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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 November 11, 2021, there were 424,928,670 shares of the registrant's common stock, par value $0.001 per share, outstanding.

Table of Contents

Part I – Financial Information

Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
	(Unaudited)	
Assets:		
Current assets:		
Cash	$ 104,841	$ 80,486
Accounts receivable, net of allowance for credit losses of $1,351 and $1,118 as of September 30, 2021 and December 31, 2020, respectively	37,402	32,382
Inventory	7,362	7,993
Prepaid and other current assets	10,374	7,543
Total current assets	159,979	128,404
Fixed assets, net	1,388	1,942
License rights and other intangible assets, net	39,617	41,445
Right of use assets	8,391	9,566
Other non-current assets	253	253
Total assets	$ 209,628	$ 181,610
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	$ 15,000	$ —
Accounts payable	19,592	21,068
Accrued expenses and other current liabilities	51,674	38,170
Total current liabilities	86,266	59,238
Long-term debt, net	171,738	237,698
Operating lease liabilities	8,226	8,675
Other non-current liabilities	758	—
Total liabilities	266,988	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, 424,879 and 299,765 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	425	300
Additional paid-in capital	950,615	754,644
Accumulated deficit	(1,008,400)	(878,945)
Total stockholders' deficit	(57,360)	(124,001)
Total liabilities and stockholders' equity	$ 209,628	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue, net:				
Product	$ 24,469	$ 17,342	$ 67,102	$ 40,294
License	937	2,000	1,171	2,000
Total revenue, net	25,406	19,342	68,273	42,294
Cost of goods sold	5,282	3,279	14,101	10,394
Total gross profit	20,124	16,063	54,172	31,900
Operating expenses:				
Selling and marketing	30,005	22,373	86,193	91,056
General and administrative	28,435	16,637	66,691	53,740
Research and development	1,605	2,027	5,666	8,038
Total operating expenses	60,045	41,037	158,550	152,834
Loss from operations	(39,921)	(24,974)	(104,378)	(120,934)
Other (expense) income:				
Interest expense and other financing costs	(7,518)	(7,680)	(25,341)	(20,969)
Other income, net	19	42	264	466
Total other (expense), net	(7,499)	(7,638)	(25,077)	(20,503)
Loss before income taxes	(47,420)	(32,612)	(129,455)	(141,437)
Provision for income taxes	—	—	—	—
Net loss	$ (47,420)	$ (32,612)	$ (129,455)	$ (141,437)
Loss per common share, basic and diluted	$ (0.11)	$ (0.12)	$ (0.33)	$ (0.52)
Weighted average common shares, basic and diluted	422,216	272,565	388,111	271,969

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	Accumulated	
	Shares	Amount	Capital	Deficit	Total
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, net of cashless exercises	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)
Shares issued for sale of common stock, net of cost	125	—	163	—	163
Shares issued for exercise of warrants	600	1	227	—	228
Shares issued for exercise of options	54	—	21	—	21
Shares issued for vested restricted stock units	929	1	(1)	—	—
Shares issued for sale of common stock related to employee stock purchase plan	150	—	134	—	134
Share-based compensation	—	—	2,510	—	2,510
Net loss	—	—	—	(42,652)	(42,652)
Balance, June 30, 2021	395,048	395	911,511	(960,980)	(49,074)
Shares issued for sale of common stock, net of cost	28,770	29	31,790	—	31,819
Shares issued for exercise of options	7	—	3	—	3
Shares issued for vested restricted stock units	1,054	1	(1)	—	—
Share-based compensation	—	—	7,312	—	7,312
Net loss	—	—	—	(47,420)	(47,420)
Balance, September 30, 2021	424,879	$ 425	$ 950,615	$ (1,008,400)	$ (57,360)
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)
Shares issued for exercise of options	313	1	94	—	95
Shares issued for vested restricted stock units	303	—	—	—	—
Share-based compensation	—	—	3,003	—	3,003
Net loss	—	—	—	(51,976)	(51,976)
Balance, June 30, 2020	272,294	272	709,886	(804,246)	(94,088)
Shares issued for exercise of options and warrants, net	518	1	105	—	106
Warrants issued in relation to debt financing agreement	—	—	7,428	—	7,428
Share-based compensation	—	—	3,133	—	3,133
Net loss	—	—	—	(32,612)	(32,612)
Balance, September 30, 2020	272,812	$ 273	$ 720,552	$ (836,858)	$ (116,033)

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

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (129,455)	$ (141,437)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,091	3,039
Charges (credits) to provision for doubtful accounts	540	(47)
Inventory charge	1,082	5,744
Debt financing fees	4,158	1,645
Share-based compensation	12,779	8,502
Other	726	1,719
Changes in operating assets and liabilities:		
Accounts receivable	(5,560)	384
Inventory	(451)	(3,816)
Prepaid and other current assets	(2,831)	2,038
Accounts payable	(1,476)	(3,072)
Accrued expenses and other current liabilities	13,504	(3,813)
Other non-current liabilities	758	—
Total adjustments	26,320	12,323
Net cash used in operating activities	(103,135)	(129,114)
Cash flows from investing activities:		
Payment of patent related costs	(675)	(1,065)
Purchase of fixed assets	(34)	(39)
Net cash used in investing activities	(709)	(1,104)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	182,881	—
Proceeds from exercise of options and warrants	302	272
Proceeds from sale of common stock related to employee stock purchase plan	134	—
Repayments of debt	(50,000)	—
Borrowings of debt	—	50,000
Payment of debt financing fees	(5,118)	(1,250)
Net cash provided by financing activities	128,199	49,022
Net increase (decrease) in cash	24,355	(81,196)
Cash, beginning of period	80,486	160,830
Cash, end of period	$ 104,841	$ 79,634
Supplemental disclosure of noncash financing activities:		
Warrants issued in relation to debt financing agreement	$ —	$ 7,428
Supplemental disclosure of cash flow information:		
Interest paid	$ 19,675	$ 12,032

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

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®, vitaCare™, IMVEXXY®, BIJUVA® and ANNOVERA®, which are protected under applicable intellectual property laws and are the property of, or licensed to, the Company. Solely for convenience, trademarks, trade names and service marks referred to in this 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, and 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. The ultimate global recovery from the pandemic will be dependent on, among other things, actions taken by governments and businesses to contain and combat the virus, including any variant strains, the speed and effectiveness of vaccine production and global distribution, as well as how quickly, and to what extent, normal economic and operating conditions can resume on a sustainable basis globally.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. 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. In addition, we are planning to implement a significant cost savings initiative that is designed to reduce our annual costs in 2022 by at least $40.0 million. This figure does not include cost savings from, or the costs associated with the sale of an interest in vitaCare Prescription Services, which annualized cost savings are estimated at approximately $20.0 million.

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 2021. As of the date of issuance of these consolidated financial statements, the future extent to which the COVID-19 pandemic may continue to materially impact our financial condition, liquidity, or results of operations remains uncertain. We are continuing to assess the effect of the COVID-19 pandemic on our operations by monitoring the spread of COVID-19 and the various actions implemented to combat the pandemic throughout the world. Even after the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

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

Going Concern

As of the filing date of this Quarterly Report on Form 10-Q, our cash balance was above the $60.0 million balance as required by the Financing Agreement described below in Note 8. Based on our current projections, we will need to raise additional capital to remain in compliance with this minimum cash balance covenant for the next twelve months from the issuance of these financial statements. To address our projected capital needs, we are pursuing various equity financing and other alternatives including the sale of an interest in vitaCare Prescription Services for which we commenced a sale process. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this Quarterly Report on Form 10-Q.

If we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA. See also Note 3- Inventory for additional information regarding risks associated with our contract manufacturers, particularly for ANNOVERA. The presence of these projected factors in conjunction with the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements. Additionally, if circumstances were to require our independent registered public accounting firm to include a going concern uncertainty in their report on our annual consolidated financial statements, such matter would also take us out of compliance with certain of the Financing Agreement covenants. If we are unable to 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.

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

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, including type of operating expenses, 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		540
Write-off of uncollectible receivables		(307)
Balance as of September 30, 2021	$	1,351

3. Inventory

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

One of our third party contract manufacturers that manufactures ANNOVERA has recently experienced an increase in difficulties with the manufacturing process for ANNOVERA, which has resulted in batch failures. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA consistently within the approved specification at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021 we filed a supplemental New Drug Application with the U.S. Food and Drug Administration ("FDA") to modify the manufacturing (testing) specifications for ANNOVERA to allow for normal manufacturing variation that would increase the consistency of manufacturing and supply of ANNOVERA. There can be no

assurance that such a modification will be approved by the FDA. If the FDA fails to approve the requested modification by the Prescription Drug User Fee Act ("PDUFA") date of December 12, 2021, our third party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market or generate sufficient revenue to meet the covenants under the Financing Agreement. If we are unable to 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.

If any of our third party contract manufacturers or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of an agreement between us, or do not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience additional interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations and financial position and ability to meet our revenue and other covenants under our Financing Agreement.

Our inventory consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 3,487	$ 4,423
Work in process	688	220
Finished products	3,187	3,350
Inventory	$ 7,362	$ 7,993

4. Prepaid and other current assets

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

	September 30, 2021	December 31, 2020
Insurance	$ 3,801	$ 2,568
Paragraph IV legal proceeding costs	2,858	—
Other	3,715	4,975
Prepaid and other current assets	$ 10,374	$ 7,543

5. Fixed assets

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

	September 30, 2021	December 31, 2020
Furniture and fixtures	$ 1,407	$ 1,407
Computer and office equipment	1,855	1,784
Computer software	375	412
Leasehold improvements	80	80
Fixed assets	3,717	3,683
Less: accumulated depreciation and amortization	2,329	1,741
Fixed assets, net	$ 1,388	$ 1,942

We recorded depreciation expense of $0.2 million for the three months ended September 30, 2021 and 2020, and $0.6 million for the nine months ended September 30, 2021 and 2020.

6. Licensed rights and other intangible assets

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

	September 30, 2021			December 31, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Licensed rights and intangible assets subject to amortization:						
License rights	$ 40,000	$ 6,070	$ 33,930	$ 40,000	$ 3,803	$ 36,197
Hormone therapy drug patents	4,732	985	3,747	4,045	749	3,296
Hormone therapy drug patents applied and pending approval	1,596	—	1,596	1,629	—	1,629
License rights and other intangible assets subject to amortization	46,328	7,055	39,273	45,674	4,552	41,122
Intangible assets not subject to amortization:						
Trademarks/trade name rights	344	—	344	323	—	323
License rights and other intangible assets, net	$ 46,672	$ 7,055	$ 39,617	$ 45,997	$ 4,552	$ 41,445

Licensed rights

We recorded amortization expense related to the exclusive license rights agreement (the “Population Council License Agreement”) with Population Council of $0.8 million for the three months ended September 30, 2021 and 2020, and $2.3 million for the nine months ended September 30, 2021 and 2020.**Other intangible assets**

As of September 30, 2021, we had a total of 87 patents, of which 46 were domestic. As of December 31, 2020, we had a total of 77 patents, of which 38 were domestic. We recorded amortization expense related to patents of $0.1 million for the three months ended September 30, 2021 and 2020, and $0.2 million for the nine months ended September 30, 2021 and 2020, respectively.

We use a combination of qualitative and quantitative factors to assess licensed rights and intangible assets for impairment. As a result of performing these assessments, we determined that no impairment existed as of September 30, 2021 and, therefore, recorded no write-downs to any of our licensed rights and other intangible assets. However, during the nine months ended September 30, 2020, we wrote off $584,509 in costs related to trademarks and patents.

7. Accrued expenses and other current liabilities

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

	September 30, 2021	December 31, 2020
Payroll and related costs	$ 14,346	$ 11,179
Rebates	15,421	11,011
Sales returns and coupons	3,200	7,057
Sales and marketing	6,223	228
Wholesale distributor fees	4,626	2,632
Professional fees	2,477	925
Other accrued expenses and current liabilities	5,381	5,138
Accrued expenses and other current liabilities	$ 51,674	$ 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 accompanying 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 quarterly principal repayments plus the prepayment fees described below starting on March 31, 2022 through March 31, 2024. Additionally, 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):

	September 30, 2021	December 31, 2020
Financing Agreement	$ 200,000	$ 250,000
Less: deferred financing fees	13,262	12,302
Debt, net	186,738	237,698
Current maturities of long-term debt	15,000	—
Long-term debt	$ 171,738	$ 237,698

Our future principal payments under the Financing Agreement are as follows (in thousands), excluding the prepayment fees described above:

	Due on				
	March 31,	June 30,	September 30,	December 31,	Total
2022	$ 5,000	$ 5,000	$ 5,000	$ 10,000	$ 25,000
2023	10,000	41,250	41,250	41,250	133,750
2024	41,250	—	—	—	41,250
					$ 200,000

Interest and financing costs

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Interest expense	$ 5,391	$ 6,727	$ 17,175	$ 19,324
Interest prepayment fees	650	—	4,008	—
Financing fees amortization	1,477	953	4,158	1,645
Interest expense and other financing costs	$ 7,518	$ 7,680	$ 25,341	$ 20,969

Both Amendment No. 7 and No. 8 were 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 estimated future amortization of our deferred financing fees is as follows (in thousands):

Year Ending December 31,	
2021 (3 months)	$ 1,532
2022	6,346
2023	4,990
2024	394
	$ 13,262

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, we will need to raise additional capital to 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. See Note 1 – Basis of presentation and summary of significant accounting policies - Going Concern above.

The Financing Agreement also requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants, which could also be affected by the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers. These and other terms in the Financing Agreement must 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 September 30, 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 have met our minimum purchase number of units in all material respects. 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. In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal. On September 2, 2021, the District Court made available a public version of the order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

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 September 30, 2021, in the aggregate, we have incurred and recorded paragraph IV legal proceeding costs amounting to $2.9 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 28,600,689 shares of our common stock at an average sale price of $1.75 per share. For the 2020 ATM Program, we received net proceeds of $48.1 million, after deducting the discounts and commissions to the sales agent and estimated offering expenses.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued 59,459,460 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 equity 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 sales agent 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 September 30, 2021, we have sold a total of 33,705,315 shares of our common stock under the 2021 ATM Program at an average sale price of $1.21 per share and we received estimated net proceeds of $38.8 million, after deducting discounts and commissions to the sales agent and estimated offering expenses. Subsequently, through the date of this 10-Q Report, 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.

Warrants

The following tables summarizes the status of our outstanding and exercisable warrants and related transactions since December 31, 2020 (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Warrants outstanding and exercisable			
	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of December 31, 2020	6,535	$ 1.55	$ 1,041	7.3
Exercised	(1,163)	0.31		
Expired	(245)	4.80		
As of September 30, 2021	5,127	$ 1.52	$ -	8.6

The aggregate intrinsic value of warrants exercised during the nine months ended September 30, 2021 was $1.1 million.

Share-based compensation payment plans

At the 2021 annual meeting of stockholders of the Company, held on May 27, 2021, our stockholders among other things approved the First Amendment to the TherapeuticsMD, Inc. 2019 Stock Incentive Plan (the "2019 Plan") to increase the number of shares of our common stock available under the 2019 Plan by 22,475,000 shares. As of September 30, 2021, there were 10,182,803 shares of common stock available for issuance under the 2019 Plan, consisting of (i) new shares, (ii) unallocated shares previously available for issuance under the 2012 Stock Incentive Plan (the "2012 Plan") that were not then subject to outstanding "Awards" (as defined in the 2012 Plan), and (iii) unallocated shares previously available for issuance under the 2009 Long-Term Incentive Compensation Plan (the "2009 Plan" and together with the 2019 Plan and the 2012 Plan, the "Plans") that were not then subject to outstanding "Awards" (as defined in the 2009 Plan). Any shares subject to outstanding options or other equity "Awards" under the 2019 Plan, the 2012 Plan and the 2009 Plan that are forfeited, expire or otherwise terminate without issuance of the underlying shares, or if any such Award is settled for cash or otherwise does not result in the issuance of all or a portion of the shares subject to such Award (other than shares tendered or withheld in connection with the exercise of an Award or the satisfaction of withholding tax liabilities), the shares to which

those Awards were subject, shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, again be available for delivery with respect to Awards under the 2019 Plan. As of December 31, 2020, there were 2,583,565 shares of common stock available for issuance under the 2019 Plan.

In August 2021, the Company hired a new President and granted an "inducement grant" under Listing Rule 5635(c)(4) of The Nasdaq Stock Market LLC ("Nasdaq") of 2,750,000 restricted stock units designated as "Time-Based Units" and 2,750,000 restricted stock units designated as "Performance Units" (the "August Inducement Grant"). The Time-Based Units and Performance Units were granted pursuant to certain Inducement Grant Restricted Stock Unit Agreement; accordingly, these equity awards were not counted against the shares of common stock available for issuance under the 2019 Plan.

At the 2021 annual meeting of stockholders of the Company, our stockholders approved an Offer to Exchange Eligible Options for New Restricted Stock Units (the "Exchange Offer"). The Exchange Offer allowed certain employee option holders, excluding the Company's named executive officers, advisers, consultants, contractors, or present or past non-employee directors, to exchange some or all of their outstanding options to purchase shares of common stock that were granted before August 26, 2019, and had a per share exercise price equal to or greater than $5.01 ("Eligible Options"), for an award of restricted stock units of the Company ("New RSUs"), subject to specified conditions. In September 2021, following the expiration of the Exchange Offer, 69 eligible employees elected to exchange Eligible Options, and the Company accepted for cancellation Eligible Options to purchase an aggregate of 4,493,000 shares of common stock, representing approximately 91.5% of the total shares of common stock underlying the Eligible Options. Also, in September 2021, promptly following the expiration of the Exchange Offer, the Company granted 700,264 New RSUs in exchange for the cancellation of the tendered Eligible Options. The New RSUs vest in three equal annual installments beginning on September 29, 2022, subject to the terms and conditions of the 2019 Plan.

The following table summarizes the status of our outstanding and exercisable options and related transactions under the Plans, including the Exchange Offer, since December 31, 2020 (in thousands, except weighed average exercise price and weighted average remaining contractual life data):

	Options awards outstanding				Options awards exercisable			
	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of December 31, 2020	23,782	$ 4.80	$ 152	5.2	19,863	$ 5.06	$ 117	4.6
Granted	60	1.21						
Exercised	(61)	0.40						
Cancelled/Forfeited	(4,885)	4.95						
Expired	(483)	5.59						
As of September 30, 2021	18,413	$ 4.40	$ 21	4.2	17,228	$ 4.53	$ 21	3.9

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2021 was less than $0.1 million.

The following table summarizes the status of our restricted stock units ("RSUs") and related transactions, including the Exchange Offer and the August Inducement Grant since December 31, 2020 (in thousands, except weighed average grant date fair value):

	RSUs awards outstanding			RSUs awards vested and not settled		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of December 31, 2020	7,061	$ 1.76	$ 8,544	—	$ —	$ —
Granted	11,684	1.09				
Vested and settled	(2,034)	1.17				
Cancelled/Forfeited	(593)	1.92				
As of September 30, 2021	16,118	$ 1.34	$ 11,927	2,566	$ 1.79	$ 2,566

The aggregate intrinsic value of RSUs vested and settled during the nine months ended September 30, 2021 was $2.1 million.

The following table summarizes the status of our performance stock units ("PSUs") and related transactions, including the August Inducement Grant since December 31, 2020 (in thousands, except weighed average grant date fair value):

	PSUs awards outstanding			PSUs awards vested and not settled		
	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of December 31, 2020	2,404	$ 1.08	$ 2,909	—	$ —	$ —
Granted	7,337	1.05				
Vested and settled	—	—				
Cancelled/Forfeited	(72)	1.07				
As of September 30, 2021	9,669 (1)	$ 1.06	$ 7,155	1,680	$ 1.16	$ 1,243

(1) The number of PSUs represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and 14,901,178 depending on the Company's achievement of certain revenue milestones over the period from 2021 through 2023 and certain earnings before interest, taxes, depreciation and amortization (EBITDA) milestones between 2021 and 2023.

In June 2020, our stockholders approved the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan ("ESPP"), which reserved 5,400,000 shares of our common stock for purchase by eligible employees. The ESPP permits eligible employees to purchase our common stock at a price per share which is equal to 85% of the lesser of (i) the fair market value of the shares on the offering date of the offering period or (ii) the fair market value of the shares on the purchase date. In May 2021, 150,078 shares were sold under the ESPP at an average sale price of $0.89 per share and we received proceeds of $0.1 million.

We recorded share-based compensation related to previously issued options, RSU and PSUs, as well as shares of common stock issued under the ESPP totaling $7.3 million and $3.1 million for the three months ended September 30, 2021 and 2020, respectively, and $12.8 million and $8.5 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, we had $22.7 million of unrecognized share-based compensation cost related to unvested options, RSUs and PSUs as well as shares issuable under the ESPP, which is included as additional paid-in capital in the accompanying consolidated balance sheets and may be adjusted for future changes in forfeitures.

The unrecognized share-based compensation cost as of September 30, 2021 is expected to be recognized as share-based compensation over a weighted average period of 2.2 years as follows (in thousands):

Year Ending December 31,	
2021 (3 months)	$ 3,280
2022	10,693
2023	6,206
2024	2,465
2025	6
	$ 22,650

11. Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue:				
ANNOVERA	$ 11,807	$ 6,419	$ 30,112	$ 10,527
IMVEXXY	8,016	6,841	24,866	18,319
BIJUVA	3,298	1,646	7,899	4,110
Prescription vitamin	1,348	2,436	4,225	7,338
Product revenue, net	24,469	17,342	67,102	40,294
License revenue	937	2,000	1,171	2,000
Total revenue, net	$ 25,406	$ 19,342	$ 68,273	$ 42,294

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

For the three months and nine months ended September 30, 2021, we recorded BIJUVA sales of $0.7 million made through the Theramex License Agreement. As of September 30, 2021, no BIJUVA sales have been made through the Knight License Agreement. Additionally, as of September 30, 2021, no IMVEXXY sales have been made through either of the licensing agreements.

12. Income taxes

We do not expect to pay any significant federal or state income taxes as a result of (i) the losses recorded during the three and nine months ended September 30, 2021 and 2020, (ii) additional losses expected for the remainder of 2021 or losses 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 and nine months ended September 30, 2021 and 2020. Accordingly, there were no provisions for income taxes for the three and nine months ended September 30, 2021 and 2020. Additionally, as of September 30, 2021 and December 31, 2020, we maintain a full valuation allowance for all deferred tax assets.

13. Loss per common share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (47,420)	$ (32,612)	$ (129,455)	$ (141,437)
Denominator:				
Weighted average common shares for basic loss per common share	422,216	272,565	388,111	271,969
Effect of dilutive securities	—	—	—	—
Weighted average common shares for diluted loss per common share	422,216	272,565	388,111	271,969
Loss per common share, basic and diluted	$ (0.11)	$ (0.12)	$ (0.33)	$ (0.52)

Since we reported a net loss for the three and nine months ended September 30, 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 and nine months ended September 30, 2021 and 2020.

The following table sets forth the outstanding securities as of the periods presented which were not included in the calculation of diluted earnings per common share during the respective three and nine months ended September 30, 2021 and 2020 (in thousands):

	As of September 30,	
	2021	2020
Stock options	18,413	24,590
RSUs	16,118	6,030
PSUs	9,669	2,423
Warrants	5,127	1,783
	49,327	34,826

14. 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. For manufacturing activities, Catalent billed us $1.1 million and $0.5 million for the three months ended September 30, 2021 and 2020, respectively, and $2.6 million for the nine months ended September 30, 2021 and 2020. As of September 30, 2021 and December 31, 2020, we have estimated amounts payable to Catalent totaling less than $0.1 million and $0.3 million, 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, was 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. For various insurance premiums, AIG billed us less than $0.1 million for the nine months ended September 30, 2021, and $0.1 million and $0.2 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021 and December 31, 2020, we have no amounts payable to AIG.

15. Business concentrations

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

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

	Nine Months Ended September 30,	
	2021	2020
Customer A	10%	14%
Customer B	16%	8%
Customer C	18%	9%
Customer D	*	8%
Customer E	12%	*

* 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:

	September 30, 2021	December 31, 2020
Customer A	*	17%
Customer B	22%	19%
Customer C	32%	25%
Customer D	*	11%

* Balance was less than 10% of accounts receivable, gross

We rely on third parties for the manufacture and supply of our products, as well as third-party logistics providers. In instances where these parties fail to perform their obligations, we may be unable to find 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:

	Nine Months Ended September 30,	
	2021	2020
Catalent	27%	39%
Vendor A	41%	18%
Vendor B	30%	36%

* 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:

	September 30, 2021	December 31, 2020
Vendor E	15%	17%
Vendor F	23%	16%
Vendor G	*	10%
Vendor H	15%	*

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

Forward-looking statements

This 10-Q Report 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, as updated and supplemented by Part II, Item 1A of this 10-Q 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 ability to maintain the listing of our common stock on Nasdaq; our ability to continue as a going concern; 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, including product net revenue requirements and liquidity requirements; 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 and the manufacturing supplement for ANNOVERA; 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; potential disruptions in our supply chains related to our third party contract manufacturers and their ability to provide the materials necessary to manufacture our products, to successfully manufacture our products, and to timely ship bulk and finished product to their intended destinations; 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, Inc. ("vitaCare Prescription Services"), a Florida corporation, 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.

During the first nine months of 2021, the recovery from the COVID-19 pandemic drove improved access to health care providers for our sales force and increased consumer demand for our products, which had a positive impact on our net product revenue relating to ANNOVERA, IMVEXXY, and BIJUVA. We believe the growth in our net product revenue will continue to be affected by the pace of recovery from the COVID-19 pandemic.

Product portfolio

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

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 September 30, 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. In May 2021 we resubmitted the 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 has been accepted for review by the FDA with a target action date for the completion of the FDA's review under the Prescription Drug User Fee Act of March 21, 2022. 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 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. During the third quarter and the first nine months of 2021, we had BIJUVA sales of $0.7 million made through the Theramex License Agreement, and such sales were included as product revenue in the statement of operations. As of September 30, 2021, no BIJUVA sales have been made through the Knight License Agreement.

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 the 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 September 30, 2021 compared with three months ended September 30, 2020

Revenue. Our total revenue for the third quarter of 2021 was $25.4 million, an increase of $6.1 million, or 31.6%, compared to the third quarter of 2020. The following table sets forth our revenue during these periods (in thousands):

	Three Months Ended September 30,	
	2021	2020
ANNOVERA	$ 11,807	$ 6,419
IMVEXXY	8,016	6,841
BIJUVA	3,298	1,646
Prescription vitamin	1,348	2,436
Product revenue, net	24,469	17,342
License revenue	937	2,000
Total revenue, net	$ 25,406	$ 19,342

Our sales of ANNOVERA were $11.8 million for the third quarter of 2021, an increase of $5.4 million, or 83.9%, compared to the third quarter of 2020. This increase was primarily due to a 107.6% increase in sales volume, which was partially offset by a 11.4% decrease in the average sale price.

Our sales of IMVEXXY were $8.0 million for the third quarter of 2021, an increase of $1.2 million, or 17.2%, compared to the third quarter of 2020. This increase was primarily attributable to a 34.9% increase in the average sale price, which was partially offset by a 13.1% decrease in sales volume.

Our sales of BIJUVA were $3.3 million for the third quarter of 2021, an increase of $1.7 million, or 100.4%, compared to the third quarter of 2020. Included in our BIJUVA sales for the third quarter of 2021 was $0.7 million of sales made through the Theramex License Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA were $2.6 million for the third quarter of 2021, an increase of $1.0 million, or 58.0%, compared to the third quarter of 2020. This increase was primarily attributable to a 47.0% increase in the average sale price and a 7.5% 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 the 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.

Our prescription vitamin sales were $1.3 million for the third quarter of 2021, a decrease of $1.1 million, or 44.7%, compared to the third quarter of 2020. This decrease was primarily due to a 32.8% decrease in sales volume and a 17.6% decrease in the average sale price.

On a consolidated basis, our total product sales were $24.5 million for the third quarter of 2021, an increase of $7.1 million, or 41.1%, compared to the third quarter of 2020.

Our license revenue was $0.9 million for the third quarter of 2021, a decrease of $1.1 million, or 53.2%, compared to the third quarter of 2020. This decrease was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for the third quarter of 2021 was $20.1 million, an increase of $4.1 million, or 25.3%, compared to the third quarter of 2020. The following table sets forth our gross profit during these periods (in thousands):

	Three Months Ended September 30,	
	2021	2020
Product	$ 19,187	$ 14,063
License	937	2,000
Total gross profit	$ 20,124	$ 16,063

The increase in our gross profit was primarily a result of an increase of 41.1% in product revenue, partially offset by a 2.7% decrease in our product gross margin from 81.1% for the third quarter of 2020 to 78.4% for the third quarter of 2021. This decrease in product gross margins reflects the impact of $0.7 million of BIJUVA export sales, which were sold at cost.

Operating expenses. Total operating expenses for the third quarter of 2021 were $60.0 million, an increase of $19.0 million, or 46.3%, compared to the third quarter of 2020. Of the total increase, $7.3 million was related non-cash and cash severances recorded for certain former senior executives during the third quarter of 2021. The remining increase was $11.7 million, or 28.5%, compared to the third quarter of 2020. The type of operating expenses reported in prior periods have been reclassified to conform to the current period's presentation. The following table sets forth our operating expense categories (in thousands):

	Three Months Ended September 30,	
	2021	2020
Selling and marketing	$ 30,005	$ 22,373
General and administrative	28,435	16,637
Research and development	1,605	2,027
Total operating expenses	$ 60,045	$ 41,037

Our selling and marketing costs were $30.0 million for the third quarter of 2021, an increase of $7.6 million, or 34.1%, compared to the third quarter of 2020. This increase was primarily due to $6.4 million in higher advertising, $2.2 million in higher compensation and employee benefit costs 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, and $0.8 million in higher marketing costs. These increases were partially offset by $1.6 million in lower outsourced sales personnel costs mainly attributable to the onboarding of such sales personnel in the third quarter of 2020 and $0.5 million in lower product sample costs.

Our general and administrative costs were $28.4 million for the third quarter of 2021, an increase of $11.8 million, or 70.9%, compared to the third quarter of 2020. Of the total increase, $7.3 million was related to non-cash and cash severances recorded for certain former senior executives during the third quarter of 2021. The remaining increase was $4.5 million, or 27.0%, compared to the third quarter of 2020. This increase was primarily related to $2.9 million in higher compensation and employee benefit costs, of which $1.1 million was related to the accrual of bonuses expected to be paid in the first quarter of 2022, and $2.1 million in higher expenditures attributable to various professional fees, such as consulting, recruiting, legal, etc., in support of our efforts to expand the commercialization of our products. These increases were partially offset by $0.6 million in lower expenditures attributable to the write-off of certain intangible assets during the third quarter of 2020.

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 $1.6 million for the third quarter of 2021, a decrease of $0.4 million, or 20.8%, compared to the third quarter of 2020. This decrease was primarily attributable to $0.5 million in lower lab research costs, partially offset by $0.1 million in higher compensation and employee benefit costs. 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 third quarter of 2021, we had a loss from operations of $39.9 million, compared to $25.0 million for the third quarter of 2020. Of the $14.9 million total increase, $7.3 million was related non-cash and cash severances recorded for certain former senior executives during the third quarter of 2021. The remaining increase of $7.6 million was attributable to higher operating expenses, partially offset by $4.1 million in higher gross profit. 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 third quarter of 2021, our non-operating expenses were $7.5 million, compared to $7.6 million for the third quarter of 2020. This $0.1 million decrease was attributable to $1.3 million in lower interest expense due to overall lower average debt balance during the third quarter of 2021 compared to the third quarter of 2020, partially offset by the recording of an $0.7 million accrual for interest prepayment fees in the third quarter of 2021 associated with our future debt service, and $0.5 million in higher amortization expense of deferred financing costs.

Net Loss. For the third quarter of 2021, we had a net loss of $47.4 million, or $0.11 per basic and diluted common share, compared to $32.6 million, or $0.12 per basic and diluted common share, for the third quarter of 2020. Our net loss for the third quarter of 2021 included $7.3 million of non-cash and cash severances recorded for certain former senior executives. Without such severances, we would have had a net loss of $40.1 million, or $0.10 per basic and diluted common share, for the third quarter of 2021.

Nine months ended September 30, 2021 compared with nine months ended September 30, 2020

Revenue. Our total revenue for the first nine months of 2021 was $68.3 million, an increase of $26.0 million, or 61.4%, compared to the first nine months of 2020. The following table sets forth our revenue during these periods (in thousands):

	Nine Months Ended September 30,	
	2021	2020
ANNOVERA	$ 30,112	$ 10,527
IMVEXXY	24,866	18,319
BIJUVA	7,899	4,110
Prescription vitamin	4,225	7,338
Product revenue, net	67,102	40,294
License revenue	1,171	2,000
Total revenue, net	$ 68,273	$ 42,294

Our sales of ANNOVERA were $30.1 million for the first nine months of 2021, an increase of $19.6 million, or 186.0%, compared to the first nine months of 2020. This increase was primarily due to a 236.4% increase in sales volume, which was partially offset by a 15.0% decrease in the average sale price.

Our sales of IMVEXXY were $24.9 million for the first nine months of 2021, an increase of $6.5 million, or 35.7%, compared to the first nine months of 2020. This increase was primarily attributable to a 40.8% increase in the average sale price, which was partially offset by a 3.6% decrease in sales volume.

Our sales of BIJUVA were $7.9 million for the first nine months of 2021, an increase of $3.8 million, or 92.2%, compared to the first nine months of 2020. Included in our BIJUVA sales for the first nine months of 2021 was $0.7 million of sales made through the Theramex License Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA were $7.2 million for the third quarter of 2021, an increase of $3.1 million, or 75.2%, compared to the first nine months of 2020. This increase was primarily attributable to a 55.9% increase in the average sale price and a 12.4% 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.

Our prescription vitamin sales were $4.2 million for the first nine months of 2021, a decrease of $3.1 million, or 42.4%, compared to the first nine months of 2020. This decrease was primarily due to a 29.6% decrease in sales volume and a 18.2% decrease in the average sale price.

On a consolidated basis, our total product sales were $67.1 million for the first nine months of 2021, an increase of $26.8 million, or 66.5%, compared to the first nine months of 2020.

Our license revenue was $1.2 million for the first nine months of 2021, a decrease of $0.8 million, or 41.5%, compared to the first nine months of 2020. This decrease was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for the first nine months of 2021 was $54.2 million, an increase of $22.3 million, or 69.8%, compared to the first nine months of 2020. The following table sets forth our gross profit during these periods (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Product	$ 53,001	$ 29,900
License	1,171	2,000
Total gross profit	$ 54,172	$ 31,900

The increase in our gross profit was primarily a result of an increase of 66.5% in product revenue and a 4.8% increase in our product gross margin from 74.2% for the first nine months of 2020 to 79.0% for the first nine months of 2021. This increase was mainly due to $1.1 million in lower inventory obsolescence charges for the first nine months of 2021 compared to the first nine months of 2020, and an overall improvement in the profit margins of our products of 0.9%.

Operating expenses. Total operating expenses for the first nine months of 2021 were $158.6 million, an increase of $5.7 million, or 3.7%, compared to the first nine months of 2020. Of the total increase, $7.3 million was related non-cash and cash severances recorded for certain former senior executives during the third quarter of 2021. Without such severances, our total operating expenses for the first nine months of 2021 would have decreased by $1.6 million, or 1.0%, compared to the first nine months of 2020. The type of operating expenses reported in prior periods have been reclassified to conform to the current period's presentation. The following table sets forth our operating expense categories (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Selling and marketing	$ 86,193	$ 91,056
General and administrative	66,691	53,740
Research and development	5,666	8,038
Total operating expenses	$ 158,550	$ 152,834

Our selling and marketing costs were $86.2 million for the first nine months of 2021, a decrease of $4.9 million, or 5.3%, compared to the first nine months of 2020. This decrease was primarily due to $13.4 million in lower outsourced sales personnel costs mainly attributable to the onboarding of such sales personnel in the third quarter of 2020, $5.5 million in lower product sample costs mainly due to the third quarter of 2020 write down of product samples, primarily related to BIJUVA, and $2.5 million in lower marketing costs primarily related to a national selling and marketing event that occurred during the first nine months of 2020 prior to the COVID-19 pandemic. These decreases were partially offset by $9.3 million in higher advertising expenditures, $6.4 million in higher salaries and employee benefit costs 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, and $0.9 million and in higher costs related to physician education expenses and transportation expenses for traveling sales staff. Overall, our lower selling and marketing costs for the first nine months of 2021 reflect our cost cutting initiatives put in place at the beginning of the COVID-19 pandemic.

Our general and administrative costs were $66.7 million for the first nine months of 2021, an increase of $13.0 million, or 24.1%, compared to the first nine months of 2020. Of the total increase, $7.3 million was related non-cash and cash severances recorded for certain former senior executives during the third quarter of 2021. The remaining increase was $5.7 million, or 10.5%, compared to the first nine months of 2020. This increase was primarily attributable to $4.5 million in higher compensation and employee benefit costs, of which $2.3 million was related to the accrual of bonuses expected to be paid in the first quarter of 2022, $1.4 million in higher costs attributable to bad debt expense and insurance, and $1.1 million in higher professional fees, such as consulting, recruiting, legal, etc., in support of our efforts to expand the commercialization of our products. These increases were partially offset by $1.3 million in lower expenditures attributable to information technology and dues and subscriptions.

Our R&D costs were $5.7 million for the first nine months of 2021, a decrease of $2.4 million, or 29.5%, compared to the first nine months of 2020. This decrease was primarily attributable to $1.6 million in lower lab research costs, $0.4 million in lower compensation and employee benefit costs and $0.3 million in lower 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 nine months of 2021, we had a loss from operations of $104.4 million, compared to $120.9 million for the first nine months of 2020. This $16.5 million improvement was attributable to higher gross profit of $22.3 million, partially offset by $5.7 million in higher operating expenses. Our loss from operations for the first nine months of 2021 included $7.3 million of non-cash and cash severances recorded for certain former senior executives. Without such severances, we would have had a loss from operations of $97.1 million for the first nine months of 2021. 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 nine months of 2021, our non-operating expenses were $25.1 million, compared to $20.5 million for the first nine months of 2020. This $4.6 million increase was primarily attributable to a $4.0 million increase in interest prepayment fees, including the recording of an $1.5 million accrual for interest prepayment fees in the first nine months of 2021 associated with our future debt service, and $2.5 million in higher amortization expense of deferred financing costs. These increases were partially offset by $2.1 million in lower interest expense due to overall lower average debt balance during the first nine months of 2021 compared to the first nine months of 2020.

Net Loss. For the first nine months of 2021, we had a net loss of $129.5 million, or $0.33 per basic and diluted common share, compared to $141.4 million, or $0.52 per basic and diluted common share, for the first nine months of 2020. Our net loss for the first nine months of 2021 included $7.3 million of non-cash and cash severances recorded for certain former senior executives. Without such severances, we would have had a net loss of $122.2 million, or $0.31 per basic and diluted common share, for the first nine months of 2021.

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 September 30, 2021, we had cash totaling $104.8 million. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of approximately $0.3 million 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 28,600,689 shares of our common stock at an average sale price of $1.75 per share. For the 2020 ATM Program, we received net proceeds of $48.1 million, after deducting the discounts and commissions to the sales agent and estimated offering expenses.

In February 2021, we closed on an underwritten public offering of our common stock, pursuant to which we issued 59,459,460 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 sales agent 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 September 30, 2021, we have sold a total of 33,705,315 shares of our common stock under the 2021 ATM Program at an average sale price of $1.21 per share and we received estimated net proceeds of $38.8 million, after deducting discounts and commissions to the sales agent and estimated offering expenses. Subsequently, through the date of this 10-Q Report, 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).

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (103,135)	$ (129,114)
Net cash used in investing activities	(709)	(1,104)
Net cash provided by financing activities	128,199	49,022

Operating Activities. The principal use of cash in operating activities was to fund our current expenditures in support of our continued commercialization activities for IMVEXXY, BIJUVA, and ANNOVERA, sales, marketing, scale-up and manufacturing activities, adjusted for non-cash items. For the first nine months of 2021, net cash used in operating activities was $103.1 million, compared to net cash used in operating activities of $129.1 million for the first nine months of 2020. This decrease of $26.0 million, or 20.1%, was primarily due to a $12.0 million decrease in our net loss, a $12.2 million decrease in cash usage related to changes in operating assets and liabilities, and a $2.8 million increase in non-cash expenditure adjustments.

Investing Activities. For the first nine months of 2021, net cash used in investing activities was $0.7 million, compared to net cash used in investing activities of $1.1 million for the first nine months of 2020. This decrease of $0.4 million, or 35.8%, was primarily due to lower patent related costs.

Financing Activities. Financing activities currently represent the principal source of our cash flow. For the first nine months of 2021, net cash provided by financing activities was $128.2 million, compared to net cash provided by financing activities of $49.0 million for the first nine months of 2020. This increase of $79.2 million, or 161.5%, was primarily related to sales of our common stock, consisting of $182.9 million in net proceeds in 2021, partially offset by a $50.0 million in repayment of debt in 2021, a $3.9 million increase in the payment of debt financing fees in 2021, and $50.0 million in borrowing of debt in 2020.

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

Other liquidity measures

Receivable. Our net days sales outstanding (“DSO”) is calculated by dividing average gross accounts receivable less the reserve for doubtful accounts, chargebacks, and payment discounts by the average daily net product revenue during the last four quarters for each respective quarterly period. Our net DSO was 126 days as of September 30, 2021, compared to 165 days as of December 31, 2020 and 128 days as of September 30, 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. Our gross DSO was 61 days as of September 30, 2021, compared to 67 days as of December 31, 2020 and 50 days as of September 30, 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.

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

One of our third party contract manufacturers that manufactures ANNOVERA has recently experienced an increase in difficulties with the manufacturing process for ANNOVERA resulting in batch failures. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA consistently within the approved specification at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021 we filed a supplemental NDA to modify the manufacturing (testing) specification to allow for normal manufacturing variation that would increase the consistency of manufacturing and supply of ANNOVERA. There can be no assurance that such a modification will be approved by the FDA. If the FDA fails to approve the requested modification by the Prescription Drug User Fee Act (“PDUFA”) date of December 12, 2021, our third party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market or generate sufficient revenue to meet the covenants under the

Financing Agreement. If we are unable to 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.

If any of our third party contract manufacturers or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of an agreement between us, or do not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience additional interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations and financial position and ability to meet our revenue and other covenants under our Financing Agreement.

Debt. We had $200.0 million and $250.0 million in term loans outstanding under our Financing Agreement as of September 30, 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, we will need to raise additional capital to remain in compliance with the minimum cash balance covenant for the next twelve months from the date of this 10-Q Report. In order to address our projected capital needs, we are pursuing various equity financing and other alternatives including the sale of an interest in vitaCare Prescription Services for which we commenced a sale process. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this Quarterly Report on Form 10-Q.

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

The Financing Agreement also requires us to maintain certain minimum quarterly product net revenue requirements and several other restrictive covenants which could also be affected by the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third-party contract manufacturers. 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. The ultimate global recovery from the pandemic will be dependent on, among other things, actions taken by governments and businesses to contain and combat the virus, including any variant strains, the speed and effectiveness of vaccine production and global distribution, as well as how quickly, and to what extent, normal economic and operating conditions can resume on a sustainable basis globally.

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.

Going Concern

As of the filing date of this Quarterly Report on Form 10-Q, our cash balance was above the $60.0 million balance as required by the Financing Agreement. Based on our current projections, we will need to raise additional capital to remain in compliance with this minimum cash balance covenant for the next twelve months from the issuance of these financial statements. In order to address our projected capital needs, we are pursuing various equity financing and other alternatives including the sale of an interest in vitaCare Prescription Services for which we commenced a sale process. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this Quarterly Report on Form 10-Q.

If we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic or issues in our supply chains related to our third party contract manufacturers on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA. If we are unable to comply with these covenants 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. The presence of these projected factors in conjunction with the uncertainty of the capital markets raises substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these financial statements. Additionally, if circumstances were to require our independent registered public accounting firm to include a going concern uncertainty in their report on our annual consolidated financial statements, such matter would also take us out of compliance with certain of the Financing Agreement covenants. If we are unable to comply with these covenants 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.

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

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 formerly 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 $104.8 million as of September 30, 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 September 30, 2021, a 1.0% change in interest rates would result in an impact to loss before income taxes of $2.0 million per annum.

LIBOR is expected to be discontinued after 2021, with one-month LIBOR being discontinued in 2023. The Financing Agreement provides procedures for determining a replacement or alternative rate in the event that LIBOR is unavailable. We may also continue to elect the prime rate in the event that LIBOR is unavailable regardless of whether a replacement or alternative rate has been determined. The prime rate or LIBOR replacement or alternative rate may be more or less favorable to us than LIBOR. Due to these features of the Financing Agreement, we do not believe that the LIBOR transition will have a material impact on our financial statements.

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 September 30, 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. Except as set forth below, there have been no material changes to the Company's risk factors since the 2020 10-K Report.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

On September 15, 2021, we received a deficiency letter (the "Notice") from the Listing Qualifications Department (the "Staff") of Nasdaq notifying us that for the prior 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, which is the minimum closing price required to maintain continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). The Notice had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days to regain compliance with the Minimum Bid Requirement (the "Compliance Period"). To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days during the Compliance Period, at which time the Staff will provide written notification that the Company complies with the Minimum Bid Requirement. The Compliance Period expires on March 14, 2022.

If we do not regain compliance within the Compliance Period, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to meet the continued listing requirement for market value of publicly held shares and all other Nasdaq listing standards, with the exception of the Minimum Bid Requirement, and provide written notice to the Staff of our intention to cure the deficiency during the second 180 calendar day compliance period, including by effecting a reverse stock split, if necessary. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, the Staff could provide notice that our common stock will become subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any such delisting determination by the Staff to a Hearings Panel.

We will continue to monitor the closing bid price of our common stock and are evaluating available options to regain compliance with the Minimum Bid Requirement, including by effecting a reverse stock split. There can be no assurance that we will be able to regain compliance with the Minimum Bid Requirement or that we will otherwise remain in compliance with the other listing standards for the Nasdaq listing requirements. If we are unable to comply with the Nasdaq listing requirements, our common stock could be delisted from Nasdaq, which could have material adverse effects on our ability to finance our operations and our stockholders' ability to monetize the investment in our Company.

Even after the approval of IMVEXXY, BIJUVA, and ANNOVERA, and even if we obtain regulatory approval for other pharmaceutical product candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

With respect to IMVEXXY, BIJUVA, and ANNOVERA, the FDA may still impose significant restrictions on a product's indicated uses or marketing or to the conditions for approval or impose ongoing requirements for potentially costly post-approval studies, including phase 4 clinical trials or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for IMVEXXY, BIJUVA, and ANNOVERA contains restrictions on use and warnings. The Food and Drug Administration Amendments Act of 2007 ("FDAAA) gives the FDA enhanced post-market authority, including the Risk Evaluation and Mitigation Strategy ("REMS") explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. IMVEXXY, BIJUVA, and ANNOVERA will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance and reporting, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of

its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirement.

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 such as IMVEXXY. As part of the FDA's approval of ANNOVERA, the FDA has required four non-closed post-marketing studies, including both post-marketing reviews and post-marketing commitments. Each study has a timeline for completion and submission of a final report to the FDA. If a post-approval study is not fulfilled according to FDA requirements, the FDA may impose certain further requirements and/or penalties against the holder of the NDA. For ANNOVERA, certain of the studies are being performed by the Population Council. To the extent that the Population Council does not fulfil these studies to the FDA's satisfaction, FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA. In July 2021, we received a letter from the FDA indicating that the post-marketing commitment study being conducted by the Population Council for ANNOVERA to characterize the in vivo release rate of ANNOVERA was not fulfilled to FDA's satisfaction. In addition, the final reports for the two post-marketing requirement studies being performed by the Population Council for ANNOVERA were not submitted by the initial listed submission deadline, which deadlines have since been extended by FDA. We are working with Population Council to complete the post-marketing commitment study to the FDA's satisfaction and reduce the delay in submitting the post-marketing requirement final reports. To the extent that the Population Council does not fulfil these studies to the FDA's satisfaction, the FDA may impose additional requirements and penalties against us, as we hold the NDA for ANNOVERA.

Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our pharmaceutical product candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of an approved NDA also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of certain clinical trial results on a publicly available database.

Manufacturers of pharmaceutical products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's current Good Manufacturing Practice regulations and other regulatory requirements, such as adverse event reporting. If we or a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS program. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws and are subject to review by FDA. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and may be required to provide corrective information. Should we fail to comply with these requirements, we may be subject to significant liability including civil and administrative actions as well as criminal sanctions.

Commercial products must now meet the requirements of the Drug Supply Chain Security Act ("DSCSA") which imposes obligations on manufacturers of prescription pharmaceutical products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and re-packagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act ("PDMA") and its implementing regulations. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period

of years, with FDA indicating enforcement discretion on certain aspects due to the COVID-19 pandemic. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- exclude us from providing our products to those participating in government healthcare programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

Our dependence upon third parties for the manufacture and supply of our existing women's healthcare products may cause delays in, or prevent us from, successfully commercializing, and marketing our products.

We do not currently have, nor do we currently plan to build or acquire, the infrastructure or capability to internally manufacture our existing women's healthcare products, IMVEXXY, BIJUVA, and ANNOVERA. We have relied, and will continue to rely, on third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements, including the FDA's current Good Manufacturing Practice ("cGMPs"). We have entered into long-term supply agreements with Catalent Pharma Solutions, LLC for the commercial supply of IMVEXXY and BIJUVA. Under the terms of the agreements, we are obligated to purchase certain minimum annual amounts of each product. We have also entered into a long-term supply contract with QPharma AB, now known as Sever Pharma Solutions, for ANNOVERA. Under the terms of the QPharma AB agreement, we are obligated to purchase certain minimum annual amounts of ANNOVERA. We depend on Lang, a full-service, private label and corporate brand manufacturer, to supply our vitaMedMD and BocaGreen products. We do not have long-term contracts for the commercial supply of our vitaMedMD and BocaGreen products, however, in certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells.

Regulatory requirements could pose barriers to the manufacture of our women's healthcare products and our pharmaceutical product candidates. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third-party contract manufacturing organization ("CMO"). All of our existing products are manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. The CMO that manufactures IMVEXXY and BIJUVA has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that is used for the manufacture of the commercial supply of IMVEXXY and BIJUVA. The CMO that manufactures ANNOVERA has previously been inspected by the FDA and received Form 483 observations with respect to its facility that is used for the commercial supply of ANNOVERA. We believe that corrective actions to address the compliance issues identified in the referenced Forms 483 have been implemented by the CMOs; however, the FDA has not yet reinspected the CMOs to confirm that the corrective actions were implemented as described to the agency in the respective Form 483 responses.

If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, our regulatory submissions may be delayed or disapproved, and our marketed products may be affected. If these facilities are not in compliance for the manufacture of our products, we may need to find alternative manufacturing facilities, which would result in substantial disruptions of our sales of existing products and significant delays of up to several years in obtaining approval for our pharmaceutical product candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. After generally suspending in-person inspections due to COVID-19, the FDA announced it would resume domestic facility inspections, although the agency continues its general suspension of foreign facility inspections (although "mission-critical" inspections may be considered on a case-by-case basis). Because of the global pandemic, decision-making around facility inspections by the FDA (including preapproval inspections) continues to evolve. Failure by any of our manufacturers to comply with applicable cGMP regulations or other applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, violation letters, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which

could have an adverse impact on our business, financial condition, results of operations, and prospects. We do not currently have alternative manufacturers, and we may not be able to enter into a long-term agreement with alternative manufacturers, or do so on commercially reasonable terms, and if we do enter into agreements with alternative manufacturers, those alternative manufacturers may not be approved by the FDA, any of which could have an adverse impact on our business. We also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products to the delay or other detriment of our products and proposed products, or otherwise do not satisfactorily perform according to the terms of their agreements with us. Finally, we could experience manufacturing delays or interruptions as a result of the ongoing COVID-19 pandemic.

One of our third party contract manufacturer has recently experienced an increase in difficulties with the manufacturing process for ANNOVERA resulting in batch failures. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This has recently resulted in challenges to supply ANNOVERA consistently within the approved specification at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021 we filed a supplemental NDA with the FDA to modify the manufacturing (testing) specification to allow for normal manufacturing variation that would increase the consistency of manufacturing and supply of ANNOVERA. There can be no assurance that such a modification will be approved by the FDA. If the FDA fails to approve the requested modification by the PDUFA date of December 12, 2021, our third party contract manufacturer may not be able to supply us with sufficient ANNOVERA to adequately supply the market or generate sufficient revenue to meet the revenue covenants under the Financing Agreement. If we are unable to 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.

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

We also do not have long-term contracts for the supply of the API used in BIJUVA, and ANNOVERA. If any supplier of the API or other products used in our products or pharmaceutical product candidates experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of an agreement between us, or does not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our products or pharmaceutical product candidates, which could impair our ability to supply our products or pharmaceutical product candidates at the levels required for commercialization and prevent or delay their successful commercialization.

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

None.

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	Executive Employment Agreement, dated as of August 3, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd (1)
10.2	TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated as of August 31, 2021, by and between TherapeuticsMD, Inc. and Hugh O'Dowd(2)
10.3	Executive Employment Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman(3)
10.4	TherapeuticsMD, Inc. Inducement Grant Restricted Stock Unit Agreement, dated October 15, 2021, by and between TherapeuticsMD, Inc. and Mark Glickman(4)
10.5	Amendment to Employment Agreement between TherapeuticsMD, Inc. and James C. D'Arecca, dated October 15, 2021
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1**	Section 1350 Certification of Chief Executive Officer
32.2**	Section 1350 Certification of Chief Financial Officer
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set

* Filed herewith.

** Furnished herewith.

(1) Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 9, 2021 and incorporated herein by reference (File No. 001-00100).

(2) Filed as Exhibit 10.1 to the Company's Form S-8 filed with the SEC on August 31, 2021 and incorporated herein by reference (File No. 333-259221).

(3) Filed as Exhibit 10.1 to the Company's Form S-8 filed with the SEC on October 15, 2021 and incorporated herein by reference (File No. 333-260295).

(4) Filed as Exhibit 10.2 to the Company's Form S-8 filed with the SEC on October 15, 2021 and incorporated herein by reference (File No. . 333-260295).

Signatures

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

Date: November 12, 2021

TherapeuticsMD, Inc.

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.5

AMENDMENT TO JAMES D'ARECCA'S EMPLOYMENT AGREEMENT

This Amendment ("Amendment") to the Employment Agreement ("Agreement"), effective June 1, 2020, by and between **TherapeuticsMD, Inc.** with a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431 ("TherapeuticsMD"); and **James D'Arecca** with a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431 ("D'Arecca").

WHEREAS, the Agreement exists between TherapeuticsMD and D'Arecca (collectively herein as the "Parties") relating to the terms of D'Arecca's employment; and

WHEREAS, the Parties have agreed to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, intending to be legally bound, the Parties hereby agree as follows:

1. To replace Section 1(b) with the following:

Duties of Executive. Executive shall serve as the Chief Financial Officer of the Company, shall diligently perform all services as may be reasonably assigned to Executive by the Company's Board of Directors (the "Board") or the Company's Chief Executive Officer (the "CEO"). Executive shall exercise such power and authority as may from time to time be delegated to Executive by the Board or the CEO. Executive shall report solely and directly to the CEO. During Executive's employment, Executive shall devote substantially all of Executive's full business time, energy, and ability exclusively to the business and interests of the Company, shall generally be physically present at the Company's offices in Boca Raton, Florida during normal business hours each week (other than permitted periods of working remotely, paid time off ("PTO") and on appropriate business travel for the benefit of the Company and shall not, without the Company's prior written consent, be engaged in any other business activity pursued for gain, profit, or other pecuniary advantage if such activity interferes in any material respect with Executive's duties and responsibilities hereunder. In Executive's capacity as the Chief Financial Officer of the Company, Executive shall do and perform all services, acts, or things necessary or advisable to manage and conduct the business of the Company, subject to the policies and procedures set by the Company, including but not limited to performing the Company's budgeting and forecasting, record keeping, internal and external reporting; performing financial risk management; managing – in conjunction with the CEO – the Company's internal relations functions; managing the Company's fundraising plans and capital structure; maintaining the Company's SOX compliance program, managing the Company's cash flow, overseeing the Company's finance

systems; managing taxes, treasury, and other functions, and managing the finance organization. Except as otherwise agreed in writing by the Company, it shall not be a violation of this Agreement for Executive, and Executive shall be permitted, to (i) serve on any civic or charitable boards; (ii) deliver lectures, fulfill speaking engagements, or teach at educational institutions and other institutions; (iii) subject to any applicable Company policies, make personal investments in such form or manner as will neither require Executive's services in the operation or affairs of the companies or enterprises in which such investments are made nor subject Executive to any conflict of interest with respect to Executive's duties to the Company; and (iv) serve, with the written approval of the Board, as a director of one or more private or public companies, in each case so long as any such activities do not significantly interfere with the performance of Executive's responsibilities under this Agreement, create a conflict of interest, or create an adverse interest or position detrimental to Company.

2. Except as specifically referenced herein, the Agreement shall remain unchanged and shall continue in full force and effect.

This Amendment may be executed in any number of counterparts, each of which shall be enforceable against the Parties actually executing such counterparts, and all of which shall constitute one instrument.

[Remainder of page left intentionally blank]

TherapeuticsMD, Inc.

/s/ Robert Finizio — Date: 10/15/2021 | 9:38 AM EDT

Signature

Robert Finizio, Chief Executive Officer

Printed Name and Title

James D'Arecca

/s/ James D' Arecca — Date: 10/4/2021 | 5:14 PM EDT

Signature

James C. D'Arecca Chief Financial Officer

Printed Name and Title

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: November 12, 2021

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal 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: November 12, 2021

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer
(Principal 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 September 30, 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: November 12, 2021

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

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

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 September 30, 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: November 12, 2021

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer
(Principal Financial Officer)

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