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 June 30, 2022
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: **001-00100**

THERAPEUTICSMD, 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 August 8, 2022, there were 9,424,892 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
(Unaudited - in thousands, except per share data)

	June 30, 2022	December 31, 2021
Assets:		
Current assets:		
Cash	$ 26,303	$ 65,122
Restricted cash	11,250	—
Accounts receivable, net of allowance for credit losses of $1,587 and $1,334 as of June 30, 2022 and December 31, 2021, respectively	45,804	36,176
Inventory	6,150	7,622
Prepaid and other current assets	9,096	10,548
Total current assets	98,603	119,468
Fixed assets, net	710	1,199
License rights and other intangible assets, net	38,721	40,318
Right of use assets	7,914	8,234
Other non-current assets	254	253
Total assets	$ 146,202	$ 169,472
Liabilities and stockholders' deficit:		
Current liabilities:		
Current maturities of debt	$ 90,780	$ 188,269
Accounts payable	13,978	20,318
Accrued expenses and other current liabilities	59,228	44,304
Total current liabilities	163,986	252,891
Operating lease liabilities	7,728	8,063
Other non-current liabilities	554	2,139
Total liabilities	172,268	263,093
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Preferred stock, par value $0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value $0.001; 12,000 shares authorized, 8,860 and 8,598 (adjusted for the 50-for-1 reverse stock split) shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	9	9
Additional paid-in capital	962,025	957,730
Accumulated deficit	(988,100)	(1,051,360)
Total stockholders' deficit	(26,066)	(93,621)
Total liabilities and stockholders' deficit	$ 146,202	$ 169,472

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue, net:				
Product	$ 28,496	$ 22,951	$ 47,410	$ 42,583
License and service	65	50	484	284
Total revenue, net	28,561	23,001	47,894	42,867
Cost of goods sold	4,740	4,132	9,600	8,819
Total gross profit	23,821	18,869	38,294	34,048
Operating expenses:				
Selling and marketing	23,679	32,164	42,574	56,188
General and administrative	17,403	19,873	37,810	38,256
Research and development	1,580	2,011	2,980	4,061
Total operating expenses	42,662	54,048	83,364	98,505
Loss from operations	(18,841)	(35,179)	(45,070)	(64,457)
Other income (expense):				
Gain on sale of business	143,384	—	143,384	—
Loss on extinguishment of debt	—	—	(8,380)	—
Interest expense and other financing costs	(11,696)	(7,596)	(26,108)	(17,823)
Other income, net	(16)	123	(16)	245
Total other income (expense), net	131,672	(7,473)	108,880	(17,578)
Income (loss) before income taxes	112,831	(42,652)	63,810	(82,035)
Provision for income taxes	550	—	550	—
Net income (loss)	$ 112,281	$ (42,652)	$ 63,260	$ (82,035)
Earnings (loss) per common share, basic	$ 12.83	$ (5.41)	$ 7.29	$ (11.06)
Weighted average common shares, basic	8,750	7,881	8,682	7,416
Earnings (loss) per common share, diluted	$ 12.39	$ (5.41)	$ 7.05	$ (11.06)
Weighted average common shares, diluted	9,059	7,881	8,971	7,416
Comprehensive income (loss):				
Net income (loss)	$ 112,281	$ (42,652)	$ 63,260	$ (82,035)
Other comprehensive income	—	—	—	—
Comprehensive income (loss)	$ 112,281	$ (42,652)	$ 63,260	$ (82,035)

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

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

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, January 1, 2022	8,598	$ 9	$ 957,730	$ (1,051,360)	$ (93,621)
Shares issued for vested restricted stock units	71	—	—	—	—
Share-based compensation	—	—	2,062	—	2,062
Net loss	—	—	—	(49,021)	(49,021)
Balance, March 31, 2022	8,669	9	959,792	(1,100,381)	(140,580)
Shares issued for rounding up of fractional shares in connection with the reverse stock split	142	—	—	—	—
Shares issued for vested restricted stock units	44	—	—	—	—
Shares issued for sale of common stock related to employee stock purchase plan	5	—	14	—	14
Share-based compensation	—	—	2,219	—	2,219
Net income	—	—	—	112,281	112,281
Balance, June 30, 2022	8,860	$ 9	$ 962,025	$ (988,100)	$ (26,066)
Balance, January 1, 2021	5,996	$ 6	$ 754,938	$ (878,945)	$ (124,001)
Shares issued for sale of common stock, net of cost	1,857	2	150,897	—	150,899
Shares issued for exercise of warrants, net of cashless exercises	10	—	50	—	50
Shares issued for vested restricted stock units	1	—	—	—	—
Share-based compensation	—	—	2,957	—	2,957
Net loss	—	—	—	(39,383)	(39,383)
Balance, March 31, 2021	7,864	8	908,842	(918,328)	(9,478)
Shares issued for sale of common stock, net of cost	3	—	163	—	163
Shares issued for exercise of warrants	12	—	228	—	228
Shares issued for exercise of options	1	—	21	—	21
Shares issued for vested restricted stock units	19	—	—	—	—
Shares issued for sale of common stock related to employee stock purchase plan	3	—	134	—	134
Share-based compensation	—	—	2,510	—	2,510
Net loss	—	—	—	(42,652)	(42,652)
Balance, June 30, 2021	7,902	$ 8	$ 911,898	$ (960,980)	$ (49,074)

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

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net income (loss)	$ 63,260	$ (82,035)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	2,146	2,061
Charges (credits) to provision for doubtful accounts	542	445
Inventory charge	73	502
Debt financing fees	16,971	2,681
Share-based compensation	4,281	5,467
Gain on sale of business	(143,384)	—
Loss on extinguishment of debt	8,380	—
Other	(15)	434
Changes in operating assets and liabilities:		
Accounts receivable	(10,603)	(1,544)
Inventory	1,399	(83)
Prepaid and other current assets	1,373	365
Accounts payable	(5,591)	(6,503)
Accrued expenses and other current liabilities	16,913	12,940
Other non-current liabilities	(675)	358
Total adjustments	(108,190)	17,123
Net cash used in operating activities	(44,930)	(64,912)
Cash flows from investing activities:		
Proceeds from sale of business, net of transaction costs	142,634	—
Payment of patent related costs	(267)	(423)
Purchase of fixed assets	(20)	(104)
Net cash provided by (used in) investing activities	142,347	(527)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	—	151,062
Proceeds from exercise of options and warrants	—	299
Proceeds from sale of common stock related to employee stock purchase plan	14	134
Repayments of debt	(125,000)	(50,000)
Payment of debt financing fees	—	(5,118)
Net cash (used in) provided by financing activities	(124,986)	96,377
Net (decrease) increase in cash and restricted cash	(27,569)	30,938
Cash and restricted cash, beginning of period	65,122	80,486
Cash and restricted cash, end of period	$ 37,553	$ 111,424
Supplemental disclosure of cash flow information:		
Interest paid	$ 9,137	$ 14,284
Supplemental disclosure of noncash financing activities:		
Paid in kind ("PIK") debt financing fees with corresponding increase in debt	$ 15,780	$ —

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

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

General

TherapeuticsMD, Inc., a Nevada corporation (the "Company") and its consolidated subsidiaries are referred to collectively in this Quarterly Report on Form 10-Q ("10-Q Report") as "TherapeuticsMD," "we," "our" and "us." This 10-Q Report includes our trademarks, trade names and service marks, such as TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA®, which are protected under applicable intellectual property laws and are the property of, or licensed to, the Company. Solely for convenience, trademarks, trade names and service marks referred to in this 10-Q Report may appear without the ®, ™ 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.

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. ("vitaCare") with the sale of all of vitaCare's issued and outstanding capital stock (the "vitaCare Divestiture"). We received net proceeds of $142.6 million, net of transaction costs of $7.2 million, and we recognized a gain on sale of business of $143.4 million. Included in the net proceeds amount was $11.3 million of customary holdbacks as provided in the stock purchase agreement (the "Purchase Agreement"), which is recorded as restricted cash in the consolidated balance sheets. The restricted cash is held by an escrow agent and will be released to us in April 2023 upon a joint written direction from the buyer and us being delivered to the escrow agent to disburse to us an amount equal to the amount of escrow funds less any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement. Any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement shall be retained by the escrow agent until each such claim subject thereto is resolved. Additionally, we may receive up to an additional $7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement. We will record the contingent consideration at the settlement amount when the consideration is realized or realizable.

The Purchase Agreement contains customary representations and warranties, covenants, and indemnities of the parties thereto. In addition, upon closing of the vitaCare Divestiture, (i) we entered into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products, and (ii) we entered into a transition services agreement with vitaCare for us to provide certain transition services to vitaCare for up to 12 months following the closing. Under the long-term services agreement, we are required to pay to vitaCare a minimum service fee for each respective annual contract year. Our estimated minimum service fee commitments for vitaCare are as follows: $3.9 million for the period from July 1, 2022 to December 31, 2022, $10.7 million for 2023, $13.4 million for 2024, $15.4 million for 2025, $16.2 million for 2026, and $5.5 million for the period from January 1, 2027 to April 14, 2027.

COVID-19

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

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

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

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

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

Going concern

We incurred a loss from operations of $45.1 million and interest expense and other financing costs of $26.1 million during the six months ended June 30, 2022, and as of that date, our current liabilities exceeded our current assets by $65.4 million and our total liabilities exceeded our total assets by $26.1 million. We will need to raise additional capital to repay the entire principal balance of the Financing Agreement, dated as of April 24, 2019, as amended (the "Financing Agreement"), with Sixth Street Specialty Lending, Inc., as administrative agent (the "Administrative Agent" or "Sixth Street"), various lenders from time to time party thereto (the "Lenders"), and certain of our subsidiaries party thereto from time to time as guarantors, and to provide additional liquidity to fund our losses until our operations become cash flow positive. The Financing Agreement matures on September 30, 2022, with two extensions to October 31, 2022 and November 30, 2022 at the Company's option if, in each case, the Company receives not less than $7.0 million in cash proceeds from an equity issuance, which, if preferred equity, is on substantially the same terms as the Series A Preferred Stock.

To address our capital needs, we are pursuing various equity and debt refinancing and other strategic alternatives, including the possibility that we will file for Chapter 11 protection if our equity and debt refinancing or other strategic alternatives fail prior to the maturity date of our Financing Agreement. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock and the potential delisting of our common stock from the Nasdaq Global Select Market, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us. Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses.

On May 27, 2022, the Company, Athene Parent, Inc., a Nevada corporation (“Parent”), and Athene Merger Sub, Inc., a Nevada corporation and a wholly owned subsidiary of Parent (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”). Parent is an affiliate of investment funds advised by EW Healthcare Partners (“EW”). Under the Merger Agreement, Merger Sub commenced a tender offer (the “Offer”) to purchase all of the outstanding shares of the Company’s common stock at a purchase price of $10.00 per share, following completion of which Merger Sub would have been merged with and into the Company, with the Company becoming a wholly owned subsidiary of Parent (the “Merger”). Merger Sub did not acquire the required majority of shares of the Company’s common stock by the extended offer deadline of one minute after 11:59 PM Eastern Time on July 12, 2022 and the Offer expired in accordance with its terms. As the Offer Closing (as defined in the Merger Agreement) had not occurred on or before 11:59 p.m. Eastern Time on July 13, 2022, immediately after 11:59 PM Eastern Time on July 13, 2022 the Company delivered a written termination notice to Parent and Merger Sub terminating the Merger Agreement pursuant to the terms thereof, effective immediately.

See Note 16, Subsequent events for additional information regarding amendments to the Financing Agreement and equity financing developments.

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

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

Common stock reverse stock split

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

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

A. Basis of presentation

We prepared the consolidated financial statements included in this 10-Q Report following the requirements of the United States (“U.S.”) Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules, certain notes or other financial information that are normally required by accounting principles generally accepted in the U.S. (“U.S. GAAP”) for complete financial statements can be condensed or omitted. However, except as disclosed herein, there has been no material change in the information disclosed in the notes included in our 2021 Annual Report on Form 10-K ("2021 10-K Report").

Revenues, expenses, assets, liabilities, and equities can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be representative of those for the full year. In our opinion, all adjustments necessary for a fair statement of the financial statements, which are of a normal and recurring nature, have been made for the interim periods reported. The information included in this 10-Q Report should be read in conjunction with the consolidated financial statements and accompanying notes included in our 2021 10-K Report. Certain amounts in the consolidated financial statements and accompanying notes may not add due to rounding, and all percentages have been calculated using unrounded amounts.

B. New accounting standards

Adoption of new accounting standards

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

Accounting standards issued but not yet adopted

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

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

C. Estimates and assumptions

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

D. Significant accounting policies

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

Restricted Cash

Restricted cash is comprised of escrowed funds deposited with a bank relating to the vitaCare Divestiture.

E. Reclassification of prior year presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported consolidated balance sheets and consolidated statements of cash flows. An adjustment has been made to the consolidated statements of operations for the three and six months ended June 30, 2021 to reclassify vitaCare service revenue.

2. Accounts receivable

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

Balance as of January 1, 2022	$	1,334
Charges to provision for credit losses		542
Write-off of uncollectible receivables		(289)
Balance as of June 30, 2022	$	1,587

3. Inventory

Our inventory consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 434	$ 3,042
Work in process	1,683	1,642
Finished products	4,033	2,938
Inventory	$ 6,150	$ 7,622

We recorded no inventory charges for the three months ended June 30, 2022 and 2021, and $0.1 million and $0.5 million for the six months ended June 30, 2022 and 2021, respectively.

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

One of our third-party contract manufacturers that manufactures ANNOVERA experienced an increase in difficulties with manufacturing of ANNOVERA, which resulted in intermittent supply interruptions of ANNOVERA for commercial distribution. The challenges are multifactorial and include variability in raw material supply and normal manufacturing variation due to a semi-manual process. This resulted in challenges to supply ANNOVERA at a rate that meets the projected demand for ANNOVERA. To mitigate the manufacturing challenges, in August 2021, we filed a supplemental New Drug Application ("NDA") with the FDA to modify the testing specifications for ANNOVERA to allow increased consistency of supply of ANNOVERA. In December 2021, the FDA determined that it could not approve the supplemental NDA without additional information. In its complete response letter ("CRL"), the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided additional information to the FDA and modified the request to revise the manufacturing testing limits. In May 2022, the FDA approved the supplemental NDA for ANNOVERA. With this approval, we expect our third-party contract manufacturer will be able to supply us with sufficient ANNOVERA to better meet customer demand.

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

4. Prepaid and other current assets

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

	June 30, 2022	December 31, 2021
Insurance	$ 558	$ 2,731
Paragraph IV legal proceeding costs	2,309	2,304
Other	6,229	5,513
Prepaid and other current assets	$ 9,096	$ 10,548

5. Fixed assets

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

	June 30, 2022	December 31, 2021
Furniture and fixtures	$ 1,304	$ 1,407
Computer and office equipment	1,803	1,855
Computer software	375	375
Leasehold improvements	65	80
Fixed assets	3,547	3,717
Less: accumulated depreciation and amortization	2,837	2,518
Fixed assets, net	$ 710	$ 1,199

We recorded depreciation expense of $0.2 million for the three months ended June 30, 2022 and 2021, and $0.3 million and $0.4 million for the six months ended June 30, 2022 and 2021, respectively.

6. Licensed rights and other intangible assets

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

	June 30, 2022			December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Licensed rights and intangible assets subject to amortization:						
License rights	$ 40,000	$ 8,333	$ 31,667	$ 40,000	$ 6,826	$ 33,174
Hormone therapy drug patents	6,161	1,363	4,798	5,834	1,042	4,792
Hormone therapy drug patents applied and pending approval	1,936	—	1,936	2,020	—	2,020
License rights and other intangible assets subject to amortization	48,097	9,696	38,401	47,854	7,868	39,986
Intangible assets not subject to amortization:						
Trademarks/trade name rights	320	—	320	332	—	332
License rights and other intangible assets, net	$ 48,417	$ 9,696	$ 38,721	$ 48,186	$ 7,868	$ 40,318

We recorded amortization expense related to the exclusive license rights agreement with Population Council of $0.8 million for the three months ended June 30, 2022 and 2021, and $1.5 million for the six months ended June 30, 2022 and 2021. We recorded amortization expense related to patents of $0.1 million for the three months ended June 30, 2022 and 2021, and $0.3 million and $0.2 million for the six months ended June 30, 2022 and 2021, respectively.

7. Accrued expenses and other current liabilities

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

	June 30, 2022	December 31, 2021
Payroll and related costs	$ 9,194	$ 13,764
Rebates	24,267	11,010
Sales returns and coupons	2,452	2,422
Selling and marketing	4,619	2,850
Research and development expenses	2,212	1,995
Wholesale distributor fees	6,150	3,614
Professional fees	2,028	2,571
Operating lease liabilities	1,376	1,361
Interest payable	3,056	1,250
Income taxes payable	550	—
Other accrued expenses and current liabilities	3,324	3,467
Accrued expenses and other current liabilities	$ 59,228	$ 44,304

We expense advertising costs when incurred, which amounted to $5.9 million and $13.5 million for the three months ended June 30, 2022 and 2021, respectively, and $7.9 million and $19.8 million for the six months ended June 30, 2022 and 2021, respectively.

8. Debt

Our debt consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Financing Agreement	$ 90,780	$ 200,000
Less: deferred financing fees	-	11,731
Debt, net	$ 90,780	$ 188,269

Financing agreement

In March 2022, we entered into Amendment No. 9 to the Financing Agreement ("Amendment No. 9") pursuant to which, among other amendments, (i) the lenders waived various Company breaches of the Financing Agreement, including breaches of the $60.0 million minimum cash covenant and the minimum net revenue covenants for the fourth quarter of 2021; (ii) the Company and the lenders agreed to a reduced minimum cash covenant and to the removal of the minimum net revenue covenant for the first quarter of 2022; (iii) the lenders waived the existing $60.0 million prepayment penalty under the Financing Agreement and the Company agreed to pay a paid in kind ("PIK") amendment financing fee of $30.0 million, which fee was added to the principal amount of the loans under the Financing Agreement, $16.0 million of which fee was waivable in certain conditions; (iv) the maturity date of the Financing Agreement was amended to June 1, 2022; and (v) the Company agreed to pay to the Lenders as a prepayment of the loans under the Financing Agreement the first $120.0 million of net proceeds from the vitaCare Divestiture and all net proceeds of the vitaCare Divestiture in excess of $135.0 million. Amendment No. 9 was accounted for as an extinguishment of debt modification in accordance with U.S. GAAP. Accordingly, in March 2022, we recorded an $8.4 million loss on extinguishment of debt, which represented the unamortized deferred financing fees, net of previously accrued prepayment fees. Additionally, the Amendment No. 9 PIK financing fee was recorded as deferred financing fees and was amortized over the remaining term of the Financing Agreement. In April 2022, we utilized $120.0 million of net proceeds from the vitaCare Divestiture to make a prepayment of the loans under the Financing Agreement under the terms of Amendment No. 9. Additionally, with the prepayment on the debt, $16.0 million of the PIK financing fee was waived in accordance with Amendment No. 9.

In May 2022, we entered into Amendment No. 10 to the Financing Agreement ("Amendment No. 10") pursuant to which, among other amendments, (i) interest payments under the Financing Agreement were paused, such that interest on each term loan shall be payable in cash and in arrears (a) upon any prepayment of that term loan, whether voluntary or mandatory, to the extent accrued on the amount being prepaid and (b) on the maturity date, (ii) the minimum cash covenant was set at $10.0 million, (iii) the maturity date of the Financing Agreement was amended to July 13, 2022, (iv) the termination of the Merger Agreement was added as an event of default, and (v) we agreed to a PIK financing fee of $1.8 million, which fee was added to the principal amount of the loans under the Financing Agreement. Amendment No. 10 was accounted for as a debt amendment in accordance with U.S. GAAP. Accordingly, in May 2022, the Amendment No. 10 PIK financing fee was recorded as deferred financing fees and was amortized over the remaining term of the Financing Agreement.

As of June 30, 2022, there were no unamortized deferred financing fees.

Also in May 2022, we entered into Amendment No. 11 ("Amendment No. 11") to the Financing Agreement. Amendment No. 11 contains amendments to the Financing Agreement that would have gone into effect upon the satisfaction of certain conditions on or before July 13, 2022 (the "Amendment Effective Date"), including (i) the consummation of the Merger, (ii) the payment in cash of (a) all accrued and unpaid interest under the Financing Agreement through and including the Amendment Effective Date and (b) all fees, costs, expenses and taxes then payable pursuant to Section 2.7 or 10.2 of the Financing Agreement, and (iii) the delivery to the administrative agent of certain customary documents, including a Pledge Agreement, executed by Parent, with respect to the pledge of 100% of the capital stock of the Company. Since the consummation of the Merger did not occur, Amendment No. 11 never became effective.

Debt covenants

The Financing Agreement contains customary restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, we are required to maintain a minimum unrestricted cash balance. From February 7, 2022 to March 8, 2022, we did not maintain the required unrestricted cash balance of $60.0 million. In connection with Amendment No. 9, the lenders waived this event of default and reduced the required minimum unrestricted cash balance. As defined in Amendment No. 9, the minimum unrestricted cash balance was a base amount (the "Base Amount") minus specified payables, which fluctuated based on our accounts payable balance. As per Amendment No.9, the Base Amount decreases over the period from March 1, 2022 through May 7, 2022, and the Base Amount was $10.0 million minus specified payables from May 8, 2022 to May 26, 2022. As defined in Amendment No. 10, the minimum unrestricted cash balance was set at $10.0 million. Our unrestricted cash balance was above the minimum unrestricted cash balance covenant, as per Amendment Nos. 9 and 10, at all times from March 1, 2022 through August 15, 2022, the filing date of this 10-Q Report.

Interest and financing costs

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Interest expense	$ 3,773	$ 5,329	$ 9,137	$ 11,784
Interest prepayment fees	—	858	—	3,358
Financing fees amortization	7,923	1,409	16,971	2,681
Interest expense and other financing costs	$ 11,696	$ 7,596	$ 26,108	$ 17,823

9. Commitments and contingencies

Minimum purchase commitments

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

Furthermore, in connection with the vitaCare Divestiture, we entered into a long-term services agreement with vitaCare to continue utilization of the vitaCare platform with respect to our products. Under the long-term services agreement, we are required to pay to vitaCare a minimum service fee for each respective annual contract year. The annual contract period for vitaCare services ends each April.

For each of the three annual contract years ending in 2022 for BIJUVA, IMVEXXY and ANNOVERA, we have met our minimum purchase number of units in all material respects. For annual contract years ending in 2023 and thereafter for BIJUVA, IMVEXXY, ANNOVERA, and vitaCare Services, we will continue to evaluate whether we will be able to meet each annual contract year's respective minimum purchase commitment and will record a liability for estimated minimum commitment fees if we believe that we will not be able to reasonably meet the minimum purchase commitment. We believe that minimum commitment fees that we may pay in 2022 and 2023, if any, will not have a material impact to our financial position and operating results.

Legal proceedings

IMVEXXY patents

In February 2020, we received a Paragraph IV certification notice letter (the "IMVEXXY Notice Letter") regarding an Abbreviated New Drug Application ("ANDA") submitted to the FDA by Teva Pharmaceuticals USA, Inc. ("Teva"). The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the IMVEXXY Notice Letter, Teva alleges that TherapeuticsMD patents listed in the FDA's Orange Book that claim compositions and methods of IMVEXXY (the "IMVEXXY Patents") are invalid, unenforceable, and/or will not be infringed by Teva's commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the IMVEXXY Notice Letter expire in 2032 or 2033. In April 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed.

In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal. In September 2021, the District Court made available a public version of the order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents the FDA from granting final approval of the ANDA for 30 months from the date of the IMVEXXY Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

As of June 30, 2022, for the IMVEXXY Paragraph IV legal proceeding, we have incurred and recorded legal costs amounting to $2.3 million in prepaid expenses and other current assets since we believe that we will successfully prevail in this legal proceeding. Upon the successful conclusion of the legal proceeding, the related capitalized legal costs will be reclassified to patents, in license rights and other intangible assets, net, in the accompanying consolidated balance sheets, and such costs will be amortized over the remaining useful life of the patents. If we are unsuccessful in this legal proceeding, then the related capitalized legal costs for this legal preceding and any unamortized IMVEXXY patent costs that were previously capitalized will be immediately expensed in the period in which we become aware of an unsuccessful legal proceeding.

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

10. Stockholders' equity (deficit)

Warrants

As of June 30, 2022, the following table summarizes the status of our outstanding and exercisable warrants and related transactions (each adjusted to account for the 50-for-1 reverse stock split) since December 31, 2021 (in thousands, except weighted average exercise price and weighted average remaining contractual life data):

	Outstanding				Exercisable			
	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of January 1, 2022	103	$ 76.19	$ —	8.3	103	$ 76.19	$ —	8.3
Granted	1	58.50						
Expired	(3)	341.50						
As of June 30, 2022	101	$ 69.45	$ —	7.9	101	$ 69.51	$ —	7.9

Share-based compensation payment plans

As of June 30, 2022, 691,825 shares of common stock were subject to outstanding awards under our share-based payment award plans and inducement grants (calculated using the base number of PSUs that may vest). If we assume the maximum achievement of performance goals for PSUs, then 799,833 shares of common stock will be subject to outstanding awards under our share-based payment award plans and inducement grants. As of June 30, 2022, 203,125 shares of common stock were available for future grants of share-based payment awards under the TherapeuticsMD, Inc. 2019 Stock Incentive Plan.

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

	Outstanding				Exercisable			
	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)	Options Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (in Years)
As of January 1, 2022	353	$ 225.98	$ -	3.8	336	$ 230.93	$ -	3.6
Cancelled/Forfeited	(1)	129.65						
Expired	(95)	243.77						
As of June 30, 2022	257	$ 219.75	$ -	3.6	246	$ 224.15	$ -	3.5

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

	Outstanding			Vested and not settled		
	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	RSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of January 1, 2022	272	$ 58.93	$ 4,891	31	$ 105.28	$ 566
Granted	106	21.71				
Vested and settled	(63)	81.39	787			
Cancelled/Forfeited	(34)	55.33				
As of June 30, 2022	281	$ 40.20	$ 2,783	10	$ 77.67	$ 102

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

	Outstanding			Vested and not settled		
	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value	PSUs	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
As of January 1, 2022	164	$ 51.50	$ 2,953	39	$ 58.81	$ 709
Granted	63	34.50				
Vested and settled	(52)	58.26	108			
Cancelled/Forfeited	(20)	58.69				
As of June 30, 2022	155 (1)	$ 41.41	$ 1,543	—	$ —	$ —

(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 263,048 depending on the Company's achievement of certain performance goals.

Share-based payment compensation cost

Share-based payment compensation cost for PSUs is based on our current assessment of the most likely probability of the Company's achievement of certain performance goals. In connection with previously granted options, RSUs and PSUs, and shares of common stock issuable under the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan ("ESPP"), we recorded share-based payment compensation costs of $2.2 million and $2.5 million for the three months ended June 30, 2022 and 2021, respectively, and $4.3 million and $5.5 million for the six months ended June 30, 2022 and 2021, respectively.

As of June 30, 2022, we had $12.2 million of unrecognized share-based payment award compensation cost related to unvested options, RSUs and PSUs as well as shares issuable under the ESPP, which may be adjusted if certain performance targets are achieved and for future changes in forfeitures and is included as additional paid-in capital in the accompanying consolidated balance sheets. No tax benefit was realized due to a continued pattern of net losses. The unrecognized compensation cost as of June 30, 2022 is expected to be recognized as share-based payment award compensation over a weighted average period of 2.2 years as follows (in thousands):

Year Ending December 31,		
2022 (6 months)	$	3,277
2023		5,193
2024		3,331
2025		352
	$	12,153

11. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue:				
ANNOVERA	$ 18,271	$ 9,555	$ 26,781	$ 18,305
IMVEXXY	6,667	9,838	13,636	16,850
BIJUVA	2,654	2,156	5,214	4,601
Prescription vitamin	904	1,402	1,779	2,827
Product revenue, net	28,496	22,951	47,410	42,583
License and service	65	50	484	284
Total revenue, net	$ 28,561	$ 23,001	$ 47,894	$ 42,867

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

BIJUVA sales through the Theramex License Agreement started in the third quarter of 2021, and we recorded BIJUVA sales through the Theramex License Agreement of $0.3 million and $1.0 million for the three and six months ended June 30, 2022, respectively. As of June 30, 2022, no BIJUVA sales have been made through the Knight License Agreement, and no IMVEXXY sales have been made through either of the licensing agreements.

12. Income taxes

We do not expect to pay any significant federal income taxes as a result of (i) losses expected for the remainder of 2022 or losses recorded in 2021, or (ii) net operating losses carry forwards from prior years.

For the three and six months ended June 30, 2022, we recorded a provision for income taxes of $0.6 million due to limitation of using net operating losses carry forwards in certain states. For the three and six months ended June 30, 2021, no provision or benefits for income taxes were recorded since we recorded net losses and full valuation allowance for such periods. As of June 30, 2022 and December 31, 2021, we maintain a full valuation allowance for all deferred tax assets.

13. Earnings (loss) per common share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	$ 112,281	$ (42,652)	$ 63,260	$ (82,035)
Denominator:				
Weighted average common shares for basic loss per common share	8,750	7,881	8,682	7,416
Effect of dilutive securities	309	—	289	—
Weighted average common shares for diluted loss per common share	9,059	7,881	8,971	7,416
Earnings (loss) per common share, basic	$ 12.83	$ (5.41)	$ 7.29	$ (11.06)
Earnings (loss) per common share, diluted	$ 12.39	$ (5.41)	$ 7.05	$ (11.06)

Since we reported a net loss for the three and six months ended June 30, 2021, our potentially dilutive securities are deemed to be anti-dilutive, accordingly, there was no effect of dilutive securities. Therefore, our basic and diluted loss per common share and our basic and diluted weighted average common share are the same for the three and six months ended June 30, 2021.

The following table sets forth the outstanding securities as of the periods presented which were not included in the calculation of diluted earnings per common share during the respective three and six months ended June 30, 2022 and 2021 (in thousands):

	As of June 30,	
	2022	2021
Stock options	257	470
RSUs	—	128
PSUs	155	48
Warrants	101	103
	513	749

14. Related parties

A former member of our Board, J. Martin Carroll, who resigned in December 2021, is a member of Catalent's Board. Accordingly, Catalent ceased to be a related a party to the Company in December 2021. From time to time, we have entered into agreements with Catalent and its affiliates in the normal course of business. From July 2015 to December 2021, agreements with Catalent have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For manufacturing activities, Catalent billed us $0.7 million and $1.5 million for the three and six months ended June 30, 2021. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 9, Commitments and contingencies.

A member of our Board, Karen L. Ling, was an executive vice president and chief human resources officer of American International Group, Inc. ("AIG") until May 2021, which is when AIG ceased to be a related a party to the Company. From time to time, we have entered into agreements with AIG in the normal course of business. From April 2020 to May 2021, agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company. For various insurance premiums, AIG billed us less than $0.1 million for the three and six months ended June 20, 2021.

15. Business concentrations

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

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

	Six Months Ended June 30,	
	2022	2021
Customer A	*	14%
Customer B	17%	17%
Customer C	16%	19%
Customer E	11%	*
Customer F	14%	*

* Less than 10% of total product revenue

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

	June 30, 2022	December 31, 2021
Customer B	20%	21%
Customer C	27%	35%
Customer D	*	11%
Customer F	22%	*
Customer G	12%	*

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

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

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

	Six Months Ended June 30,	
	2022	2021
Catalent	23%	28%
Vendor A	47%	42%
Vendor B	27%	29%

* 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:

	June 30, 2022	December 31, 2021
Vendor E	12%	19%
Vendor F	23%	20%

* Balance was less than 10% of total accounts payable

16. Subsequent events

On July 13, 2022, we entered into Amendment No. 12 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 24, 2022, and we agreed to pay the Lenders a PIK amendment fee in the amount of $1.2 million.

On July 24, 2022, we entered into Amendment No. 13 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 27, 2022, we agreed to pay the Lenders a payment of accrued and unpaid interest of $2.9 million, and we agreed to retain Jeffrey Varsalone from G2 Capital Advisors as our chief restructuring officer.

On July 27, 2022, we entered into Amendment No. 14 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 28, 2022.

On July 28, 2022, we entered into Amendment No. 15 to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to July 29, 2022.

On July 29, 2022, we entered into a Subscription Agreement (the "Subscription Agreement") with Rubric Capital Management LP (the "Investor"), pursuant to which we issued and sold, in a private placement offering (the "Offering"), (i) 15,000 shares of the Company's newly-designated Series A Preferred Stock, par value $0.001 per share ("Preferred Stock"), for a purchase price per share of Preferred Stock equal to $822.21 and an aggregate purchase price of $12.3 million, and (ii) 565,000 shares of the Company's common stock, par value $0.001 per share ("Common Stock"), for a purchase price per share of Common Stock equal to $4.72 and an aggregate purchase price of $2.7 million. The Subscription Agreement contains customary representations, warranties and agreements by the Company and the Investor. The Offering closed on July 29, 2022 (the "Closing"). We received aggregate gross proceeds of $15.0 million from the Offering, before expenses, and we intend to use the net proceeds from the Offering for working capital and general corporate purposes. The Preferred Stock is not convertible into Common Stock and ranks senior to Common Stock, with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the Preferred Stock has a liquidation preference equal to $1,333 per share. The Preferred Stock will not have any voting rights other than as required by applicable law. The holders of Preferred Stock are entitled to dividends equal to 25% of cash dividends actually paid, if any, on shares of Common Stock, paid pro rata on the outstanding shares of Preferred Stock. If the Company undergoes certain change of control transactions, the holders of Preferred Stock may require the Company to redeem their shares of Preferred Stock at a redemption price per share of Preferred Stock, payable in cash, equal to the liquidation preference of $1,333 per share of Preferred Stock. We also have the option to redeem the shares of Preferred Stock on such terms if the Company undergoes certain change of control transactions. Each holder of the Preferred Stock has the right to cause the Company to redeem all, but not less than all, of their shares of the Preferred Stock upon the occurrence of certain events, including, without limitation, the Company's failure to comply with any covenants under the Certificate of Designation filed with the Secretary of State of the State of Nevada or if the Company commences a bankruptcy proceeding, subject to certain conditions. Under such circumstances, the Company is required to redeem all, but not less than all, of the holder's outstanding shares of Preferred Stock at a redemption price per share of Preferred Stock, payable in cash, equal to the liquidation preference of $1,333 per share. The Preferred Stock matures on December 31, 2022, subject to certain extension terms, as set forth in the Certificate of Designation, and the Company is required to redeem the shares on such date at a redemption price per share of Preferred Stock, payable in cash, equal to the liquidation preference of $1,333 per share.

On July 29, 2022, the Company entered into Amendment No. 16 ("Amendment No. 16") to the Financing Agreement pursuant to which the maturity date of the Financing Agreement was extended to September 30, 2022, and we will have the option to further extend the maturity date to October 31, 2022, and November 30, 2022, in each case if the Company receives not less than $7.0 million in cash proceeds from an equity issuance, which, if preferred equity, is on substantially the same terms as the Preferred Stock. In lieu of a cash amendment fee, to induce the Lenders to enter into Amendment No. 16, on July 29, 2022, the Company issued warrants (the "Lender Warrants"), to the Lenders to purchase an aggregate of 185,000 shares of Common Stock, pursuant to a subscription agreement by and among the Company and the Lenders (the "Lender Subscription Agreement"). The Lender Warrants have an exercise price of $0.01 per share of Common Stock, subject to certain adjustment as provided therein, and an expiration date of November 26, 2022. The Lender Warrants may also be exercised via cashless exercise pursuant to the terms thereof. No registration rights were issued pursuant to the Lender Warrants or Lender Subscription Agreement.

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

The following discussion should be read in conjunction with our 2021 Annual Report on Form 10-K ("2021 10-K Report"), and the consolidated financial statements and related notes in Item 1, Financial Statements, appearing elsewhere in this this Quarterly Report on Form 10-Q ("10-Q Report"). The following discussion may contain forward-looking statements, and our actual results may differ materially from the results suggested by these forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A of our 2021 10-K Report under the heading "Risk Factors," as updated and supplemented by Part II, Item 1A of this 10-Q Report. The Company assumes no obligation to revise or update any forward-looking statements for any reason, except as required by law. Certain amounts in the following discussion may not add due to rounding, and all percentages have been calculated using unrounded amounts.

Forward-looking statements

This 10-Q Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve substantial risks and uncertainties. For example, statements regarding our operations, financial position, debt position, liquidity, business strategy, product development, and other plans and objectives for future operations, and assumptions and predictions about future product development and demand, cost reduction strategies, research and development ("R&D"), marketing, expenses and sales are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect," or the negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date of this 10-Q Report, and but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. We do not undertake to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments, except as required by law or by the rules and regulations of the SEC.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Factors that could cause or contribute to such differences include, but are not limited to, our liquidity requirements, supply chain issues, management transitions, risks related to the Financing Agreement, market and general economic factors, and the other risks discussed in Part I, Item 1A of our 2021 10-K Report, as updated and supplemented by Part II, Item 1A of this 10-Q Report.

Business overview

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

vitaCare Divestiture

On April 14, 2022, we completed the divestiture of vitaCare Prescription Services, Inc. ("vitaCare") with the sale of all of vitaCare's issued and outstanding capital stock (the "vitaCare Divestiture"). We received net proceeds of $142.6 million, net of transaction costs of $7.2 million, and we recognized a gain on sale of business of $143.4 million. Included in the net proceeds amount was $11.3 million of customary holdbacks as provided in the stock purchase agreement (the "Purchase Agreement"), which is recorded as restricted cash in the consolidated balance sheets. The restricted cash is held by an escrow agent and will be released to us in April 2023 upon a joint written direction from the buyer and us being delivered to the escrow agent to disburse to us an amount equal to the amount of escrow funds less any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement. Any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement shall be retained by the escrow agent until each such claim subject thereto is resolved. Additionally, we may receive up to an additional $7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement. We will record the contingent consideration at the settlement amount when the consideration is realized or realizable.

The Purchase Agreement contains customary representations and warranties, covenants and indemnities of the parties thereto. In addition, upon closing of the vitaCare Divestiture, (i) we entered into a long-term services agreement with vitaCare to continue utilization

of the vitaCare platform with respect to our products, and (ii) we entered into a transition services agreement with vitaCare for us to provide certain transition services to vitaCare for up to 12 months following the closing.

COVID-19

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

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

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

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

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

Going concern

We incurred a loss from operations of $45.1 million and interest expense and other financing costs of $26.1 million during the six months ended June 30, 2022, and as of that date, our current liabilities exceeded our current assets by $65.4 million and our total liabilities exceeded our total assets by $26.1 million. We will need to raise additional capital to repay the entire principal balance of the Financing Agreement, dated as of April 24, 2019, as amended (the "Financing Agreement"), with Sixth Street Specialty Lending, Inc., as administrative agent (the "Administrative Agent" or "Sixth Street"), various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, and to provide additional liquidity to fund our losses until our operations become cash flow positive. The Financing Agreement matures on September 30, 2022, with two extensions to October 31, 2022 and November 30, 2022 at the Company's option if, in each case, the Company receives not less than $7.0 million in cash proceeds from an equity issuance, which, if preferred equity, is on substantially the same terms as the Series A Preferred Stock.

To address our capital needs, we are pursuing various equity and debt refinancing and other strategic alternatives, including the possibility that we will file for Chapter 11 protection if our equity and debt refinancing or other strategic alternatives fail prior to the maturity date of our Financing Agreement. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions, including the market price of our common stock and the potential delisting of our common stock from the Nasdaq Global Select Market, and our available authorized shares. To the extent that we raise additional capital through the sale of such securities, the ownership interests of

our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we are not successful in obtaining additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us. Along with considering additional financings, we have reviewed numerous potential scenarios in connection with steps that we may take to reduce our operating expenses.

On May 27, 2022, the Company, Athene Parent, Inc., a Nevada corporation ("Parent"), and Athene Merger Sub, Inc., a Nevada corporation and a wholly owned subsidiary of Parent ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement"). Parent is an affiliate of investment funds advised by EW Healthcare Partners ("EW"). Under the Merger Agreement, Merger Sub commenced a tender offer (the "Offer") to purchase all of the outstanding shares of the Company's common stock at a purchase price of $10.00 per share, following completion of which Merger Sub would have been merged with and into the Company, with the Company becoming a wholly owned subsidiary of Parent (the "Merger"). Merger Sub did not acquire the required majority of shares of the Company's common stock by the extended offer deadline of one minute after 11:59 PM Eastern Time on July 12, 2022 and the Offer expired in accordance with its terms. As the Offer Closing (as defined in the Merger Agreement) had not occurred on or before 11:59 p.m. Eastern Time on July 13, 2022, immediately after 11:59 PM Eastern Time on July 13, 2022 the Company delivered a written termination notice to Parent and Merger Sub terminating the Merger Agreement pursuant to the terms thereof, effective immediately.

See Note 16, Subsequent events, in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report for additional information regarding amendments to the Financing Agreement and equity financing developments.

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

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

Product portfolio

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

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

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

In August 2021, we filed a supplemental New Drug Application ("NDA") with the FDA to modify the testing specifications for ANNOVERA to allow increased consistency of supply of ANNOVERA. In December 2021, the FDA determined that it could not approve the supplemental NDA without additional information. In its complete response letter ("CRL"), the FDA provided recommendations and requested additional information that could support approval of revisions to certain testing specifications. In January 2022, we responded to the CRL, and provided additional information to the FDA and modified the request to revise the manufacturing testing limits. In May 2022, the FDA approved the supplemental NDA for ANNOVERA. We have continued to manufacture and supply ANNOVERA under the existing specifications as well as (i) ramping up manufacturing sufficient to better meet future demand notwithstanding existing challenges, (ii) adding resources to increase production volumes, (iii) increasing yield per manufacturing batch, and (iv) increasing production capacity to better meet product demands to realize revenue potential, including

reducing dependency on labor resources, increasing efficiency in manufacturing and testing, and automating some of the processes. With the FDA approval of the supplemental NDA, we expect our third-party contract manufacturer will be able to supply us with sufficient ANNOVERA to better meet customer demand.

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

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

We market and sell IMVEXXY in the U.S. and have entered into licensing agreements with third parties to market and sell IMVEXXY outside of the U.S. We have entered into a license and supply agreement (the "Knight License Agreement"), with Knight Therapeutics, Inc. ("Knight") pursuant to which, we granted Knight an exclusive license to commercialize IMVEXXY in Canada and Israel. We have entered into a licensing and supply agreement (the "Theramex License Agreement") with Theramex HQ UK Limited ("Theramex") pursuant to which we granted Theramex an exclusive license to commercialize IMVEXXY for human use outside of the U.S., except for Canada and Israel. As of June 30, 2022, no IMVEXXY sales have been made through these licensing agreements.

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

This pharmaceutical product is the first and only FDA approved bioidentical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus. We market and sell BIJUVA in the U.S. and have entered into licensing agreements with third parties to market and sell BIJUVA outside of the U.S. We have entered into the Knight License Agreement with Knight pursuant to which we granted Knight an exclusive license to commercialize BIJUVA in Canada and Israel. We have entered into the Theramex License Agreement with Theramex pursuant to which we granted Theramex an exclusive license to commercialize BIJUVA for human use outside of the U.S., except for Canada and Israel. BIJUVA sales through the Theramex Licenses Agreement started in the first quarter of 2022, and we recorded BIJUVA sales through the Theramex License Agreement of $0.3 million and $1.0 million for the three and six months ended June 30, 2022. As of June 30, 2021, no BIJUVA sales have been made through the Knight License Agreement.

Prenatal vitamin products

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

Results of operations

Three months ended June 30, 2022 compared with three months ended June 30, 2021

Revenue. Our total revenue for the second quarter of 2022 was $28.6 million, an increase of $5.6 million, or 24.2%, compared to the second quarter of 2021.

The following table sets forth our revenue during these periods (in thousands):

	Three Months Ended June 30,	
	2022	2021
Product revenue:		
ANNOVERA	$ 18,271	$ 9,555
IMVEXXY	6,667	9,838
BIJUVA	2,654	2,156
Prescription vitamin	904	1,402
Product revenue, net	28,496	22,951
License and service	65	50
Total revenue, net	$ 28,561	$ 23,001

Our sales of ANNOVERA were $18.3 million for the second quarter of 2022, an increase of $8.7 million, or 91.2%, compared to the second quarter of 2021. This increase was primarily due to a 102.0% increase in sales volume partially offset by a 5.3% decrease in the average sale price.

Our sales of IMVEXXY were $6.7 million for the second quarter of 2022, a decrease of $3.2 million, or 32.2%, compared to the second quarter of 2021. This decrease was primarily due to a 12.5% decrease in sales volume and a 22.6% decrease in the average sale price.

Our sales of BIJUVA were $2.7 million for the second quarter of 2022, an increase of $0.5 million, or 23.1%, compared to the second quarter of 2021. Included in our BIJUVA sales for the second quarter of 2022 was $0.3 million of sales made through the Theramex License Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA were $2.3 million for the second quarter of 2022, an increase of $0.2 million, or 7.0%, compared to the second quarter of 2021. This increase was primarily attributable to a 10.5% increase in sales volume partially offset by a 3.2% decrease in the average sale price.

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

Our prescription vitamin sales were $0.9 million for the second quarter of 2022, a decrease of $0.5 million, or 35.5%, compared to the second quarter of 2021. This decrease was primarily due to a 16.3% decrease in sales volume and a 23.0% decrease in the average sale price.

On a consolidated basis, our total product sales were $28.5 million for the second quarter of 2022, an increase of $5.5 million, or 24.2%, compared to the second quarter of 2021.

We recorded service revenue related to pharmacy services provided by our vitaCare business to pharmaceutical companies of $0.1 million for the second quarter of 2022 and 2021. We recorded no license revenue for the second quarter of 2022 and 2021.

Gross profit. Our gross profit for the second quarter of 2022 was $23.8 million, an increase of $5.0 million, or 26.2%, compared to the second quarter of 2021. The following table sets forth our gross profit during these periods (in thousands):

	Three Months Ended June 30,	
	2022	2021
Product	$ 23,756	$ 18,819
License and service	65	50
Total gross profit	$ 23,821	$ 18,869

The increase in our gross profit was a result an increase of 1.4% in our product gross margin to 83.4% and an increase of 24.2% in product revenue for the second quarter of 2022. The increase in product gross margins was mainly due to changes in product sales mix as result of increases in sales volumes for ANNOVERA and BIJUVA, and decrease in sales volume of IMVEXXY.

Operating expenses. Total operating expenses for the second quarter of 2022 were $42.7 million, a decrease of $11.4 million, or 21.1%, compared to the second quarter of 2021. The decrease in operating expenses reflects our efforts to reduce operating expenses, including the reduction of vitaCare operating expenses in connection with its divestiture in April 2022.

The following table sets forth our operating expense categories (in thousands):

	Three Months Ended June 30,	
	2022	2021
Selling and marketing	$ 23,679	$ 32,164
General and administrative	17,403	19,873
Research and development	1,580	2,011
Total operating expenses	$ 42,662	$ 54,048

Our selling and marketing costs were $23.7 million for the second quarter of 2022, a decrease of $8.5 million, or 26.4%, compared to the second quarter of 2021. This decrease was primarily due to $9.8 million in lower advertising and marketing expenses, $0.5 million in lower compensation and employee benefit costs and consulting expenses, and $0.2 million in lower samples expense. These decreases were partially offset by $2.0 million in higher education and conference expenses and $0.3 million in higher software development expenses.

Our general and administrative costs were $17.4 million for the second quarter of 2022, a decrease of $2.5 million, or 12.4%, compared to the second quarter of 2021. This decrease was primarily related to $4.1 million in lower compensation and employee benefit costs, $0.9 million in lower information technology expenditures, $0.4 million in lower investor relations expenses, and $0.3 in lower corporate rent. These decreases were partially offset by $3.1 million in higher expenditures attributable to various professional fees, such as legal, consulting, etc., and $0.1 million in higher amortization expenses.

Our R&D costs were $1.6 million for the second quarter of 2022, a decrease of $0.4 million, or 21.4%, compared to the second quarter of 2021. This decrease was primarily attributable to $0.5 million in lower compensation and employee benefit costs, partially offset by $0.1 million in higher lab research costs. As we refocus our resources towards the continued commercialization of our pharmaceutical products, our R&D expenditures have declined over the last few years. We continue to deploy limited resources in the development of new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For the second quarter of 2022, we had a loss from operations of $18.8 million, a decrease of $16.3 million, or 46.4%, compared to the second quarter of 2021. This decrease was attributable to $11.4 million in lower operating expenses and $5.0 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 ANNOVERA, IMVEXXY and BIJUVA, although there is no assurance that our efforts will be successful.

Other income/expense, net. For the second quarter of 2022, we had non-operating income of $131.7 million compared to non-operating expense of $7.5 million for the second quarter of 2021. This $139.1 million positive change was primarily attributable to the $143.4 gain on the sale of the vitaCare business, net of transaction costs, $1.6 million in lower interest expense related to lower average debt balance, and $0.9 million in lower interest prepayment fee due to elimination of prepayment fees with Amendment No. 9 to the Financing Agreement. These positive changes were partially offset by $6.5 million in higher amortization of deferred financing costs compared to the second quarter of 2021.

Net income/loss. For the second quarter of 2022, we had net income of $112.3 million, or $12.83 per basic common share and $12.39 per diluted common share. Our results for the second quarter of 2022 included a non-recurring gain on sale of business related to the vitaCare Divestiture of $142.8 million, net of taxes, or $16.33 per basic common share and $15.77 per diluted common share. Without the non-recurring gain, for the second quarter of 2022, we would have had a net loss of $30.6 million, or $3.49 per basic and diluted common share, compared to a net loss of $42.7 million, or $5.41 per basic and diluted common share, for the second quarter of 2021. The historical per share data have been adjusted to give effect of the May 2022 reverse stock split.

Six months ended June 30, 2022 compared with six months ended June 30, 2021

Revenue. Our total revenue for the first six months of 2022 was $47.9 million, an increase of $5.0 million, or 11.7%, compared to the first six months of 2021.

The following table sets forth our revenue during these periods (in thousands):

	Six Months Ended June 30,	
	2022	2021
Product revenue:		
ANNOVERA	$ 26,781	$ 18,305
IMVEXXY	13,636	16,850
BIJUVA	5,214	4,601
Prescription vitamin	1,779	2,827
Product revenue, net	47,410	42,583
License and service	484	284
Total revenue, net	$ 47,894	$ 42,867

Our sales of ANNOVERA were $26.8 million for the first six months of 2022, an increase of $8.5 million, or 46.3%, compared to the first six months of 2021. This increase was primarily due to a 50.5% increase in sales volume partially offset by a 2.8% decrease in the average sale price.

Our sales of IMVEXXY were $13.6 million for the first six months of 2022, a decrease of $3.2 million, or 19.1%, compared to the first six months of 2021. This decrease was primarily attributable to a 6.5% decrease in sales volume and a 13.5% decrease in the average sales price.

Our sales of BIJUVA were $5.2 million for the first six months of 2022, an increase of $0.6 million, or 13.3%, compared to the first six months of 2021. Included in our BIJUVA sales for the first six months of 2022 was $1.0 million of sales made through the Theramex License Agreement. Without the sales made through the Theramex License Agreement, our sales of BIJUVA were $4.2 million for the

first six months of 2022, a decrease of $0.4 million, or 9.3%, compared to the first six months of 2021. This decrease was primarily attributable to a 4.8% decrease in sales volume and a 4.8% decrease in the average sale price.

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

Our prescription vitamin sales were $1.8 million for the first six months of 2022, a decrease of $1.0 million, or 37.1%, compared to the first six months of 2021. This decrease was primarily due to a 26.7% decrease in sales volume and a 14.2% decrease in the average sale price.

On a consolidated basis, our total product sales were $47.4 million for the first six months of 2022, an increase of $4.8 million, or 11.3%, compared to the first six months of 2021.

We recorded service revenue related to pharmacy services provided by our vitaCare business to pharmaceutical companies of $0.5 million for the first six months of 2022, an increase of $0.4 million, or 868.0%, compared to the first six months of 2021. We recorded no license revenue for the first six months of 2022 and our license revenue was $0.3 million for the first six months of 2021. This change in license revenue was entirely due to the timing of achieving previously established milestone payment targets.

Gross profit. Our gross profit for the first six months of 2022 was $38.3 million, an increase of $4.2 million, or 12.5%, compared to the first six months of 2021. The following table sets forth our gross profit during these periods (in thousands):

	Six Months Ended June 30,	
	2022	2021
Product	$ 37,810	$ 33,764
License and service	484	284
Total gross profit	$ 38,294	$ 34,048

The increase in our gross profit was a result an increase of 0.5% in our product gross margin to 79.8% and an increase of 11.3% in product revenue for the first six months of 2022. The increase in product gross margins was mainly due to changes in product sales mix as result of sales volumes for ANNOVERA, and decreases in sales volume of IMVEXXY and BIJUVA.

Operating expenses. Total operating expenses for the first six months of 2022 were $83.4 million, a decrease of $15.1 million, or 15.4%, compared to the first six months of 2021. The decrease in operating expenses reflects our efforts to reduce operating expenses, including the reduction of vitaCare operating expenses in connection with its divestiture in April 2022. The following table sets forth our operating expense categories (in thousands):

	Six Months Ended June 30,	
	2022	2021
Selling and marketing	$ 42,574	$ 56,188
General and administrative	37,810	38,256
Research and development	2,980	4,061
Total operating expenses	$ 83,364	$ 98,505

Our selling and marketing costs were $42.6 million for the first six months of 2022, a decrease of $13.6 million, or 24.2%, compared to the first six months of 2021. This decrease was primarily due to $16.0 million in lower advertising and marketing expenses, $0.6 million in lower compensation and employee benefit costs and consulting expenses, and $0.4 million in lower samples expense. These decreases were partially offset by $3.3 million in higher education and conference expenses and $0.5 million in higher software development expenses.

Our general and administrative costs were $37.8 million for the first six months of 2022, a decrease of $0.4 million, or 1.2%, compared to the first six months of 2021. This decrease was primarily related to $2.9 million in lower compensation and employee benefit costs, $1.9 million in lower information technology expenditures, $0.5 in lower corporate rent, and $0.4 million in lower investor relations expenses. These decreases were partially offset by $5.0 million in higher expenditures attributable to various professional fees, such as legal, consulting, etc., and $0.2 million in higher amortization expenses.

Our R&D costs were $3.0 million for the first six months of 2022, a decrease of $1.1 million, or 26.6%, compared to the first six months of 2021. This decrease was primarily attributable to $1.0 million in lower compensation and employee benefit costs, partially offset by $0.1 million in higher lab research costs. As we refocus our resources towards the continued commercialization of our pharmaceutical products, our R&D expenditures have declined over the last few years. We continue to deploy limited resources in the development of

new products, to perform stability testing and validation on our pharmaceutical products, to develop and validate secondary manufacturers, to prepare regulatory submissions, and work with regulatory authorities on existing submissions.

Loss from operations. For the first six months of 2022, we had a loss from operations of $45.1 million, a decrease of $19.4 million, or 30.1%, compared to the first six months of 2021. This decrease was attributable to $15.1 million in lower operating expenses and $4.2 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 ANNOVERA, IMVEXXY and BIJUVA, although there is no assurance that our efforts will be successful.

Other income/expense, net. For the first six months of 2022, we had non-operating income of $108.9 million compared to non-operating expense of $17.6 million for the first six months of 2021. This $126.5 positive change was primarily attributable to the $143.4 gain on the sale of the vitaCare business, net of transaction costs, $2.6 million in lower interest expense related to lower average debt balance, and $3.4 million in lower interest prepayment fee due to elimination of prepayment fees with Amendment No. 9 to the Financing Agreement. These positive changes were partially offset by $14.3 million in higher amortization of deferred financing costs, and $8.4 million in loss on extinguishment of debt in connection with Amendment No. 9 to the Financing Agreement, which is recorded as an extinguishment of debt for accounting purposes, compared to the first six months of 2021.

Net income/loss. For the first six months of 2022, we had net income of $63.3 million, or $7.29 per basic common share and $7.05 per diluted common share. Our results for the first six months of 2022 included a non-recurring gain on sale of business related to the vitaCare Divestiture of $142.8 million, net of taxes, or $16.45 per basic common share and $15.92 per diluted common share. Without the non-recurring gain, we would have had a net loss of $79.6 million, or $9.17 per basic and diluted common share, for the first six months of 2022 compared to a net loss of $82.0 million, or $11.06 per basic and diluted common share, for the first six months of 2021. The historical per share data have been adjusted to give effect of the May 2022 reverse stock split.

Liquidity and capital resources

Our primary use of cash is to fund the continued commercialization of our hormone therapy and contraceptive products. We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities. As of June 30, 2022, we had cash totaling $26.3 million. We maintain cash at financial institutions that at times may exceed the Federal Deposit Insurance Corporation insured limits of $0.25 million per bank. We have never experienced any losses related to these funds.

On April 14, 2022, we completed the vitaCare Divestiture and received net proceeds of $142.6 million, net of transaction costs. Included in the net proceeds amount was $11.3 million of customary holdbacks as provided in the Purchase Agreement, which is recorded as restricted cash in the consolidated balance sheets. The restricted cash is held by an escrow agent and will be released to us in April 2023 upon a joint written direction from the buyer and us being delivered to the escrow agent to disburse to us an amount equal to the amount of escrow funds less any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement. Any amounts subject to a claim notice in accordance with the terms set forth in the Purchase Agreement shall be retained by the escrow agent until each such claim subject thereto is resolved. Additionally, we may receive up to an additional $7.0 million in earn-out consideration, contingent upon vitaCare's financial performance through 2023 as determined in accordance with the terms of the Purchase Agreement. We utilized $120.0 million of net proceeds from the vitaCare Divestiture to make a prepayment of the loans under the Financing Agreement under the terms of Amendment No. 9 of the Financing Agreement.

See "Going Concern" above for further discussion related to our ability to generate and obtain adequate amounts of cash to meet our liquidity needs and our plans for to satisfy our such needs in the short-term and in the long-term.

Cash flows

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

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	$ (44,930)	$ (64,912)
Net cash provided by (used in) investing activities	142,347	(527)
Net cash (used in) provided by financing activities	(124,986)	96,377
Net (decrease) increase in cash and restricted cash	$ (27,569)	$ 30,938

Operating Activities. The principal use of cash in operating activities was to fund our current expenditures in support of our continued commercialization activities for ANNOVERA, IMVEXXY, and BIJUVA, sales, marketing, scale-up and manufacturing activities, adjusted for non-cash items. For the first six months of 2022, net cash used in operating activities was $44.9 million, compared to net cash used in operating activities of $64.9 million for the first six months of 2021. This decrease of $20.0 million, or 30.8%, was primarily due to a $122.6 million decrease in non-cash expenditure adjustments and a $2.7 million increase in cash generated from changes in operating assets and liabilities, partially offset by a $145.3 million increase in our net income.

Investing Activities. For the first six months of 2022, net cash provided by investing activities was $142.3 million, compared to net cash used in investing activities of $0.5 million for the first six months of 2021. This increase of $142.9 million, or 27110.8%, was primarily due to $142.6 million in proceeds from the 2022 sale of the vitaCare business, net of transaction costs, partially offset by lower patent related costs and less fixed asset purchases.

Financing Activities. Financing activities have historically represented the principal source of our cash flow. For the first six months of 2022, net cash used in financing activities was $125.0 million, entirely attributable to debt prepayment, compared to net cash provided by financing activities of $96.4 million for the first six months of 2021. This change of $221.4 million, or 229.7%, was primarily related to net proceeds from sales of our common stock in 2021 of $151.1 million, and the exercise of options and warrants in 2021 of $0.3 million, partially offset by an increase of $75.0 million in repayment of debt, $5.1 million in payments of debt financing fees in 2021, and lower employee stock purchase plan proceeds.

For additional details, see the consolidated statements of cash flows and Note 16, Subsequent events, 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 159 days as of June 30, 2022, compared to 146 days as of December 31, 2021 and 114 days as of June 30, 2021. Our gross DSO is calculated by dividing average gross accounts receivable by the average daily gross product revenue to distributors during the last four quarters for each respective quarterly period. Our gross DSO was 77 days as of June 30, 2022, compared to 72 days as of December 31, 2021 and 54 days as of June 30, 2021. Our DSOs have fluctuated and will continue to fluctuate in the future due to variety of factors, including longer payment terms associated with the continued commercialization of ANNOVERA, IMVEXXY, and BIJUVA changes in the healthcare industry. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future.

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

Debt. We had $90.8 million and $200.0 million in term loans outstanding under our Financing Agreement as of June 30, 2022 and December 31, 2021, respectively. For additional information, see Note 8, Debt and Note 16, Subsequent events, in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report.

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

Except for entering into Amendment No. 9 to the Financing Agreement in March 2022, Amendments 10 and 11 to the Financing Agreement in May 2022, and the long-term services agreement with vitaCare, which we are required to pay a minimum service fee for each respective annual contract year, there were no other material changes from December 31, 2021 to June 30, 2022. Our estimated minimum service fee commitments for vitaCare are as follows: $3.9 million for the period from July 1, 2022 to December 31, 2022, $10.7 million for 2023, $13.4 million for 2024, $15.4 million for 2025, $16.2 million for 2026, and $5.5 million for the period from January 1, 2027 to April 14, 2027. For discussion on amendments to the Financing Agreement, see Note 8, Debt and Note 16, Subsequent events, in Item 1, Financial Statements, appearing elsewhere in this 10-Q Report. For a discussion of matters in this section, refer to Item 7 - Contractual obligations, off-balance sheet arrangements and purchase commitments and employment agreements of our 2021 10-K Report.

Critical accounting policies and estimates

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

Item 3. Quantitative and qualitative disclosures about market risk

As a “smaller reporting company,” as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide this information.

Item 4. Controls and procedures

Management’s evaluation of disclosure controls and procedures

Disclosure Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

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

Our management, including our Chief Executive Officer and Interim Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, misstatements, errors, and instances of fraud, if any, within our company have been or will be prevented or detected. Further, internal controls may become inadequate as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

Changes in internal controls over financing reporting

There were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the three months ended June 30, 2022.

Part II – Other Information

Item 1. Legal proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of our business. Other than the legal proceedings disclosed in Note 9, Commitments and contingencies in Part I, Item 1, Financial Statements, appearing elsewhere in this 10-Q Report, we are not involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

Item 1A. Risk factors

The business, financial condition and operating results of the Company can be affected by a number of factors, whether currently known or unknown, including but not limited to those described in Part I, Item 1A of the 2021 10-K Report under the heading “Risk Factors,” any one or more of which could, directly or indirectly, cause the Company’s actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect the Company’s business, financial condition, operating results and stock price. Except as set forth below, there have been no material changes to the Company’s risk factors since the 2021 10-K Report.

Our level of indebtedness and other liabilities, and the terms of the Financing Agreement, which matures in September 2022, raise substantial doubt about our ability to continue as a going concern.

Our substantial amount of indebtedness and other liabilities could adversely affect our business. As of June 30, 2022, we had $90.8 million of debt outstanding under the Financing Agreement. In addition, in July 2022, we issued 15 thousand shares of our newly-designated Series A Preferred Stock, par value $0.001 per share (the “Series A Preferred Stock”). The Series A Preferred Stock has a

liquidation preference equal to $1,333 per share of Series A Preferred Stock and matures on December 31, 2022, subject to certain extension terms, as set forth in the Certificate of Designation, Preferences and Rights of Series A Preferred Stock (the "Certificate of Designation"), and the Company is required to redeem the shares on such date at a redemption price per share of Series A Preferred Stock, payable in cash, equal to the liquidation preference. Our high level of indebtedness and other liabilities could affect our business in the following ways, among other things: make it more difficult for us to satisfy our contractual and commercial commitments; require us to use a substantial portion of our cash flow from operations to pay interest and principal, which would reduce funds available for working capital, capital expenditures and other general corporate purposes; limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes; heighten our vulnerability to downturns in our business, our industry or in the general economy; place us at a disadvantage compared to those of our competitors that may have proportionately less debt and other liabilities; limit management's discretion in operating our business; and limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy.

The Financing Agreement contains a minimum unrestricted cash balance requirement and several other restrictive covenants. The Financing Agreement requires that we and our subsidiaries party to the Financing Agreement must maintain a minimum unrestricted cash balance of $10.0 million. The Financing Agreement also contains covenants that limit, among other things, the ability of us and our subsidiaries party to the Financing Agreement to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, and (vii) enter into transactions with affiliates, in each case subject to certain exceptions. 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. To maintain compliance with the minimum unrestricted cash balance requirement of the Financing Agreement, we anticipate that we may need to raise additional capital. We cannot guarantee that future financing sufficient to maintain or exceed the minimum unrestricted cash balance will be available in sufficient amounts, in a timely fashion, or on terms acceptable to us, if at all. If we are unable to maintain the minimum unrestricted cash balance 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.

In addition, in July 2022, we entered into Amendment No. 16 to the Financing Agreement ("Amendment No. 16"). Pursuant to Amendment No. 16, the Financing Agreement matures on September 30, 2022, and the entire principal balance under the Financing Agreement is due and payable as of such date. We will have the option to further extend the maturity date to October 31, 2022, and November 30, 2022, in each case if we receive not less than $7 million in cash proceeds from an equity issuance, which, if preferred equity, is on substantially the same terms as our Series A Preferred Stock. Any additional issuances of preferred equity on substantially the same terms as our Series A Preferred Stock would increase our liabilities. Our current cash on hand is not sufficient to pay the amounts due under the Financing Agreement. This raises substantial doubt about our ability to continue as a going concern. We will need to raise additional capital to repay the entire principal balance of the Financing Agreement upon maturity. The report of our independent registered public accounting firm on our audited financial statements contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our audited financial statements as of and for the year ended December 31, 2021 and our unaudited financial statements as of and for the three and six months ended June 30, 2022 do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Further, we currently have approximately 1.2 million shares of Common Stock available to be issued under our current authorization, which limits our ability to raise capital through equity financing. In addition, the Certificate of Designation establishing the powers, designations, preferences and privileges and the qualifications, limitations or restrictions of our Series A Preferred Stock contains restrictions that could limit our ability to raise more capital, including a prohibition on incurring certain indebtedness or liens. If we cannot continue as a going concern, our investors may lose their entire investment in our securities. Until we can generate significant cash flows, we expect to satisfy our future cash needs through debt or equity financing; however, there can be no assurance that such capital will be available, or if available, that it will be on terms acceptable to us.

If we are unable raise additional capital or to generate cash flow through operations, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under the Financing Agreement.

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

None.

Item 3. Defaults upon senior securities

None.

Item 4. Mine safety disclosures

None.

Item 5. Other information

None.

Item 6. Exhibits

Exhibit No.	Description
3.1	Certificate of Designation, Preferences and Rights of Series A Preferred Stock(1)
3.2	Second Amendment to Bylaws of the Company, dated May 27, 2022(2)
3.3	Third Amendment to Bylaws of the Company, dated July 29, 2022(1)
10.1	Amendment No. 10 to the Financing Agreement, dated May 27, 2022, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(3)
10.2	Amendment No. 11 to the Financing Agreement, dated May 27, 2022, by and among TherapeuticsMD, Inc. as the Borrower, vitaMedMD, LLC, BocaGreenMD, Inc. and vitaCare Prescription Services, Inc. as the Guarantors, TPG Specialty Lending, Inc., Top IV Talents, LLC and Tao Talents, LLC as the Lenders(3)
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

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

(2) Filed as an exhibit to the Company’s Current Report on Form 8-K filed with the SEC on June 3, 2022, as amended on June 6, 2022 and incorporated herein by reference (SEC File No. 001-00100).

(3) Filed as an exhibit to the Company’s Current Report on Form 8-K filed with the SEC on May 31, 2022 and incorporated herein by reference (SEC File No. 001-00100).

Signatures

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

Date: August 15, 2022

TherapeuticsMD, Inc.

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief Executive Officer
(Principal Executive Officer)

/s/ Michael C. Donegan
Michael C. Donegan
Interim Chief Financial Officer, Chief Accounting Officer and Vice President Finance
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Chief Executive Officer

I, Hugh O'Dowd, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 15, 2022

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer

I, Michael C. Donegan, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;

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

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

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

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

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

(c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

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

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

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

Date: August 15, 2022

/s/ Michael C. Donegan

Michael C. Donegan
Interim Chief Financial Officer, Chief Accounting Officer and Vice President Finance
(Principal Financial and Accounting 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 June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Hugh O'Dowd, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 15, 2022

/s/ Hugh O'Dowd
Hugh O'Dowd
Chief Executive Officer
(Principal Executive Officer)

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

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 June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael C. Donegan, Interim Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 15, 2022

/s/ Michael C. Donegan
Michael C. Donegan
Interim Chief Financial Officer, Chief Accounting Officer and Vice President Finance
(Principal Financial and Accounting Officer)

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