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, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-00100

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

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

As of May 6, 2021, there were 393,190,000 shares of the registrant’s common stock outstanding.

Table of Contents

Table of Contents

Part I – Financial Information

Item 1. Financial Statements

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

	March 31, 2021 (Unaudited)	December 31, 2020
Assets:		
Current assets:		
Cash	$ 137,617	$ 80,486
Accounts receivable, net of allowance of credit losses of $1,231 and $1,118 as of March 31, 2021 and December 31, 2020, respectively	33,719	32,382
Inventory	7,346	7,993
Prepaid and other current assets	8,360	7,543
Total current assets	187,042	128,404
Fixed assets, net	1,812	1,942
License rights and other intangible assets, net	40,994	41,445
Right of use assets	9,205	9,566
Other non-current assets	253	253
Total assets	$ 239,306	$ 181,610
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	$ 5,000	$ —
Accounts payable	10,310	21,068
Accrued expenses and other current liabilities	45,974	38,170
Total current liabilities	61,284	59,238
Long-term debt, net	178,970	237,698
Operating lease liabilities	8,530	8,675
Total liabilities	248,784	305,611
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock, par value $ 0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value $ 0.001; 600,000 shares authorized, 393,190 and 299,765 issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	393	300
Additional paid-in capital	908,457	754,644
Accumulated deficit	(918,328)	(878,945)
Total stockholders' deficit	(9,478)	(124,001)
Total liabilities and stockholders' equity (deficit)	$ 239,306	$ 181,610

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,	
	2021	2020
Product revenue, net	$ 19,632	$ 12,251
License revenue	234	—
Total revenue, net	19,866	12,251
Cost of goods sold	4,687	2,715
Gross profit	15,179	9,536
Operating expenses:		
Selling, general and administrative	42,407	57,189
Research and development	2,050	3,269
Total operating expenses	44,457	60,458
Loss from operations	(29,278)	(50,922)
Other (expense) income:		
Interest expense and other financing costs	(10,227)	(6,262)
Other income, net	122	335
Other (expense), net	(10,105)	(5,927)
Loss before income taxes	(39,383)	(56,849)
Provision for income taxes	—	—
Net loss	$ (39,383)	$ (56,849)
Loss per common share, basic and diluted	$ (0.11)	$ (0.21)
Weighted average common shares, basic and diluted	347,219	271,460

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

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

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2021	299,765	$ 300	$754,644	$ (878,945)	$ (124,001)
Shares issued for sale of common stock, net of cost	92,870	93	150,806	—	150,899
Shares issued for exercise of warrants	503	—	50	—	50
Shares issued for vested restricted stock units	52	—	—	—	—
Share-based compensation	—	—	2,957	—	2,957
Net loss	—	—	—	(39,383)	(39,383)
Balance, March 31, 2021	393,190	$ 393	$908,457	$ (918,328)	$ (9,478)
Balance, January 1, 2020	271,177	$ 271	$704,351	$ (695,421)	$ 9,201
Shares issued for exercise of options	351	—	72	—	72
Shares issued for vested restricted stock units	150	—	—	—	—
Share-based compensation	—	—	2,366	—	2,366
Net loss	—	—	—	(56,849)	(56,849)
Balance, March 31, 2020	271,678	$ 271	$706,789	$ (752,270)	$ (45,210)

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

TherapeuticsMD, Inc. and Subsidiaries
Consolidated S tatements of Cash Flows
(Unaudited - in thousands, except per share data)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (39,383)	$ (56,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,019	1,008
Charges (credits) to provision for doubtful accounts	230	(123)
Inventory charge	502	136
Debt financing fees	1,272	320
Non-cash operating lease expense	216	352
Share-based compensation	2,957	2,366
Changes in operating assets and liabilities		
Accounts receivable	(1,567)	3,855
Inventory	145	(2,883)
Prepaid and other current assets	(817)	4,436
Accounts payable	(10,758)	9,533
Accrued expenses and other current liabilities	7,804	(1,262)
Total adjustments	1,003	17,738
Net cash used in operating activities	(38,380)	(39,111)
Cash flows from investing activities:		
Payment of patent related costs	(375)	(422)
Purchase of fixed assets	(63)	(21)
Net cash used in investing activities	(438)	(443)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	150,899	—
Proceeds from exercise of options and warrants	50	72
Repayments of debt	(50,000)	—
Borrowings of debt	—	50,000
Payment of debt financing fees	(5,000)	(1,250)
Net cash provided by financing activities	95,949	48,822
Net increase in cash	57,131	9,268
Cash, beginning of period	80,486	160,830
Cash, end of period	$ 137,617	$ 170,098
Supplemental disclosure of cash flow information:		
Interest paid	$ 8,955	$ 5,893

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

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

1. Basis of presentation 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, our company. Solely for convenience, trademarks, trade names and service marks referred to in this 10-Q Report may appear without the ®, ™ or ℠ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

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

Principles of consolidation

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") can be condensed or omitted.

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 2020 Annual Report on Form 10-K ("2020 10-K Report"). Certain amounts in the consolidated financial statements and accompanying notes may not add due to rounding. All percentages have been calculated using unrounded amounts.

Risks and uncertainties related to COVID-19

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. We continue to provide an uninterrupted supply of our portfolio of products for patients. We believe we have sufficient inventory of finished products to meet anticipated demand in the near future. Additionally, we believe we have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. One of our subsidiaries, vitaCare™ Prescription Services, Inc. ("vitaCare Prescription Services"), a Florida corporation, assists patients in obtaining easy and convenient access to their prescriptions for products at a pharmacy of their choice, including via home delivery pharmacy options. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause which provide patients real-time access to both diagnosis and treatment. We continue to support prescribers' needs with samples and product materials through our sales force. If access is restricted, we have mailing options in place for these materials. We also have business continuity plans and infrastructure in place that allows for live virtual e-detailing of our products.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses for 2020. We also implemented cost saving measures in 2020, 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.

The full impact of the COVID-19 pandemic continues to evolve. However, we remain committed to the execution of our corporate goals, despite the ongoing COVID-19 pandemic, as demonstrated in part by the increase in product revenue throughout 2020. 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 the effect 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 are 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.

Significant accounting policies

The significant accounting policies we use for quarterly financial reporting are disclosed in Note 2, Summary of Significant Accounting Policies of the accompanying notes to the consolidated financial statements included in our 2020 10-K Report, and in the section below.

Accounting standards issued but not yet adopted

There have been no recently issued accounting standards not yet adopted by us which are expected, upon adoption, to have a material impact on our consolidated financial statements or processes.

Reclassification

Certain amounts reported in prior periods in the financial statements have been reclassified to conform to the current period’s presentation.

2. Accounts receivable

We extend credit on an unsecured basis to most of our customers. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. While we actively manage our credit exposure and work to respond to both changes in our customers’ financial conditions or macroeconomic events, there can be no guarantee we will be able to mitigate all of these risks successfully. 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.

We review accounts receivable for uncollectible accounts and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, reasonable supportable forecasts and existing economic conditions and we record an allowance that presents the net amount expected to be collected. We evaluate trade accounts receivable for delinquency. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off when received as an increase in the allowance for doubtful accounts. To the extent data we use to calculate these estimates does not accurately reflect bad debts, adjustments to these reserves may be required.

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

	Total
Balance as of January 1, 2021	$1,118
Charges to provision for credit losses	230
Write-off of uncollectible receivables	(117)
Balance as of March 31, 2021	$1,231

3. Inventory

We have optimized the level of our inventory on hand, and we believe we have sufficient finished products to meet anticipated demand in the near future and sufficient raw materials for the continued manufacture of our finished products. 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, however, we do not have a long-term supply agreement for the manufacture of our prescription vitamins. Additionally, we do not have long-term contracts for the supply of the active pharmaceutical ingredients ("API") used in ANNOVERA and BIJUVA. If any of our third party contract manufacturers or any suppliers of the API experiences any significant difficulties in its respective manufacturing processes, 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, we could experience significant interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations and financial position.

Our inventory consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	$ 4,487	$ 4,423
Work in process	222	220
Finished products	2,637	3,350
Inventory	$ 7,346	$ 7,993

4. Prepaid and other current assets

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

	March 31, 2021	December 31, 2020
Insurance	$ 1,522	$ 2,568
Paragraph IV legal proceeding costs	1,926	—
Other	4,912	4,975
Prepaid and other current assets	$ 8,360	$ 7,543

5. Fixed assets, net

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

	March 31, 2021	December 31, 2020
Furniture and fixtures	$ 1,407	$ 1,407
Computer and office equipment	1,810	1,784
Computer software	450	412
Leasehold improvements	80	80
Fixed assets	3,747	3,683
Less: accumulated depreciation and amortization	1,935	1,741
Fixed assets, net	$ 1,812	$ 1,942

For the three months ended March 31, 2021 and 2020, we recorded depreciation expense of $193 thousand and $199 thousand, respectively.

6. License rights and other intangible assets, net

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

	March 31, 2021			December 31, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets subject to amortization						
License rights agreement	$40,000	$ 4,559	$35,441	$40,000	$ 3,803	$36,197
Hormone therapy drug patents	4,181	818	3,363	4,045	748	3,297
Hormone therapy drug patents applied and pending approval	1,857	—	1,857	1,628	—	1,628
	46,038	5,377	40,661	45,673	4,551	41,122
Intangible assets not subject to amortization Trademarks/trade name rights	333	—	333	323	—	323
	$46,371	$ 5,377	$40,994	$45,996	$ 4,551	$41,445

During the three months ended March 31, 2021 and 2020, we recorded $756 thousand and $746 thousand, respectively, in amortization expense related to an exclusive license agreement (the “Population Council License Agreement”) with Population Council to commercially manufacture and sell ANNOVERA in the U.S., which was recorded as a component of cost of sales. As of March 31, 2021 and December 31, 2020, respectively, we had a total of 79 patents, of which 40 were domestic, and a total of 77 patents, of which 38 were domestic. We recorded $70 thousand and $63 thousand of amortization expense related to patents for the three months ended March 31, 2021 and 2020, respectively.

We use a combination of qualitative and quantitative factors to assess intangible assets for impairment. As a result of performing these assessments, we determined that no impairment existed as of March 31, 2021 and, therefore, recorded no write-downs to any of our intangible assets.

7. Accrued expenses and other current liabilities

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

	March 31, 2021	December 31, 2020
Payroll and related costs	$ 8,311	$ 11,179
Rebates	12,691	11,011
Sales returns and coupons	5,676	7,057
Wholesale distributor fees	4,243	2,632
Professional fees	6,198	925
Other accrued expenses and current liabilities	8,855	5,366
Accrued expenses and other current liabilities	$45,974	$ 38,170

8. Debt

We are party to a Financing Agreement, as amended (the “Financing Agreement”), with Sixth Street Specialty Lending, Inc., as administrative agent (the “Administrative Agent”), various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors. Interest on amounts borrowed under the Financing Agreement is due and payable quarterly in arrears, and the Financing Agreement matures on March 31, 2024.

In January 2021, we entered into Amendment No. 7 to the Financing Agreement (“Amendment No. 7”) pursuant to which, among other amendments, the minimum quarterly product net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA for the fiscal quarters ending March 31, 2021 and June 30, 2021 were reduced, and we paid an amendment financing fee of $5.0 million, which was included as a component of deferred financing fees in long-term debt in the accompany consolidated balance sheets. Additionally, in connection with entering into Amendment No. 7, the warrants issued to the Administrative Agent and the lenders under the Financing Agreement on August 5, 2020 were further amended to provide for an additional adjustment to the exercise price if we conducted certain dilutive issuances prior to March 31, 2021. No such adjustments were made to the exercise price of these warrants prior to the expiration of such period.

In March 2021, we entered into Amendment No. 8 to the Financing Agreement ("Amendment No. 8") pursuant to which, among other amendments, the minimum quarterly product net revenue requirements attributable to commercial sales of IMVEXXY, BIJUVA, and ANNOVERA were revised, the amortization and prepayment terms of the borrowings under the Financing Agreement were revised, and the Administrative Agent consented to a framework for our potential disposition of our vitaCare Prescription Services business. With respect to amortization and prepayment terms of the borrowings under the Financing Agreement, in connection with Amendment No. 8, we (i) repaid $50.0 million in principal under the Financing Agreement during the three months ended March 31, 2021, plus a 5.0% prepayment fee, and (ii) agreed to make additional principal repayments as follows: (x) $5.0 million on each of March 31, 2022, June 30, 2022 and September 30, 2022; (y) $10.0 million on each of December 31, 2022 and March 31, 2023; and (z) $41.25 million on each of June 30, 2023, September 30, 2023, December 31, 2023 and March 31, 2024, plus the prepayment fees described in the following sentence. In connection with Amendment No. 8, the prepayment fees on principal amounts being prepaid under the Financing Agreement were revised as follows: (i) 30.0% of the principal amount being repaid through March 31, 2022 (excluding the scheduled $5.0 million principal repayment on such date, which is subject to a 5.0% prepayment fee); (ii) 5.0% of the principal amount being repaid from April 1, 2022 through March 31, 2023; (iii) 3.0% of the principal amount being repaid from April 1, 2023 through March 31, 2024; and (iv) thereafter, none, in each case subject to certain limited exceptions, including with respect to a repayment in full of the obligations under the Financing Agreement.

Our debt consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Financing Agreement	$200,000	$ 250,000
Less: deferred financing fees	16,030	12,302
Debt, net	183,970	237,698
Current maturities of long-term debt	5,000	—
Long-term debt	$178,970	$ 237,698

Interest and financing costs

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

	Three Months Ended March 31,	
	2021	2020
Interest expense	$ 6,455	$5,942
Interest prepayment fees	2,500	—
Financing fees amortization	1,272	320
Interest expense and other financing costs	$10,227	$6,262

Amendment No. 7 and No. 8 were both accounted for as debt modification in accordance with U.S. GAAP. Accordingly, the unamortized deferred financing fees at each amendment date and the financing fee of $5.0 million for Amendment No. 7 are being deferred. These deferred financing fees are being amortized over the remining term of our Financing Agreement. The future estimated amortization of our deferred financing fees is as follows (in thousands):

	Year Ended December 31,
2021 (9 months)	$ 4,377
2022	5,875
2023	5,078
2024	700
	$ 16,030

Debt covenants compliance

The Financing Agreement requires us to have a minimum unrestricted cash balance of $60.0 million. As of the filing date of this 10-Q Report, our cash balance was above the required minimum balance. Based on our current projections, along with financing that may be available to us under our at-the-market equity offering program relating to shares of our common stock, we

anticipate that we will remain in compliance with the minimum cash balance covenant for the next twelve months from the issuance of the consolidated financial statements included in this 10-Q Report. In addition, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 pandemic on our business and we believe that our existing cash reserves are sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the issuance of the consolidated financial statements included in this 10-Q Report. However, if we are unsuccessful with the commercialization of IMVEXXY, BIJUVA, or ANNOVERA, if such commercialization is delayed, or if the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, among other circumstances, we may consume funds significantly faster than we currently anticipate and our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA.

The Financing Agreement also requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants. These and other terms in the Financing Agreement have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business. If we are unable to maintain the minimum unrestricted cash balance, achieve any of the total minimum net revenue requirements or otherwise comply with any other covenant of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have an adverse effect on our business, results of operations and financial condition. As of March 31, 2021, we were in compliance, in all material respects, with our covenants under the Financing Agreement.

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 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 expect to meet our minimum purchase number of units in all material respects, accordingly, 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. 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.

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. A trial date has not been set.

In March 2020, we received a Paragraph IV certification notice letter (the “BIJUVA Notice Letter”) regarding an ANDA submitted to FDA by Amneal Pharmaceuticals (“Amneal”). The ANDA seeks approval from FDA to commercially manufacture, use, or sell a generic version of BIJUVA. In the BIJUVA Notice Letter, Amneal alleges that TherapeuticsMD patents listed in FDA’s Orange Book that claim compositions and methods of BIJUVA (the “BIJUVA Patents”) are invalid, unenforceable, and/or will not be infringed by Amneal’s

commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the BIJUVA Notice Letter expire in 2032. In April 2020, we filed a complaint for patent infringement against Amneal in the United States District Court for the District of New Jersey arising from Amneal's ANDA filing with FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal's ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set. In February 2021, the District Court entered an order temporarily staying all proceedings in the BIJUVA litigation. The District Court stay also extends the 30-month stay for the period in which the BIJUVA litigation has been stayed.

As of March 31, 2021, in the aggregate, we have incurred and recorded paragraph IV legal proceeding costs amounting to $1.9 million in prepaid expenses and other current assets in the accompanying consolidated balance sheets since we believe that we will successfully prevail in these two legal proceedings. Upon the successful conclusion of each of the above legal proceeding, the related capitalized legal costs for that legal proceeding will be reclassified to patents, in license rights, and other intangible assets, net in the accompanying consolidated balance sheets and such costs will be amortized over the remaining useful of the respective patent. If we are unsuccessful in either one of the above legal proceedings, then the related capitalized legal costs and respective unamortized patent costs for that legal proceeding will be immediately expensed in the period in which we become aware of unsuccessful legal proceeding.

10. Stockholders' equity (deficit)

Common stock

In November 2020, we entered into an at-the-market offering program (the "2020 ATM Program") relating to shares of our common stock. The 2020 ATM Program permitted us to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through or to the sales agent under the 2020 ATM Program. Sales of our common stock were permitted to be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including by means of ordinary broker's transactions on the Nasdaq Stock Exchange or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. As of February 8, 2021, sales of shares of our common stock under the 2020 ATM Program were completed when we sold an aggregate total of 28.6 million shares of our common stock at an average sale price of $1.75 per share, and we received net proceeds of $47.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued an aggregate total of 59.5 million shares of our common stock at an offering price of $1.85 per share, and we received net proceeds of $96.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In March 2021, we entered into an at-the-market offering program (the "2021 ATM Program") relating to shares of our common stock. The 2021 ATM Program permits us to offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through or to the under the 2021 ATM Program sales agent. Sales of our common stock may be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act, including by means of ordinary broker's transactions on the Nasdaq Stock Exchange or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The investment bank will be entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. The sales agent is not required to sell any specific number or dollar amounts of securities but will act as sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between us and the sales agent. Through March 31, 2021, we have sold 4.8 million shares of our common stock at an average sale price of $1.59 per share and we received estimated net proceeds of $7.0 million, after deducting the underwriting discounts and commissions and estimated offering expenses. Subsequently, and through the date of this 10-Q Report filing, we have not sold any additional shares of our common stock under the 2021 ATM Program. Future sales, if any, under the 2021 ATM Program will depend on a variety of factors, including among others, market conditions, the trading price of our common stock, determinations by us of the appropriate sources of funding, and potential uses of funding available to us.

Restricted stock units

During the three months ended March 31, 2021, we granted 327 thousand restricted stock units ("RSUs") at a weighted average grant date fair value of $1.58 per unit. The weighted average vesting life of these RSUs was 2.1 years. Additionally, we settled 52 thousand vested RSUs during the three months ended March 31, 2021 and the weighted average grant date fair value of these RSUs was $1.86 per unit. Furthermore, during the three months ended March 31, 2021, there were 732 thousand RSUs that vested, but were not yet settled as of March 31, 2021, and for which the weighted average grant date fair value was $1.07 per unit. We anticipate that settlement of these RSUs will occur in May 2021.

Warrants

In March 2021, a warrant holder exercised the holder's right to purchase an aggregate of 205 thousand shares of our common stock for $50 thousand. Also, in March 2021, warrant holders exercised their rights to purchase an aggregate of 358 thousand shares of common stock pursuant to the warrant's cashless exercise provision, wherein 298 thousand shares of our common stock were issued. In total, during the three months ended March 31, 2021, warrants to purchase an aggregate of 563 thousand shares of common stock were exercised and the weighted average exercise price of these warrants was $0.24 per share.

11. Revenue

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

	Three Months Ended March 31,	
	2021	2020
ANNOVERA	$ 8,750	$ 2,273
IMVEXXY	7,012	6,392
BIJUVA	2,445	1,112
Prescription vitamin	1,425	2,474
Product revenue, net	19,632	12,251
License revenue	234	—
Total revenue, net	$19,866	$12,251

12. Operating expenses

The following provides information about operating expenses (in thousands):

	Three Months Ended March 31,	
	2021	2020
Compensation and employee benefits	$ 19,891	$ 18,018
Selling and marketing	13,865	29,742
General and administrative	8,651	9,429
Research and development	2,050	3,269
Total operating expenses	$ 44,457	$ 60,458

Our compensation and employee benefits exclude those employees who perform research & development ("R&D") related activities. Our R&D costs consist mainly of costs incurred under agreements with contract research organizations ("CROs") and other third parties that conduct our clinical related studies, compensation and benefit costs related employees engaged in R&D activities, costs to developing our chemistry, manufacturing, and controls capabilities, costs related to manufacturing validation, and costs associated with other research activities and regulatory approvals. With regards to costs of clinical trials, they may vary significantly over the life of a project owing to a variety of factors and we base our expenses related to clinical trials on estimates based on our experience and estimates from CROs and other third parties. R&D expenditures for the drug products will continue after the clinical trial completes for on-going stability and laboratory testing, regulatory submission, and response work.

13. 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, 2021 and 2020, (ii) additional losses expected for the remainder of 2021 or recorded in 2020, 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, 2021 and 2020. Accordingly, there were no provisions for income taxes for the three months ended March 31, 2021 and 2020. Additionally, as of March 31, 2021 and December 31, 2020, we maintain a full valuation allowance for all deferred tax assets.

14. Loss per common share

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

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	$ (39,383)	$ (56,849)
Denominator:		
Weighted average common shares for basic loss per common share	347,219	271,460
Effect of dilutive securities	—	—
Weighted average common shares for diluted loss per common share	347,219	271,460
Loss per common share, basic and diluted	$ (0.11)	$ (0.21)

Since we reported a net loss for the three months ended March 31, 2021 and 2020, 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, 2021 and 2020.

The following table sets forth the securities which are not included in the calculation of diluted earnings per common share (in thousands):

	Three Months Ended March 31,	
	2021	2020
Stock options	23,710	25,155
RSUs	7,326	4,474
PSUs	2,393	2,384
Warrants	5,852	1,833
	39,281	33,846

15. Related parties

A member of our Board of Directors, J. Martin Carrol, is also a director of Catalent. From time to time, we have entered into agreements with Catalent and its affiliates in the normal course of business. Agreements with Catalent have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. During the three months ended March 31, 2021 and 2020, we were billed by Catalent of $772 thousand and $1.3 million, respectively, for manufacturing activities. As of March 31, 2021 and December 31, 2020, we have estimated amounts payable to Catalent totaling $639 thousand and $276 thousand, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 9, Commitments and contingencies.

A member of our Board of Directors, Karen L. Ling, is an executive vice president and chief human resources officer of American International Group, Inc. (“AIG”). From time to time, we have entered into agreements with AIG in the normal course of business. Agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. During the three months ended March 31, 2021 and 2020, we were billed by AIG of $13 thousand and $71 thousand, respectively, for various insurance premiums. As of March 31, 2021 and December 31, 2020, we have no amounts payable to AIG.

16. 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,	
	2021	2020
Customer A	13%	26%
Customer B	18%	18%
Customer C	22%	15%
Customer D	*	10%

* 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, 2021	December 31, 2020
Customer A	14%	17%
Customer B	20%	19%
Customer C	33%	25%
Customer D	*	11%

* Balance was less than 10% of total accounts receivable

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

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

	Three Months Ended March 31,	
	2021	2020
Catalent	29%	24%
Vendor A	33%	28%
Vendor B	32%	32%
Vendor C	*	13%

* 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, 2021	December 31, 2020
Vendor D	19%	*
Vendor E	*	17%
Vendor F	*	16%
Vendor G	*	10%

* 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 2020 Annual Report on Form 10-K ("2020 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 2020 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.

Forward-looking statements

This 10-Q Report may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans, and strategies as well as statements, other than historical facts, that address activities, events, or developments that we intend, expect, project, believe, or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy," and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements are made as of the date of this 10-Q Report and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise, 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. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our 2020 10-K Report, and include the following: the effects of the COVID-19 pandemic; our ability to maintain or increase sales of our approved products; our ability to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, and to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor, including pursuant to our 2021 ATM Program; our commercialization, marketing, and manufacturing capabilities and strategy for our approved products; the size of markets and the potential market opportunity for which our products are approved and our ability to penetrate such markets; the rate and degree of market acceptance of our products; the willingness of healthcare providers to prescribe and patients to use our products; our ability to obtain additional financing when needed and to service our debt; our competitive position and the success of competing products that are or become available for the indications that we are pursuing; our intellectual property position; whether we will be able to comply with the covenants and conditions under our term loan facility; the length, cost, and uncertain results of our clinical trials, the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; whether the U.S. Food and Drug Administration ("FDA") will approve the efficacy supplement for the lower dose of BIJUVA; our ability to protect our intellectual property, including with respect to the Paragraph IV notice letters we received regarding IMVEXXY and BIJUVA; the length, cost, and uncertain results of future clinical trials; our reliance on third parties to conduct our manufacturing, R&D and clinical trials; the ability of our licensees to commercialize and distribute our products; the ability of our marketing contractors to market our products; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation; the potential disposition of vitaCare Prescription Services or any other divestitures we may pursue in the future; the volatility of the trading price of our common stock and the concentration of power in our stock ownership.

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.

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 second 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.

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. The 4-µg formulation of IMVEXXY represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY is a small, digitally inserted, softgel vaginal insert that dissolves when inserted into the vagina. It is administered mess-free, without the need for an applicator, and can be used any time of day. IMVEXXY provides a mechanism of action and dosing that are familiar and comfortable for patients, with no patient education required for dose application or applicators. IMVEXXY demonstrated efficacy as early as two weeks (secondary endpoint) and maintained efficacy through week 12 in clinical studies, with no increase in systemic hormone levels beyond the normal postmenopausal range (the clinical relevance of systemic absorption rates for vaginal estrogen therapies is not known).

As part of the FDA's approval of IMVEXXY, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen. The FDA has also asked the sponsors of other vaginal estrogen products to participate in the observational study. In connection with the observational study, we will be required to provide progress reports to the FDA on an annual basis. The development of this method is underway, and we do not believe that the costs will be material on an annual basis.

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, 2021, no IMVEXXY sales have been made through these licensing agreements.

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

This pharmaceutical product is the first and only FDA-approved bioidentical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus. The estrogen and progesterone in BIJUVA have the same chemical and molecular structure as the hormones that are naturally produced in a woman's body.

BIJUVA offers the convenience of a single-capsule combination of two hormones (estradiol and progesterone), which may improve a user's compliance. The estradiol and progesterone in BIJUVA are plant-based, not animal-sourced, and does not contain peanut oil unlike other FDA-approved progesterone products. BIJUVA provides a sustained steady state of estradiol which reduced the frequency and severity of hot flashes in clinical studies with no demonstrated impact on a patient's weight or blood pressure. Additionally, through clinical trials, BIJUVA has demonstrated endometrial safety and greater than 90% amenorrhea rates, while providing no clinically meaningful changes in mammograms.

In January 2020, we submitted a New Drug Application ("NDA"), efficacy supplement for the 0.5 mg/100 mg dose of BIJUVA to the FDA for review and potential approval. The NDA efficacy supplement used existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. In November 2020, we withdrew the NDA efficacy supplement. We filed a Formal Dispute Resolution Request ("FDRR") with the FDA that disputed the FDA's requirement that the NDA efficacy supplement meet approval standards that have not been required of other approved drugs in BIJUVA's therapeutic class. In March 2021, the FDA granted the FDRR in our favor. Notwithstanding our FDRR, there can be no assurance that FDA will approve the 0.5 mg/100 mg dose of BIJUVA, or, if approved, the timing of such approval. We have a Type B meeting scheduled with the FDA in May 2021 to discuss a potential pathway toward approval.

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. As of March 31, 2020, no BIJUVA sales have been made through these licensing agreements.

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, which is made with a silicone elastomer, contains SA, a 19-nor progesterone derivative also known as Nestorone®, and EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. SA is classified as a new chemical entity by the FDA and is a potent progestin that, based on pharmacological studies in animals and in vitro, does not bind to the androgen or estrogen receptors and has no glucocorticoid activity at contraceptive doses.

ANNOVERA can be inserted and removed by the woman herself without the aid of a healthcare provider and, unlike oral contraceptives, ANNOVERA does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA for seven days, thereby providing a regular bleeding pattern (i.e., withdrawal/scheduled bleeding). The same CVS is then re-inserted for additional 21/7-days in/out, for up to a total of 13 cycles (one year). ANNOVERA releases daily vaginal doses of both active ingredients (SA and EE). The claimed release rate of 150 µg/day SA and 13 µg/day EE is supported by the calculated average release rate from an ex vivo analysis of ANNOVERA used for 13 cycles and is also supported by data from 13 cycles of in vitro release.

ANNOVERA is commercially sold by us in the U.S. pursuant to the terms of the Population Council License Agreement with Population Council. 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 to Population Council under the Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

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

We believe that the strong initial commercial net revenue per unit of ANNOVERA and commercial insurance adoption provide us with an opportunity to deploy additional financial resources to maximize ANNOVERA's consumer-focused commercialization strategy and leverage the ability of doctor/patient choice of contraceptive to override insurance company formularies when necessary. As part of this strategy, we are pursuing distribution opportunities for ANNOVERA to provide women with additional access to ANNOVERA, particularly during the COVID-19 pandemic, with multiple telehealth platforms that extend the reach of ANNOVERA.

Prenatal vitamin products

We manufacture and distribute our prescription prenatal vitamin product lines under our vitaMedMD brand name and authorized generic formulations of some of our prescription prenatal vitamin products under our BocaGreenMD Prena1 name. We will continue to support the vitaMedMD and BocaGreenMD products as they are important products to our core customers and help provide us with continued access to sell our women's health portfolio. Our current prenatal vitamin product line features a unique, proprietary combination of FOLMAX™, FePlus™, and pur-DHA™ and includes the following products: vitaTrue™, vitaPearl™, vitaMedMD One Rx Prenatal Multivitamin, vitaMedMD RediChew® Rx Prenatal Multivitamin, BocaGreenMD Prena1 True, BocaGreenMD Prena1 Pearl, and BocaGreenMD Prena1 Chew. All of our prenatal vitamins are gluten, sugar, and lactose-free. A prenatal vitamin option that is both vegan and kosher is also available for women with special dietary needs. We believe our product attributes result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality and patented ingredients.

Results of operations

Three months ended March 31, 2021 compared with three months ended March 31, 2020

Revenue and gross profit. Our revenue for the first quarter of 2021 was $19.9 million, an increase of $7.6 million, or 62.2%, compared to the first quarter of 2020. Our gross profit for the first quarter of 2021 was $15.2 million, an increase of $5.6 million, or 59.2%, compared to the first quarter of 2020.

The following table sets forth our revenue by product, costs of goods sold and gross profit during these periods (in thousands):

	Three Months Ended March 31,	
	2021	2020
ANNOVERA	$ 8,750	$ 2,273
IMVEXXY	7,012	6,392
BIJUVA	2,445	1,112
Prescription vitamin	1,425	2,474
Product revenue, net	19,632	12,251
License revenue	234	—
Total revenue, net	19,866	12,251
Cost of goods sold	4,687	2,715
Gross profit	$15,179	$ 9,536

Our sales of ANNOVERA were $8.8 million for the first quarter of 2021, an increase of $6.5 million, or 285.0%, compared to the first quarter of 2020. This increase was primarily due to an increase in sales volume, which was partially offset by a lower average sale price.

Our sales of IMVEXXY were $7.0 million for the first quarter of 2021, an increase of $620 thousand, or 9.74%, compared to the first quarter of 2020. This increase was primarily attributable to a higher average sale price, which was partially offset by a decrease in sales volume. Both the higher average sale price and lower sales volume was primarily a result of a change in the IMVEXXY copay assistance program to increase the price paid by the customer.

Our sales of BIJUVA were $2.4 million for the first quarter of 2021, an increase of $1.3 million, or 119.9%, compared to the first quarter of 2020. This increase was primarily attributable to a higher average sale price and an increase in sales volume.

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

Although our product revenue relating to ANNOVERA, IMVEXXY, and BIJUVA increased for the quarter ended March 31, 2021 when compared to the quarter ended March 31, 2020, its growth continued to be slower than had been previously anticipated primarily due to the continuing impact of COVID-19.

Our prescription vitamin sales were $1.4 million for the first quarter of 2021, a decrease of $1.0 million, or 42.4%, compared to the first quarter of 2020. This decrease was primarily due to a decrease in sales volume and a lower average sale price.

Our license revenue for the first quarter of 2021 was $234 thousand related to the achievement of a milestone during 2021 under the Theramex License Agreement for BIJUVA.

Our gross profit increased $5.6 million, or 59.2%, for the first quarter of 2021 compared to the first quarter of 2020, primarily as a result of an increase in product revenue of 60.2%. Our product gross margin was 76.1% for the first quarter of 2021 compared to 77.8% for the first quarter of 2020. This decrease was primarily related to an inventory charge of $502 thousand for the first quarter of 2021, compared to $136 thousand for the first quarter of 2020.

Operating expenses. Total operating expenses for the first quarter of 2021 were $44.5 million, a decrease of $16.0 million, or 26.5%, compared to the first quarter of 2020. The following table sets forth our operating expense categories (in thousands):

	Three Months Ended March 31,	
	2021	2020
Compensation and employee benefits	$19,891	$18,018
Selling and marketing	13,865	29,742
General and administrative	8,651	9,429
Research and development	2,050	3,269
Total operating expenses	$44,457	$60,458

The decrease in total operating expenses was primarily due to $15.9 million in lower selling and marketing costs, $1.2 million in lower R&D costs, and $778 thousand in lower general and administrative costs. Partially offsetting these decreases was $1.9 million in higher compensation and employee benefits.

Our compensation and employee benefits, excluding those employees who perform R&D related activities, were $19.9 million for the first quarter of 2021, an increase of $1.9 million, or 10.4%, compared to the first quarter of 2020. This increase was primarily related to $2.9 million in higher salaries and employee benefits mostly in sales, marketing and regulatory areas to support the sales growth of our pharmaceutical products, reflecting the continued impact of our formerly outsourced sales personnel who were onboarded in the third quarter of 2020. This increase was partially offset by $1.0 million in lower incentive compensation.

Our selling and marketing costs were $13.9 million for the first quarter of 2021, a decrease of $15.9 million, or 53.4%, compared to the first quarter of 2020. This decrease was primarily due to $6.0 million in lower outsourced sales personnel costs mainly attributable to costs related to the onboarding of such sales personnel in the third quarter of 2020, $5.5 million in lower advertising and marketing costs, and $1.4 million in lower product sample costs as well as $2.8 million in costs related to a national selling and marketing event that occurred during the first quarter of 2020 prior to the COVID-19 pandemic. Overall, our lower selling and marketing costs reflect our cost cutting initiatives put in place at the beginning of the COVID-19 pandemic.

Our general and administrative costs were $8.7 million for the first quarter of 2021, a decrease of $778 thousand, or 8.3%, compared to the first quarter of 2020. This decrease was primarily attributable to $829 thousand in lower legal and professional fees.

Our R&D costs consist mainly of costs incurred under agreements with contract research organizations (“CROs”) and other third parties that conduct our clinical related studies, compensation, and benefit costs related employees engaged in R&D activities, costs to developing our chemistry, manufacturing, and controls capabilities, costs related to manufacturing validation, and costs associated with other research activities and regulatory approvals. With regards to costs of clinical trials, they may vary significantly over the life of a project owing to a variety of factors and we base our expenses related to clinical trials on estimates based on our experience and estimates from CROs and other third parties. R&D expenditures for the drug products will continue after the clinical trial completes for on-going stability and laboratory testing, regulatory submission, and response work.

Our R&D costs were $2.1 million for the first quarter of 2021, a decrease of $1.2 million, or 37.3%, compared to the first quarter of 2020. This decrease was primarily attributable to $436 thousand in lower R&D compensation and employee benefits, $387 thousand in lower lab research costs, and $298 thousand in lower R&D legal and professional fees. We have reduced our R&D expenditures since 2019 as we refocus our resources towards the continued commercialization of our pharmaceutical products. Accordingly, we continue to deploy limited resources in the development of new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For the first quarter of 2021, we had a loss from operations of $29.3 million, compared to $50.9 million for the first quarter of 2020. This $21.6 million decrease was attributable to higher gross profit of $5.6 million, as well as lower operating expenses of $16.0 million. We anticipate that we will continue to have operating losses for the near future until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that our efforts will be successful.

Other expense, net. For the first quarter of 2021, our non-operating expenses were $10.1 million, compared to $5.9 million for the first quarter of 2020. This $4.2 increase was primarily attributable to a $2.5 million interest prepayment premium associated with the repayment of a portion of our debt in the first quarter of 2021 and an aggregate higher amortization expense and interest expense of $1.5 million related to higher overall average deferred financing costs and debt balance in the first quarter of 2021 compared to the first quarter of 2020.

Net Loss. For the first quarter of 2021, we had a net loss of $39.4 million, or $0.11 per basic and diluted common share, compared to a net loss of $56.8 million, or $0.21 per basic and diluted common share, for the first quarter of 2020.

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, 2021, we had cash totaling $137.6 million. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of $250,000 per bank. We have never experienced any losses related to these funds.

In November 2020, we entered into an at-the-market offering program (the "2020 ATM Program") relating to shares of our common stock. The 2020 ATM Program permitted us to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through or to the sales agent under the 2020 ATM Program. Sales of our common stock were permitted to be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including by means of ordinary broker's transactions on the Nasdaq Stock Exchange or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The sales agent was entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. As of February 8, 2021, sales of shares of our common stock under the 2020 ATM Program were completed when we sold an aggregate total of 28.6 million shares of our common stock at an average sale price of $1.75 per share, and we received net proceeds of $47.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued an aggregate total of 59.5 million shares of our common stock at an offering price of $1.85 per share, and we received net proceeds of $96.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

In March 2021, we entered into an at-the-market offering program (the "2021 ATM Program") relating to shares of our common stock. The 2021 ATM Program permits us to offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through or to the sales agent under the 2021 ATM Program. Sales of our common stock may be made from time to time in at-the-market offerings as defined in Rule 415 of the Securities Act, including by means of ordinary broker's transactions on the Nasdaq Stock Exchange or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices, or as otherwise agreed to with the sales agent. The investment bank will be entitled to compensation at a fixed commission rate of 3.0% of the aggregate gross sales price per share sold. The sales agent is not required to sell any specific number or dollar amounts of securities but will act as sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between us and the sales agent. Through March 31, 2021, we sold 4.8 million shares of our common stock at an average sale price of $1.59 per share and received estimated net proceeds of $7.0 million, after deducting the underwriting discounts and commissions and estimated offering expenses. Subsequently, and through the date of this 10-Q Report filing, we have not sold any additional shares of our common stock under the 2021 ATM Program. Future sales, if any, under the 2021 ATM Program will depend on a variety of factors, including among others, market conditions, the trading price of our common stock, determinations by us of the appropriate sources of funding, and potential uses of funding available to us.

Cash flows

The following table reflects the major categories of cash flows for each of the periods (in thousands). For additional details, see the consolidated statements of cash flows in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$(38,380)	$(39,111)
Net cash used in investing activities	$ (438)	$ (443)
Net cash provided by financing activities	$ 95,949	$ 48,822

Operating Activities. The principal use of cash in operating activities for the first quarter of 2021 was to fund our current expenses related to supporting our continued commercialization activities for IMVEXXY, BIJUVA, and ANNOVERA, sales, marketing, scale-up and manufacturing activities and clinical development, adjusted for non-cash items. For the first three months of 2021, net cash used in operating activities was $38.4 million, compared to net cash used in operating activities of $39.1 million for the first quarter of 2020.

This decrease of $731 thousand, or 1.9%, was primarily due to a $17.5 million decrease in our net loss and $2.1 million increase in non-cash expenditure adjustment, partially offset by $18.9 million in cash usage changes related to the components of working capital.

Investing Activities. For the first quarter of 2021, net cash used in investing activities was $438 thousand, compared to net cash used in investing activities of $443 thousand for the first quarter of 2020.

Financing Activities. Financing activities currently represent the principal source of our cash flow. For the first quarter of 2021, net cash provided by financing activities was $95.9 million, compared to net cash provided by financing activities of $48.8 million for the first quarter of 2020. The $47.1 million increase was primarily related to increased sales of our common stock, consisting of $150.9 million in net proceeds from sales of common stock in 2021, partially offset by a $50.0 million repayment of debt in 2021, a $3.8 million increase in the payment of debt financing fees in 2021, and $50.0 million in borrowing of debt in 2020.

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. For the first quarter of 2021, our net DSO was 141 days, compared to 165 days for the fourth quarter of 2020 and 154 days for first quarter of 2020. 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. For the first quarter of 2021, our gross DSO was 62 days, compared to 67 days for the fourth quarter of 2020 and 51 days for the first quarter of 2020. Our DSO have fluctuated and will continue to fluctuate in the future due to variety of factors, including longer payment terms associated with the continued commercialization of IMVEXXY, BIJUVA, and ANNOVERA and changes in the healthcare industry. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future.

Debt. We had $200.0 million and $250.0 million in term loans outstanding under the Financing Agreement as of March 31, 2021 and December 31, 2020, respectively. For additional information, see Note 8, Debt in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

The Financing Agreement requires us to maintain a minimum unrestricted cash balance of $60.0 million. As of the filing date of this 10-Q Report, our cash balance was above the required minimum balance. Based on our current projections, along with financing that may be available to us under the 2021 ATM Program, we anticipate that we will remain in compliance with the minimum cash balance covenant for the next twelve months from the date of this 10-Q Report. In addition, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 pandemic on our business, and we believe that our existing cash reserves are sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this 10-Q Report. However, if we are unsuccessful with the commercialization of IMVEXXY, BIJUVA, or ANNOVERA, if such commercialization is delayed, or if the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, among other circumstances, we may consume funds significantly faster than we currently anticipate and our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA.

The Financing Agreement also requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants. These and other terms in the Financing Agreement have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business. If we are unable to maintain the minimum unrestricted cash balance, achieve any of the total minimum net revenue requirements or otherwise comply with any other covenant of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have an adverse effect on our business, results of operations and financial condition.

Risks and uncertainties related to COVID-19.

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. We continue to provide an uninterrupted supply of our portfolio of products for patients. We believe we have sufficient inventory of finished products to meet anticipated demand in the near future. Additionally, we believe we have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products. For additional information, see the discussion of our risks and uncertainties related to COVID-19 in Note 1, Basis of presentation and summary of significant accounting policies in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report, and in our 2020 10-K Report.

Recent accounting pronouncements

Information regarding new accounting pronouncements is included in Note 1, Basis of presentation and summary of significant accounting policies in Item 1, Financial Statements appearing elsewhere in this 10-Q Report.

Critical accounting estimates

Calculation of variable consideration related to sales deductions

The determination of a transaction price is one of the five-steps which we access in accordance with the revenue recognition accounting guidance. The transaction price of a contract is the amount of consideration which we expect to be entitled to in exchange for transferring promised goods or services to a customer. Prescription products are sold at fixed wholesale acquisition cost ("WAC"), determined based on our list price. However, the total transaction price is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. These estimates are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). In order to determine the transaction price, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract or each variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative product revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. In determining amounts of variable consideration to include in a contract's transaction price, we rely on our historical experience and other evidence that supports our qualitative assessment of whether product revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a product revenue reversal arising from an uncertain future event and the magnitude of the reversal if that uncertain event were to occur. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our original estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

We accept returns of unsalable prescription products sold through wholesale distributors within a return period of six months prior to and up to 12 months following product expiration. ANNOVERA cannot be returned before the expiration date and expired ANNOVERA can be returned up to 12 months past the expiration date. Our prescription vitamins, IMVEXXY and BIJUVA currently have a shelf life of 24 months from the date of manufacture and ANNOVERA currently has a shelf life of 18 months from the date of manufacture. We do not allow product returns for prescription products that have been dispensed to a patient. We estimate the amount of our product sales that may be returned by our customers and record this estimate as a reduction of product revenue in the period the related product revenue is recognized. Where historical rates of return exist, we use history as a basis to establish a returns reserve for products shipped to wholesalers. For our newly launched products, for which the right of return exists but for which we currently do not have history of product returns, we estimate returns based on available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel. At the end of each reporting period, we may decide to constrain product revenue for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of products currently being shipped, price changes of competitive products and any introductions of generic products. We recognize the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since our returns primarily consist of expired and short dated products that will not be resold, we do not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of product revenue is deferred due to the anticipated return).

We offer various rebate and discount programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. Estimates relating to these rebates and coupons are deducted from gross product revenue at the time the product revenue is recognized. We record distributor fees based on amounts stated in contracts. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. We provide invoice discounts to our customers for prompt payment. Estimates relating to invoice discounts and chargebacks are deducted from gross product revenue at the time the product revenue is recognized.

We offer a co-pay assistance program for eligible enrolled patients whose out of pocket costs are reduced to a more affordable price. This allows patients to access the product at a reasonable cost and is in line with our responsible pricing approach. We reimburse pharmacies for this discount through third-party vendors. The variable consideration is estimated based on contract prices, the estimated percentage of patients that will utilize the copay assistance, the average assistance paid, the estimated levels of inventory in the distribution channel and the current level of prescriptions covered by patients' insurance. Payers may change coverage levels for our prescription products positively or negatively, at any time up to the time that we have formally contracted coverage with the payer. As

such, the net transaction price of our prescription products is susceptible to such changes in coverage levels, which are outside of our influence. As a result, we constrain variable consideration for our prescription products to an amount that will not result in a significant product revenue reversal in future periods. Our ability to estimate the net transaction price for our prescription products is constrained by our estimates of the amount to be paid for the co-pay assistance program which is directly related to the level of prescriptions paid for by insurance. As such, we record an accrual to reduce gross sales for the estimated co-pay and other patient assistance based on currently available third-party data and our internal analyses.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We had a cash balance of $137.6 million as of March 31, 2021. We hold certain portions of our cash balances in overnight money market placements all of which are fully available to us to support our cash flow requirements. The primary objective of our investment policy is to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer, or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain an investment portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Our debt under the Financing Agreement accrues interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.20%. Based on our debt under the Financing Agreement balance of $200.0 million as of March 31, 2021, a 1.0% change in interest rates would result in an impact to loss before income taxes of $2.0 million per annum.

Item 4. Controls and Procedures

Management’s evaluation of disclosure controls and procedures

Disclosure Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

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

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the 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, 2021.

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 2020 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. There have been no material changes to the Company’s risk factors since the 2020 10-K Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In March 2021, a warrant holder exercised the holder’s right to purchase an aggregate of 205 thousand shares of our common stock for $50 thousand. Also, in March 2021, warrant holders exercised their rights to purchase an aggregate of 358 thousand shares of common stock pursuant to the warrant’s cashless exercise provision, wherein 298 thousand shares of our common stock were issued. In total, during the three months ended March 31, 2021, warrants to purchase an aggregate of 563 thousand shares of common stock were exercised and the weighted average exercise price of these warrants was $0.24 per share. Proceeds from the cash exercise were used in working capital. The shares of common stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description
10.1	Amendment No. 7 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC, dated as of January 13, 2021(1)
10.2	Second Amendment to Company Warrant issued by the Company to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020(2)
10.3	Amendment No. 8 to the Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC, dated as of March 1, 2021(3)

Exhibit No.	Description
10.4	Amendment to Warrant issued by the Company to Robert Finizio, dated as of February 18, 2021[4]
10.5	Amendment to Warrant issued by the Company to John C.K. Milligan, IV, dated as of February 20, 2021[5]
10.6	Controlled Equity OfferingSM Sales Agreement, dated March 3, 2021, by and between TherapeuticsMD, Inc. and Cantor Fitzgerald & Co.[6]
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 Executive Officer
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, “Financial Statements” of this Quarterly Report on Form 10-Q
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set

* Filed herewith.

** Furnished herewith.

(1) Filed as Exhibit 10.24 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(2) Filed as Exhibit 10.12 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(3) Filed as Exhibit 10.25 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(4) Filed as Exhibit 10.14 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(5) Filed as Exhibit 10.16 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 001-00100).

(6) Filed as Exhibit 1.2 to the Company’s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on March 4, 2021 and incorporated herein by reference (SEC File No. 333-253851).

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 6, 2021

TherapeuticsMD, Inc.

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

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

Exhibit 31.1

Certification of Chief Executive Officer

I, Robert G. Finizio, 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 6, 2021

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, James C. D'Arecca, 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 6, 2021

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

Exhibit 32.1

Section 1350 Certification of Chief Executive Officer

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert G. Finizio, 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 6, 2021

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

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

Exhibit 32.2

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James C. D'Arecca, Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The 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 6, 2021

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

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