NOLs carryforward as of December 31, 2022 will be limited.

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

	2022	2021
Federal statutory tax rate	21.0%	21.0%
State tax rate, net of federal tax benefit	3.9%	4.7%
Adjustment in valuation allowances	(3228.6%)	(17.8%)
Excess stock benefits	835.2%	(3.2%)
Interest expense accretion	0.0%	0.0%
Permanent and other differences	2368.5%	(4.6%)
Provision for income taxes	0.0%	0.0%

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred income tax asset as of December 31, 2022 and 2021 are as follows (in thousands):

	As of December 31,	
	2022	2021
Deferred income tax assets:		
Net operating loss	\$ 176,631	\$ 224,660
Share-based payment compensation	8,590	17,698
Interest expense limitation	19,707	20,391
Gain on sale of ANNOVERA	(3,624)	-
Accrual for sales returns and coupons	-	-
R&D credit	186	186
Other, net	(1,062)	(1,250)
Deferred income tax asset	200,428	261,685
Valuation allowance	(200,428)	(261,685)
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 a portion of tax benefits related to the deferred tax assets and as such, a valuation allowance has been established against a portion of the deferred tax assets as of both December 31, 2022 and 2021.

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, 2022 and 2021, we had no tax positions relating to open tax returns that were considered to be uncertain, and we had no unrecognized tax benefits.

12. Income (loss) per common share

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

	2022	2021
Numerator:		
Net income (loss) from continuing operations	\$ 1,074	\$ (79,305)
Net income (loss) from discontinued operations	110,923	(93,110)
Net income (loss)	\$ 111,997	\$ (172,415)
Denominator:		
Weighted average common shares for basic income (loss) per common share	9,028	7,960
Effect of dilutive securities	338	-
Weighted average common shares for diluted income (loss) per common share	9,366	7,960

Income (loss) per common share, continuing operations

Basic	\$ 0.12	\$ (9.96)
Diluted	\$ 0.11	\$ (9.96)

Income (loss) per common share, discontinued operations

Basic	\$ 12.29	\$ (11.70)
Diluted	\$ 11.84	\$ (11.70)

Since we reported a net loss for 2021, 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.

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 2022 and 2021 (in thousands):

	As of December 31,	
	2022	2021
Stock options	172	353
RSUs	-	272
PSUs	-	164
Warrants	101	103
	273	892

13. Related parties

A former member of our Board, J. Martin Carroll, 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 and \$3.0 million for 2021 and 2020, respectively. As of December 31, 2021, estimated amounts payable to Catalent was \$0.9 million. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 8, Commitments and contingencies to the financial statements included in this Annual Report. The Catalent supply agreements were assigned to Mayne as part of our transaction with Mayne Pharma.

On August 23, 2022, we appointed Mr. Justin Roberts as a director to fill a newly created vacancy on the Board. Mr. Roberts will serve until the Company's 2022 Annual Meeting of Stockholders or until his successor is duly elected or appointed or his earlier death or resignation. As a director of the Company, Mr. Roberts is entitled to receive compensation in the same manner as our other non-employee directors, described in the section entitled "Director Compensation" in our Amendment No. 1 to Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission on April 29, 2022, but he has elected not to receive any.

compensation for his service as a non-employee director at this time. Mr. Roberts currently serves as a Partner of the Preferred Stock Investor. On July 29, 2022, September 30, 2022 and October 28, 2022, we entered into subscription agreements with Preferred Stock Investor. On December 30, 2022, and in accordance with the terms of the Certificate of Designation, the Company redeemed all 29,000 outstanding shares of Series A Preferred Stock at a purchase price of \$1,333 per share. The Company also paid certain affiliates of the Preferred Stock Investor approximately \$3.0 million as a make-whole payment pursuant to the subscription agreements previously entered into between the Company and Preferred Stock Investor. See Note 9, Mandatory Redeemable Preferred Stock and Stockholders' Equity (Deficit) for additional information.

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 were 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, we had no amounts payable to AIG.

14. Business concentrations

TherapeuticsMD was previously 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. In December 2022, we changed our business to become a pharmaceutical royalty company, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. As part of the transformation that included License Agreement with Mayne Pharma, historical results of commercial operations have been reflected as discontinued operations in the Company's consolidated financial statements for all periods prior to the Closing Date. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2.

In 2022, 98% of license revenue related to one customer - Mayne Pharma. In 2021, 100% of license revenue related to one customer - Theramex.

As of December 31, 2022, we had a royalty receivable of \$1.5 million relating to the short-term portion of receivable from Mayne Pharma and \$20.3 million relating to long term portion of royalty receivable which includes royalties recognized from the Minimum Annual Royalty (see L. Revenue Recognition above). As of December 31, 2022, we also recorded \$1.0 million in prepaid royalties that we received from Mayne Pharma which were recorded in accrued expenses and other current liabilities.

As of December 31, 2022, three vendors each accounted for more than 10% of our accounts payable related to continued operations. As of December 31, 2021, one vendor accounted for 54.5% of our accounts payable balance at December 31, 2021 related to continued operations.

15. Subsequent events

On March 28, 2023, we received escrowed funds of \$11.3 million related to customary holdbacks related to the vitaCare transaction that were recorded as restricted cash in the consolidated balance sheets as of December 31, 2022.