

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

or

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

For the transition period from _____ to _____

Commission File Number: 001-00100

TherapeuticsMD, Inc.
(Exact name of Registrant as specified in its Charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

951 Yamato Road, Suite 220
Boca Raton, Florida

(Address of principal executive offices)

87-0233535

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

33431

(Zip Code)

561-961-1900

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 11, 2024, there were 11,532,432 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

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Part I - Financial Information

Item 1. Financial statements

TherapeuticsMD, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands, except per share data)

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets:		
Current assets:		
Cash and cash equivalents	\$ 5,047	\$ 4,327
Royalty receivable, current portion	3,323	3,090
Prepaid and other current assets	3,784	4,035
Current assets of discontinued operations	—	344
Total current assets	12,154	11,796
License rights and other intangible assets, net	4,428	6,098
Right of use assets	6,302	6,873
Royalty receivable, long term	16,610	18,484
Other non-current assets	58	58
Total assets	\$ 39,552	\$ 43,309
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	\$ 234	\$ 27
Accrued expenses and other current liabilities	2,818	3,133
Current liabilities of discontinued operations	2,924	3,694
Total current liabilities	5,976	6,854
Operating lease liabilities	5,777	6,532
Other non-current liabilities	705	636
Total liabilities	12,458	14,022
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value \$0.001; 32,000 shares authorized, 11,532 issued and outstanding as of September 30, 2024 and December 31, 2023	11	11
Additional paid-in capital	979,157	978,917
Accumulated deficit	(952,074)	(949,641)
Total stockholders' equity	27,094	29,287
Total liabilities and stockholders' equity	\$ 39,552	\$ 43,309

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

TherapeuticsMD, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited - in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue, net:				
License and service revenue	\$ 547	\$ (53)	\$ 1,094	\$ 800
Operating expenses:				
Selling, general and administrative	1,310	1,590	3,865	7,427
Impairment of long-lived assets (Note 4)	—	—	1,261	—
Depreciation & amortization	96	130	409	285
Total operating expenses	1,406	1,720	5,535	7,712
Loss from operations	(859)	(1,773)	(4,441)	(6,912)
Other income (expense):				
Interest expense and other financing costs	(3)	(20)	(8)	(115)
Miscellaneous income	295	359	2,023	869
Total other income, net	292	339	2,015	754
Loss from continuing operations before income taxes	(567)	(1,434)	(2,426)	(6,158)
Provision for income taxes	—	—	—	—
Loss from continuing operations, net of income taxes	(567)	(1,434)	(2,426)	(6,158)
Loss from discontinued operations, net of income taxes	(42)	(1,944)	(7)	(3,237)
Net loss	\$ (609)	\$ (3,378)	\$ (2,433)	\$ (9,395)
Loss per common share, basic and diluted:				
Continuing operations	\$ (0.05)	\$ (0.13)	\$ (0.21)	\$ (0.60)
Discontinued operations, net	—	(0.18)	—	(0.32)
Net loss per common share, basic and diluted	\$ (0.05)	\$ (0.32)	\$ (0.21)	\$ (0.92)
Weighted average common shares, basic	11,532	10,701	11,532	10,241
Weighted average common shares, diluted	11,532	10,701	11,532	10,241

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

TherapeuticsMD, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited - in thousands)

Three and Nine Months Ended September 30, 2024

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2024	11,532	\$ 11	\$ 978,917	\$ (949,641)	\$ 29,287
Share-based compensation	—	—	111	—	111
Net loss	—	—	—	(734)	(734)
Balance, March 31, 2024	11,532	\$ 11	\$ 979,028	\$ (950,375)	\$ 28,664
Share-based compensation	—	—	96	—	96
Net loss	—	—	—	(1,090)	(1,090)
Balance, June 30, 2024	11,532	\$ 11	\$ 979,124	\$ (951,465)	\$ 27,670
Share-based compensation	—	—	33	—	33
Net loss	—	—	—	(609)	(609)
Balance, September 30, 2024	<u>11,532</u>	<u>\$ 11</u>	<u>\$ 979,157</u>	<u>\$ (952,074)</u>	<u>\$ 27,094</u>

Three and Nine Months Ended September 30, 2023

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2023	9,498	\$ 9	\$ 974,497	\$ (939,363)	\$ 35,143
Shares issued for vested restricted stock units	455	1	-	-	1
Share-based compensation	-	-	483	-	483
Net loss	-	-	-	(3,603)	(3,603)
Balance, March 31, 2023	9,953	\$ 10	\$ 974,980	\$ (942,966)	\$ 32,024
Shares issued for vested restricted stock units	60	-	-	-	-
Shares issued for sale of common stock related to private placement sale	313	1	1,149	-	1,150
Share-based compensation	-	-	437	-	437
Shares issued for exercise of warrants	249	-	-	-	-
Net loss	-	-	-	(2,414)	(2,414)
Balance, June 30, 2023	10,575	\$ 11	\$ 976,566	\$ (945,380)	\$ 31,197
Share-based compensation	-	-	233	-	233
Net loss	-	-	-	(3,378)	(3,378)
Balance, September 30, 2023	<u>10,575</u>	<u>\$ 11</u>	<u>\$ 976,799</u>	<u>\$ (948,758)</u>	<u>\$ 28,052</u>

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

TherapeuticsMD, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited - in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (2,433)	\$ (9,395)
Less: Loss from discontinued operations, net of income taxes	(7)	(3,237)
Net loss from continuing operations	(2,426)	(6,158)
Adjustments to reconcile net loss to net cash provided by (used in) continuing operating activities:		
Depreciation and amortization	409	285
Impairment of long-lived assets (Note 4)	1,261	—
Write-off of patents and trademarks	—	59
Share-based compensation	240	1,155
Other	572	525
Changes in operating assets and liabilities:		
Other assets	1,874	1,185
Prepaid and other current assets	17	(1,241)
Accounts payable	207	(1,466)
Accrued expenses and other current liabilities	(315)	(11,918)
Lease liabilities	(755)	(629)
Other non-current liabilities	69	82
Total adjustments	3,579	(11,963)
Net cash provided by (used in) continuing operating activities	1,153	(18,121)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	—	1,149
Net cash provided by continuing financing activities	—	1,149
Discontinued operations:		
Net cash used in operating activities	(433)	(22,179)
Net cash used in discontinued operations	(433)	(22,179)
Net increase (decrease) in cash	720	(39,151)
Cash and cash equivalents - continuing operations, beginning of period	4,327	49,317
Total cash and cash equivalents, end of period	\$ 5,047	\$ 10,166

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

TherapeuticsMD, Inc. and Subsidiaries
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

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

General

TherapeuticsMD, Inc. (the “Company”), a Nevada corporation, and its condensed consolidated subsidiaries are referred to collectively in this Quarterly Report on Form 10-Q (“10-Q Report”) as “TherapeuticsMD,” “we,” “our” and “us.” This 10-Q Report includes trademarks, trade names and service marks, such as TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, 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 10-Q 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 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 minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments, including as described below. Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

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 and the grant of the licenses under the Mayne Transaction Agreement was (i) a cash payment of \$140.0 million at closing, (ii) a cash payment of approximately \$12.1 million at closing for the acquisition of net working capital as determined in accordance with the Transaction Agreement and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the Mayne License Agreement Amendment (as defined below) and (iv) the right to receive the contingent consideration set forth in the Mayne License Agreement, as amended. The acquisition of net working capital was determined in accordance with the Transaction Agreement and included significant estimates which could change materially for a period of up to two years following the Closing Date.

On the Closing Date, 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, including our minimum payment obligations thereunder. As the parties agreed, 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.

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 condensed consolidated financial statements. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in our condensed consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2 of our condensed consolidated financial statements.

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. Knight obtained regulatory approval for IMVEXXY and BIJUVA and began commercialization efforts in 2024.
- 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 have been paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2023 and September 30, 2024, 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 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.

Going concern

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 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 intends to resolve this matter through the dispute resolution process outlined in the Transaction Agreement. The Company continues to believe its estimated allowances for payer rebates and wholesale distributor fees are reasonable. 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.

In addition, the Company has received information from Mayne Pharma pertaining to the allowance for returns that differs from the Company’s estimate of the allowance. As of September 30, 2024, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement, as the Company cannot reasonably estimate a range of loss. 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.

Basis of presentation

We prepared the condensed consolidated financial statements included in this 10-Q Report following the requirements of the United States (“U.S.”) Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules, certain notes or other financial information that are normally required by accounting principles generally accepted in the U.S. (“U.S. GAAP”) for complete financial statements can be condensed or omitted. However, except as disclosed herein, there has been no material change in the information disclosed in the notes included in our 2023 Annual Report on Form 10-K (the “2023 10-K Report”).

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

Revenues, expenses, assets, liabilities, and equities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be representative of those for the full year. In our opinion, all adjustments necessary for a fair presentation of the financial statements, which are of a normal and recurring nature, have been made for the interim periods reported. The information included in this 10-Q Report should be read in conjunction with the consolidated financial statements and accompanying notes included in our 2023 10-K Report. Certain amounts in the consolidated financial statements and accompanying notes may not add due to rounding, and all percentages have been calculated using unrounded amounts. Certain prior period amounts have been reclassified to conform to current-period presentation.

New accounting standards

Adoption of new accounting standards

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Update 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures” (“Update 2023-07”). Update 2023-07 applies to all public entities that are required to report segment information in accordance with Topic 280. The amendments in Update 2023-07 revise reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments in Update 2023-07 do not change how a public entity identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments. Update 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Update 2023-07 should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting Update 2023-07.

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”). 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.

Estimates and assumptions

The preparation of our condensed consolidated financial statements in conformity with 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 condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. We evaluate our estimates and 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.

Significant accounting policies

The significant accounting policies we use for quarterly financial reporting are disclosed in Note 1 of the notes to the consolidated financial statements included in our 2023 10-K report.

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 condensed 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.

Additionally, the related assets and liabilities have been reported as assets and liabilities of discontinued operations in our condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023.

As described in Note 1, the acquisition of net working capital by Mayne Pharma 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. 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. Refer to Note 6 for a further discussion of net working capital contingencies.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product revenue, net	\$ —	\$ (833)	\$ —	\$ (833)
General and administrative expenses	42	(39)	202	296
Total operating expenses	42	(39)	202	296
Operating loss from discontinued operations	(42)	(794)	(202)	(1,129)
Other income (expense), net	—	(1,150)	195	(2,108)
Total other income (expense), net	—	(1,150)	195	(2,108)
Loss from discontinued operations, net of income taxes	\$ (42)	\$ (1,944)	\$ (7)	\$ (3,237)

The following table presents the carrying amounts of the classes of assets and liabilities of discontinued operations as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Assets:		
Accounts receivable	\$ -	\$ 344
Liabilities:		
Accrued expenses and other current liabilities	\$ 2,924	\$ 3,694

3. Prepaid and other current assets

Our prepaid and other current assets consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Insurance	\$ 161	\$ 253
Capitalized legal	2,334	2,334
Other	1,289	1,448
Prepaid and other current assets	<u>\$ 3,784</u>	<u>\$ 4,035</u>

4. Licensed rights and other intangible assets

The following provides information about our license rights and other intangible assets, net as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Hormone therapy drug patents	\$ 5,753	\$ 1,957	\$ 3,796	\$ 6,818	\$ 1,871	\$ 4,947
Hormone therapy drug patents applied and pending approval	323	—	323	842	—	842
Intangible assets subject to amortization	6,076	1,957	4,119	7,660	1,871	5,789
Intangible assets not subject to amortization:						
Trademarks/trade name rights	309	—	309	309	—	309
License rights and other intangible assets, net	<u>\$ 6,385</u>	<u>\$ 1,957</u>	<u>\$ 4,428</u>	<u>\$ 7,969</u>	<u>\$ 1,871</u>	<u>\$ 6,098</u>

We recorded, in continuing operations, amortization expense related to patents of \$96 thousand and \$110 thousand for the three months ended September 30, 2024 and 2023, respectively, and \$409 thousand and \$227 thousand for the nine months ended September 30, 2024 and 2023, respectively.

The Company conducts regular reviews of the individual patents and portfolios. As a result of this review, also based on input from its licensing partners in the three months ended June 30, 2024, the Company determined it had an indicator of impairment, as it had abandoned the legal right and title to a portion of its granted patent portfolio and had ceased pursuit of a portion of its pending patents based on input from its licensing partners. The Company recognized an impairment loss of \$1,261 thousand related to those abandoned patents and applications, which is classified as an impairment of long-lived assets on the Company's condensed consolidated statements of operations for the nine months ended September 30, 2024.

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

Year ending December 31,	
2024	\$ 97
2025	384
2026	384
2027	384
2028	384
Thereafter	2,163
Total	<u>\$ 3,796</u>

5. Accrued expenses and other current liabilities

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

	September 30, 2024	December 31, 2023
Payroll and related costs	\$ 455	\$ 762
Professional fees	296	489
Operating lease liabilities	1,623	1,473
Other accrued expenses and current liabilities	444	409
Accrued expenses and other current liabilities	<u>\$ 2,818</u>	<u>\$ 3,133</u>

6. Commitments and contingencies

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 increased certain accrual estimates including increasing our working capital adjustment accrual by \$2.0 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. Of the \$5.5 million, \$2.0 million increased the allowance for net working capital allowances remaining to be trued up.

The Company's estimate of the allowance for payer rebates and wholesale distributor fees was determined in accordance with the Transaction Agreement which establishes the process for the determination of net working capital. 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 intends to resolve this matter through the dispute resolution process outlined in the Transaction Agreement.

The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable. The timing and 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.

In addition, the Company has received information from Mayne Pharma pertaining to the allowance for returns that differs from the Company's estimate of the allowance. As of September 30, 2024, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns, as the Company cannot reasonably estimate a range of loss. 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.

Mayne Pharma has also made certain indemnification demands under the Transaction Agreement, which the Company disputes. As of September 30, 2024, the Company believes no additional accrual is required for such claims, as the Company cannot reasonably estimate a range of loss.

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 \$2,334 thousand in prepaid expenses and other current assets as of September 30, 2024, 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 condensed 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 proceeding and any unamortized IMVEXXY patent costs that were previously capitalized will be immediately expensed in the period in which we become aware of an unsuccessful legal proceeding.

In June 2024, Mayne received a Paragraph IV certification notice letter (the “Sun Notice Letter”) regarding an ANDA submitted to the FDA by Sun Pharma Inc. (“Sun Pharma”). 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 Sun Notice Letter, Sun Pharma alleges that the IMVEXXY Patents are invalid, unenforceable, and/or will not be infringed by Sun Pharma’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the Sun Notice Letter expire in 2032 or 2033. In July 2024, we and Mayne Pharma filed a complaint for patent infringement against Sun Pharma in the United States District Court for the District of New Jersey arising from Sun Pharma’s ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Sun Pharma’s ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Sun Pharma from infringing the IMVEXXY Patents.

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

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 condensed consolidated financial condition, results of operations, or cash flows.

Off-balance sheet arrangements

As of September 30, 2024 and December 31, 2023 there were 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 September 30, 2024, 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. In the aggregate, as of September 30, 2024, we have accrued severance liabilities for executive termination obligations of \$56 thousand.

7. Stockholders' equity

Warrants

As of September 30, 2024, the following table summarizes the status of our outstanding and exercisable warrants and related transactions since December 31, 2023 (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)
As of January 1, 2024	99	\$ 66.61	\$ —	6.5
Expired	(2)	281.50	—	—
As of September 30, 2024	97	\$ 63.33	\$ —	5.8

Share-based compensation payment plans

As of September 30, 2024, 61,530 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 September 30, 2024, 405,719 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 since December 31, 2023 (in thousands, except weighted 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, 2024	72	\$ 258.55	\$ —	3.0	72	\$ 258.46	\$ —	3.0
Expired	(10)	224.58	—	—	(10)	—	—	—
As of September 30, 2024	62	\$ 264.66	\$ —	2.8	62	\$ 264.54	\$ —	2.8

The following table summarizes the status of our RSUs and related transactions since December 31, 2023 (in thousands, except weighted average grant date fair value):

	RSUs awards outstanding		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of January 1, 2024	40	\$ 9.67	\$ 89.60
Vested	(38)	9.11	—
As of September 30, 2024	2	\$ 21.78	\$ 2.88

The following table summarizes the status of our PSUs and related transactions since December 31, 2023 (in thousands, except weighted average grant date fair value):

	Outstanding		
	PSUs ⁽¹⁾	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested, as of January 1, 2024	12	\$ 49.36	\$ 32.57
Vested	(7)	60.50	16.16
Unvested, as of September 30, 2024	5	\$ 34.50	\$ 8.63

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

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 \$33 thousand and \$234 thousand for the three months ended September 30, 2024 and 2023, respectively, and \$240 thousand and \$1,155 thousand for the nine months ended September 30, 2024 and 2023, respectively.

As of September 30, 2024, we had \$48 thousand 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 condensed consolidated balance sheets. No tax benefit was realized due to a continued pattern of net losses. The unrecognized compensation cost of \$48 thousand is expected to be recognized as share-based payment award compensation over a weighted average period of 0.5 years.

8. 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 minimal annual royalties of \$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments. 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.

9. Income taxes

We do not expect to pay any significant federal or state income taxes as a result of (i) the losses recorded during the three and nine months ended September 30, 2024 and 2023, (ii) additional losses expected for the remainder of 2024 or losses recorded in 2023, or (iii) net operating loss carry forwards from prior years.

We recorded a full valuation allowance of the net operating losses for the three and nine months ended September 30, 2024 and 2023. Accordingly, there were no provisions for income taxes for the three and nine months ended September 30, 2024 and 2023. Additionally, as of September 30, 2024 and December 31, 2023, we maintain a full valuation allowance for all deferred tax assets.

10. Income (Loss) per common share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Loss from continuing operations, net of income taxes	\$ (567)	\$ (1,434)	\$ (2,426)	\$ (6,158)
Loss from discontinued operations, net of income taxes	(42)	(1,944)	(7)	(3,237)
Net loss	\$ (609)	\$ (3,378)	\$ (2,433)	\$ (9,395)
Denominator:				
Weighted average common shares for basic loss per common share	11,532	10,701	11,532	10,241
Effect of dilutive securities	—	—	—	—
Weighted average common shares for diluted loss per common share	11,532	10,701	11,532	10,241
Loss per common share, continuing operations, net of income taxes				
Basic	\$ (0.05)	\$ (0.13)	\$ (0.21)	\$ (0.60)
Diluted	\$ (0.05)	\$ (0.13)	\$ (0.21)	\$ (0.60)
Loss per common share, discontinued operations, net of income taxes				
Basic	\$ —	\$ (0.18)	\$ —	\$ (0.32)
Diluted	\$ —	\$ (0.18)	\$ —	\$ (0.32)

Since we reported a net loss from continuing operations for the three and nine months ended September 30, 2024 and 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 the three and nine months ended September 30, 2024 and 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 the respective three and nine months ended September 30, 2024 and 2023 (in thousands):

	As of September 30,	
	2024	2023
Stock options	62	80
RSUs	2	84
PSUs	5	12
Warrants	97	99
	<u>166</u>	<u>275</u>

11. 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, 2023, filed with the Securities and Exchange Commission on April 29, 2024, 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 and 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.

12. 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 condensed consolidated financial statements. Assets and liabilities associated with the commercial business are classified as assets and liabilities of discontinued operations in our condensed consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2.

For the three and nine months ended September 30, 2024, 100% of license revenue related to Mayne Pharma, Theramex and Knight.

As of September 30, 2024, we had a royalty receivable of \$3,323 thousand relating to the short-term portion of receivable from Mayne Pharma, Theramex and Knight and \$16,610 thousand 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.

Item 2. Management’s discussion and analysis of financial condition and results of operations

The following discussion should be read in conjunction with our 2023 Annual Report on Form 10-K (“2023 10-K Report”), and the condensed consolidated financial statements and related notes in Item 1, Financial Statements, appearing elsewhere in this Quarterly Report on Form 10-Q (“10-Q Report”). The following discussion may contain forward-looking statements, and our actual results may differ materially from the results suggested by these forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A of our 2023 10-K Report under the heading “Risk Factors.” We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

Certain amounts in the following discussion may not add due to rounding, and all percentages have been calculated using unrounded amounts.

Forward-looking statements

This 10-Q 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, debt position, liquidity, business strategy, and other plans and objectives for future operations, and assumptions and predictions about future cost reduction strategies, expenses and royalties are all forward-looking statements. 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 10-Q Report, and 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. 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, except as required by law or by the rules and regulations of the SEC.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Factors that could cause or contribute to such differences include, but are not limited to, our liquidity requirements, supply chain issues, management transitions, risks related to our licensing agreements, market and general economic factors, and the other risks discussed in Part I, Item 1A of our 2023 10-K Report, as updated and supplemented by Part II, Item 1A of this 10-Q Report.

Our company

TherapeuticsMD was previously a women’s healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through menopause. In December 2022, we changed our business to become a pharmaceutical royalty company, primarily collecting royalties from our licensees. We are no longer engaged in research and development or commercial operations. 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, pursuant to which we (i) granted Mayne Pharma an exclusive license to commercialize 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.

Pursuant to 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. 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 (the “Minimum Annual Royalty”). Upon the expiry of the 20-year royalty term, the licenses granted to Mayne Pharma under the Mayne License Agreement will become a fully paid-up and royalty free license for the Licensed Products.

Pursuant to a Transaction Agreement, dated December 4, 2022, between 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 our exclusive license from the Population Council to commercialize ANNOVERA (the “Transferred Assets”).

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

This action represented a shift in our business and therefore, the related assets and liabilities associated with commercial operations are classified as discontinued operations on our condensed consolidated balance sheets and the results of operations have been presented as discontinued operations within our condensed consolidated statements of operations for all periods presented. See Note 2 – Discontinued Operations to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for further details.

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. Knight obtained regulatory approval for IMVEXXY and BIJUVA and began commercialization efforts in 2024.
- 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 the first quarter of 2023 and severance obligations for terminated executive officers have been paid in accordance with their employment agreements and separation agreements as previously disclosed. As of December 31, 2023 and September 30, 2024, we employed one full-time employee primarily engaged in an executive position. We have engaged external consultants, including certain former members of our management team, who support our relationship with current partners and assist with certain financial, legal and regulatory matters and the continued wind-down of our historical business operations.

Going concern

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 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.

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 true-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.

The Company's estimate of the allowance for payer rebates and wholesale distributor fees was determined in accordance with the Transaction Agreement which establishes the process for the determination of net working capital. 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 intends to resolve this matter through the dispute resolution process outlined in the Transaction Agreement.

The Company believes its estimated allowances for payer rebates and wholesale distributor fees are reasonable. The timing and 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.

In addition, the Company has received information from Mayne Pharma pertaining to the allowance for returns that differs from the Company's estimate of the allowance. As of September 30, 2024, the Company believes no additional accrual is required for amounts that may be owed for the allowance for returns under the Transaction Agreement, as the Company cannot reasonably estimate a range of loss. 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

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- μ g and 10- μ g

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.

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 September 30, 2024, no IMVEXXY sales had been made through the Theramex licensing 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.

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

As part of the transformation that included the Mayne License Agreement, historical results of commercial operations have been reflected as discontinued operations in our condensed 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 our condensed consolidated balance sheets. Additional disclosures regarding discontinued operations are provided in Note 2 to the condensed consolidated financial statements included in this Quarterly Report.

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

Three months ended September 30, 2024 compared with three months ended September 30, 2023

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

	Three Months Ended September 30,	
	2024	2023
Revenue:		
License and service revenue	\$ 547	\$ (53)
Operating expenses:		
Selling, general and administrative	1,310	1,590
Impairment of long-lived assets (Note 4)	—	—
Depreciation and amortization	96	130
Total operating expenses	1,406	1,720
Loss from operations	(859)	(1,773)
Other income (expense):		
Interest expense and other financing costs	(3)	(20)
Miscellaneous income	295	359
Total other income, net	292	339
Loss from continuing operations before income taxes	(567)	(1,434)
Provision for income taxes	—	—
Net loss from continuing operations	(567)	(1,434)
Loss from discontinued operations, net of income taxes	(42)	(1,944)
Net loss	\$ (609)	\$ (3,378)

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

We recorded \$547 thousand in license revenue for the third quarter of 2024, primarily from the Mayne License Agreement, an increase of \$600 thousand, compared to \$(53) thousand in license revenue for the third quarter of 2023. The increase is primarily attributable to changes in sales of licensed products. Reported negative license revenue of \$(53) thousand in the third quarter of 2023 was due to product sales adjustments reported by our licensees.

Operating expenses. Total operating expenses for the third quarter of 2024 were \$1,406 thousand, a decrease of \$314 thousand, or 18.3%, compared to the third quarter of 2023. This decrease was due to the further optimization of our business through the reduction of costs following our transition to a royalty-based business.

Selling, general and administrative. Selling, general and administrative expenses were \$1,310 thousand for the third quarter of 2024, a decrease of \$280 thousand, or 17.6%, compared to the third quarter of 2023. This decrease was due to the increased efficiencies realized following our transition to a royalty-based business.

Depreciation & amortization. Depreciation and amortization expense was \$96 thousand for the third quarter of 2024, a decrease of \$34 thousand, or 26.2%, compared to the third quarter of 2023. In the 2024 period, this balance is entirely comprised of amortization of license rights and intangible assets.

Loss from operations. In the third quarter of 2024, we had a loss from operations of \$859 thousand, as compared to a loss from operations of \$1,773 thousand for the third quarter of 2023. This change reflects the streamlining of our business and increased efficiencies realized as a royalty-based business.

Other income (expense), net. During the third quarter of 2024, we had other income of \$292 thousand compared to other income of \$339 thousand in the third quarter of 2023. Other income in the 2024 period was mainly comprised of interest income, while other income in the prior year period was mainly comprised of royalties.

Provision for income taxes. During the third quarter of 2024 and 2023, we recorded no provision for income taxes for continuing operations.

Net loss from continuing operations. For the third quarter of 2024, we had a net loss of \$567 thousand, or \$0.05 per basic and diluted common share, compared to a net loss of \$1,434 thousand, or \$0.13 per basic and diluted common share, for the third quarter of 2023.

Discontinued Operations – Net loss from discontinued operations was \$42 thousand for the third quarter of 2024, compared to a net loss from discontinued operations of \$1,944 thousand for the third quarter of 2023.

Nine months ended September 30, 2024 compared with nine months ended September 30, 2023

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

	Nine Months Ended September 30,	
	2024	2023
Revenue:		
License and service revenue	\$ 1,094	\$ 800
Operating expenses:		
Selling, general and administrative	3,865	7,427
Impairment of long-lived assets (Note 4)	1,261	—
Depreciation and amortization	409	285
Total operating expenses	5,535	7,712
Loss from operations	(4,441)	(6,912)
Other income (expense):		
Interest expense and other financing costs	(8)	(115)
Miscellaneous income	2,023	869
Total other income, net	2,015	754
Loss from continuing operations before income taxes	(2,426)	(6,158)
Provision for income taxes	—	—
Net loss from continuing operations	(2,426)	(6,158)
Loss from discontinued operations, net of income taxes	(7)	(3,237)
Net loss	\$ (2,433)	\$ (9,395)

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

We recorded \$1,094 thousand in license revenue for the first nine months of 2024, primarily from the Mayne License Agreement, an increase of \$294 thousand, or 36.8%, compared to \$800 thousand in license revenue for the first nine months of 2023. The increase is primarily attributable to changes in sales of licensed products.

Operating expenses. Total operating expenses for the first nine months of 2024 were \$5,535 thousand, a decrease of \$2,177 thousand, or 28.2 %, compared to the first nine months of 2023. This decrease was due to the further optimization of our business through the reduction of costs following our transition to a royalty-based business and is partially off-set by the patent impairment recognized in the second quarter of 2024.

Selling, general and administrative. Selling, general and administrative expenses were \$3,865 thousand for the first nine months of 2024, a decrease of \$3,562 thousand, or 48.0%, compared to the first nine months of 2023. This decrease was due to the increased efficiencies realized following our transition to a royalty-based business.

Depreciation & amortization. Depreciation and amortization expense was \$409 thousand for the first nine months of 2024, an increase of \$124 thousand, or 43.5%, compared to the first nine months of 2023. In the 2024 period, this balance is entirely comprised of amortization of license rights and intangible assets.

Loss from operations. In the first nine months of 2024, we had a loss from operations of \$4,441 thousand, as compared to a loss from operations of \$6,912 thousand for the first nine months of 2023. This change reflects the streamlining of our business and increased efficiencies realized as a royalty-based business.

Other income, net. During the first nine months of 2024, we had other income of \$2,015 thousand compared to other income of \$754 thousand in the first nine months of 2023. The difference is mainly due to a \$1,250 thousand one-time payment the Company received from its sublessee on its early termination on the sublease, which was recognized in the second quarter of 2024. Royalties reported as other income for intellectual property licensed by us totaled approximately \$660 thousand in the first nine months of 2024.

Provision for income taxes. During the first nine months of 2024 and 2023, we recorded no provision for income taxes for continuing operations.

Net loss from continuing operations. For the first nine months of 2024, we had a net loss of \$2,426 thousand, or \$0.21 per basic and diluted common share, compared to a net loss of \$6,158 thousand, or \$0.60 per basic and diluted common share, for the first nine months of 2023.

Discontinued Operations - Net loss from discontinued operations was \$7 thousand for the first nine months of 2024, compared to a net loss from discontinued operations of \$3,237 thousand for the first nine months of 2023. This change reflects the continued wind-down of our legacy business.

For additional information, see Note 2 - Discontinued Operations, in the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Liquidity and capital resources

Our primary use of cash is to fund our continued 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 September 30, 2024, we had cash and cash equivalents totaling \$5,047 thousand. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of \$250 thousand per bank. We have never experienced any losses related to these funds.

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 dated December 4, 2022, and subject to certain adjustments, (iii) a cash payment of approximately \$1.0 million at closing for prepaid royalties in connection with the 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.

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 drawdowns 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.

Managed Client Agreement with IWG

On September 30, 2024 (the “Commencement Date”), we entered into a Managed Client Agreement (the “Managed Client Agreement”) with RGN-MCA Florida VI, LLC (“IWG”) pursuant to which IWG agreed to provide managed services for flexible workspaces under the “HQ” brand for 21,330 square feet of our office spaces located at 951 Yamato Road, Boca Raton, Florida 33431 (the “Premises”). The Managed Client Agreement is subject to termination by us or IWG if either party does not approve the specification, plans and drawings for the fit out of the Premises on or before the date that is 120 days after the Commencement Date.

See “Going Concern” above for further discussion related to our ability to generate and obtain adequate amounts of cash to meet our liquidity needs and our plans to satisfy our such needs in the short-term and in the long-term. As a result, there is substantial doubt about our ability to continue as a going concern for the next twelve months from the issuance of these financial statements.

Cash flows

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

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in) continuing operating activities	\$ 1,153	\$ (18,121)
Net cash provided by financing activities	—	1,149
Net cash used in discontinued operations	(433)	(22,179)
Net increase (decrease) in cash	<u>\$ 720</u>	<u>\$ (39,151)</u>

Operating Activities from continuing operations. For the first nine months of 2024, net cash provided by operating activities was \$1,153 thousand, compared to net cash used in operating activities of \$18,121 thousand for the first nine months of 2023. This change of \$19,274 thousand was primarily due to a \$3,732 thousand decrease in our net loss from continuing operations following our transition from a manufacturing and commercialization business to a royalty-based business combined with the pay-down of current liabilities in the prior-year period.

Financing Activities from continuing operations. For the first nine months of 2024, there was no cash received from financing activities, compared to net cash received from financing activities of \$1,149 thousand for the first nine months of 2023, reflecting the sale of common stock during the first nine months of 2023.

Net cash used in discontinued operations. Net cash used in operating activities from discontinued operations for the first nine months of 2024 was \$433 thousand as compared to net cash used in operating activities of \$22,179 thousand for the first nine months of 2023. This change relates primarily to a decrease in expenses incurred and the payment of current liabilities associated with our transition from a manufacturing and commercialization business to a royalty-based business.

For additional details, see the condensed consolidated statements of cash flows in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

Other liquidity measures

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 September 30, 2024, we had a royalty receivable of \$3,160 thousand relating to the short-term portion of receivable from Mayne Pharma and \$16,610 thousand 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 our 2023 10-K Report.

Inventory. On December 30, 2022, Mayne Pharma acquired our inventory balance of approximately \$6.6 million, which is subject to certain net working capital adjustments.

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

Our contractual obligations and off-balance sheet arrangements are set forth below. For additional information on any of the following and other obligations and arrangements, see “Note 6. Commitments and Contingencies” to the condensed consolidated financial statements included in this 10-Q Report.

In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions, which, in our judgment, are normal and customary for companies in our industry sector. Pursuant to these agreements, we agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is sometimes unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we had no liabilities recorded for these provisions as of September 30, 2024 and December 31, 2023.

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 condensed consolidated financial statements.

Critical accounting policies and estimates

Management’s discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements included elsewhere in this 10-Q Report, which has been prepared in accordance with U.S. GAAP and SEC rules and regulations related to interim financial reporting. We make estimates and assumptions that affect the reported amounts on our condensed consolidated financial statements and accompanying notes as of the date of the condensed consolidated financial statements. The critical accounting policies and estimates used are disclosed in Item 7 – Management’s discussion and analysis of financial condition and results of operations – Critical accounting policies and estimates in our 2023 10-K Report.

Item 3. 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 4. Controls and procedures

Management’s evaluation of disclosure controls and procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports filed or submitted under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported, within the time period specified in the SEC’s rules and forms and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, in order to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this 10-Q Report. Based on that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures as of the end of the period covered by this 10-Q Report were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our Chief Executive Officer does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits 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 as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

Changes in internal controls over financial reporting

In connection with our transformation into a pharmaceutical royalty company, we terminated our executive management team and all other employees, except for our former General Counsel and current Chief Executive Officer. As of September 30, 2024, 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 commercial business operations. As a result of these changes, we have updated our risk assessment and design of internal controls over financial reporting that align with reduced transaction volume and reliance on external consultants to manage the day-to-day operations of the Company. The Company is and will continue to evaluate changes to processes, information technology systems and other components of internal controls over financial reporting as part of its ongoing business transformation activities, and as a result, controls may be periodically changed. The Company believes, however, that it will be able to maintain sufficient controls over its financial reporting throughout this transformation process.

During the first quarter of fiscal year 2024, we deployed a new ERP system which is anticipated to enhance our operating and financial processes over time. Processes and internal controls have been updated and are consistent with our internal control framework, and we have evaluated the operating effectiveness of related key controls. Control processes continue to be evaluated to give appropriate consideration of modifications needed to maintain the effectiveness of internal controls over financial reporting.

Part II - Other Information

Item 1. Legal proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of our business. Other than the legal proceedings disclosed in Note 6, Commitments and contingencies in Part I, Item 1, Financial Statements, appearing elsewhere in this 10-Q Report, we are not involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

Item 1A. Risk factors

Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described in Part I, Item 1A of the 2023 10-K Report under the heading "Risk Factors," any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price. There have been no material changes to our risk factors since the 2023 10-K Report.

Item 2. Unregistered sales of equity securities and use of proceeds

None.

Item 3. Defaults upon senior securities

None.

Item 4. Mine safety disclosures

None.

Item 5. Other information

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2024, none of the Company's directors or officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits

Exhibit No.	Description
31.1†	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a).
31.2†	Certification of Principal 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 Principal Financial Officer
101†	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, “Financial Statements” of this Quarterly Report on Form 10-Q
104†	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set

† Filed herewith.

†† Furnished herewith.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2024

TherapeuticsMD, Inc.

/s/ Marlan D. Walker

Marlan D. Walker

Chief Executive Officer

(Principal Executive Officer)

/s/ Joseph Ziegler

Joseph Ziegler

Principal Financial and Accounting Officer

Certification of Chief Executive Officer

I, Marlan D. Walker, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (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: November 12, 2024

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

Certification of Principal Financial Officer

I, Joseph Ziegler, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (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: November 12, 2024

/s/ Joseph Ziegler

Joseph Ziegler

Principal Financial Officer

Section 1350 Certification of Chief Executive Officer

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), 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 Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2024

/s/ Marlan D. Walker

Marlan D. Walker

Chief Executive Officer

The foregoing certification is being furnished as an exhibit to the Report pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 and, accordingly, is not being filed with the Securities and Exchange Commission as part of the Report and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report, irrespective of any general incorporation language contained in such filing).

Section 1350 Certification of Principal Financial Officer

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), 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 Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2024

/s/ Joseph Ziegler

Joseph Ziegler

Principal Financial Officer

The foregoing certification is being furnished as an exhibit to the Report pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 and, accordingly, is not being filed with the Securities and Exchange Commission as part of the Report and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report, irrespective of any general incorporation language contained in such filing).