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, 2023

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

THERAPEUTICSMD, INC.
(Exact name of Registrant as specified in its Charter)

Nevada	**87-0233535**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
951 Yamato Road, Suite 220 Boca Raton, Florida	**33431**
(Address of principal executive offices)	(Zip Code)

561-961-1900
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**TXMD**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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

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

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

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, 2023, 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 $34,439,072.

As of March 27, 2024, there were outstanding 11,532,443 shares of the registrant's common stock, par value $0.001 per share.

Documents Incorporated by Reference

Part III (Items 10, 11, 12, 13 and 14) of this annual report on Form 10-K is incorporated by reference from the definitive Proxy Statement for the 2024 Annual Meeting of Stockholders or an amendment to this annual report on Form 10-K to be filed with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year covered by this report.

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Part I

Item 1. Business

Overview

Throughout this Annual Report on Form 10-K ("2023 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®, vitaCareTM, BIJUVA®, and IMVEXXY®, which are protected under applicable intellectual property laws and are the property of the Company. This 2023 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 2023 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 2023 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 2023 10-K Report, this information could prove to be inaccurate as a result of a variety of matters.

Forward-looking statements

This 2023 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 2023 10-K Report entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this 2023 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 2023 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 2023 10-K Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this 2023 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 2023 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 2023 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, currently receiving royalties on products licensed to pharmaceutical organizations that possess commercial capabilities in the relevant territories. On December 30, 2022 (the "Closing Date"), we 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, in which we and our subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize our 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 our 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.

In a License Agreement, dated December 4, 2022, between TherapeuticsMD and Mayne Pharma (the "Mayne License Agreement"), we 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.

Under the Mayne License Agreement, Mayne Pharma will pay us one-time milestone payments 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 us royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first $80.0 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 us 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.

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

The total consideration from Mayne Pharma to TherapeuticsMD for the purchase of the Transferred Assets under the Transaction Agreement 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, TherapeuticsMD 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 us approximately $1.0 million in prepaid royalties on the Closing Date. The prepaid royalties reduced the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to $257 thousand per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment was paid to us. We and Mayne Pharma settled the $1.5 million of consideration due to Mayne Pharma for the assumed obligations under a long-term services agreement (see the section entitled "vitaCare divestiture" below for a discussion of the long-term services agreement), including our minimum payment obligations thereunder. As the parties agreed, Mayne Pharma reduced the second quarterly royalty payment otherwise payable to us by an additional $0.6 million, and in August 2023 we remitted the remaining consideration of $0.9 million.

Mayne Pharma paid us approximately $12.1 million at closing on the Closing Date for the acquisition of net working capital, subject to certain adjustments as determined in accordance with the Transaction Agreement. While the Transaction Agreement calls for much of the net working capital to be trued-up shortly after the Closing Date in 2023, for a period of one year following the Closing Date in the case of payer rebates and wholesale distributor fees and two years following the Closing Date in the case for allowance for returns, net working capital amounts will be adjusted to arrive at final net working capital under the Transaction Agreement.

In September 2023, we revised certain accrual estimates including increasing our working capital adjustment accrual from $3.5 million to $5.5 million for amounts anticipated to be owed under the Transaction Agreement. In December 2023, we made a $5.5 million payment to Mayne Pharma to settle certain working capital amounts that were required to be trued-up shortly after the Closing Date, excluding the allowance for returns, allowance for payer rebates, and allowance for wholesale distributor fees.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

As of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma that may be material.

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

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.

Employees

In connection with our 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 were paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2023, we employed one full-time employee primarily engaged in an executive position.

We have engaged external consultants 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. On August 15, 2023, we entered into a master services agreement with JZ Advisory Group, pursuant to which Joseph Ziegler would serve as our Principal Financial and Accounting Officer. On August 17, 2023 Michael C. Donegan notified us of his decision to resign from the positions of Principal Financial and Accounting Officer of our Company effective as of August 17, 2023. Mr. Ziegler succeeded Mr. Donegan as Principal Financial and Accounting Officer as of the date of Mr. Donegan's resignation.

vitaCare divestiture

On April 14, 2022, we completed the divestiture of our former subsidiary 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, after deducting 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 we received in 2023. Additionally, the Purchase Agreement provides that 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; however, we do not believe this earnout will be realized.

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.

The divestiture of vitaCare was determined to be a component of discontinued operations in December 2022, when we changed our business by becoming a royalty company and as a result vitaCare activities were reclassified to discontinued operations for the years ended December 31, 2023 and 2022.

Going concern

On the Closing Date of the Mayne Transaction, 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 our 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 is 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.

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.

On May 1, 2023, we entered into a Subscription Agreement (the "Subscription Agreement") with Rubric Capital Management LP ("Rubric"), pursuant to which we agreed to sell to Rubric, or one or more of its affiliates, up to an aggregate of 5,000,000 shares of our common stock, par value $0.001 per share (our "Common Stock"), from time to time during the term of the Subscription Agreement at a purchase price of the five-day volume-weighted average price of the Common Stock at the time of the sale of such shares of Common Stock, at an aggregate purchase price of up to $5,000,000. On June 29, 2023, we issued and sold 312,525 shares of Common Stock at a price per share equal to $3.6797 pursuant to the Subscription Agreement. We received gross proceeds of $1.15 million from the draw down, before expenses. On November 15, 2023 Rubric drew down an additional 877,192 shares of Common Stock at a price per share equal to $2.2761. We received gross proceeds of $2.0 million from the drawdown, before expenses.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees pursuant to the Transaction Agreement which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

As of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma may be material.

If Mayne Pharma's sales of Licensed Products grow more slowly than expected or decline, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than our current estimates, if we are unsuccessful with future financings or the supply chains related to the third-party contract manufacturers are worse than we anticipate, our existing cash reserves may be insufficient to satisfy our liquidity requirements. The potential impact of these factors in conjunction with the uncertainty of the capital markets raises substantial doubt about our 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 we are unable to continue as a going concern.

Portfolio of our royalty-bearing products

On December 30, 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 IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD and vitaMedMD brands and assigned our 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 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 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, 2023, no IMVEXXY sales had been made through the Theramex and Knight 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 Mayne 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 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.

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

On December 30, 2022, we assigned our 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. Our obligations to perform the post-approval study have been transferred to Mayne Pharma as part of the Mayne License Agreement.

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 prenatal name to Mayne Pharma.

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 2023 10-K Report. Currently, the Company collects license revenue from two 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 of our licensed products has been transferred to our licensees.

Research and development

As of December 30, 2022, we no longer conduct any research and development activities. Historically, our product development programs were 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, 2023, we have many domestic and foreign patents that cover our licensed products, including many for each of BIJUVA and IMVEXXY that are Orange Book listed for the licensed products.

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 soft gel manufacturing plant. The observations and associated corrective actions related to the BIJUVA product were 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. 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 2023 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.

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. The information contained on our website or that can be accessed through our website is not incorporated by reference into this 2023 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 2023 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.
- 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 take such actions or be successful.
- If efforts to protect the proprietary nature of the intellectual property covering our hormone therapy pharmaceutical products and other products are not adequate, our licensees may not be able to compete effectively in the market, which would adversely affect our royalties.
- Our products face significant competition from branded and generic products, and our operating results will suffer if our products 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 or effectively implement sales strategies will impede our growth.
- Our future success depends on our ability to attract and retain qualified personnel.
- 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 licensed 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. In addition, our revenue from royalties is based on information compiled by, and received from, our licensees. If the sales information provided by our licensees is erroneous, it could have an adverse effect on our business, financial condition and results of operations.

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 the past, we have incurred recurring net losses, including net losses of $10.3 million and $172.4 million for 2023 and 2021, respectively. In 2022, we recognized net income of $112.0 million due to the net proceeds from the Mayne Transaction and vitaCare divestiture exceeding our costs and expenses. We utilized most of the net proceeds to repay borrowings and redeem our preferred stock. As of December 31, 2023, our stockholders' equity was $29.3 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 winddown 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, because the royalties of our products are insufficient or otherwise, 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 Berkowitz Pollack Brant, Advisors + CPAs, our independent registered public accounting firm for the fiscal year ended December 31, 2023, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2023, indicating such. If Mayne Pharma's sales of IMVEXXY, BIJUVA, or ANNOVERA grow more slowly than expected or decline, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than our current estimates, if we are unsuccessful with future financings or if the supply chains related to the third-party contract manufacturers are worse than we anticipate, our existing cash reserves may be insufficient to satisfy our liquidity requirements. 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 sell equity securities, convertible securities or other securities current investors may be materially diluted by subsequent sales. 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 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 the 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. We believe that our licensees evolved these relationships based on the products they licensed from us. We continue to provide support for the third party manufacturers and our licensees as needed.

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 and that the CMOs continue to have the right to manufacture under current regulations.

If the manufacturers of our products 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. 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 seek to enter into long-term agreements with alternative manufacturers on commercially reasonable terms, and if they do enter into agreements with alternative manufacturers, those alternative manufacturers may not be approved by the FDA or subsequently lose FDA approval to manufacture our drugs, 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.

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, chooses to cease supplying, 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 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 payers 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 payer 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. Despite our licensees coverage with commercial payers, there is no guarantee that our licensees will be able to retain ours or their 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 in the future will reduce our cash resources and take up large portions of our employees' and consultants' time. We have received certain invoices related to our historic operations that we are currently disputing. Our accruals related to such invoices reflect the amount we believe we will be responsible for based on the current information we have. Any litigation related to such disputes or to the winding down of our operations, as well as any unforeseen liabilities related to the same, could have a material impact on our business, growth, financial conditions, results of operations and cash flows. There is no guarantee that our cash and cash equivalents on hand at any given time will be enough to cover our liabilities associated with winding down our historic operations.

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, 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 the ways in which unfavorable economic conditions and financial market conditions could harm our business.

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, or the amount of any such payments;
- 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.

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.

If Mayne Pharma, with respect to the ANNOVERA license agreement that we have assigned to Mayne Pharma, fails to meet obligations under that license agreement in a material respect, the Population Council could have the right to terminate the 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 Mayne Pharma and developed during the period the agreement was in force that relate to the applicable technology. This means that Population Council could effectively take control of the development and commercialization of ANNOVERA after an uncured, material breach of the agreement by us or Mayne Pharma. 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 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.

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")
- The Civil Monetary Penalties Law ("CMPL")
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA")
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH")
- Section 5(a) of the Federal Trade Commission Act
- The Physician Payments Sunshine Act
- Analogous state laws and regulations

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 or we may discover 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, and exclusion from government healthcare programs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, and could result in related stockholder suits, any of which could also have an adverse effect on our business, financial condition and results of operations.

In addition, from time to time in the future, we or our licensees 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. 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.

Recently enacted or 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, which could adversely affect our royalty revenues. Recently enacted federal and state laws have put considerable pressure on the pricing of pharmaceutical products.

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 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 re-packagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act ("PDMA") and its implementing regulations. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years. 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 fraud, abuse, and other laws, including, but not limited to the AKS, False Claims Act, FDCA, HIPAA, HITECH, Ryan Haight Act, and others, including marketing and promotional compliance programs or codes of conduct, and law or rules requiring reporting of commercial activities.

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.

The violations of any of these law or rules may result in penalties that 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.

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 siphon off our consumers.

In February 2020, we received a Paragraph IV certification notice letter (the "IMVEXXY Notice Letter") regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). See "If our efforts or 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.

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

Our business was impacted by the COVID-19 pandemic and it may be impacted by any future pandemics or epidemics. The severity of the impact of any pandemic on our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted.

During the COVID-19 pandemic, 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.

Further. our future results of operations and liquidity could be adversely affected during or following any future pandemics or epidemics 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.

Also, 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 any future pandemic or epidemic on capital markets and economies worldwide, and it is possible that a 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 2024.

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, 2023, we had federal net operating loss ("NOL") carryforwards of $577.0 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 fail to adequately promote our products, our business prospects could suffer.

Risks related to our intellectual property

If our efforts or 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.

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 or our licenses have filed may fail to result in issued patents in the U.S. or in foreign jurisdictions;
- patents issued or licensed to us, or our partners, may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we, 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, or may have created bars under U.S. or foreign laws that would preclude the issuance of patents;

- 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 or our licensees. In such event, ours or our licensee's 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 or the post-grant approval processes that exists in the U.S. and foreign jurisdictions 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 or our licensees 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 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

We may be treated as a "public shell" company which could have negative consequences, including potential Nasdaq delisting of our common stock.

Our common stock is currently listed on the Nasdaq Global Select Market. We have no current plans to delist our common stock from Nasdaq. However, following the transaction with Mayne Pharma, when we changed our business to become a royalty company, we may be treated as a "public shell" company under the Nasdaq rules and the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Although Nasdaq evaluates whether a listed company is a public shell company based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

If our common stock is delisted from Nasdaq, or if in the future we determine to delist our common stock, we would expect that such securities would qualify for trading over-the-counter, or OTC, in the United States on a market colloquially referred to as the "Pink Sheets." Securities quoted OTC are generally subject to lesser requirements than securities listed for trading on a U.S. national stock exchange, such as Nasdaq, including reduced corporate governance and public reporting standards.

If Nasdaq should delist our common stock from trading, or if in the future we determine to delist our common stock, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of our common stock; the number of institutional and general investors that will consider investing in our common stock; the number of investors in general that will consider investing in our common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of our common stock; and the number of broker-dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the inability to utilize Form S-8 for the registration of employee benefit plan securities.

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, 2023, Rubric Capital Management LP ("Rubric") and its affiliates beneficially owned approximately 25.6% 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 currently intend to pay dividends on our common stock so any returns may 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 may 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 (the "Board") 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;
- 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 in the past 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 are 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 is uncertain and subject to differing interpretations, especially when evaluated against new technologies and services. The impact of 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. Despite our layered security controls, experienced computer programmers and hackers may be able to penetrate our information systems or the information systems of our licensees 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 or those of our licensees because of cyber-attacks or other tactics could disrupt our business, result in the release or misuse of protected health information, or PHI, confidential or proprietary business information or financial loss, damage our reputation, increase our administrative expenses, and expose us to additional risk of liability to federal or state governments or individuals. Although we believe that we have robust information security procedures and other safeguards in place, as cyber threats continue to evolve, we may be required to expend additional resources to continue to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service and loss of existing or potential patients and disruption of our operations. In addition, breaches of our security measures and the unauthorized dissemination of patient healthcare and other sensitive information, proprietary or confidential information about us or other third-parties could expose such persons' private information to the risk of financial or medical identity theft or expose us or such persons to a risk of loss or misuse of this information, result in litigation and potential liability for us, damage our brand and reputation or otherwise harm our business. Any of these disruptions or breaches of security could have an adverse effect on our business, financial condition, and results of operations.

Our failure to comply with foreign data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation the ("GDPR") in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, 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 invalidated 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. On October 7, 2022, President Biden introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework (the "DPF"), and on July 10, 2023, the European Commission adopted its Final Implementing Decision granting the U.S. adequacy (Adequacy Decision) for EU-U.S. transfers of personal information for companies that self-certify to the DPF. While we have yet to determine the full impact of the DPF on our business, any transfers by us or our vendors or licensees of personal information subject to the GDPR may not comply with data protection law and may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions.

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.

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 or our licensees, 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 rely and 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, we employ and 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 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have implemented and maintain various information security processes designed to assess, identify and manage material risks from cybersecurity threats to our critical systems and information. Such processes are integrated into our overall risk management processes. For example, cybersecurity risk is addressed as a component of our enterprise risk management program and has historically been included as part of compliance reports provided to our audit committee.

Our officers, contractors and third-party IT vendors help assess, identify and manage our cybersecurity threats and risks by monitoring and evaluating our threat environment and risk profile using various methods including, for example: through the use of automated tools; conducting audits and threat assessments for internal and external threats; analyzing reports of threats and actors; conducting vulnerability assessments to identify vulnerabilities; evaluating our and our industry's risk profile; and evaluating threats reported to us.

We implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our critical systems and information, including, for example: multi-factor authentication, encryption, anti-malware functionality, access controls and systems monitoring.

We use third-party service providers to perform a variety of functions throughout our business, including but not limited to application providers and hosting companies. All of our critical information is hosted by a third-party service provider. We have a vendor management program to assess cybersecurity risks associated with our use of these providers. Further, we also rely upon such third-party service providers to both assist us in identifying cybersecurity threats, as well as to review and notify us of any data breach on their systems.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this 2023 10-K Report, including the risk factor captioned "We may not be able to maintain effective and efficient information systems or properly safeguard our information systems." While to date we have not identified any breaches from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, the sophistication of cybersecurity threats continues to increase, and the preventative actions we take to reduce the risk of cybersecurity incidents and protect our systems and information may be insufficient. Accordingly, no matter how well our program is designed or implemented, we will not be able to anticipate all security breaches, and we may not be able to implement effective preventive measures against such security breaches in a timely manner.

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function. The audit committee of our board of directors bears primary responsibility for the board's oversight of our cybersecurity risk. Periodically management updates our audit committee about various risks facing the Company, of which cybersecurity may be included.

Our cybersecurity risk assessment and management processes are implemented and maintained by management and IT consultants. The IT consultants have relevant expertise, experience, education and training as well as knowledge of our company's critical systems and information technology policies.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to our chief executive officer, who would be responsible, along with third parties including our IT consultants, for assessing the materiality of, and mitigating and remediating, any cybersecurity incidents of which we are notified. In addition, our incident response processes include a procedure for reporting certain cybersecurity incidents to the board of directors.

Item 2. Properties

Our headquarters are in Boca Raton, Florida. We operate from a fully remote environment. We have a lease that includes 62,748 rentable square feet, or the full premises, of which the lease of 7,561 square feet commenced in 2018 and the lease of 55,187 square feet commenced in August of 2019, or the full premises commencement date. 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. 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. We have sublet 41,418 square feet and are in the process of subletting the remaining 21,330 square feet of 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 had 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 29, 2023, the closing price of our common stock on Nasdaq was $2.25 per share. As of March 29, 2024, there were 80 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 2023 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 2023 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 relevant territories. On December 30, 2022 (the "Closing Date"), we 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, in which we and our subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize our 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 our 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.

In a License Agreement, dated December 4, 2022, between TherapeuticsMD and Mayne Pharma (the "Mayne License Agreement"), we 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.

Under the Mayne License Agreement, Mayne Pharma will pay us one-time milestone payments 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 us royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first $80.0 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 us 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.

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

The total consideration from Mayne Pharma to TherapeuticsMD for the purchase of the Transferred Assets under the Transaction Agreement 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. 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, TherapeuticsMD 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 us approximately $1.0 million in prepaid royalties on the Closing Date. The prepaid royalties reduced the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to $257 thousand per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment was paid to us. We and Mayne Pharma settled the $1.5 million of consideration due to Mayne for the assumed obligations under a long-term services agreement (see the section entitled "vitaCare divestiture" below for a discussion of the long-term services agreement), including our minimum payment obligations thereunder. As the parties agreed, during the second quarter of 2023, Mayne Parma held back our royalty payment of $0.6 million and we funded an additional $0.9 million in August 2023 to settle the original $1.5 million payable.

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

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" 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 our 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 were paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2023, we employed one full-time employee primarily engaged in an executive position.

We have engaged external consultants 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. On August 15, 2023, we entered into a master services agreement with JZ Advisory Group, pursuant to which Joseph Ziegler would serve as our Principal Financial and Accounting Officer. On August 17, 2023 Michael C. Donegan notified us of his decision to resign from the positions of Principal Financial and Accounting Officer of our Company effective as of August 17, 2023. Mr. Ziegler succeeded Mr. Donegan as Principal Financial and Accounting Officer as of the date of Mr. Donegan's resignation.

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 between us and GoodRx, Inc. (the "Purchase Agreement"), which was recorded as restricted cash in the consolidated balance sheets until the cash was released to us. 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, however we do not believe this earnout will be realized. 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. Our 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, we owed Mayne Pharma $1.5 million payable from one royalty payment. During the second quarter of 2023, Mayne Pharma held back our royalty payment of $0.6 million and we funded an additional $0.9 million in August 2023 to settle the original $1.5 million payable.

The pre-divesture operations of vitaCare were reclassified to discontinued operations in December 2022 when we transitioned to becoming a royalty company and licensed our products to Mayne Pharma.

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 IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD and vitaMedMD brands and assigning our 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 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, 2023, no IMVEXXY sales had been made through the Theramex and Knight 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 Mayne 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 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.

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

On December 30, 2022, we assigned our 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. Our obligations to perform the post-approval study have been transferred to Mayne Pharma as part of the Mayne License Agreement.

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 Prenatal 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 assigned our 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 consolidated financial statements included in this 2023 10-K Report.

The following table sets forth the results of our operations (in thousands):

	Years ended December 31,	
	2023	2022
Revenue, net:		
License and service revenue	$ 1,302	$ 69,963
Total revenue, net	1,302	69,963
Cost of revenue	—	1,397
Gross profit	1,302	68,566
Operating expenses:		
Selling, general and administrative	8,903	56,710
Depreciation & amortization	922	1,193
Restructuring	—	9,472
Total operating expenses	9,825	67,375
Income (loss) from operations	(8,523)	1,191
Other income (expense):		
Miscellaneous income (expense)	781	(117)
Total other income (loss), net	781	(117)
Income (loss) from continuing operations before income taxes	(7,742)	1,074
Benefit (provision) for income taxes	43	—
Net income (loss) from continuing operations	(7,699)	1,074
Income (loss) from discontinued operations, net of income taxes	(2,579)	110,923
Net income (loss)	$ (10,278)	$ 111,997

Revenue. As part of our transformation 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.

We recorded $1.3 million in license revenue during the year ended December 31, 2023 primarily from the Mayne License Agreement, a decrease of $68.7 million, compared to $70.0 million in license revenue recorded for the allocation of the initial upfront payment and guaranteed minimum royalties from the Mayne License Agreement during the year ended December 31, 2022.

Gross profit. Our gross profit for 2023 was $1.3 million, a decrease of $67.3 million, compared to $68.6 million for 2022. This decrease in our gross profit was primarily a result of the license revenue related to the initial upfront payment and guaranteed minimums from the Mayne Transaction that was recognized during the year ended December 31, 2022.

Operating expenses. Total operating expenses for 2023 were $9.8 million, a decrease of $57.6 million, compared to the $67.4 million we had for 2022. Total operating expenses decreased primarily due to lower general and administrative expenses due to the transition of our business from a manufacturing and commercialization business to a royalty- based business with limited infrastructure.

Income (loss) from operations. For 2023, we had a loss from operations of $8.5 million, a decrease of $9.7 million, compared to income from operations of $1.2 million for 2022. This change was primarily attributable to the transition of our business from a manufacturing and commercialization business to a royalty-based business and the 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.

Other income (expense), net. In 2023, we had other income of $0.8 million, an increase of $0.9 million, compared to other expense of $0.1 million in 2022. Other income (expense), net represents interest income from bank accounts as well the present value of the minimum royalty receivables recorded compared to actual minimum royalties received and other miscellaneous items. The year ended December 31, 2023 also includes $0.5 million in other income pertaining to royalty sales of ANNOVERA.

Benefit (provision) for income taxes. In 2023, the Company recognized an immaterial benefit for income taxes from continuing operations, while no provision for income taxes was recognized in 2022 from continuing operations.

Net income (loss) from continuing operations. For 2023, we had net loss from continuing operations of $7.7 million, or $0.74 per basic and diluted common share, a decrease of $8.8 million, compared to net income from continuing operations of $1.1 million, or $0.12 per basic and $0.11 per diluted common share, for 2022.

Discontinued Operations — For 2023 revenues from discontinued operations were $(0.8) million, a decrease of $81.5 million, as compared to $80.7 million in 2022. Revenue in 2023 reflected adjustments to earnings under the Mayne Agreement. In 2023, operating expenses from discontinued operations were $0.5 million, a decrease of $97.1 million, compared to $97.6 million in 2022. For 2023, net loss from discontinued operations was $2.6 million, a decrease of $113.5 million, compared to net income from discontinued operations of $110.9 million for 2022.

For additional information, see Note 2 – Discontinued Operations, in the notes to the consolidated financial statements appearing elsewhere in this 2023 10-K Report.

Liquidity and capital resources

Our primary use of cash is to fund our continuing operations. We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities, the divestiture of our former subsidiary vitaCare, and the transactions with Mayne Pharma. As of December 31, 2023, we had cash and cash equivalents totaling $4.3 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.

vitaCare Divestiture

On April 14, 2022, we completed the vitaCare Divestiture. 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, however we do not believe this earnout will be realized. We utilized $120.0 million of net proceeds from the vitaCare Divestiture to make a prepayment of the loans under the Financing Agreement.

Mayne Pharma License 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 Mayne License Agreement consisted of (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.

Pursuant to the Mayne License Agreement, Mayne Pharma will pay us one-time, milestone payments 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 us 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 us 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.

Mayne Pharma paid us approximately $12.1 million at closing on the Closing Date for the acquisition of net working capital, subject to certain adjustments as determined in accordance with the Transaction Agreement. While the Transaction Agreement calls for much of the net working capital to be trued-up shortly after the Closing Date in 2023, for a period of one year following the Closing Date in the case of payer rebates and wholesale distributor fees and two years following the Closing Date in the case for allowance for returns, net working capital amounts will be adjusted to arrive at final net working capital under the Transaction Agreement.

In September 2023, we revised certain accrual estimates including increasing our working capital adjustment accrual from $3.5 million to $5.5 million for amounts anticipated to be owed under the Transaction Agreement. In December 2023, we made a $5.5 million payment to Mayne Pharma to settle certain working capital amounts that were required to be trued-up shortly after the Closing Date, excluding the allowance for returns, allowance for payer rebates, and allowance for wholesale distributor fees.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

As of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma that may be material.

Subscription Agreement with Rubric Capital Management LP

On May 1, 2023, we entered into the Subscription Agreement with Rubric, pursuant to which we agreed to sell to Rubric, or one or more of its affiliates, up to an aggregate of 5,000,000 shares of Common Stock, from time to time during the term of the Subscription Agreement in separate draw downs at our election, at a purchase price of the five-day volume-weighted average price of our common stock at the time of the sale of such shares, at an aggregate purchase price of up to $5,000,000 (collectively, the "Private Placement").

The initial draw down occurred on June 29, 2023 consisting of a sale of 312,525 shares of Common Stock at a price per share equal to $3.6797. We received gross proceeds of $1.15 million from the drawdown, before expenses. On November 15, 2023 Rubric drew down an additional 877,192 shares of Common Stock at a price per share equal to $2.2761. We received gross proceeds of $2.0 million from the drawdown, before expenses.

Going concern

On the Closing Date of the Mayne Transaction, 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 our 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 is 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.

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.

On May 1, 2023, we entered into a Subscription Agreement (the "Subscription Agreement") with Rubric Capital Management LP ("Rubric"), pursuant to which we agreed to sell to Rubric, or one or more of its affiliates, up to an aggregate of 5,000,000 shares of our common stock, par value $0.001 per share (our "Common Stock"), from time to time during the term of the Subscription Agreement at a purchase price of the five-day volume-weighted average price of the Common Stock at the time of the sale of such shares of Common Stock, at an aggregate purchase price of up to $5,000,000. On June 29, 2023, we issued and sold 312,525 shares of Common Stock at a price per share equal to $3.6797 pursuant to the Subscription Agreement. We received gross proceeds of $1.15 million from the draw down, before expenses. On November 15, 2023 Rubric drew down an additional 877,192 shares of Common Stock at a price per share equal to $2.2761. We received gross proceeds of $2.0 million from the drawdown, before expenses.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees pursuant to the Transaction Agreement which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

As of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma may be material.

If Mayne Pharma's sales of Licensed Products grow more slowly than expected or decline, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than our current estimates, if we are unsuccessful with future financings or the supply chains related to the third-party contract manufacturers are worse than we anticipate, our existing cash reserves may be insufficient to satisfy our liquidity requirements. The potential impact of these factors in conjunction with the uncertainty of the capital markets raises substantial doubt about our 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 we are unable to continue as a going concern.

Cash flows

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

	Years ended December 31,	
Cash flow from continuing operations	2023	2022
Net cash provided by (used in) operating activities	$ (23,081)	$ 9,359
Net cash (used in) investing activities	—	(355)
Net cash provided by (used in) financing activities	3,151	(235,206)
Net cash provided by (used in) discontinued operations	(25,060)	210,397
Net decrease in cash	$ (44,990)	$ (15,805)

Operating Activities from continuing operations. Net cash used in operating activities in 2023 was $23.1 million, a decrease of $32.4 million, compared to net cash provided by operating activities of $9.4 million for 2022. This change was due our transition from a manufacturing and commercialization business to a royalty-based business. Cash outflows in 2023 primarily related to maintaining our operating activities as a royalty company and paying down commercial amounts accrued for at December 31, 2022.

Investing Activities from continuing operations. Net cash used in investing activities for 2023 was $0.0 million, a decrease of $0.4 million, compared to net cash used in investing activities of $0.4 million for 2022. This change was due our transition from a manufacturing and commercialization business to a royalty-based business.

Financing Activities from continuing operations. Net cash provided by financing activities for 2023 was $3.2 million, a decrease of $238.4 million, compared to net cash used by financing activities of $235.2 million for 2022. Cash proceeds in 2023 are from stock sales to Rubric Capital Management and cash outflows during 2022 reflect our paydowns of debt.

Discontinued operations. Net cash used in discontinued operations for 2023 was $25.1 million, a decrease of $235.5 million, as compared to net cash provided by discontinued operations of $210.4 million for 2022. This change was due to our transition from a manufacturing and commercialization business to a royalty-based business as well as proceeds from the divesture of vitaCare of $142.6 million and proceeds from the sale of ANNOVERA of $81.2 million which occurred during 2022.

For additional details, see the consolidated statements of cash flows included in our consolidated financial statements in this 2023 10-K Report.

Other liquidity measure

Receivable from Mayne. On December 30, 2022, Mayne Pharma acquired our accounts receivable balance of approximately $29.3 million which is subject to certain working capital adjustments. As of December 31, 2023, we had a royalty receivable of $3.1 million relating to the short-term portion of receivable from Mayne Pharma and $18.5 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 (Revenue Recognition) to the consolidated financial statements included in this 2023 10-K Report.

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

Our contractual obligations and off-balance sheet arrangements are discussed below. For additional information on any of the following and other obligations and arrangements, see “Note 8. Commitments and Contingencies” to the consolidated financial statements included in this 2023 10-K Report.

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 consolidated financial statements.

Commitments

Information regarding commitments is in “Note 8. Commitments and contingencies” to the consolidated financial statements included in this 2023 10-K Report.

Employment agreements

Information regarding employment agreements is in “Note 8. Commitments and contingencies” to the consolidated financial statements included in this 2023 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 2023 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 2023 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, 2023 and 2022 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.

Loss contingencies – Mayne Pharma

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.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

The Company believes no additional accrual is required for amounts that may be owed for the allowance for returns. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma that may be material.

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 consolidated financial statements included in this 2023 10-K 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 2023 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 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 originally 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, 2023, 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 "J. 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 2023 10-K Report.

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 issued or effective in 2023 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 2023 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 2023 10-K Report. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that, as of December 31, 2023, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) is accumulated and communicated to our management, including our 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, 2023. 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, 2023.

This 2023 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 2023 10-K Report.

Item 9B. Other information

Effective March 22, 2024, Tommy G. Thompson resigned as the Company's Executive Chairman of the Board and was reappointed as the Company's Chairman of the Board.

Item 9C. Disclosure regarding foreign jurisdictions that prevent inspections

None.

PART III

Item 10. Directors, executive officers, and corporate governance

This information will be contained in our definitive proxy statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC not later than 120 days after the end of our fiscal year covered by this report, and incorporated herein by reference or, alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 11. Executive compensation

This information will be contained in our definitive proxy statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC not later than 120 days after the end of our fiscal year covered by this report, and incorporated herein by reference or, alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

This information will be contained in our definitive proxy statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC not later than 120 days after the end of our fiscal year covered by this report, and incorporated herein by reference or, alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 13. Certain relationships and related transactions, and director independence

This information will be contained in our definitive proxy statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC not later than 120 days after the end of our fiscal year covered by this report, and incorporated herein by reference or, alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 14. Principal accountant fees and services

This information will be contained in our definitive proxy statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC not later than 120 days after the end of our fiscal year covered by this report, and incorporated herein by reference or, alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

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 2023 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. (5)
3.1	Articles of Conversion of AMHN, Inc. filed in the State of Nevada, dated July 20, 2010 (6)
3.2	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada, dated July 20, 2010 (6)
3.3	Composite Amended and Restated Articles of Incorporation of the Company, as amended (7)
3.4	Bylaws of the AMHN, Inc. (8)
3.5	First Amendment to Bylaws of the Company, dated December 17, 2015 (9)
3.6	Second Amendment to Bylaws of the Company, adopted May 27, 2022 (10)
3.7	Third Amendment to Bylaws of the Company, dated July 29, 2022 (11)
3.8	Certificate of Change to Articles of Incorporation of the Company (12)
3.9	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (11)
3.10	Fourth Amendment to Bylaws of the Company, dated June 29, 2023 (13)
4.1	Form of Certificate of Common Stock (14)
4.2	Description of Securities of the Company (15)
10.1	Form of Common Stock Purchase Warrant (16)
10.2*	Form of Non-Qualified Stock Option Agreement (16)
10.3*	TherapeuticsMD, Inc. 2019 Stock Incentive Plan (17)
10.4*	First Amendment to the TherapeuticsMD, Inc. 2019 Stock Incentive Plan (18)
10.5*	Amended and Restated 2012 Stock Incentive Plan (19)
10.6*	2009 Long Term Incentive Compensation Plan, as amended (20)
10.7*	TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan (21)
10.8	Form of Common Stock Purchase Warrant, dated February 24, 2012 (22)
10.9	Common Stock Purchase Warrant, issued to Plato & Associates, LLC, dated January 31, 2013 (23)
10.10	Form of Warrant to Purchase Common Stock, dated August 5, 2020 (24)
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 (25)
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 (26)
10.13	Warrant issued by the Company to Robert Finizio (26)
10.14	Amendment to Warrant issued by the Company to Robert Finizio (26)
10.15*	Warrant issued by the Company to John C.K. Milligan, IV (26)
10.16*	Amendment to Warrant issued by the Company to John C.K. Milligan, IV (26)
10.17	Subscription Agreement, dated August 5, 2020, by and among TherapeuticsMD, Inc. and the Subscribers identified on the Schedule of Subscribers attached thereto (24)
10.18***	License Agreement, dated July 30, 2018, by and between TherapeuticsMD, Inc. and The Population Council, Inc. (27)
10.19***	Lease, dated October 5, 2018, by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc. (28)
10.20***	License and Supply Agreement, dated June 6, 2019, by and between TherapeuticsMD, Inc. and Theramex HQ UK Limited (29)
10.21*	Form of Indemnification Agreement between TherapeuticsMD, Inc. and each of its executive officers and directors (25)
10.22*	2022 Executive Retention and Performance Bonus Plan. (ERB-Plan) (30)
10.23	Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated July 29, 2022 (11)
10.24	Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TOA Talents, LLC, dated July 29, 2022 (11)
10.25	Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated September 30, 2022 (31)
10.26	Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TAO Talents, LLC, dated September 30, 2022 (31)

10.27	Subscription Agreement between TherapeuticsMD, Inc. and Rubric Capital Management LP, dated October 28, 2022 (32)
10.28	Subscription Agreement by and among TherapeuticsMD, Inc., Sixth Street Specialty Lending, Inc., TOP IV Talents, LLC and TAO Talents, LLC, dated October 28, 2022 (32)
10.29***+	License Agreement by and between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated December 4, 2022 (33)
10.30***+	Transaction Agreement by and between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated December 4, 2022 (33)
10.31**	Amendment No. 1 to the License Agreement between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated as of December 30, 2022 (15)
10.32	Amendment No. 1 to the Transaction Agreement between TherapeuticsMD, Inc. and Mayne Pharma LLC, dated as of December 30, 2022 (15)
10.33*	Amended and Restated Employment Agreement, dated as of December 18, 2018, by and between TherapeuticsMD, Inc. and Marlan Walker (15)
10.34*	Amendment, effective October 15, 2021, to the Employment Agreement, dated as of December 18, 2018, by and between TherapeuticsMD, Inc. and Marlan Walker (15)
10.35*	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 (34)
10.36*	General Consulting and Services Agreement by and between TherapeuticsMD, Inc. and MCD Consulting Management Services, LLC, dated February 21, 2023 (34)
10.37	Subscription Agreement, dated May 1, 2023, between TherapeuticsMD, Inc. and Rubric Capital Management LP (35)
10.38*	Master Services Agreement, dated August 15, 2023, between TherapeuticsMD, Inc. and JZ Advisory Group (36)
21.1†	Subsidiaries of the Company
23.1†	Consent of Berkowitz Pollack Brant
23.2†	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
97.1†	TherapeuticsMD, Inc. Policy on Recoupment of Incentive Compensation
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 8-K filed with the Commission on March 10, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(6) 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).

(7) Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2023 filed with the Commission on August 14, 2023 and incorporated herein by reference (SEC File No. 001-00100).

(8) 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).

(9) 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).

(10) Filed as an exhibit to Form 8-K filed with the Commission on June 3, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(11) Filed as an exhibit to Form 8-K filed with the Commission on August 1, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(12) Filed as an exhibit to Form 8-K filed with the Commission on May 9, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(13) Filed as an exhibit to Form 8-K filed with the Commission on July 6, 2023 and incorporated herein by reference (SEC File No. 001-00100).

(14) 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).

(15) Filed as an exhibit to Form 10-K for the year ended December 31, 2022 filed with the Commission on April 7, 2023 and incorporated herein by reference (SEC File No. 001-00100).

(16) 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).

(17) 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).

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

(19) 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).

(20) 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).

(21) 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).

(22) 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).

(23) 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).

(24) 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).

(25) 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).

(26) 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).

(27) 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).

(28) 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).

(29) 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).

(30) 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 (SEC File No. 001-00100).

(31) Filed as an exhibit to Form 8-K filed with the Commission on October 3, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(32) Filed as an exhibit to Form 8-K filed with the Commission on October 31, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(33) Filed as an exhibit to Form 8-K filed with the Commission on December 5, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(34) Filed as an exhibit to Form 8-K filed with the Commission on February 27, 2023 and incorporated herein by reference (SEC SEC File No. 001-00100).

(35) Filed as an appendix to the Definitive Proxy Statement filed with the Commission on May 17, 2023 and incorporated herein by reference (SEC File No. 001-00100).

(36) Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2023, filed with the Commission on November 14, 2023 and incorporated herein by reference (SEC File No. 001-00100).

Item 16. Form 10-K summary

None.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this 2023 10-K Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 29, 2024.

THERAPEUTICSMD, INC.

/s/ Marlan D. Walker
Marlan D. Walker
Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this 2023 10-K Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 29, 2024.

Signature	Title
/s/ Marlan D. Walker Marlan D. Walker	Chief Executive Officer (Principal Executive Officer)
/s/ Joseph Ziegler Joseph Ziegler	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

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of TherapeuticsMD, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of TherapeuticsMD, Inc. and Subsidiaries (the "Company") as of December 31, 2023, and the related consolidated statement of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the recent change in operations and negative cash flow position along with other conditions 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Acquisition of Net Working Capital

As described further in Note 1 to the consolidated financial statements, the Company determined the acquisition of net working capital by Mayne Pharma, LLC in accordance with the Transaction Agreement. The Transaction Agreement included significant estimates, which are subject to change for a period of up to two years. The Company received financial claims from Mayne Pharma, LLC related to this agreement for amounts owed under the provisions of the Transaction Agreement related to distributor fees, rebates and returns of licensed products. The Company does not believe these claims are substantiated and thus, did not record an amount due to the licensee as of December 31, 2023. We identified the acquisition of net working capital as a critical audit matter. The principal consideration for our determination that the acquisition of net working capital pursuant to the provisions of the Transaction Agreement as a critical audit matter is due to the significant estimates and judgements required by management when determining the inputs and assumptions utilized in the development of the initial net working capital calculation included in the Transaction Agreement. The subjectivity of the estimates increases the level of estimation uncertainty, auditor judgement and level of effort required to evaluate management's evidence supporting the projected final net working capital acquisition amount as it relates to the allowance for returns, rebates and distributor fees, including assumptions that no further liability will be incurred.

Our audit procedures performed to address the critical matter included, among others:

- Review the letter sent to the licensee in response to financial claims.
- Review original Transaction Agreement and subsequent amendments.
- Review the rebates and returns analysis performed by the Company, assess method utilized, calculation, and conclusion reached for reasonableness.

/s/ Berkowitz Pollack Brant, Advisors + CPAs

We have served as the Company's auditor since 2023.

West Palm Beach, FL

March 29, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
TherapeuticsMD, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheet of TherapeuticsMD, Inc. (a Nevada corporation) and subsidiaries (the "Company") as of December 31, 2022, the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for the year then ended, 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 the results of its operations and its cash flows for the year 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/S/ GRANT THORNTON LLP

We served as the Company's auditor from 2015 to 2023.

Miami, Florida
April 7, 2023

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

	As of December 31,	
	2023	2022
Assets:		
Current assets:		
Cash and cash equivalents	$ 4,327	$ 38,067
Restricted cash	—	11,250
Royalty receivable, current portion	3,090	—
Prepaid and other current assets	4,035	6,034
Current assets of discontinued operations	344	—
Total current assets	11,796	55,351
Fixed assets, net	—	78
License rights and other intangible assets, net	6,098	6,943
Royalty receivable, long term	18,484	20,253
Other non-current assets	58	253
Right of use assets	6,873	7,580
Total assets	$ 43,309	$ 90,458
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 27	$ 2,162
Accrued expenses and other current liabilities	3,133	18,846
Current liabilities of discontinued operations	3,694	25,831
Total current liabilities	6,854	46,839
Operating lease liabilities, non-current	6,532	7,369
Other non-current liabilities	636	1,107
Total liabilities	14,022	55,315
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock, par value $0.001; 32,000 and 12,000 shares authorized, 11,532 and 9,498 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	11	9
Additional paid-in capital	978,917	974,497
Accumulated deficit	(949,641)	(939,363)
Total stockholders' equity	29,287	35,143
Total liabilities and stockholders' equity	$ 43,309	$ 90,458

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)

	Years ended December 31,	
	2023	2022
Revenue, net:		
License and service revenue	$ 1,302	$ 69,963
Total revenue, net	1,302	69,963
Cost of revenue	—	1,397
Gross profit	1,302	68,566
Operating expenses:		
Selling, general and administrative	8,903	56,710
Depreciation & amortization	922	1,193
Restructuring	—	9,472
Total operating expenses	9,825	67,375
Income (loss) from operations	(8,523)	1,191
Other income (expense):		
Miscellaneous income (expense)	781	(117)
Total other income (loss), net	781	(117)
Income (loss) from continuing operations before income taxes	(7,742)	1,074
Benefit (provision) for income taxes	43	—
Net income (loss) from continuing operations	(7,699)	1,074
Income (loss) from discontinued operations, net of income taxes	(2,579)	110,923
Net income (loss)	$ (10,278)	$ 111,997
Income (loss) per common share, basic:		
Continuing operations	(0.74)	0. 12
Discontinued operations, net	(0.25)	12.29
Net income (loss) per common share, basic	$ (0.98)	$ 12.41
Income (loss) per common share, diluted:		
Continuing operations	(0.74)	0.11
Discontinued operations, net	(0.25)	11.84
Net income (loss) per common share, diluted	$ (0.98)	$ 11.96
Weighted average common shares, basic	10,441	9,028
Weighted average common shares, diluted	10,441	9,366
Net income (loss)	$ (10,278)	$ 111,997
Other comprehensive income	—	—
Comprehensive income (loss):	$ (10,278)	$ 111,997

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	Accumulated	
	Shares	Amount	Capital	Deficit	Total
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
Shares issued for vested restricted stock units	844	1	—	—	1
Share-based compensation	—	—	1,271	—	1,271
Shares issued for sale of common stock related to private placement sale	1,190	1	3,149	—	3,150
Net loss	—	—	—	(10,278)	(10,278)
Balance, December 31, 2023	11,532	$ 11	$ 978,917	$ (949,641)	$ 29,287

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

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

	Years ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	$ (10,278)	$ 111,997
Less: Income (loss) from discontinued operations, net of tax	(2,579)	110,923
Net income (loss) from continuing operations	(7,699)	1,074
Adjustments to reconcile net income (loss) to net cash provided by (used in) continuing operating activities:		
Depreciation and amortization	922	1,193
Share-based payment compensation costs	1,271	11,572
Make-whole payment accretion	—	(354)
Other	(129)	(40)
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,999	620
Other assets	(1,126)	(7,636)
Accounts payable	(2,135)	(1,211)
Accrued expenses and other current liabilities	(15,713)	4,262
Other non-current liabilities	(471)	(121)
Total adjustments	(15,382)	8,285
Net cash provided by (used in) continuing operating activities	(23,081)	9,359
Cash flows from continuing investing activities:		
Receipts (payment) for patents	—	(355)
Net cash used in continuing investing activities	—	(355)
Cash flows from continuing financing activities:		
Proceeds from sale of common stock, net of costs	3,151	2,454
Proceeds from sale of common stock related to employee stock purchase plan	—	14
Repayments of debt	—	(219,432)
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)
Net cash provided by (used in) continuing financing activities	3,151	(235,206)
Discontinued operations:		
Net cash used in operating activities	(25,060)	(13,437)
Net cash provided by investing activities	—	223,834
Net cash provided by financing activities	—	—
Net cash provided by (used in) discontinued operations	(25,060)	210,397
Net decrease in cash	(44,990)	(15,805)
Cash and restricted cash - continuing operations, beginning of period	49,317	64,907
Cash and restricted cash - discontinued operations, beginning of period	—	215
Total cash and restricted cash, end of period	$ 4,327	$ 49,317
Supplemental disclosure of cash flow information:		
Interest paid	$ —	$ 13,545
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.

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 ("2023 10-K Report") as "TherapeuticsMD," "we," "our" and "us." This 2023 10-K Report includes trademarks, trade names and service marks, such as TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, vitaCareTM, IMVEXXY®, and BIJUVA®, which are protected under applicable intellectual property laws and are the property of, or licensed by or to, us. Solely for convenience, trademarks, trade names and service marks referred to in this 2023 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"), we 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, in which we and our subsidiaries (i) granted Mayne Pharma an exclusive license to commercialize our 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 our 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.

In a License Agreement, dated December 4, 2022, between TherapeuticsMD and Mayne Pharma (the "Mayne License Agreement"), we 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.

Under the Mayne License Agreement, Mayne Pharma will pay us one-time milestone payments 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 us royalties on net sales of all Products in the United States at a royalty rate of 8.0% on the first $80.0 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 us 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.

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

The total consideration from Mayne Pharma to TherapeuticsMD for the purchase of the Transferred Assets under the Transaction Agreement 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. 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, TherapeuticsMD 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 us approximately $1.0 million in prepaid royalties on the Closing Date. The prepaid royalties reduced the first four quarterly payments that would have otherwise been payable pursuant to the Mayne License Agreement by an amount equal to $257 thousand per quarterly royalty payment plus interest calculated at 19% per annum accruing from the Closing Date until the date such quarterly royalty payment was paid to us. We and Mayne Pharma settled the $1.5 million of consideration due to Mayne for the assumed obligations under a long-term services agreement (see the section entitled "vitaCare Divestiture" below for a discussion of the long-term services agreement), including our minimum payment obligations thereunder. As the parties agreed, during the second quarter of 2023, Mayne Parma held back our royalty payment of $0.6 million and we funded an additional $0.9 million in August 2023 to settle the original $1.5 million payable.

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

We also have 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 September 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 our 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 were paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2022 and 2023, we employed one full-time employee primarily engaged in an executive position.

We have engaged external consultants 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. On August 15, 2023, we entered into a master services agreement with JZ Advisory Group, pursuant to which Joseph Ziegler would serve as our Principal Financial and Accounting Officer. On August 17, 2023 Michael C. Donegan notified us of his decision to resign from the positions of Principal Financial and Accounting Officer of our Company effective as of August 17, 2023. Mr. Ziegler succeeded Mr. Donegan as Principal Financial and Accounting Officer as of the date of Mr. Donegan's resignation.

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of our former subsidiary 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, after deducting 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 we received in 2023. Additionally, the Purchase Agreement provides that 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; however, we do not believe this earnout will be realized. We will record the contingent consideration at the settlement amount if and 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.

The divestiture of vitaCare was determined to be a component of discontinued operations in December 2022, when we changed our business by becoming a royalty company and as a result vitaCare activities were reclassified to discontinued operations for 2023 and 2022.

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 our 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 TherapeuticsMD for the purchase of the Transferred Assets under the Transaction Agreement and the grant of the licenses under the Mayne License Agreement consisted of (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 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, 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 our 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 is 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.

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.

On May 1, 2023, we entered into a Subscription Agreement (the "Subscription Agreement") with Rubric Capital Management LP ("Rubric"), pursuant to which we agreed to sell to Rubric, or one or more of its affiliates, up to an aggregate of 5,000,000 shares of our common stock, par value $0.001 per share (our "Common Stock"), from time to time during the term of the Subscription Agreement in separate draw-downs at our election. On June 29, 2023, we issued and sold 312,525 shares of Common Stock at a price per share equal to $3.6797 pursuant to the Subscription Agreement. We received gross proceeds of $1.15 million from the draw down, before expenses. On November 15, 2023 Rubric drew down an additional 1,000,000 shares of Common Stock at a price per share equal to $2.28. We received gross proceeds of $2.0 million from the drawdown, before expenses.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

As of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma that may be material.

If Mayne Pharma's sales of IMVEXXY, BIJUVA, or ANNOVERA grow more slowly than expected or decline, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than our current estimates, if we are unsuccessful with future financings or if the supply chains related to the third-party contract manufacturers are worse than we anticipate, our existing cash reserves may be insufficient to satisfy our liquidity requirements. The potential impact of these factors in conjunction with the uncertainty of the capital markets raises substantial doubt about our 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 we are 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 Unites 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 and as a result of the vitaCare divestiture and the Mayne Transaction, historical results of commercial operations for all periods prior to the Closing Date have been reflected as discontinued operations in the consolidated financial statements. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in the consolidated balance sheet. Additional disclosures regarding discontinued operations are provided in Note 2 of these consolidated financial statements.

Certain amounts in the notes to the consolidated financial statements may not add due to rounding. Certain prior period amounts have been reclassified to conform to current-period presentation.

B. New accounting standards

Adoption of new accounting standards

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-09, "Income Taxes (Topic 740) - Improvements to Income Tax Disclosures." ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures by requiring consistent categories and greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. ASU 2023-09 will be effective for the Company in its income tax disclosure included in its 2025 Annual Report on Form 10-K and will be applied on a prospective basis. However, retrospective application is permitted. Early adoption is also permitted. The Company is evaluating the impact of ASU 2023-09 on the Company's income tax disclosures and on its consolidated financial statements.

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, 2023 and 2022 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 the 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, 2023 and 2022. 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

For the purpose of the statements of cash flows, all highly liquid investments with an original maturity of three months or less are considered to be cash equivalents. The carrying value of these investments approximates fair value.

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 was comprised of escrowed funds deposited with a bank relating to the vitaCare Divestiture. All restrictions were lifted in March 2023.

F. 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.

G. 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.

H. License rights and other intangibles assets

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

License rights costs 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 2022 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.

I. 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.

J. 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.

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.

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 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.

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 2023 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 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 2023, and is further subject to offset by Mayne Pharma (see L. 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 2023, we recorded BIJUVA license sales of $0.3 million made through the Theramex License Agreement and $1.0 million pertaining to our licensed products with Mayne Pharma, which was recognized as license revenue. Additionally, we recognized $0.5 million in other income pertaining to royalty sales of ANNOVERA.

K. 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 as a result of the transaction with Mayne Pharma.

L. Contract Assets and Liabilities

Contract assets totaling $21.6 million as of December 31, 2023, include royalties recognized from the Minimum Annual Royalty (see J. Revenue Recognition above).

M. 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.

Common stock reverse stock split

On May 6, 2022, we completed a reverse stock split of our Common Stock. As a result, shares of our outstanding 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 numbers 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.

Increase of authorized shares

On June 26, 2023, at our combined 2022 and 2023 Annual Meeting, our stockholders approved an amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of Common Stock from 12 million shares to 32 million shares.

N. 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.

O. 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.

P. 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 assets 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.

We sublease our unoccupied facilities to third parties. Any impairment to the associated right-of-use asset, leasehold improvements, or other assets as a result of the sublease is recognized in the period when a decision to sublease is made and recorded in our consolidated statement of operations. We recognize sublease income on a straight-line basis over the sublease term.

Q. 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. See Note 8 for more information.

R. 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. There were no restructuring costs incurred during the year ended December 31, 2023. Restructuring 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	$ 9,472
Employee termination benefits	$ 4,813
Other contract termination costs	1,367
Total restructuring expenses - discontinued operations	$ 6,180

At December 31, 2023 and 2022 respectively, $2.5 million and $6.2 million of restructuring costs were included in current liabilities of discontinued operations in the accompanying consolidated balance sheets. At December 31, 2022, $9.3 million related to restructuring costs was included in accrued expenses and other current liabilities.

S. Reclassification of prior year presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation.

2. Discontinued Operations

As discussed in Note 1, we changed our business in 2022 by licensing our products to receive royalties and future sales related milestone payments, after granting an exclusive license to commercialize our IMVEXXY, BIJUVA, and prescription prenatal vitamin products sold under the BocaGreenMD and vitaMedMD brands in the United States and assigning our exclusive license to commercialize ANNOVERA to Mayne Pharma.

This plan represented a strategic shift having a major effect on our operations and financial results. Upon our conversion from a commercial pharmaceutical company to a licensing only company with the consummation of the Mayne Transaction, we 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. We have not allocated any amounts for shared general and administrative operating support expense to discontinued operations. As required by the terms of the Financing Agreement, proceeds from the Mayne Transaction and the vitaCare Divestiture 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 our consolidated balance sheet as of December 31, 2023 and 2022.

The total consideration from Mayne Pharma consisted of (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 Mayne License Agreement Amendment and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended.

Our 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 final net working capital includes significant estimates which could change materially for a period of up to two years following the Closing Date.

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

	Years ended December 31,	
	2023	2022
Product revenue, net	$ (833)	$ 80,749
Cost of goods sold	—	15,640
Gross profit (loss)	(833)	65,109
Operating expenses:		
Selling and marketing	—	75,208
General and administrative	481	11,301
Research and development	—	4,942
Restructuring charges	—	6,180
Total operating expenses	481	97,631
Loss from discontinued operations	(1,314)	(32,522)
Other income (expense):		
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)
Expense for accretion of Series A Preferred Stock	—	(16,973)
Loss on disposal of assets	(1,150)	—
Other expense, net	(115)	—
Total other income (expense), net	(1,265)	143,997
Loss before from income taxes	(2,579)	111,475
Benefit (provision) for income taxes	—	(552)
Net income (loss) from discontinued operations	$ (2,579)	$ 110,923

The following table presents the carrying amounts of the classes of assets and liabilities of discontinued operations (in thousands):

	As of December 31,	
	2023	2022
Assets:		
Current assets:		
Accounts receivable	$ 344	$ —
Total assets	344	—
Current liabilities:		
Accounts payable	$ —	$ 12,243
Accrued expenses and other current liabilities	3,694	13,588
Total liabilities	$ 3,694	$ 25,831

3. Prepaid and other current assets

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

	December 31,	
	2023	2022
Insurance	$ 253	$ 1,167
Capitalized legal	2,334	2,334
Other	1,448	2,533
Prepaid and other current assets	$ 4,035	$ 6,034

4. Fixed assets

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

	December 31,	
	2023	2022
Furniture and fixtures	$ 931	$ 931
Computer and office equipment	1,167	1,168
Computer software	375	375
Leasehold improvements	49	49
Fixed assets	2,522	2,523
Less: accumulated depreciation and amortization	2,522	2,445
Fixed assets, net	$ —	$ 78

We recorded in continuing operations, depreciation expense of $0.1 million for 2023 and $0.6 million for 2022.

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, 2023			As of December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Hormone therapy drug patents	$ 6,818	$ 1,871	$ 4,947	$ 6,225	$ 1,598	$ 4,627
Hormone therapy drug patents applied and pending approval	842	—	842	1,995	—	1,995
Intangible assets subject to amortization	7,660	1,871	5,789	8,220	1,598	6,622
Intangible assets not subject to amortization:						
Trademarks/trade name rights	309	—	309	321	—	321
Intangible assets, net	$ 7,969	$ 1,871	$ 6,098	$ 8,541	$ 1,598	$ 6,943

We recorded, in continuing operations, amortization expense related to patents of $0.8 million for 2023, of which $0.5 million is accelerated amortization as a result of a review of our intangible assets, and $0.6 million for 2022. We recorded amortization expense related to the exclusive license rights agreement with Population Council of $3.0 million for 2022, which was reclassified to discontinued operations after we completed transaction with Mayne Pharma in December 2022, and excluded from the table above.

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

Year ending December 31,	
2024	533
2025	445
2026	445
2027	445
2028	445
Thereafter	5,347
Total	$ 7,660

We use a combination of qualitative and quantitative factors to assess licensed rights and intangible assets for impairment. In the year ending December 31, 2023, we have not impaired any of our hormone therapy drug patent 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,	
	2023	2022
Payroll and related costs	$ 762	$ 8,748
Accrued contract termination costs	—	4,700
Research and development expenses	—	978
Professional fees	489	415
Operating lease liabilities	1,473	1,390
Prepaid royalty	—	1,011
Other accrued expenses and current liabilities	409	1,604
Accrued expenses and other current liabilities	$ 3,133	$ 18,846

We expense advertising costs when incurred, which amounted to $13.2 million for 2022, which was reclassified to discontinued operations as a result of our business shift following the Mayne Transaction. We incurred no advertising costs in 2023.

7. Debt

Financing agreement

We were party to the Financing Agreement with Sixth Street Specialty Lending, Inc., as 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.

Interest and financing costs

Included in miscellaneous income in 2023 is $0.3 million of interest income and $0.2 million of interest expense. In 2022 and recorded in discontinued operations, we recognized $13.5 million of debt-related interest expense and $22.5 million of financing fees amortization.

8. Commitments and contingencies

Leases

In October 2018, we entered into a lease for executive, administrative, operations and sales offices in Boca Raton, Florida. The lease includes 62,748 rentable square feet, or the full premises, of which the lease on 7,561 square feet commenced in 2018 and the lease on 48,651 square feet commenced in August 2019, or the full premises commencement date. 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. 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. As a result of shifting our business to become a license company and terminating our employees, we have sublet the majority of our headquarters and are in the process of subleasing the remainder. 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 2023.

For 2023 and 2022, operating lease expense (including all variable costs) related to our real estate leases was $2.3 and $2.1 million, respectively. In 2023 and 2022, our rental income on sublease of our three suites which were subleased following the vitaCare transaction was $1.3 million and $0.0 million, respectively.

As of December 31, 2023, our remaining lease payments were as follows (in thousands):

Year ending December 31,	
2024	1,477
2025	1,513
2026	1,551
2027	1,590
2028	1,630
Thereafter	2,664
Total undiscounted lease payments	10,425
Less: imputed interest	2,420
Present value of lease payments	$ 8,005

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

	As of December 31,	
	2023	2022
Assets:		
Operating lease right-of-use assets	$ 6,873	$ 7,580
Liabilities:		
Operating lease liabilities current (included in accrued expenses and other current liabilities)	$ 1,473	$ 1,390
Operating lease liabilities, non-current	$ 6,532	7,369
Total operating lease liabilities	$ 8,005	$ 8,759

The following table presents other information related to leases:

	As of December 31,	
	2023	2022
Weighted average remaining term (years) - operating leases	6.7	7.7
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)	$ 1,443	$ 1,413
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 on December 30, 2022, for the acquisition of net working capital, subject to certain adjustments as determined in accordance with the Transaction Agreement. While the Transaction Agreement calls for much of the net working capital to be trued-up shortly after the Closing Date in 2023, for a period of one year following the Closing Date in the case of payer rebates and wholesale distributor fees and two years following the Closing Date in the case for allowance for returns, net working capital amounts will be adjusted to arrive at final net working capital under the Transaction Agreement.

In September 2023, we revised certain accrual estimates including increasing our working capital adjustment accrual from $3.5 million to $5.5 million for amounts anticipated to be owed under the Transaction Agreement. In December 2023, we made a $5.5 million payment to Mayne Pharma to settle certain working capital amounts that were required to be trued-up shortly after the Closing Date, excluding the allowance for returns, allowance for payer rebates, and allowance for wholesale distributor fees.

In February 2024, the Company received Mayne Pharma's calculation of allowance for payer rebates and wholesale distributor fees which differed significantly from the Company's estimate of the allowances. The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable and intends to resolve this matter through the process outlined in the Transaction Agreement. Given the recent receipt of Mayne Pharma's allowance 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 allowance calculation for payer rebates and wholesale distributor fees.

Additionally and as of December 31, 2023, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns. The Company has not recorded any contingent gains or receivables for any such allowances. Management continues to monitor the unresolved and pending net working capital items as changes to estimated amounts owed or amounts due from Mayne Pharma that may be material.

Population Council License Agreement

Under the terms of our license agreement with the Population Council, Inc. (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 New Drug Application ("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. Our rights and obligations under the Population Council License Agreement have been transferred to Mayne Pharma and may revert back to us upon the occurrence of certain events.

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. We have incurred and recorded legal costs amounting to $2.3 million in prepaid expenses and other current assets as of December 31, 2023, for the IMVEXXY Paragraph IV legal proceeding 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.

Beginning on December 30, 2022 and per the Mayne License Agreement, Mayne Pharma is responsible for all enforcement of our patents, including the litigation discussed above with respect to Teva.

In September 2023, one of our former contractors retained to market ANNOVERA under Title X, filed a lawsuit that accused us of breach of contract. We answered their complaint and filed breach of contract counterclaims.

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

Off-balance sheet arrangements

As of December 31, 2023 and 2022 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 we consider material.

Employment agreements

In connection with our 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 30, 2022. Severance obligations for all employees other than executive officers were paid in full in the first quarter of 2023. As of December 31, 2023, we employ one full-time employee primarily engaged in an executive position. We have engaged external consultants 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 TherapeuticsMD was each a termination without "Good Cause," as defined in their respective employment agreements. In the aggregate, as of December 31, 2023, we have accrued severance liabilities for executive termination obligations of $0.4 million.

9. Stockholders' Equity

Increase of authorized shares

On June 26, 2023, at our combined 2022 and 2023 Annual Meeting, our stockholders approved an amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of Common Stock from 12 million shares to 32 million shares.

Warrants

As of December 31, 2023, the following table summarizes the status of our outstanding and exercisable warrants and related transactions since December 31, 2021 (in thousands, except weighted 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, 2021	103	$ 76.19	$ —	8.3
Granted	436	0.14		
Expired	(3)	341.5		
Balance, December 31, 2022	536	13.10	2,427	9.3
Exercised	(435)	0.01	(2,270)	
Expired	(2)	0.89		
Balance, December 31, 2023	99	$ 66.61	$ 1,793	6.5

We used the Black Scholes option pricing model to estimate the fair value of the 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%.

Share-based compensation payment plans

As of December 31, 2023, 126,573 shares of common stock were subject to outstanding awards under our share-based payment award plans and inducement grants (calculated using the base number of PSUs that may vest). As of December 31, 2023, 394,669 shares of common stock were available for future grants of share-based payment awards under the TherapeuticsMD, Inc. 2019 Stock Incentive Plan.

The following table summarizes the status of our outstanding and exercisable options and related transactions (each adjusted to account for the Reverse Stock Split) since December 31, 2022 (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Outstanding				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)
As of January 1, 2022	353	$ 225.98	—	3.8	336	230.93	$ —	3.6
Granted	—	—	—	—	—	—	—	—
Exercised	—	—	—	—	—	—	—	—
Cancelled/Forfeited	(4)	94.99	—	—	—	—	—	—
Expired	(177)	226.56	—	—	—	—	—	—
As of December 31, 2022	172	228.28	—	3.6	170	229.43	—	3.6
Granted	—	—	—	—	—	—	—	—
Exercised	—	—	—	—	—	—	—	—
Cancelled/Forfeited	—	—	—	—	—	—	—	—
Expired	(100)	206.15	—	—	—	—	—	—
As of December 31, 2023	72	$ 258.55	$ —	3.0	73	258.46	$ —	3.0

The following table summarizes the status of our RSUs and related transactions (each adjusted to account for the Reverse Stock Split) (in thousands, except weighed average grant date fair value):

	RSUs awards outstanding		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Balance, January 1, 2022	272	$ 58.00	$ 4,890.00
Granted	170	16.05	
Vested	(327)	48.20	
Cancelled/Forfeited	(58)	37	
Balance, as of December 31, 2022	57	14.57	318.63
Granted	163	4.82	—
Vested	(180)	6.83	—
Cancelled/Forfeited	—	—	—
Balance, as of December 31, 2023	40	$ 9.67	$ 89.6

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

	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Balance, December 31, 2021	164	$ 51.50	$ 2,953
Granted	63	34.50	
Vested and settled	(133)	47.12	(2,382.98)
Cancelled/Forfeited	(75)	(44.85)	
Unvested, as of January 1, 2023	19	52.15	107.55
Granted	—	—	—
Vested	(5)	56.05	(10.72)
Cancelled/Forfeited	—	—	—
Unvested, as of December 31, 2023	14	$ 50.87	$ 33

Share-based payment compensation cost

Share-based payment compensation expense for PSUs is based on 100% vesting which was a part of the termination 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 our employee stock purchase plan (“ESPP”) totaling $1.3 million for 2023 and $11.6 million for 2022.

As of December 31, 2023, we had $0.3 million of unrecognized share-based payment award compensation cost related to unvested options, RSUs and PSUs as well as shares issuable under our 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, 2023 of $0.3 million is expected to be recognized as share-based payment award compensation over a weighted average period of 0.8 years.

10. Revenue

Pursuant to 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. 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.

In 2023, we recorded BIJUVA license sales of $0.3 million made through the Theramex License Agreement and $1.0 million pertaining to our licensed products with Mayne Pharma, which was recorded as license revenue. Additionally, we recognized $0.5 million in other income pertaining to royalty sales of ANNOVERA.

11. Income taxes

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

	Year Ending December 31,	
	2023	2022
United States	$ (7,742)	$ 1,074

For the year ended December 31, 2023, there was no provision for income taxes in discontinued operations, current or deferred. For the year ended, December 31, 2023, we recorded a benefit of 0.5% in continuing operations. 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.

As of December 31, 2023, we had federal net operating loss (“NOL”) carryforwards of $577.0 million, which is available to offset future taxable income. Approximately $19.2 million of the federal NOLs can be carried forward for 20 years and will begin to expire in 2035. The remaining $557.8 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, 2023 will be limited.

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

	2023		2022
Federal statutory tax rate	$ (1,626)	21.0%	21.0%
State tax rate, net of federal tax benefit	—	0.0%	3.9%
Adjustment in valuation allowances	(22,173)	286.4%	(3,228.6)%
Excess stock benefits	2,460	(31.8)%	835.2%
Interest expense accretion	35	(0.5)%	0.0%
Permanent and other differences	21,261	(274.6)%	2,368.5%
(Benefit) provision for income taxes	$ (43)	0.5%	0.0%

We do not expect to pay any significant federal or state income taxes as a result of (i) the losses recorded during 2023, (ii) net operating losses carry forwards from prior years.

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 tax assets as of December 31, 2023 and 2022 are as follows:

	December 31,	
	2023	2022
Deferred income tax assets (liabilities):		
Net operating loss	$ 158,040	$ 176,631
Share-based payment compensation	3,339	8,590
Interest expense limitation	19,547	19,707
Gain on sale of ANNOVERA	(3,401)	(3,624)
Accrual for sales returns and coupons	288	—
R&D credit	186	186
Other, net	256	(1,062)
Deferred income tax asset	178,255	(200,428)
Valuation allowance	(178,255)	200,428
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 tax benefits related to our deferred tax assets and as such, a valuation allowance has been established against all the deferred tax assets as of both December 31, 2023 and 2022.

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, 2023 and 2022, 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 (each adjusted to account for the Reverse Stock Split) for the periods presented (in thousands, except per share amounts):

	Years Ending December 31,	
	2023	2022
Numerator:		
Net income (loss) from continuing operations	$ (7,699)	$ 1,074
Net income (loss) from discontinued operations	(2,579)	110,923
Net income (loss)	$ (10,278)	$ 111,997
Denominator:		
Weighted average common shares for basic income (loss) per common share	10,441	9,028
Effect of dilutive securities	—	338
Weighted average common shares for diluted income (loss) per common share	10,441	9,366
Income (loss) per common share, continuing operations		
Basic	$ (0.74)	$ 0.12
Diluted	$ (0.74)	$ 0.11
Income (loss) per common share, discontinued operations		
Basic	$ (0.25)	$ 12.29
Diluted	$ (0.25)	$ 11.84

Since we reported a net loss from continuing operations for 2023, 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 shares are the same for 2023.

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 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Stock options	72	172
RSUs	40	—
PSUs	14	—
Warrants	99	101
	225	273

13. Related parties

On August 23, 2022, we appointed Mr. Justin Roberts as a director to fill a newly created vacancy on our Board of Directors. Mr. Roberts was elected to serve as a director at our combined 2022 and 2023 Annual Meeting held on June 26, 2023. Mr. Roberts will serve until our next Annual Meeting of Stockholders or until his successor is duly elected or appointed or his earlier death or resignation. As a director of our 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, 2022, filed with the Securities and Exchange Commission on May 1, 2023, 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 Rubric. On July 29, 2022, September 30, 2022, October 28, 2022, and May 1, 2023, we entered into subscription agreements with Rubric. On December 30, 2022, in accordance with the terms of the Certificate of Designation, we redeemed all 29,000 outstanding shares of Series A Preferred Stock previously issued to affiliates of Rubric at a purchase price of $1,333 per share. also paid certain affiliates of Rubric approximately $3.0 million as a make-whole payment pursuant to the subscription agreements previously entered into between us and Rubric. On June 29, 2023, we issued and sold 312,525 shares of Common Stock to Rubric at a price per share equal to $3.6797 pursuant to the Subscription Agreement and received gross proceeds of $1.15 million, before expenses. On November 15, 2023 Rubric drew down an additional 877,192 shares of Common Stock at a price per share equal to $2.2761. We received gross proceeds of $2.0 million from the drawdown, before expenses.

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

For the year ended December 31, 2023, 100% of license revenue related to Mayne Pharma and Theramex.

As of December 31, 2023, we had a royalty receivable of $3.1 million relating to the short-term portion of receivable from Mayne Pharma and Theramex and $18.5 million relating to the long-term portion of royalty receivable which includes royalties recognized from the minimum annual royalty that Mayne Pharma is obligated to pay to us under the Mayne License Agreement.

15. Subsequent Events

Effective March 22, 2024, Tommy G. Thompson resigned as the Company's Executive Chairman of the Board and was reappointed as the Company's Chairman of the Board.

Exhibit 21.1

Subsidiaries of the Company

Name	State or Jurisdiction of Incorporation or Organization
VitaMedMD, LLC	Delaware
BocagreenMD, Inc.	Nevada

Exhibit 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (File No. 333-191730, File No. 333-232268, File No. 333-242363, File No. 333-256879, File No. 333-259221 and File No. 333-260295) of TherapeuticsMD, Inc. of our report dated March 29, 2024 on the consolidated statements of financial position of TherapeuticsMD, Inc. and Subsidiaries as of December 31, 2023, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year ended December 31, 2023, included herein on the annual report of TherapeuticsMD, Inc. on Form 10-K.

/s/ Berkowitz Pollack Brant, Advisors + CPAs
West Palm Beach, FL
March 29, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated April 7, 2023, with respect to the consolidated financial statements included in the Annual Report of TherapeuticsMD, Inc. on Form 10-K for the year ended December 31, 2023. We consent to the incorporation by reference of said report in the Registration Statements of TherapeuticsMD, Inc. on Form S-8 (File No. 333-191730, File No. 333-232268, File No. 333-242363, File No. 333-256879, File No. 333-259221 and File No. 333-260295).

/S/ GRANT THORNTON LLP

Miami, Florida
March 29, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Marlan D. Walker, certify that:

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

(2) Based on my knowledge, this 10-K Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 10-K Report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this 10-K Report based on such evaluation; and

(d) disclosed in this 10-K Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2024

/s/ Marlan D. Walker
Marlan D. Walker
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Joseph Ziegler, certify that:

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

(2) Based on my knowledge, this 10-K Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 10-K Report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this 10-K Report based on such evaluation; and

(d) disclosed in this 10-K Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2024

/s/ Joseph Ziegler

Joseph Ziegler
Principal Financial and
Accounting Officer

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the Annual Report on Form 10-K of TherapeuticsMD, Inc. (the "Company") for the year ended December 31, 2023 (the "10-K Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Marlan D. Walker, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The 10-K Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.78m(a) or 78o(d)); and

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

March 29, 2024

/s/ Marlan D. Walker
Marlan D. Walker
Chief Executive Officer

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

Exhibit 32.2

SECTION 1350 CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

In connection with the Annual Report on Form 10-K of TherapeuticsMD, Inc. (the "Company") for the year ended December 31, 2023 (the "10-K Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Joseph Ziegler, Principal Financial Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The 10-K Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and

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

March 29, 2024

/s/ Joseph Ziegler
Joseph Ziegler
Principal Financial Officer

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

THERAPEUTICSMD, INC.
POLICY ON RECOUPMENT OF INCENTIVE COMPENSATION

Introduction

The Board of Directors (the "Board") of TherapeuticsMD, Inc. (the "Company") has adopted this Policy on Recoupment of Incentive Compensation (this "Policy"), which provides for the recoupment of compensation in certain circumstances in the event of a restatement of financial results by the Company. This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission ("SEC") rules and Nasdaq Stock Market ("Nasdaq") listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

Administration

This Policy shall be administered by the Compensation Committee (the "Compensation Committee") of the Board. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. The Board or Compensation Committee may amend this Policy from time to time in its discretion.

Covered Executives

This Policy applies to any current or former "executive officer," within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended, of the Company or a subsidiary of the Company (each such individual, an "Executive"). This Policy shall be binding and enforceable against all Executives and their beneficiaries, executors, administrators, and other legal representatives.

Recoupment Upon Financial Restatement

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "Financial Restatement"), the Compensation Committee shall cause the Company to recoup from each Executive, as promptly as reasonably possible, any erroneously awarded Incentive-Based Compensation, as defined below.

No-Fault Recovery

Recoupment under this Policy shall be required regardless of whether the Executive or any other person was at fault or responsible for accounting errors that contributed to the need for the Financial Restatement or engaged in any misconduct.

Compensation Subject to Recovery; Enforcement

This Policy applies to all compensation granted, earned or vested based wholly or in part upon the attainment of any financial reporting measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, whether or not presented within the Company's financial statements or included in a filing with the SEC, including stock price and total shareholder return ("TSR"), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Executive ("Incentive-Based Compensation"). Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events, such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board or Compensation Committee and not based on the attainment of any financial measure, is not subject to this Policy.

In the event of a Financial Restatement, the amount to be recovered will be the excess of (i) the Incentive-Based Compensation received by the Executive during the Recovery Period (as defined below) based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive-Based Compensation that would have been received by the Executive had it been calculated based on the restated financial information, as determined by the Compensation Committee. For purposes of this Policy, "Recovery Period" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Financial Restatement, as determined in accordance with the last sentence of this paragraph, or any transition period that results from a change in the Company's fiscal year (as set forth in Section 5608(b)(i)(D) of the Nasdaq Listing Rules). The date on which the Company is required to prepare a Financial Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare a Financial Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare a Financial Restatement.

For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Financial Restatement, then the Compensation Committee shall determine the amount to be recovered based on a reasonable estimate of the effect of the Financial Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received and the Company shall document the determination of that estimate and provide it to Nasdaq.

Incentive-Based Compensation is considered to have been received by an Executive in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

The Company may use any legal or equitable remedies that are available to the Company to recoup any erroneously awarded Incentive-Based Compensation, including but not limited to by collecting from the Executive cash payments or shares of Company common stock from or by forfeiting any amounts that the Company owes to the Executive. Executives shall be solely responsible for any tax consequences to them that result from the recoupment or recovery of any amount pursuant to this Policy, and the Company shall have no obligation to administer the Policy in a manner that avoids or minimizes any such tax consequences.

No Indemnification

The Company shall not indemnify any Executive or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Executive under this Policy or any claims relating to the Company's enforcement of rights under this Policy.

Exceptions

The compensation recouped under this Policy shall not include Incentive-Based Compensation received by an Executive (i) prior to beginning service as an Executive or (ii) if he or she did not serve as an Executive at any time during the performance period applicable to the Incentive-Based Compensation in question. The Compensation Committee (or a majority of independent directors serving on the Board) may determine not to seek recovery from an Executive in whole or part to the extent it determines in its sole discretion that such recovery would be impracticable because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive-Based Compensation and providing corresponding documentation of such attempt to Nasdaq), (B) recovery would violate the home country law that was adopted prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is acceptable to and provided to Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

Other Remedies Not Precluded

The exercise by the Compensation Committee of any rights pursuant to this Policy shall be without prejudice to any other rights or remedies that the Company, the Board or the Compensation Committee may have with respect to any Executive subject to this Policy, whether arising under applicable law (including pursuant to Section 304 of the Sarbanes-Oxley Act of 2002), regulation or pursuant to the terms of any other policy of the Company, employment agreement, equity award, cash incentive award or other agreement applicable to an Executive. Notwithstanding the foregoing, there shall be no duplication of recovery of the same Incentive-Based Compensation under this Policy and any other such rights or remedies.

Acknowledgment

To the extent required by the Compensation Committee, each Executive shall be required to sign and return to the Company the acknowledgement form attached hereto as Exhibit A pursuant to which such Executive will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Executive shall be fully bound by, and must comply with, the Policy, whether or not such Executive has executed and returned such acknowledgment form to the Company.

Effective Date and Applicability

This Policy has been adopted by the Board on December 1, 2023, and shall apply to any Incentive-Based Compensation that is received by an Executive on or after October 2, 2023.

EXHIBIT A

DODD-FRANK COMPENSATION CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges, confirms and agrees that the undersigned: (i) has received and reviewed a copy of the Policy; (ii) is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company; and (iii) will abide by the terms of the Policy, including, without limitation, by reasonably promptly returning any recoverable compensation to the Company as required by the Policy, as determined by the Compensation Committee in its sole discretion.

Sign: _____

Name: [Employee]

Date: _____