

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 March 31, 2022
or
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: **001-00100**

TherapeuticsMD

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 May 10, 2022, there were 8,668,558 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
Consolidated Balance Sheets
(Unaudited - in thousands, except per share data)

	March 31, 2022	December 31, 2021
Assets:		
Current assets:		
Cash	\$ 30,384	\$ 65,122
Accounts receivable, net of allowance for credit losses of \$1,334 as of March 31, 2022 and December 31, 2021	35,413	36,176
Inventory	8,967	7,622
Prepaid and other current assets	9,660	10,548
Total current assets	84,424	119,468
Fixed assets, net	1,082	1,199
License rights and other intangible assets, net	39,547	40,318
Right of use assets	8,075	8,234
Other non-current assets	253	253
Total assets	\$ 133,381	\$ 169,472
Liabilities and stockholders' deficit:		
Current liabilities:		
Current maturities of debt	\$ 202,857	\$ 188,269
Accounts payable	20,753	20,318
Accrued expenses and other current liabilities	41,225	44,304
Total current liabilities	264,835	252,891
Operating lease liabilities	7,897	8,063
Other non-current liabilities	1,229	2,139
Total liabilities	273,961	263,093
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Preferred stock, par value \$0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value \$0.001; 12,000 shares authorized, 8,669 and 8,598 (each) adjusted for the 50-for-1 reverse stock split) issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9	9
Additional paid-in capital	959,792	957,730
Accumulated deficit	(1,100,381)	(1,051,360)
Total stockholders' deficit	(140,580)	(93,621)
Total liabilities and stockholders' deficit	\$ 133,381	\$ 169,472

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

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

	Three Months Ended March 31,	
	2022	2021
Revenue, net:		
Product	\$ 18,914	\$ 19,632
License and service	419	234
Total revenue, net	19,333	19,866
Cost of goods sold	4,860	4,687
Total gross profit	14,473	15,179
Operating expenses:		
Selling and marketing	18,895	24,024
General and administrative	20,407	18,383
Research and development	1,400	2,050
Total operating expenses	40,702	44,457
Loss from operations	(26,229)	(29,278)
Other expense:		
Loss on extinguishment of debt	(8,380)	—
Interest expense and other financing costs	(14,412)	(10,227)
Other income, net	—	122
Total other expense, net	(22,792)	(10,105)
Loss before income taxes	(49,021)	(39,383)
Provision for income taxes	—	—
Net loss	\$ (49,021)	\$ (39,383)
Loss per common share, basic and diluted	\$ (5.69)	\$ (5.67)
Weighted average common shares, basic and diluted	8,614	6,945
Comprehensive loss:		
Net loss	\$ (49,021)	\$ (39,383)
Other comprehensive income	—	—
Comprehensive loss	\$ (49,021)	\$ (39,383)

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

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

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2022	8,598	\$ 9	\$ 957,730	\$ (1,051,360)	\$ (93,621)
Shares issued for vested restricted stock units	71	—	—	—	—
Share-based compensation	—	—	2,062	—	2,062
Net loss	—	—	—	(49,021)	(49,021)
Balance, March 31, 2022	8,669	\$ 9	\$ 959,792	\$ (1,100,381)	\$ (140,580)
Balance, January 1, 2021	5,996	\$ 6	\$ 754,938	\$ (878,945)	\$ (124,001)
Shares issued for sale of common stock, net of cost	1,857	2	150,897	—	150,899
Shares issued for exercise of warrants, net of cashless exercises	10	—	50	—	50
Shares issued for vested restricted stock units	1	—	—	—	—
Share-based compensation	—	—	2,957	—	2,957
Net loss	—	—	—	(39,383)	(39,383)
Balance, March 31, 2021	7,864	\$ 8	\$ 908,842	\$ (918,328)	\$ (9,478)

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

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (49,021)	\$ (39,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,100	1,019
Charges to provision for doubtful accounts	274	230
Inventory charge	73	502
Debt financing fees	9,048	1,272
Loss on extinguishment of debt	8,380	—
Share-based compensation	2,062	2,957
Other	(7)	216
Changes in operating assets and liabilities:		
Accounts receivable	489	(1,567)
Inventory	(1,418)	145
Prepaid and other current assets	888	(817)
Accounts payable	435	(10,758)
Accrued expenses and other current liabilities	(1,829)	7,804
Total adjustments	19,495	1,003
Net cash used in operating activities	(29,526)	(38,380)
Cash flows from investing activities:		
Payment of patent related costs	(170)	(375)
Purchase of fixed assets	(42)	(63)
Net cash used in investing activities	(212)	(438)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	—	150,899
Proceeds from exercise of options and warrants	—	50
Repayments of debt	(5,000)	(50,000)
Payment of debt financing fees	—	(5,000)
Net cash (used in) provided by financing activities	(5,000)	95,949
Net (decrease) increase in cash	(34,738)	57,131
Cash, beginning of period	65,122	80,486
Cash, end of period	\$ 30,384	\$ 137,617
Supplemental disclosure of cash flow information:		
Interest paid	\$ 5,364	\$ 8,955
Supplemental disclosure of noncash financing activities:		
Paid in kind ("PIK") debt financing fees with corresponding increase in debt	\$ 30,000	\$ —

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

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

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

General

TherapeuticsMD, Inc., a Nevada corporation (the “Company”) and its 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 our trademarks, trade names and service marks, such as TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA®, which are protected under applicable intellectual property laws and are the property of, or licensed to, the Company. Solely for convenience, trademarks, trade names and service marks referred to in this 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.

We are a women’s healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from a patient-controlled, long-lasting contraceptive to advanced hormone therapy pharmaceutical products. We also have a portfolio of branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands. Our portfolio of products focused on women’s health allows us to efficiently leverage our sales and marketing plan to grow our recently approved products.

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. (“vitaCare”) with the sale of all of vitaCare’s issued and outstanding capital stock (the “vitaCare Divestiture”). We received a cash payment of \$150.0 million, subject to adjustment as provided in the stock purchase agreement (the “Purchase Agreement”) and customary holdbacks. Additionally, we may receive up to an additional \$7.0 million in earn-out consideration, contingent upon vitaCare’s financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, upon closing of the vitaCare divestiture, (i) we entered into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products, and (ii) we and vitaCare entered into a transition services agreement for us to provide certain transition services to vitaCare for up to 12 months following the closing. Under the long-term services agreement, we are required to pay to vitaCare a minimum service fee for each respective annual contract year. Our estimated minimum service fee commitments for vitaCare are as follows: \$5.2 million for the period from April 15, 2022 to December 31, 2022, \$10.7 million for 2023, \$13.4 million for 2024, \$15.4 million for 2025, \$16.2 million for 2026, and \$5.5 million for the period from January 1, 2027 to April 14, 2027.

COVID-19

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

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause which provide patients real-time access to both diagnosis and treatment. We continue to support prescribers’ needs with samples and product materials through our sales force. If access is restricted, we have mailing options in place for these materials. We also have business continuity plans and infrastructure in place that allows for live virtual e-detailing of our products.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses and implemented cost saving measures, which included negotiating lower fees or suspending services from third-party vendors; implementing a company-wide hiring restriction; delaying or cancelling non-critical information technology projects; and eliminating non-essential travel, entertainment, meeting, and event expenses. In addition, we implemented a significant cost savings initiative that was designed to reduce our annual operating costs in 2022, and we reduced the operating costs of the vitaCare business with the completion of the vitaCare Divestiture on April 14, 2022. See above for additional information regarding the vitaCare Divestiture.

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

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

Going concern

We incurred a net loss of \$49.0 million during the three months ended March 31, 2022, and as of that date, our current liabilities exceeded our current assets by \$180.4 million and our total liabilities exceeded our total assets by \$140.6 million. We will need to raise additional capital to repay the entire principal balance of the Financing Agreement, dated as of April 24, 2019, as amended (the “Financing Agreement”), with Sixth Street Specialty Lending, Inc., as administrative agent (the “Administrative Agent” or “Sixth Street”), various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which matures on June 1, 2022, and to provide additional liquidity to fund our losses until our operations become cash flow positive. To address our capital needs, we are pursuing various equity and debt financing and other alternatives, including, but not limited to, the sale of vitaCare which was completed on April 14, 2022. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock and the potential delisting of our common stock from the Nasdaq Global Select Market, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us. Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses.

If we are unsuccessful with future financings and if the successful commercialization of ANNOVERA, IMVEXXY, or BIJUVA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to repay the entire principal balance of the Financing Agreement or satisfy our liquidity needs. See Note 3, Inventory for additional information regarding risks associated with our contract manufacturers, particularly for ANNOVERA. The presence of these projected factors in conjunction with the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements.

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

Common stock reverse stock split

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

In this 10-Q Report, all historical number of shares of common stock and per share data have been adjusted to give effect to the Reverse Stock Split. Additionally, since the common stock par value was unchanged, historical amounts for common stock and additional paid-in capital have been adjusted to give effect to the Reverse Stock Split.

A. Basis of presentation

We prepared the 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 2021 Annual Report on Form 10-K ("2021 10-K Report").

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 statement 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 2021 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.

B. New accounting standards

Adoption of new accounting standards

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

Accounting standards issued but not yet adopted

Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting and Scope. In March 2020 and January 2021, Accounting Standards Update ("ASU") 2020-04 and ASU 2021-01 were issued, respectively. These ASUs provide optional guidance for a limited period of time to ease potential accounting impacts associated with transitioning away from reference rates that are expected to be discontinued, such as London Interbank Offered Rate (LIBOR). These ASUs include practical expedients for contract modifications due to reference rate reform. Generally, contract modifications related to reference rate reform may be considered an event that does not require remeasurement or reassessment of a previous accounting determination at the modification date. These ASUs were effective upon issuance and may be applied prospectively to contract modifications made or evaluated on or before December 31, 2022. Our debt agreements currently include the use of alternate rates when LIBOR is not available. We do not expect the change from LIBOR to an alternate rate will have a material impact to our financial statements and, to the extent we enter into modifications of agreements that are impacted by the LIBOR phase-out, we will apply such guidance to those contract modifications.

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

C. Estimates and assumptions

The preparation of consolidated financial statements in conformity to U.S. GAAP requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We evaluate our estimated assumptions based on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ, at times in material amounts, from these estimates under different assumptions or conditions.

D. Significant accounting policies

The significant accounting policies we use for quarterly financial reporting are disclosed in Note 1, Business, basis of presentation, new accounting standards and summary of significant accounting policies of the accompanying notes to the consolidated financial statements included in our 2021 10-K Report, and in the section below.

2. Accounts receivable

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

Balance as of January 1, 2022	\$	1,334
Charges to provision for credit losses		274
Write-off of uncollectible receivables		(274)
Balance as of March 31, 2022	\$	1,334

3. Inventory

Our inventory consisted of the following (in thousands):

	March 31, 2022		December 31, 2021	
Raw materials	\$	4,394	\$	3,042
Work in process		1,231		1,642
Finished products		3,342		2,938
Inventory	\$	8,967	\$	7,622

We recorded inventory charges of \$0.1 million and \$0.5 million for the three months ended March 31, 2022 and 2021, respectively.

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

One of our third-party contract manufacturers that manufactures ANNOVERA has recently experienced an increase in difficulties with manufacturing of ANNOVERA, which has resulted in intermittent supply interruptions of ANNOVERA for commercial distribution. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021, we filed a supplemental New Drug Application (“NDA”) with the FDA to modify the testing specifications for ANNOVERA to allow increased consistency of supply of ANNOVERA. In December 2021, FDA determined that it could not approve the supplemental NDA without additional information. In its complete response letter (“CRL”), the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided additional information to the FDA and modified the request to revise the manufacturing testing limits based on the FDA feedback. We expect a response from the FDA by the end of second quarter of 2022. We have continued to manufacture and supply ANNOVERA under the existing specifications as well as (i) ramping up manufacturing sufficient to better meet second quarter of 2022 demands notwithstanding existing challenges, (ii) added resources to increase production volumes, (iii) increasing yield per manufacturing batch, and (iv) increasing production capacity to better meet product demands to realize revenue potential, including reducing dependency on labor resources, increasing efficiency in manufacturing and testing, and automating some of the processes. In the meantime, our third-party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market, which would have an adverse effect on our business,

results of operations and financial condition. Additionally, we may incur increased write-offs of ANNOVERA products manufactured in 2022 that do not meet existing specifications.

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

4. Prepaid and other current assets

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

	March 31, 2022		December 31, 2021	
Insurance	\$	1,644	\$	2,731
Paragraph IV legal proceeding costs		2,304		2,304
Other		5,712		5,513
Prepaid and other current assets	\$	9,660	\$	10,548

5. Fixed assets

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

	March 31, 2022		December 31, 2021	
Furniture and fixtures	\$	1,407	\$	1,407
Computer and office equipment		1,897		1,855
Computer software		375		375
Leasehold improvements		80		80
Fixed assets		3,759		3,717
Less: accumulated depreciation and amortization		2,677		2,518
Fixed assets, net	\$	1,082	\$	1,199

We recorded depreciation expense of \$0.2 million for the three months ended March 31, 2022 and 2021.

6. Licensed rights and other intangible assets

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

	March 31, 2022			December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Licensed rights and intangible assets subject to amortization:						
License rights	\$ 40,000	\$ 7,580	\$ 32,420	\$ 40,000	\$ 6,826	\$ 33,174
Hormone therapy drug patents	6,117	1,229	4,888	5,834	1,042	4,792
Hormone therapy drug patents applied and pending approval	1,907	—	1,907	2,020	—	2,020
License rights and other intangible assets subject to amortization	48,024	8,809	39,215	47,854	7,868	39,986
Intangible assets not subject to amortization:						
Trademarks/trade name rights	332	—	332	332	—	332
License rights and other intangible assets, net	\$ 48,356	\$ 8,809	\$ 39,547	\$ 48,186	\$ 7,868	\$ 40,318

We recorded amortization expense related to the exclusive license rights agreement with Population Council of \$0.8 million for the three months ended March 31, 2022 and 2021. We recorded amortization expense related to patents of \$0.2 million and \$0.1 million for the three months ended March 31, 2022 and 2021, respectively.

7. Accrued expenses and other current liabilities

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

	March 31, 2022		December 31, 2021	
Payroll and related costs	\$	10,845	\$	13,764
Rebates		9,810		11,010
Sales returns and coupons		1,252		2,422
Selling and marketing		2,611		2,850
Research and development expenses		2,295		1,995
Wholesale distributor fees		6,352		3,614
Professional fees		2,080		2,571
Operating lease liabilities		1,369		1,361
Other accrued expenses and current liabilities		4,611		4,717
Accrued expenses and other current liabilities	\$	41,225	\$	44,304

We expense advertising costs when incurred, which amounted to \$1.9 million and \$6.2 million for the three months ended March 31, 2022 and 2021, respectively.

8. Debt

Our debt consisted of the following (in thousands):

	March 31, 2022		December 31, 2021	
Financing Agreement	\$	225,000	\$	200,000
Less: deferred financing fees		22,143		11,731
Debt, net	\$	202,857	\$	188,269

Financing agreement

In March 2022, we entered into Amendment No. 9 to the Financing Agreement (“Amendment No. 9”) pursuant to which, among other things, (i) the lenders waived various Company breaches of the Financing Agreement, including breaches of the \$60.0 million minimum cash covenant and the minimum net revenue covenants for the fourth quarter of 2021; (ii) the Company and the lenders agreed to reduced minimum cash covenant and to the removal of the minimum net revenue covenant for the first quarter of 2022; (iii) the lenders waived the existing \$60.0 million prepayment penalty under the Financing Agreement and the Company agreed to a paid in kind amendment fee of \$30.0 million, which fee was added to the principal amount of the loans under the Financing Agreement, \$16.0 million of which fee is waivable in certain conditions; (iv) the maturity date of the Financing Agreement was amended to June 1, 2022; and (v) the Company agreed to pay to the Lenders as a prepayment of the loans under the Financing Agreement the first \$120.0 million of net proceeds from the vitaCare Divestiture and all net proceeds of the vitaCare Divestiture in excess of \$135.0 million.

Amendment No. 9 was accounted for as an extinguishment of debt modification in accordance with U.S. GAAP. Accordingly, in March 2022, we recorded an \$8.4 million loss on extinguishment of debt, which represented the unamortized deferred financing fees, net of previously accrued prepayment fees. Additionally, we made a paid in kind (“PIK”) amendment financing fee of \$30.0 million, which was added to the principal balance of the Financing Agreement. The PIK amendment financing fee was recorded as deferred financing fees and is being amortized over the remaining term of the Financing Agreement.

As of March 31, 2022, our unamortized deferred financing fees was \$22.1 million. On April 14, 2022, we utilized \$120.0 million of net proceeds from the vitaCare Divestiture to pay as prepayment on our debt under the terms of Amendment No. 9. Additionally, with the prepayment on the debt, \$16.0 million of the PIK financing fee was waived in accordance with Amendment No. 9.

Debt covenants

The Financing Agreement contains customary restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, we are required to maintain a minimum unrestricted cash balance. Beginning on February 7, 2022 to March 8, 2022, we did not maintain the required unrestricted cash balance of \$60.0 million. In connection with Amendment No. 9, the lenders waived this event of default and reduced the required minimum unrestricted cash balance. The minimum unrestricted cash balance is a base amount (the “Base Amount”) minus specified payables, as defined in Amendment No. 9. The Base Amount decreases over the period from March 1, 2022 through May 7, 2022. Our unrestricted cash balance was above the minimum unrestricted cash balance covenant, as per Amendment No.9, at all times from March 1, 2022 through May 16, 2022, the filing date of this 10-Q Report. Thereafter,

the minimum unrestricted cash balance covenant, as per Amendment No.9, will be \$10.0 million minus specified payables, which will fluctuate based on our accounts payable balance.

Interest and financing costs

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

	Three Months Ended March 31,	
	2022	2021
Interest expense	\$ 5,364	\$ 6,455
Interest prepayment fees	—	2,500
Financing fees amortization	9,048	1,272
Interest expense and other financing costs	\$ 14,412	\$ 10,227

9. Commitments and contingencies

Minimum purchase commitments

We have manufacturing and supply agreements whereby we are required to purchase from Catalent, Inc. (“Catalent”) a minimum number of units of BIJUVA and IMVEXXY softgels during each respective annual contract year. The annual contract period for BIJUVA and IMVEXXY ends each April and July, respectively. If the minimum order quantities of BIJUVA or IMVEXXY are not met, we are required to pay a minimum commitment fee equal to 50% or 60%, respectively, of the difference between the total amount we would have paid if the minimum requirement had been fulfilled and the total amount of purchases of BIJUVA or IMVEXXY during each product’s respective contract year.

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

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

Legal proceedings

In February 2020, we received a Paragraph IV certification notice letter (the “IMVEXXY Notice Letter”) regarding an Abbreviated New Drug Application (“ANDA”) submitted to FDA by Teva Pharmaceuticals USA, Inc. (“Teva”). The ANDA seeks approval from FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the IMVEXXY Notice Letter, Teva alleges that TherapeuticsMD patents listed in FDA’s Orange Book that claim compositions and methods of IMVEXXY (the “IMVEXXY Patents”) are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the IMVEXXY Notice Letter expire in 2032 or 2033. In April 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva’s ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva’s ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal. In September 2021, the District Court made available a public version of the order following the parties’ agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

As of March 31, 2022, for the IMVEXXY Paragraph IV legal proceeding, we have incurred and recorded legal costs amounting to \$2.3 million in prepaid expenses and other current assets since we believe that we will successfully prevail in this legal proceeding. Upon the successful conclusion of the legal proceeding, the related capitalized legal costs will be reclassified to patents, in license rights and other intangible assets, net, in the accompanying consolidated balance sheets, and such costs will be amortized over the remaining useful life of the patents. If we are unsuccessful in this legal proceeding, then the related capitalized legal costs for this legal 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.

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

10. Stockholders' equity (deficit)

Warrants

The following tables summarizes the status of our outstanding and exercisable warrants and related transactions (each adjusted to account for the 50-for-1 reverse stock split) since December 31, 2021 (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Outstanding and exercisable			
	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of January 1, 2022	103	\$ 76.19	\$ -	8.3
Exercised	-	-	-	-
As of March 31, 2022	103	\$ 76.19	\$ -	8.1

Share-based compensation payment plans

As of March 31, 2022, 831,066 shares of common stock were subject to outstanding awards under our share-based payment award plans and inducement grants (calculated using the base number of PSUs that may vest). If we assume the maximum achievement of performance goals for PSUs, then 963,584 shares of common stock will be subject to outstanding awards under our share-based payment award plans and inducement grants. As of March 31, 2022, 83,880 shares of common stock were available for future grants of share-based payment awards under the TherapeuticsMD, Inc. 2019 Stock Incentive Plan.

The following table summarizes the status of our outstanding and exercisable options and related transactions (each adjusted to account for the 50-for-1 reverse stock split) since December 31, 2021 (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Outstanding				Exercisable			
	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of January 1, 2022	353	\$ 225.97	\$ -	3.8	336	\$ 230.93	\$ -	3.6
Cancelled/Forfeited	(37)	161.72	-	-	-	-	-	-
Expired	-	175.77	-	-	-	-	-	-
As of March 31, 2022	316	\$ 231.87	\$ -	3.7	300	\$ 237.58	\$ -	3.6

The following table summarizes the status of our RSUs and related transactions (each adjusted to account for the 50-for-1 reverse stock split) since December 31, 2021 (in thousands, except weighed average grant date fair value):

	Outstanding			Vested and not settled		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of January 1, 2022	272	\$ 58.17	\$ 4,890	31	\$ 105.28	\$ 566
Granted	106	21.70				
Vested and settled	(32)	105.28	469			
Cancelled/Forfeited	(7)	53.74				
As of March 31, 2022	339	\$ 43.11	\$ 6,440	13	\$ 74.17	\$ 252

The following table summarizes the status of our PSU and related transactions (each adjusted to account for the 50-for-1 reverse stock split) since December 31, 2021 (in thousands, except weighed average grant date fair value):

	Outstanding			Vested and not settled		
	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of January 1, 2022	164	\$ 51.50	\$ 2,953	39	\$ 58.81	\$ 709
Granted	63	19.00				
Vested and settled	(39)	58.81	571			
Cancelled/Forfeited	(12)	57.69				
As of March 31, 2022	176 (1)	\$ 37.85	\$ 3,346	-	\$ -	\$ -

(1) The number of PSUs represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and 308,630 depending on the Company's achievement of certain performance goals.

Share-based payment compensation cost

Share-based payment compensation expense for PSUs is based on our current assessment of the most likely probability of the Company's achievement of certain performance goals. For the three months ended March 31, 2022 and 2021, we recorded share-based payment compensation costs of \$2.1 million and \$3.0 million, respectively, in connection with previously granted options, RSU and PSUs, and shares of common stock issuable under the ESPP.

As of March 31, 2022, we had \$17.8 million of unrecognized share-based payment award compensation cost related to unvested options, RSUs and PSUs as well as shares issuable under the ESPP, which may be adjusted if certain performance targets are achieved and for future changes in forfeitures and is included as additional paid-in capital in the accompanying consolidated balance sheets. No tax benefit was realized due to a continued pattern of net losses. The unrecognized compensation cost as of March 31, 2022 is expected to be recognized as share-based payment award compensation over a weighted average period of 2.2 years as follows (in thousands):

Year Ending December 31,	
2022 (9 months)	\$ 8,124
2023	5,838
2024	3,513
2025	368
	\$ 17,843

11. Revenue

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

	Three Months Ended March 31,	
	2022	2021
Product revenue:		
ANNOVERA	\$ 8,510	\$ 8,750
IMVEXXY	6,969	7,012
BIJUVA	2,560	2,445
Prescription vitamin	875	1,425
Product revenue, net	18,914	19,632
License and service	419	234
Total revenue, net	\$ 19,333	\$ 19,866

We have entered into a license and supply agreement (the “Knight License Agreement”), with Knight Therapeutics, Inc. (“Knight”) pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel. We also have entered into a licensing and supply agreement (the “Theramex License Agreement”) with Theramex HQ UK Limited (“Theramex”) pursuant to which we granted Theramex an exclusive license to commercialize IMVEXXY and BIJUVA for human use outside of the U.S., except for Canada and Israel.

BIJUVA sales through the Theramex License Agreement started in the third quarter of 2021, and we recorded BIJUVA sales of \$0.7 million for the three months ended March 31, 2022. As of March 31, 2022, no BIJUVA sales have been made through the Knight License Agreement, and no IMVEXXY sales have been made through either of the licensing agreements.

12. 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 months ended March 31, 2022 and 2021, (ii) additional losses expected for the remainder of 2022 or losses recorded in 2021, or (iii) net operating losses carry forwards from prior years.

We recorded a full valuation allowance of the net operating losses for the three months ended March 31, 2022 and 2021. Accordingly, there were no provisions for income taxes for the three months ended March 31, 2022 and 2021. Additionally, as of March 31, 2022 and December 31, 2021, we maintain a full valuation allowance for all deferred tax assets.

13. Loss per common share

The following table sets forth the computation of basic and diluted loss per common share (each adjusted to account for the 50-for-1 reverse stock split) for the periods presented (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net loss	\$ (49,021)	\$ (39,383)
Denominator:		
Weighted average common shares for basic loss per common share	8,614	6,945
Effect of dilutive securities	—	—
Weighted average common shares for diluted loss per common share	8,614	6,945
Loss per common share, basic and diluted	\$ (5.69)	\$ (5.67)

Since we reported a net loss for the three months ended March 31, 2022 and 2021, our potentially dilutive securities are deemed to be anti-dilutive, accordingly, there was no effect of dilutive securities. Therefore, our basic and diluted loss per common share and our basic and diluted weighted average common share are the same for the three months ended March 31, 2022 and 2021.

The following table sets forth the outstanding securities as of the periods presented which were not included in the calculation of diluted earnings per common share during the respective three months ended March 31, 2022 and 2021 (in thousands):

	As of March 31,	
	2022	2021
Stock options	316	475
RSUs	339	147
PSUs	176	48
Warrants	103	118
	934	788

14. Related parties

A former member of our Board, J. Martin Carroll, who resigned in December 2021, is a member of Catalent's Board. Accordingly, Catalent ceased to be a related party to the Company in December 2021. From time to time, we have entered into agreements with Catalent and its affiliates in the normal course of business. From July 2015 to December 2021, agreements with Catalent have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For manufacturing activities, Catalent billed us \$0.8 million for the three months ended March 31, 2021. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 9, Commitments and contingencies.

A member of our Board, Karen L. Ling, was an executive vice president and chief human resources officer of American International Group, Inc. ("AIG") until May 2021, which is when AIG ceased to be a related party to the Company. From time to time, we have entered into agreements with AIG in the normal course of business. From April 2020 to May 2021, agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For various insurance premiums, AIG billed us less than \$0.1 million for the three months ended March 31, 2021.

15. Business concentrations

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

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

	Three Months Ended March 31,	
	2022	2021
Customer A	11%	13%
Customer B	18%	18%
Customer C	17%	22%
Customer F	14%	*
* Less than 10% of total product revenue		

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

	March 31, 2022	December 31, 2021
Customer B	21%	21%
Customer C	34%	35%
Customer D	*	11%
Customer F	16%	*
* Balance was less than 10% of accounts receivable, gross		

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

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

	Three Months Ended March 31,	
	2022	2021
Catalent	28%	29%
Vendor A	39%	33%
Vendor B	27%	32%

* Less than 10% of total product purchases

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

	March 31, 2022	December 31, 2021
Vendor E	30%	19%
Vendor F	10%	20%

* Balance was less than 10% of total accounts payable

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

The following discussion should be read in conjunction with our 2021 Annual Report on Form 10-K (“2021 10-K Report”), and the consolidated financial statements and related notes in Item 1, Financial Statements, appearing elsewhere in this 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 2021 10-K Report under the heading “Risk Factors,” as updated and supplemented by Part II, Item 1A of this 10-Q Report. The Company assumes 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, product development, and other plans and objectives for future operations, and assumptions and predictions about future product development and demand, cost reduction strategies, research and development (“R&D”), marketing, expenses and sales 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 but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. 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 the Financing Agreement, market and general economic factors, and the other risks discussed in Part I, Item 1A of our 2021 10-K Report, as updated and supplemented by Part II, Item 1A of this 10-Q Report.

Business overview

We are a women’s healthcare company with a mission of creating and commercializing innovative products to support the lifespan of women from pregnancy prevention through menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from a patient-controlled, long-lasting contraceptive to advanced hormone therapy pharmaceutical products. We also have a portfolio of branded and generic prescription prenatal vitamins under the vitaMedMD and BocaGreenMD brands that furthers our women’s healthcare focus.

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. (“vitaCare”) with the sale of all of vitaCare’s issued and outstanding capital stock (the “vitaCare Divestiture”). We received a cash payment of \$150.0 million, subject to adjustment as provided in the stock purchase agreement (the “Purchase Agreement”) and customary holdbacks. Additionally, we may receive up to an additional \$7.0 million in earn-out consideration, contingent upon vitaCare’s financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, upon closing of the vitaCare divestiture, (i) we entered into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products; and (ii) we and vitaCare entered into a transition services agreement for us to provide certain transition services to vitaCare for up to 12 months following the closing.

COVID-19

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

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause which provide patients real-time access to both diagnosis and treatment. We continue to support prescribers’ needs with samples and product materials through our sales force. If access is restricted, we have mailing options in place for these materials. We also have business continuity plans and infrastructure in place that allows for live virtual e-detailing of our products.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses and implemented cost saving measures, which included negotiating lower fees or suspending services from third-party vendors; implementing a company-wide hiring restriction; delaying or cancelling non-critical information technology projects; and eliminating non-essential travel, entertainment, meeting, and event expenses. In addition, we implemented a significant cost savings initiative that was designed to reduce our annual operating costs in 2022, and we reduced the operating costs of the vitaCare business with the completion of the vitaCare Divestiture on April 14, 2022. See above for additional information regarding the vitaCare Divestiture.

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

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

Going concern

We incurred a net loss of \$49.0 million during the three months ended March 31, 2022, and as of that date, our current liabilities exceeded our current assets by \$180.4 million and our total liabilities exceeded our total assets by \$140.6 million. We will need to raise additional capital to repay the entire principal balance of our Financing Agreement, which matures on June 1, 2022, and to provide additional liquidity to fund our losses until our operations become cash flow positive. To address our capital needs, we are pursuing various equity

and debt financing and other alternatives, including the sale of vitaCare for which we completed on April 14, 2022. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock and the potential delisting of our common stock from the Nasdaq Global Select Market, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us. Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses.

If we are unsuccessful with future financings and if the successful commercialization of ANNOVERA, IMVEXXY, or BIJUVA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to repay the entire principal balance of the Financing Agreement or satisfy our liquidity needs. See Note 3, Inventory in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report, for additional information regarding risks associated with our contract manufacturers, particularly for ANNOVERA. The presence of these projected factors in conjunction with the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements.

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

Product portfolio

Our portfolio of products focused on women's health allows us to efficiently leverage our sales and marketing plans to grow our pharmaceutical products. We are focused on activities necessary for the continued commercialization of IMVEXXY, commercially launched in the third quarter of 2018; BIJUVA, commercially launched in the third quarter of 2019; and ANNOVERA, which we started selling in the third quarter of 2019 and commercially launched in March 2020, which was subsequently paused as a result of the COVID-19 pandemic and relaunched in July 2020. We continue to manufacture and distribute our prescription prenatal vitamin product lines, consisting of branded prenatal vitamins under vitaMedMD and authorized generic formulations of some of our prescription prenatal vitamin products under BocaGreenMD.

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

This pharmaceutical product is a one-year, ring-shaped, contraceptive vaginal system ("CVS") and the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up to a total of 13 cycles (one year). ANNOVERA is commercially sold by us in the U.S. pursuant to the terms of the Population Council License Agreement. As part of the approval of ANNOVERA, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. We have agreed to perform and pay the costs and expenses associated with this post-approval study, provided that if the costs and expenses associated with such post-approval study exceed \$20.0 million, half of such excess will offset against royalties or other payments owed by us under the Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

In August 2021, we filed a supplemental New Drug Application ("NDA") with the FDA to modify the testing specifications for ANNOVERA to allow increased consistency of supply of ANNOVERA. In December 2021, FDA determined that it could not approve the supplemental NDA without additional information. In its complete response letter ("CRL"), the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided additional information to the FDA and modified the request to revise the manufacturing testing limits based on the FDA feedback. We expect a response from the FDA by the end of second quarter of 2022. We have continued to manufacture and supply ANNOVERA under the existing specifications as well as (i) ramping up manufacturing sufficient to better meet second quarter of 2022 demands notwithstanding existing challenges, (ii) added resources to increase production volumes, (iii) increasing yield per manufacturing batch, and (iv) increasing production capacity to better meet product demands to realize revenue potential, including reducing dependency on labor resources, increasing efficiency in manufacturing and testing, and automating some of the processes. In the meantime, our third-party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market, which would have an adverse effect on our business, results of operations and financial condition. Additionally, we may incur increased write-offs of ANNOVERA products manufactured in 2022 that do not meet existing specifications.

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

This pharmaceutical product is for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy due to menopause. As part of FDA's approval of IMVEXXY, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen. The FDA has also asked two sponsors of other vaginal estrogen products to participate in the observational study. In connection with the observational study, we are required to provide various reports to the FDA per a requested timeline. We do not believe that the costs will be significant on an annual basis.

We market and sell IMVEXXY in the U.S. and have entered into licensing agreements with third parties to market and sell IMVEXXY outside of the U.S. We have entered into a license and supply agreement (the "Knight License Agreement"), with Knight Therapeutics, Inc. ("Knight") pursuant to which, we granted Knight an exclusive license to commercialize IMVEXXY in Canada and Israel. We have entered into a licensing and supply agreement (the "Theramex License Agreement") with Theramex HQ UK Limited ("Theramex") pursuant to which we granted Theramex an exclusive license to commercialize IMVEXXY for human use outside of the U.S., except for Canada and Israel. As of March 31, 2022, no IMVEXXY sales have been made through these licensing agreements.

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

This pharmaceutical product is the first and only FDA approved bioidentical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus. We market and sell BIJUVA in the U.S. and have entered into licensing agreements with third parties to market and sell BIJUVA outside of the U.S. We have entered into the Knight License Agreement with Knight pursuant to which we granted Knight an exclusive license to commercialize BIJUVA in Canada and Israel. We have entered into the Theramex License Agreement with Theramex pursuant to which we granted Theramex an exclusive license to commercialize BIJUVA for human use outside of the U.S., except for Canada and Israel. BIJUVA sales through the Theramex Licenses Agreement started in the first quarter of 2022, and we recorded BIJUVA sales of \$0.7 million for the three months ended March 31, 2022. As of March 31, 2021, no BIJUVA sales have been made through the Knight License Agreement.

Prenatal vitamin products

We manufacture and distribute our prescription prenatal vitamin product lines under our vitaMedMD brand name and authorized generic formulations of some of our prescription prenatal vitamin products under our BocaGreenMD Prena1 name. We will continue to support the vitaMedMD and BocaGreenMD products as they are important products to our core customers and help provide us with continued access to sell our women's health portfolio.

Results of operations

Three months ended March 31, 2022 compared with three months ended March 31, 2021

Revenue. Our total revenue for the first quarter of 2022 was \$19.3 million, a decrease of \$0.5 million, or 2.7%, compared to the first quarter of 2021. The following table sets forth our revenue during these periods (in thousands):

	Three Months Ended March 31,	
	2022	2021
Product revenue:		
ANNOVERA	\$ 8,510	\$ 8,750
IMVEXXY	6,969	7,012
BIJUVA	2,560	2,445
Prescription vitamin	875	1,425
Product revenue, net	18,914	19,632
License and service	419	234
Total revenue, net	\$ 19,333	\$ 19,866

Our sales of ANNOVERA were \$8.5 million for the first quarter of 2022, a decrease of \$0.2 million, or 2.7%, compared to the first quarter of 2021. This decrease was primarily due to a 1.5% decrease in sales volume and a 1.3% decrease in the average sale price.

Our sales of IMVEXXY were \$7.0 million for each of the first quarter of 2022 and 2021. The quarter over quarter change was primarily attributable to a 2.0% decrease in the average sale price, which was partially offset by a 1.4% increase in sales volume.

Our sales of BIJUVA were \$2.6 million for the first quarter of 2022, an increase of \$0.1 million, or 4.7%, compared to the first quarter of 2021. Included in our BIJUVA sales for the first quarter of 2022 was \$0.7 million of sales made through the Theramex License

Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA were \$1.9 million for the first quarter of 2022, a decrease of \$0.6 million, or 23.7%, compared to the first quarter of 2021. This decrease was primarily attributable to a 19.4% decrease in sales volume and a 5.3% decrease in the average sale price.

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

Our prescription vitamin sales were \$0.9 million for the first quarter of 2022, a decrease of \$0.6 million, or 38.6%, compared to the first quarter of 2021. This decrease was primarily due to a 35.1% decrease in sales volume and a 5.4% decrease in the average sale price.

On a consolidated basis, our total product sales were \$18.9 million for the first quarter of 2022, a decrease of \$0.7 million, or 3.7%, compared to the first quarter of 2021.

We recorded service revenue related to pharmacy services provided by our vitaCare business to pharmaceutical companies of \$0.4 million for the first quarter of 2022. There was no service revenue for the first quarter of 2021. We did not record any license revenue for the first quarter of 2022. For the first quarter of 2021, our license revenue was \$0.2 million. This decrease was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for the first quarter of 2022 was \$14.5 million, a decrease of \$0.7 million, or 4.7%, compared to the first quarter of 2021. The following table sets forth our gross profit during these periods (in thousands):

	Three Months Ended March 31,	
	2022	2021
Product	\$ 14,054	\$ 14,945
License and service	419	234
Total gross profit	\$ 14,473	\$ 15,179

The decrease in our gross profit was a result a 1.8% decrease in our product gross margin to 74.3% for the first quarter of 2022 and a decrease of 3.7% in product revenue. The decrease in product gross margins reflects the impact of \$0.7 million of BIJUVA export sales, which were sold at cost. Excluding the BIJUVA export sales, our product gross margins increased 1.0% to 77.1% for the first quarter of 2022.

Operating expenses. Total operating expenses for the first quarter of 2022 were \$40.7 million, a decrease of \$3.8 million, or 8.4%, compared to the first quarter of 2021. The type of operating expenses reported in prior year have been reclassified to conform to the current year's presentation. The following table sets forth our operating expense categories (in thousands):

	Three Months Ended March 31,	
	2022	2021
Selling and marketing	\$ 18,895	\$ 24,024
General and administrative	20,407	18,383
Research and development	1,400	2,050
Total operating expenses	\$ 40,702	\$ 44,457

Our selling and marketing costs were \$18.9 million for the first quarter of 2022, a decrease of \$5.1 million, or 21.3%, compared to the first quarter of 2021. This decrease was primarily due to \$6.1 million in lower advertising and marketing costs, partially offset by \$1.0 million in higher costs related to a national sales and marketing event.

Our general and administrative costs were \$20.4 million for the first quarter of 2022, an increase of \$2.0 million, or 11.0%, compared to the first quarter of 2021. This increase was primarily related to \$1.2 million in higher compensation and employee benefit costs, mainly related to the 2022 executive retention and performance bonus plan for certain executive officers and key non-executive officers and \$1.9 million in higher expenditures attributable to various professional fees, such as legal, consulting, etc., partially offset by \$1.0 million in lower expenditures attributable to information technology. In general, we saw temporarily reduced G&A expenditures during early 2021 due to our COVID-related cost saving measures but expect to maintain higher levels going forward to support our commercialization efforts.

Our R&D costs were \$1.4 million for the first quarter of 2022, a decrease of \$0.7 million, or 31.7%, compared to the first quarter of 2021. This decrease was primarily attributable to \$0.4 million in lower compensation and employee benefit costs and a \$0.2 million in lower lab research costs. As we refocus our resources towards the continued commercialization of our pharmaceutical products, our

R&D expenditures have declined over the last few years. We continue to deploy limited resources in the development of new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For the first quarter of 2022, we had a loss from operations of \$26.2 million, a decrease of \$3.0 million, or 10.4%, compared to the first quarter of 2021. This decrease was attributable \$3.8 million in lower operating expenses, partially offset by \$0.7 million in lower gross profit. We anticipate that we will continue to have operating losses for the near future until we are able to successfully commercialize ANNOVERA, IMVEXXY and BIJUVA, although there is no assurance that our efforts will be successful.

Other expense, net. For the first quarter of 2022, our non-operating expenses were \$22.8 million, an increase of \$12.7 million, or 125.6%, compared to the first quarter of 2021. This increase was primarily attributable to \$8.4 million in loss on extinguishment of debt in connection with Amendment No. 9 to the Financing Agreement, which is recorded as an extinguishment of debt for accounting purposes, and \$7.8 million in higher amortization of deferred financing costs related to Amendment No. 9 to the Financing Agreement. These increases were partially offset by \$2.5 million in lower interest prepayment fee due to elimination of prepayment fees with Amendment No. 9 to the Financing Agreement and \$1.1 million in lower interest expense related lower average debt balance during the first quarter of 2022 compared to the first quarter of 2021.

Net Loss. For the first quarter of 2022, we had a net loss of \$49.0 million, or \$5.69 per basic and diluted common share, compared to \$39.4 million, or \$5.67 per basic and diluted common share, for the first quarter of 2021. The historical per share data have been adjusted to give effect of the May 2022 reverse stock split.

Liquidity and capital resources

Our primary use of cash is to fund the continued commercialization of our hormone therapy and contraceptive products. We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities. As of March 31, 2022, we had cash totaling \$30.4 million. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of \$0.25 million per bank. We have never experienced any losses related to these funds.

On April 14, 2022, we completed the vitaCare Divestiture and received a cash payment of \$150.0 million, subject to adjustment as provided in the Purchase Agreement and customary holdbacks. Additionally, we may receive up to an additional of \$7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement. We utilized \$120.0 million of net proceeds from the vitaCare Divestiture to pay as prepayment on our debt under the terms of Amendment No. 9 of the Financing Agreement.

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 for to satisfy our such needs in the short-term and in the long-term.

Cash flows

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	\$ (29,526)	\$ (38,380)
Net cash used in investing activities	(212)	(438)
Net cash (used in) provided by financing activities	(5,000)	95,949
Net (decrease) increase in cash	\$ (34,738)	\$ 57,131

Operating Activities. The principal use of cash in operating activities was to fund our current expenditures in support of our continued commercialization activities for ANNOVERA, IMVEXXY, and BIJUVA, sales, marketing, scale-up and manufacturing activities, adjusted for non-cash items. For the first three months of 2022, net cash used in operating activities was \$29.5 million, compared to net cash used in operating activities of \$38.4 million for the first three months of 2021. This decrease of \$8.9 million, or 23.1%, was primarily due to a \$14.7 million increase in non-cash expenditure adjustments and a \$3.8 million increase in cash generated from changes in operating assets and liabilities, partially offset by a \$9.6 million increase in our net loss.

Investing Activities. For the first three months of 2022, net cash used in investing activities was \$0.2 million, compared to net cash used in investing activities of \$0.4 million for the first three months of 2021. This decrease of \$0.2 million, or 51.6%, was primarily due to lower patent related costs.

Financing Activities. Financing activities have historically represented the principal source of our cash flow. For the first three months of 2022, net cash used in financing activities was \$5.0 million, compared to net cash provided by financing activities of \$95.9 million for the first three months of 2021. This change of \$100.9 million, or 105.2%, was primarily related to sales of our common stock in 2021 of \$150.9 million in net proceeds in 2021, partially offset by a decrease of \$45.0 million in repayment of debt, and a \$5.0 million payment of debt financing fees in 2021.

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

Other liquidity measures

Receivable. Our net days sales outstanding (“DSO”) is calculated by dividing average gross accounts receivable less the reserve for doubtful accounts, chargebacks, and payment discounts by the average daily net product revenue during the last four quarters for each respective quarterly period. Our net DSO was 151 days as of March 31, 2022, compared to 148 days as of December 31, 2021 and 141 days as of March 31, 2021. Our gross DSO is calculated by dividing average gross accounts receivable by the average daily gross product revenue to distributors during the last four quarters for each respective quarterly period. Our gross DSO was 73 days as of March 31, 2022, compared to 72 days as of December 31, 2021 and 62 days as of March 31, 2021. Our DSOs have fluctuated and will continue to fluctuate in the future due to variety of factors, including longer payment terms associated with the continued commercialization of ANNOVERA, IMVEXXY, and BIJUVA changes in the healthcare industry. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future.

Inventory. We rely on third parties to manufacture our finished products, and we have entered into long-term supply agreements for the manufacture of ANNOVERA, IMVEXXY, and BIJUVA. We do not have a long-term supply agreement for the manufacture of our prescription vitamins. Additionally, we do not have long-term contracts for the supply of all the active pharmaceutical ingredients used in ANNOVERA and BIJUVA. For additional information, see Note 3, Inventory in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

Debt. We had \$225.0 million and \$200.0 million in term loans outstanding under our Financing Agreement as of March 31, 2022 and December 31, 2021, respectively. For additional information, see Note 8, Debt in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

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

Except for entering into Amendment No. 9 to the Financing Agreement in March 2022, there were no other material changes from December 31, 2021 to March 31, 2022. For discussion on Amendment No. 9 to the Financing Agreement, see Note 8, Debt in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report. For a discussion of matters in this section, refer to Item 7 - Contractual obligations, off-balance sheet arrangements and purchase commitments and employment agreements of our 2021 10-K Report.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included elsewhere in this 10-Q Report, which has been prepared in accordance with U.S. GAAP. We make estimates and assumptions that affect the reported amounts on our consolidated financial statements and accompanying notes as of the date of the consolidated financial statements. The critical accounting policies and estimates used are disclosed in Item 7 - Critical accounting policies and estimates in our 2021 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.

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial 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 and Interim Chief Financial 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 Interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer and Interim Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the 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 financing reporting

There were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the three months ended March 31, 2022.

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 9, 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

The business, financial condition and operating results of the Company 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 2021 10-K Report under the heading "Risk Factors," any one or more of which could, directly or indirectly, cause the Company's 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 the Company's business, financial condition, operating results and stock price. Except as set forth below, there have been no material changes to the Company's risk factors since the 2021 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

None.

Item 6. Exhibits

Exhibit No.	Description
2.1***	Stock Purchase Agreement, dated March 6, 2022, by and between TherapeuticsMD, Inc. and GoodRx, Inc. (1)
3.1†	Composite Amended and Restated Articles of Incorporation of the Company, as amended.
3.2	Certificate of Change to Articles of Incorporation of TherapeuticsMD, Inc. (2)
10.1*	2022 Executive Retention and Performance Bonus Plan. (3)
10.2***	Amendment No. 9 to the Financing Agreement, dated March 8, 2022, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders (1)
31.1†	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a).
31.2†	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a).
32.1††	Section 1350 Certification of Chief Executive Officer
32.2††	Section 1350 Certification of Chief Financial Officer
101†	Inline XBRL Document Set for the 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

* Indicates a contract with management or compensatory plan or arrangement.

*** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(2) or 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

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

† Filed herewith.

†† Furnished herewith.

(1) Filed as an exhibit to the Company’s Current Report on Form 8-K filed with the SEC on March 10, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(2) Filed as an exhibit to the Company’s Current Report on Form 8-K filed with the SEC on May 9, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(3) Filed as an exhibit to the Company’s Annual Report on Form 10-K filed with the SEC on March 23, 2022 and incorporated herein by reference (SEC File No. 000-00100).

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: May 16, 2022

TherapeuticsMD, Inc.

/s/ Hugh O'Dowd

Hugh O'Dowd

Chief Executive Officer

(Principal Executive Officer)

/s/ Michael C. Donegan

Michael C. Donegan

Interim Chief Financial Officer, Chief Accounting
Officer and Vice President Finance

(Principal Financial and Accounting Officer)

THIS COMPOSITE AMENDED AND RESTATED ARTICLES OF INCORPORATION, AS AMENDED, OF THERAPEUTICSMD, INC. (THE “CORPORATION”) REFLECTS THE PROVISIONS OF THE CORPORATION’S ARTICLES OF INCORPORATION, AS AMENDED AND RESTATED ON AUGUST 3, 2011, AND ALL AMENDMENTS THERETO FILED WITH THE SECRETARY OF STATE OF THE STATE OF NEVADA THEREAFTER ON OR PRIOR TO MAY 6, 2022, BUT IS NOT AN AMENDMENT AND/OR RESTATEMENT THEREOF.

**COMPOSITE AMENDED AND RESTATED
ARTICLES OF INCORPORATION, AS AMENDED,
OF
THERAPEUTICSMD, INC.
A NEVADA CORPORATION**

**ARTICLE I
CORPORATE NAME**

The name of the corporation is TherapeuticsMD, Inc. (the “Corporation”).

**ARTICLE II
REGISTERED AGENT**

The registered agent for the Corporation in the State of Nevada is Paracorp Incorporated, 318 N. Carson Street, Suite 208, Carson City, Nevada 87901.

**ARTICLE III
DURATION AND PURPOSE**

The duration of the Corporation shall be perpetual. The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the NRS.

**ARTICLE IV
CAPITAL STOCK**

The total number of shares of all classes of capital stock that the Corporation has the authority to issue is Twenty-Two Million (22,000,000) shares of which Twelve Million (12,000,000) shares will be designated common stock, \$0.001 par value per share (“Common Stock”) and Ten Million (10,000,000) shares will be designated preferred stock, \$0.001 par value per share (“Preferred Stock”).

The Ten Million (10,000,000) shares of Preferred Stock may be designated from time to time in one or more series upon authorization of the Corporation’s board of directors. The Corporation’s board of directors, without further approval of the Corporation’s shareholder, will be authorized to fix the dividend rights and terms, conversion rights, voting rights, redemption rights and terms, liquidation preferences, and any other rights, preferences, privileges and restrictions applicable to each series of Preferred Stock so designated.

**ARTICLE V
NUMBER OF DIRECTORS**

The business of the Corporation shall be managed by or under the direction of the Corporation’s Board of Directors. The Corporation must maintain at least one director at all times and initially sets the number of directors at four members. The number of individuals comprising the Corporation’s Board of Directors shall be fixed upon resolution of the Board of Directors and may be increased or decreased from time to time in the manner provided in the Corporation’s Bylaws.

**ARTICLE VI
BYLAWS**

In furtherance and not in limitation of the powers conferred upon the Board of Directors of the Corporation by the NRS, the Board of Directors shall have the power to alter, amend, change, add to and repeal, from time to time, the Bylaws of the Corporation, subject to the rights of the Corporation's shareholders entitled to vote with respect thereto to alter, amend, change, add to and repeal the Bylaws adopted by the Board of Directors of the Corporation.

**ARTICLE VII
LIMITATION ON LIABILITY OF DIRECTORS AND OFFICERS**

No director or officer of the Corporation shall be personally liable to the Corporation or any of its shareholders for damages for breach of fiduciary duty as a director or officer involving any act or omission of any act by such director or officer, provided, however, that the foregoing provision shall not eliminate or limit the liability of a director or officer (i) for acts or omissions which involve intentional misconduct, fraud, or a known violation of the law, or (ii) the payment of dividends in violation of Section 78.300 of the NRS. Any repeal or modification of this Article by the shareholders of the Corporation shall be prospective only and shall not adversely affect any limitations on the personal liability of a director or officer of the Corporation for acts or omissions prior to such repeal or modification.

**ARTICLE IX
INDEMNIFICATION**

The Corporation shall, to the fullest extent permitted by the provisions of 78.502 of the NRS, as the same may be amended and supplemented, indemnify any and all persons whom it shall have power to indemnify under said section from and against any and all of the expenses, liabilities, or other matters referred to in or covered by said section, and the indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under the Corporation's Bylaws, agreement, vote of shareholders, or disinterested directors, or otherwise, both as to action in his official capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such person.

Certification of Chief Executive Officer

I, Hugh O'Dowd, 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: May 16, 2022

/s/ Hugh O'Dowd

Hugh O'Dowd

Chief Executive Officer

(Principal Executive Officer)

Certification of Chief Financial Officer

I, Michael C. Donegan, 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: May 16, 2022

/s/ Michael C. Donegan

Michael C. Donegan
Interim Chief Financial Officer, Chief Accounting
Officer and Vice President Finance
(Principal Financial and Accounting 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 March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Hugh O'Dowd, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The 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: May 16, 2022

/s/ Hugh O'Dowd

Hugh O'Dowd
Chief Executive Officer
(Principal 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 Chief Financial Officer

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael C. Donegan, Interim Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The 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: May 16, 2022

/s/ Michael C. Donegan

Michael C. Donegan

Interim Chief Financial Officer, Chief Accounting

Officer and Vice President Finance

(Principal Financial and Accounting 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).