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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

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 No. **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 FL	**33431**
(Address of Principal Executive Offices)	(Zip Code)

561 961-1900

(Registrant's telephone number, including area code)

Not Applicable

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 (Check one):

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 ☒

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of November 2, 2020 was 272,812,271.

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash	$ 79,633,675	$ 160,829,713
Accounts receivable, net of allowance for doubtful accounts of $857,176 and $904,040, respectively	24,059,095	24,395,958
Inventory, net	9,932,304	11,860,716
Other current assets	8,819,239	11,329,793
Total current assets	122,444,313	208,416,180
Fixed assets, net	1,969,929	2,507,775
Other Assets:		
License rights, net	36,959,305	39,221,308
Intangible assets, net	5,537,885	5,258,211
Right of use assets	9,975,725	10,109,154
Other assets	403,643	473,009
Total other assets	52,876,558	55,061,682
Total assets	$ 177,290,800	$ 265,985,637
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 16,109,638	$ 19,181,212
Other current liabilities	31,220,484	33,823,613
Total current liabilities	47,330,122	53,004,825
Long-Term Liabilities:		
Long-term debt	237,051,202	194,634,643
Operating lease liability	8,907,995	9,145,049
Other long-term liabilities	35,000	—
Total long-term liabilities	245,994,197	203,779,692
Total liabilities	293,324,319	256,784,517
Commitments and Contingencies - See Note 15		
Stockholders' (Deficit) Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 600,000,000 and 350,000,000 shares authorized: 272,812,271 and 271,177,076 issued and outstanding, respectively	272,812	271,177
Additional paid-in capital	720,551,488	704,351,222
Accumulated deficit	(836,857,819)	(695,421,279)
Total stockholders' (deficit) equity	(116,033,519)	9,201,120
Total liabilities and stockholders' (deficit) equity	$ 177,290,800	$ 265,985,637

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Product revenue, net	$ 17,342,805	$ 8,213,341	$ 40,294,495	$ 18,238,857
License revenue	2,000,000	15,506,400	2,000,000	15,506,400
Total revenue, net	19,342,805	23,719,741	42,294,495	33,745,257
Cost of goods sold	3,278,609	1,444,308	10,394,145	3,455,995
Gross profit	16,064,196	22,275,433	31,900,350	30,289,262
Operating expenses:				
Sales, general, and administrative	38,751,250	45,126,986	144,018,899	121,378,519
Research and development	2,027,195	4,077,738	8,038,056	15,359,988
Depreciation and amortization	258,787	141,959	777,338	363,956
Total operating expenses	41,037,232	49,346,683	152,834,293	137,102,463
Operating loss	(24,973,036)	(27,071,250)	(120,933,943)	(106,813,201)
Other (expense) income				
Loss on extinguishment of debt	—	—	—	(10,057,632)
Miscellaneous income	41,405	703,662	465,745	1,878,980
Interest expense	(7,679,443)	(5,599,005)	(20,968,342)	(11,717,632)
Total other expense, net	(7,638,038)	(4,895,343)	(20,502,597)	(19,896,284)
Loss before income taxes	(32,611,074)	(31,966,593)	(141,436,540)	(126,709,485)
Provision for income taxes	—	—	—	—
Net loss	$ (32,611,074)	$ (31,966,593)	$ (141,436,540)	$ (126,709,485)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	$ (0.12)	$ (0.13)	$ (0.52)	$ (0.53)
Weighted average number of common shares outstanding, basic and diluted	272,564,635	241,261,299	271,968,981	241,163,994

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
(Unaudited)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2018	240,462,439	$ 240,463	$ 616,559,938	$ (519,276,280)	$ 97,524,121
Shares issued for exercise of options and warrants, net	759,401	759	99,348	—	100,107
Share-based compensation	—	—	2,575,369	—	2,575,369
Net loss	—	—	—	(39,506,375)	(39,506,375)
Balance, March 31, 2019	241,221,840	241,222	619,234,655	(558,782,655)	60,693,222
Balance, March 31, 2019	241,221,840	241,222	619,234,655	(558,782,655)	60,693,222
Share-based compensation	—	—	2,637,264	—	2,637,264
Net loss	—	—	—	(55,236,517)	(55,236,517)
Balance, June 30, 2019	241,221,840	241,222	621,871,919	(614,019,172)	8,093,969
Balance, June 30, 2019	241,221,840	241,222	621,871,919	(614,019,172)	8,093,969
Shares issued for exercise of options and warrants, net	55,236	55	8,494	—	8,549
Share-based compensation	—	—	2,635,146	—	2,635,146
Net loss	—	—	—	(31,966,593)	(31,966,593)
Balance, September 30, 2019	241,277,076	$ 241,277	$ 624,515,559	$ (645,985,765)	$ (21,228,929)
Balance, December 31, 2019	271,177,076	$ 271,177	$ 704,351,222	$ (695,421,279)	$ 9,201,120
Shares issued for exercise of options and warrants, net	350,666	351	71,758	—	72,109
Issuance of shares from release of restricted stock	150,000	150	(150)	—	—
Share-based compensation	—	—	2,366,453	—	2,366,453
Net loss	—	—	—	(56,848,802)	(56,848,802)
Balance, March 31, 2020	271,677,742	271,678	706,789,283	(752,270,081)	(45,209,120)
Balance, March 31, 2020	271,677,742	271,678	706,789,283	(752,270,081)	(45,209,120)
Shares issued for exercise of options and warrants, net	313,638	313	93,762	—	94,075
Issuance of shares from release of restricted stock	303,000	303	(303)	—	—
Share-based compensation	—	—	3,002,826	—	3,002,826
Net loss	—	—	—	(51,976,664)	(51,976,664)
Balance, June 30, 2020	272,294,380	272,294	709,885,568	(804,246,745)	(94,088,883)
Balance, June 30, 2020	272,294,380	272,294	709,885,568	(804,246,745)	(94,088,883)
Shares issued for exercise of options and warrants, net	517,891	518	104,976	—	105,494
Share-based compensation	—	—	3,132,765	—	3,132,765
Warrant granted in relation to Financing Agreement	—	—	7,428,179	—	7,428,179
Net loss	—	—	—	(32,611,074)	(32,611,074)
Balance, September 30, 2020	272,812,271	$ 272,812	$ 720,551,488	$ (836,857,819)	$ (116,033,519)

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (141,436,540)	$ (126,709,485)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	576,459	223,750
Amortization of intangible assets	200,879	140,206
Write off of patent and trademark costs	584,509	78,864
Write off of deferred financing fees	275,379	—
Non-cash operating lease expense	1,050,940	711,836
(Recovery of) provision for doubtful accounts	(46,864)	95,097
Lease impairment	81,309	—
Inventory obsolesence reserve	5,744,464	—
Loss on extinguishment of debt	—	10,057,632
Share-based compensation	8,502,044	7,859,357
Amortization of intellectual property license fee	2,262,002	15,998
Amortization of deferred financing fees	1,370,118	582,829
Changes in operating assets and liabilities:		
Accounts receivable	383,727	(4,354,890)
Inventory	(3,816,053)	(7,265,174)
Other assets	2,003,079	(1,128,515)
Accounts payable	(3,071,574)	1,389,665
Other current liabilities	(3,812,919)	3,402,511
Net cash used in operating activities	(129,149,041)	(114,900,319)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(1,065,062)	(1,068,542)
Purchase of fixed assets	(38,613)	(2,089,413)
Security deposit	35,000	(20,420)
Net cash used in investing activities	(1,068,675)	(3,178,375)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options and warrants	271,678	108,656
Repayment of the Credit Agreement	—	(81,660,719)
Proceeds from the Financing Agreement	50,000,000	200,000,000
Payment of deferred financing fees	(1,250,000)	(6,652,270)
Net cash provided by financing activities	49,021,678	111,795,667
Decrease in cash	(81,196,038)	(6,283,027)
Cash, beginning of period	160,829,713	161,613,077
Cash, end of period	$ 79,633,675	$ 155,330,050
Supplemental disclosure of noncash investing and financing activities		
Warrant granted in relation to Financing Agreement	$ 7,428,179	$ —
Amount accrued for intellectual property license	$ —	$ 20,000,000
Supplemental disclosure of cash flow information		
Interest paid	$ 19,172,847	$ 12,446,792

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

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has three wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and vitaCare Prescription Services, Inc., a Florida corporation, or vitaCare. Unless the context otherwise requires, TherapeuticsMD, VitaMed, BocaGreen, and vitaCare collectively are sometimes referred to as "our company," "we," "our," or "us." TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA® are registered trademarks of our company.

Nature of Business

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 manufacture and distribute 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. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our pharmaceutical products has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our pharmaceutical products. In July 2018, we launched our FDA-approved product, IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. In April 2019, we launched our FDA-approved product BIJUVA (estradiol and progesterone) capsules, our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus. In October 2019, we began a test and learn market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual patient-controlled, procedure-free, reversible prescription contraceptive option for women. Although we expected to commence the full commercial launch of ANNOVERA in the first quarter of 2020, as a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA and deferred sales and marketing initiatives into subsequent quarters as the pandemic began to negatively affect our revenue growth. We resumed the launch of ANNOVERA on July 1, 2020. On July 30, 2018, we entered into an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA in the U.S. In addition, on July 30, 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel. On June 6, 2019, we entered into an exclusive license and supply agreement, or the Theramex License Agreement, with Theramex HQ UK Limited, or Theramex, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Theramex Territory.

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements of TherapeuticsMD, Inc., which include our wholly owned subsidiaries, should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2019. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited interim consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year or any other interim period in the future.

Risks and Uncertainties

We continue to be subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the future impact of the COVID-19 pandemic on our business continues to be highly uncertain and difficult to predict. We continue to provide an uninterrupted supply of our portfolio of products for patients. We have sufficient inventory of finished product to meet anticipated demand in the near future. Additionally, we currently do not foresee any interruption in our ability to continue to manufacture additional product to be used beyond this period and have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products.

Since the early phase of the COVID-19 pandemic, we have been using substantial virtual options to ensure business continuity. Our vitaCare Prescription Services patient model assists patients in obtaining easy and convenient access to their prescriptions for products at a retail pharmacy of their choice, including via home delivery retail pharmacy options. We have also partnered with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause to ensure patients have 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 virtual detailing.

As part of our response to the COVID-19 pandemic, we implemented measures to reduce marketing expenses for 2020. We also implemented cost saving measures, which included negotiating lower fees or suspending services from third party vendors; implementing a company-wide hiring restriction; delaying or cancelling non-critical information technology projects; and eliminating non-essential travel, entertainment, meeting, and event expenses.

The full impact of the COVID-19 pandemic continues to evolve. However, we remain committed to the execution of our corporate goals, despite the ongoing COVID-19 pandemic, as demonstrated in part by the increase of our third quarter 2020 product revenues as compared to our second quarter 2020 product revenues. 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 the COVID-19 pandemic on our operations by monitoring the spread of COVID-19 and the various actions implemented to combat the virus throughout the world. Even after the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

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

Liquidity and Going Concern

As of the filing date of this Quarterly Report on Form 10-Q, our cash balance was above the $60 million balance as required by the Financing Agreement (as defined in Note 9 - Debt). On November 8, 2020, we and our subsidiaries entered into Amendment No. 6 to the Financing Agreement, or Amendment No. 6, with the Administrative Agent (as defined in Note 9 - Debt) and the lenders party thereto, pursuant to which we temporarily lowered the minimum required cash balance from $60 million to $45 million through December 31, 2020. After December 31, 2020, the minimum cash balance will revert to $60 million. Based on our current projections, we will need to raise additional capital to remain in compliance with this minimum cash balance covenant for the next twelve months from the issuance of these financial statements.

In order to address our projected capital needs, we are pursuing various equity financing and other alternatives including the sale of a controlling interest in vitaCare Prescription Services for which we commended a sale process and received initial indications of interest. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 on our business including the impact of the recent steps we have taken to reduce our operating expenses in response. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this Quarterly Report on Form 10-Q.

However, if we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA. 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 unaudited consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Recently Issued Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2018-13 which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The FASB developed the amendments to Accounting Standards Codification, or ASC, 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. The new guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. We adopted this standard on January 1, 2020, and the adoption did not have a material effect on our disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected based on historical experience, current conditions, and reasonable supportable forecasts. The amendments in this update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted no sooner than the first quarter of 2019. A modified retrospective approach is required for all investments, except debt securities for which an other-than-temporary impairment had been recognized prior to the effective date, which will require a prospective transition approach and should be applied either prospectively or retrospectively depending on the nature of the disclosure. The adoption of ASU 2016-13 requires expanded quantitative and qualitative disclosures about the Company's expected credit losses. Effective January 1, 2020, we adopted ASU 2016-13 under a modified retrospective approach for all financial assets measured at amortized cost. There was no adjustment recorded for the cumulative effect of adopting ASU 2016-13. The adoption expanded disclosures about our credit losses.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card chargebacks and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, reasonable supportable forecasts and existing economic conditions and we record an allowance that presents the net amount expected to be collected. We evaluate trade accounts receivable for delinquency. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off when received as an increase in the allowance for doubtful accounts. To the extent data we use to calculate these estimates does not accurately reflect bad debts, adjustments to these reserves may be required. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. 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.

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable, accrued expenses and long-term debt. The carrying amount of cash, accounts receivable, accounts payable and accrued expenses approximates their fair value because of the short-term maturity of such instruments, which are considered Level 1 assets under the fair value hierarchy. The carrying amount for long-term debt as of September 30, 2020 (as disclosed in Note 9) approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk (Level 2).

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by ASC 820, Fair Value Measurements, or ASC 820. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1	unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2	quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
Level 3	unobservable inputs for the assets or liabilities.

At September 30, 2020 and 2019, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with any required impairment test. During the nine months ended September 30, 2020 and 2019, we wrote off $584,509 and $78,864, respectively, in costs related to trademarks and patents.

Share-Based Compensation

We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include options, restricted stock, restricted stock units, performance-based awards, share appreciation rights, and employee share purchase plans. We amortize such compensation amounts, if any, over the respective service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, Compensation-Stock Compensation, to value options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the instrument. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. On January 1, 2017, we began using our own stock price in our volatility calculation along with the other peer entities whose stock prices were publicly available that were similar to our company and in 2019 we started using only our own stock price in the volatility calculation. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. On January 1, 2020, we began calculating the expected term of our stock-based awards, which represents the period that the stock-based awards are expected to be outstanding. Prior to January 1, 2020, the average expected life of options was based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The assumptions used in calculating the fair value of stock-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future. We recognize the compensation expense for share-based compensation granted based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense on a straight-line basis over the employee's requisite service period. Effective January 1, 2017, we account for forfeitures when they occur. On January 1, 2019, we adopted ASU 2018-07 which simplified the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expanded the scope of ASC 718 to include share-based payments granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and superseded the guidance in ASC 505-50. Prior to January 1, 2019, equity instruments issued to non-employees were recorded on a fair value basis, as required by ASC 505, Equity - Based Payments to Non-Employees.

We grant performance-based stock units and restricted stock units for shares of common stock, par value $0.001 per share, or Common Stock, to employees. We value our restricted stock units and our performance-based stock units by reference to our stock price on the date of grant. We recognize compensation expense for restricted stock units based on a straight-line basis over the requisite service period of the entire award. We recognize performance-based restricted stock as compensation expense based on the most likely probability of attaining the prescribed performance and over the requisite service period beginning at its grant date and through the date the restricted stock vests. The number of target shares that vest are determined based on the level of attainment of the targets. If a minimum level of performance is attained for the awards, restricted stock is issued based on the level of attainment.

Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers*, or ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. The provisions of ASC 606 include a five-step process by which we determine revenue recognition, depicting the transfer of goods or services to customers in amounts reflecting the payment to which we expect to be entitled in exchange for those goods or services. ASC 606 requires us to apply the following steps: (1) identify the contract with the customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, we satisfy the performance obligation.

Prescription Products

As of September 30, 2020, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, BIJUVA, which we began selling in the second quarter of 2019, and ANNOVERA, which we began selling in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the launch of ANNOVERA on July 1, 2020.

We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacies. We have one performance obligation related to prescription products sold through wholesale distributors, which is to transfer promised goods to a customer, and two performance obligations related to products sold through retail pharmacies, which are to: (1) transfer promised goods and (2) provide customer service for an immaterial fee. We treat shipping as a fulfillment activity rather than as a separate obligation. We recognize prescription product revenue only when we satisfy performance obligations by transferring a promised good or service to a customer. A good or service is considered to be transferred when the customer receives the goods or service or obtains control. Control refers to the customer's ability to direct the use of, and obtain substantially all of the remaining benefits from, an asset. Based on our contracts, we invoice customers once our performance obligations have been satisfied, at which point payment is unconditional. We disclose receivables from contracts with customers separately in the statement of financial position. Payment for goods or services sold by us is typically due between 30 and 60 days after an invoice is sent to the customer.

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

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

We offer various rebate and discount programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. Estimates relating to these rebates and coupons are deducted from gross product revenues at the time the product revenues are recognized. We record distributor fees based on amounts stated in contracts. Rebate and coupon estimates and distributor fees are recorded in other current liabilities on the consolidated balance sheet. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 8. We provide invoice discounts to our customers for prompt payment. Estimates relating to invoice discounts and chargebacks are deducted from gross product revenues at the time the product revenues are recognized.

As part of commercial launches for our FDA-approved prescription products, we introduced a co-pay assistance program for eligible enrolled patients whose out of pocket costs are reduced to a more affordable price. This allows patients to access the product at a reasonable cost and is in line with our responsible pricing approach. We reimburse pharmacies for this discount through third-party vendors. The variable consideration is estimated based on contract prices, the estimated percentage of patients that will utilize the copay assistance, the average assistance paid, the estimated levels of inventory in the distribution channel and the current level of prescriptions covered by patients' insurance. Payers may change coverage levels for our prescription products positively or negatively, at any time up to the time that we have formally contracted coverage with the payer. As such, the net transaction price of our prescription products is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain variable consideration for our prescription products to an amount that will not result in a significant product revenue reversal in future periods. Our ability to estimate the net transaction price for our prescription products is constrained by our estimates of the amount to be paid for the co-pay assistance program which is directly related to the level of prescriptions paid for by insurance. As such, we record an accrual to reduce gross sales for the estimated co-pay and other patient assistance based on currently available third-party data and our internal analyses. We re-evaluate variable consideration each reporting period.

License Revenue

License arrangements may consist of non-refundable upfront license fees, exclusive licensed rights to patented or patent pending technology, and various performance or sales milestones and future product royalty payments. Some of these arrangements may include multiple performance obligations. Non-refundable up-front fees that are not contingent on any future performance by us, and do not require continuing involvement on our part, are recognized as revenue when the right to use functional IP is transferred to the customer.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the three and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Prescription vitamins	$ 2,435,903	$ 2,550,330	$ 7,337,976	$ 7,309,174
IMVEXXY	6,841,592	4,772,354	18,319,382	9,904,744
BIJUVA	1,646,320	490,705	4,109,925	624,987
ANNOVERA	6,418,990	399,952	10,527,212	399,952
License revenue	2,000,000	15,506,400	2,000,000	15,506,400
Net revenue	$ 19,342,805	$ 23,719,741	$ 42,294,495	$ 33,745,257

License Agreement with the Population Council

On July 30, 2018, we entered into the Population Council License Agreement to commercialize ANNOVERA in the U.S. We began selling ANNOVERA in a “test and learn” market introduction in the third quarter of 2019. As a result of the uncertainty surrounding the COVID-19 pandemic, we paused the commercial launch of ANNOVERA in the first quarter of 2020 and deferred sales and marketing initiatives into subsequent quarters. We resumed the launch of ANNOVERA on July 1, 2020.

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20,000,000 within 30 days following the approval by the FDA of the new drug application, or NDA, for ANNOVERA and $20,000,000 within 30 days following the first commercial batch release of ANNOVERA. Both milestone payments of $20,000,000 were recorded as license rights in the consolidated balance sheets. We started amortizing license rights in the third quarter of 2019 once ANNOVERA became commercially available for use. The cost is amortized over the remaining useful life over which the license rights will contribute directly or indirectly to our cash flows, which is estimated to be the remaining patent life of the product, which expires in December 2032. The cost is amortized using the straight-line method as the pattern of economic benefit cannot be reliably determined. During the three and nine months ended September 30, 2020, we recorded $762,389 and $2,262,002, respectively, in amortization expense related to the license fee. During both the three and nine months ended September 30, 2019, we recorded $15,998 in amortization expense related to the license fee which was recorded as a component of cost of sales.

The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA. We are responsible for marketing expenses related to the commercialization of ANNOVERA. In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA in the U.S. by the Company and its affiliates and permitted licensees as follows: (i) if annual net sales are less than or equal to $50,000,000, a royalty of 5% of net sales; (ii) for annual net sales greater than $50,000,000 and less than or equal to $150,000,000, a royalty of 10% of such net sales; and (iii) for net sales greater than $150,000,000, a royalty of 15% of such net sales. The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of the one-year vaginal contraceptive system that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate. We are required to pay the Population Council milestone payments of $40 million upon cumulative net sales of ANNOVERA in the U.S. by us and our affiliates and permitted sublicensees of each of $200 million, $400 million and $1 billion. The Population Council has agreed to perform and pay the costs and expenses associated with four post-approval studies required by the FDA for ANNOVERA and we have agreed to perform and pay the costs and expenses associated with a post approval study required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20,000,000, half of such excess will be offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Population Council License Agreement. We will be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee. The Population Council License Agreement includes exclusive rights for us to negotiate co-development of two other investigational vaginal contraceptive systems in development by the Population Council.

License Agreement with Knight

In July 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel. Pursuant to the terms of the Knight License Agreement, Knight paid us $2,000,000 in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020, and is also required to pay us sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY and BIJUVA and royalties based on aggregate annual sales of each of IMVEXXY and BIJUVA in Canada and Israel. We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY and BIJUVA in Canada within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters. As part of the Knight License Agreement, Knight is prohibited from exporting IMVEXXY and BIJUVA to the United States.

Cost of Sales

Cost of sales includes the cost of inventory, manufacturing, manufacturing overhead and supply chain costs, and product shipping and handling costs. The Population Council License Agreement requires payment of royalties based on the sale of future products. Such royalties are recorded as a component of cost of sales. Additionally, the amortization of license fees or milestone payments related to licensed products are classified as components of cost of sales to the extent such payments become due in the future.

Inventory Obsolescence Reserve

We evaluate inventory quarterly and record an allowance for obsolescence primarily associated with materials that are not currently or likely to be used in production in the near future. As of September 30, 2020 and December 31, 2019, we recorded an inventory obsolescence reserve of $5,744,464 and $0, respectively. The reserve recorded as of September 30, 2020 was primarily related to BIJUVA and resulted from the impact of the COVID-19 pandemic on our business, which decreased demand for our products.

Segment Reporting

We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single executive leadership team that is chaired by the Chief Executive Officer of our Company, who oversees all operations. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and other costs. The activities undertaken by our regulatory consultants that were classified as R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. These consulting expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions to expenses in the period in which the facts that give rise to the revision become known.

NOTE 4 – INVENTORY, NET

Inventory, net consists of the following:

	September 30, 2020	December 31, 2019
Finished products	$ 4,794,132	$ 4,976,910
Work in process	440,149	1,182,059
Raw materials	4,698,023	5,701,747
TOTAL INVENTORY, NET	$ 9,932,304	$ 11,860,716

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2020	December 31, 2019
Prepaid sales and marketing costs	$ 686,346	$ 1,583,698
Debt financing fees on undrawn tranches (Note 9)	—	550,757
Prepaid insurance	3,599,906	1,812,135
Prepaid manufacturing	543,050	2,595,721
Other prepaid costs	3,989,937	4,787,482
TOTAL OTHER CURRENT ASSETS	$ 8,819,239	$ 11,329,793

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	September 30, 2020	December 31, 2019
Accounting system	$ 301,096	$ 301,096
Equipment	1,658,258	1,619,646
Furniture and fixtures	1,406,858	1,406,858
Computer hardware	80,211	80,211
Leasehold improvements	68,788	68,788
TOTAL FIXED ASSETS	3,515,211	3,476,599
Accumulated depreciation	(1,545,282)	(968,824)
TOTAL FIXED ASSETS, NET	$ 1,969,929	$ 2,507,775

Depreciation expense for the three months ended September 30, 2020 and 2019 was $188,810 and $90,700, respectively, and for the nine months ended September 30, 2020 and 2019 was $576,459 and $223,750, respectively.

NOTE 7 – INTANGIBLE ASSETS, NET

The following table sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets as of September 30, 2020 and December 31, 2019:

	September 30, 2020			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	$ 4,108,745	$ (679,959)	$ 3,428,786	12.25
Hormone therapy drug candidate patents (pending)	1,760,923	—	1,760,923	n/a
Non-amortizable intangible assets:				
Multiple trademarks	348,176	—	348,176	indefinite
TOTAL	$ 6,217,844	$ (679,959)	$ 5,537,885	

	December 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	$ 3,463,082	$ (478,983)	$ 2,984,099	13
Hormone therapy drug candidate patents (pending)	1,979,299	—	1,979,299	n/a
Non-amortizable intangible assets:				
Multiple trademarks	294,813	—	294,813	indefinite
TOTAL	$ 5,737,194	$ (478,983)	$ 5,258,211	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the nine months ended September 30, 2020 and 2019, we wrote off $584,509 and $78,864, respectively, in costs related to trademarks and patents.

As of September 30, 2020, we had 35 issued domestic patents and 35 issued foreign patents, including:

- 14 domestic patents and seven foreign patents that relate to BIJUVA as well as three domestic patents that relate to estradiol and progesterone product candidates. These patents establish an important intellectual property foundation and are owned by us. The domestic patents will expire in 2032. The foreign patents will expire no earlier than 2032. In addition, we have pending patent applications relating to BIJUVA in the U.S., Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.
- Ten domestic patents (eight utility and two design) and 16 foreign patents (six utility and ten design) that relate to IMVEXXY. These patents establish an important intellectual property foundation for IMVEXXY and are owned by us. The domestic patents will expire in 2032 or 2033. The foreign utility patents will expire no earlier than 2033. The foreign design patents provide protection expiring no earlier than 2025. In certain countries, the foreign design patents provide protection through at least 2037. In addition, we have pending patent applications related to IMVEXXY in the U.S., Argentina, Australia, Brazil, Canada, Europe, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.

- One domestic utility patent that relates to our topical-cream candidates, which is owned by us. The domestic patent will expire in 2035.
- One domestic utility patent and eight foreign patents that relate to our transdermal-patch candidates, which are owned by us. The domestic utility patent will expire in 2032. The foreign patents will expire no earlier than 2033. We have pending patent applications with respect to our transdermal-patch candidates in the U.S., Brazil, Canada, Mexico, and South Africa.
- Three domestic utility patents that relate to TX-009HR, a progesterone and estradiol product candidate, which are owned by us and will expire in 2037.
- Two domestic and four foreign patents that relate to formulations containing progesterone, which are owned by us. The domestic patents will expire between 2032 and 2036. The foreign patents will expire no earlier than 2033.
- One domestic utility patent that relates to our OPERA information-technology platform, which is owned by us and will expire in 2031.

Amortization expense was $69,977 and $51,259 for the three months ended September 30, 2020 and 2019, respectively, and $200,879 and $140,206 for the nine months ended September 30, 2020 and 2019, respectively. Estimated amortization expense, based on current patent cost being amortized, for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2020 (3 months)	$ 69,977
2021	$ 279,909
2022	$ 279,909
2023	$ 279,909
2024	$ 279,909

NOTE 8– OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2020	December 31, 2019
Accrued payroll, bonuses and commission costs	$ 4,381,729	$ 8,040,278
Allowance for coupons and returns	8,353,403	10,316,298
Accrued sales and marketing costs	1,578,971	3,285,662
Accrued compensated absences	2,558,055	1,463,878
Allowance for wholesale distributor fees	2,130,230	2,347,122
Accrued legal and accounting expense	1,052,935	422,336
Accrued research and development	1,059,077	1,049,603
Operating lease liability	2,404,286	1,501,539
Accrued rebates	6,629,732	3,916,672
Other accrued expenses	1,072,066	1,480,225
TOTAL OTHER CURRENT LIABILITIES	$ 31,220,484	$ 33,823,613

NOTE 9 – DEBT

On April 24, 2019, we entered into a Financing Agreement, as amended, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which provides us with up to a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for availability to us in three tranches: (i) $200,000,000 was drawn upon entering into the Financing Agreement; (ii) $50,000,000 was drawn on February 18, 2020 following our achievement of more than $11,000,000 in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019 and (iii) $50,000,000 was previously available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the quarter ended June 30, 2020 or at such earlier date as the Administrative Agent may have consented to. Due to the pause in the successful full launch of ANNOVERA caused by the COVID-19 pandemic, the undrawn $50,000,000 tranche under the Financing Agreement is no longer available. Borrowings under the Facility accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.2% as selected by us. Interest on amounts borrowed under the Facility is payable quarterly. The outstanding principal amount of the Facility is payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. We have the right to prepay borrowings under the Facility in whole or in part at any time, subject to a prepayment fee on the principal amount being prepaid of (i) 30.0% for the first two years following the initial funding date of the applicable borrowing, (ii) 5.0% for the third year following the initial funding date of the applicable borrowing, (iii) 3.0% for the fourth year following the initial funding date of the applicable borrowing and (iv) 1.0% for the fifth year following the initial funding date of the applicable borrowing but prior to March 31, 2024. In connection with the initial borrowing under the Facility, we paid, for the benefit of the lenders, a facility fee equal to 2.5% of the initial amount borrowed and will be required to pay such a facility fee in connection with any subsequent borrowings under the Facility. We are also required to pay the Administrative Agent and the lenders an annual administrative fee in addition to other fees and expenses. The Financing Agreement contains customary mandatory prepayments, restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, we are required to (i) maintain a minimum unrestricted cash balance of $60,000,000, and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our IMVEXXY, BIJUVA and ANNOVERA products beginning with the fiscal quarter ending December 31, 2020. Pursuant to Amendment No. 6, the minimum required cash balance was lowered to $45 million through December 31, 2020. As of September 30, 2020, we were in compliance with all covenants under the Financing Agreement. The Financing Agreement also includes other representations, warranties, indemnities and events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon or after an event of default, the Administrative Agent and the lenders may declare all or a portion of our obligations under the Financing Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Financing Agreement. The obligations of our company and its subsidiaries under the Financing Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all existing and after acquired assets of our company and its subsidiaries. The obligations under the Financing Agreement will be guaranteed by each of our future direct and indirect subsidiaries, subject to certain exceptions.

On May 1, 2018, we entered into a Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust, or MidCap, as agent, or Agent, and as lender, and the additional lenders party thereto from time to time (together with MidCap as a lender, the Lenders), as amended. The Credit Agreement provided a secured term loan facility in an aggregate principal amount of up to $200,000,000, or the Term Loan. Under the terms of the Credit Agreement, the Term Loan was available to be made in three separate tranches, with each tranche to be made available to us, at our option, upon our achievement of certain milestones. Amounts borrowed under the Term Loan bore interest at a rate equal to the sum of (i) one-month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum.

On April 24, 2019, we terminated the Credit Agreement. A portion of the initial tranche of borrowing under the Financing Agreement in the amount of approximately $81,661,000 was used to repay all amounts outstanding under the Credit Agreement, which included a prepayment fee of 4%, a repayment fee of 4% and other fees and expenses payable to the lenders under the Credit Agreement. As a result of the termination of the Credit Agreement, we recorded $10,057,632 in loss on extinguishment of debt in the second quarter of 2019. Interest expense for the nine months ending September 30, 2019 related to the Credit Agreement was $1,816,747. During the nine months ended September 30, 2019, and prior to the repayment of the Credit Agreement, we amortized $120,146 of deferred financing fees as interest expense in the accompanying unaudited consolidated financial statements.

On August 5, 2020, we entered into Amendment No. 5 to the Financing Agreement, or Amendment No. 5. Amendment No. 5 adjusts the covenant in the Financing Agreement regarding our achievement of minimum consolidated net revenue attributable to commercial sales of our IMVEXXY, BIJUVA, and ANNOVERA products to reflect the impact of COVID-19 on our business. The covenant is effective beginning with the fiscal quarter ending December 31, 2020. In connection with Amendment No.5 and in lieu of a cash amendment fee, we issued to the Administrative Agent and the lenders under the Financing Agreement warrants to purchase an aggregate of 4,752,116 shares of Common Stock with an exercise price of $1.58 per share and a ten-year term, or the Lender Warrants. The Lender Warrants were issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, and no registration rights were issued. The Company concluded that the modification accounting model is applicable to this transaction and recognized the fair value of the warrants as a debt discount.

As of September 30, 2020, we had $250,000,000 in borrowings outstanding under the Financing Agreement, which are classified as long-term debt in the accompanying consolidated financial statements. We incurred $7,902,270 in deferred financing fees related to the Financing Agreement. Deferred financing fees related to the entire Financing Agreement have been allocated pro rata between the funded and unfunded tranches. Allocated deferred financing fees related to the two tranches of borrowings that we received of $7,626,891 have been reflected as a debt discount upon each draw and are amortized to interest expense using the effective interest method. In addition, during the three months ended September 30, 2020, we recorded the fair value of the Lender Warrants of $7,428,179 as a debt discount, which is being amortized to interest expense using the effective interest method over the term of the Financing Agreement. During the three months ended September 30, 2020, we concluded that the undrawn $50,000,000 tranche under the Financing Agreement is no longer available to us. As such, we wrote off $275,379 of deferred financing fees associated with the unfunded tranche, which were previously deferred as assets until such tranche had been drawn.

During the three and nine months ended September 30, 2020, we amortized $677,676 and $1,370,118, respectively, of deferred financing fees related to the Financing Agreement as interest expense in the accompanying consolidated financial statements. During the three and nine months ended September 30, 2019, we amortized $265,949 and $462,683, respectively, of deferred financing fees related to the Financing Agreement as interest expense in the accompanying consolidated financial statements. Interest on amounts borrowed under the Financing Agreement is due and payable quarterly in arrears. Interest expense for the three and nine months ended September 30, 2020 was $6,726,389 and $19,322,847, respectively. Interest expense for the three and nine months ended September 30, 2019 was $5,333,056 and $9,318,056, respectively. The overall effective interest rate under the Financing Agreement was approximately 12.5% as of September 30, 2020.

As of September 30, 2020 and December 31, 2019, the carrying value of our debt consisted of the following:

	September 30, 2020	December 31, 2019
Financing Agreement	$ 250,000,000	$ 200,000,000
Debt discount and financing fees	(12,948,798)	(5,365,357)
TOTAL LONG-TERM DEBT	$ 237,051,202	$ 194,634,643

On April 27, 2020, we received a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), as administered by the U.S. Small Business Administration. The loan in the principal amount of $6,477,094 (the "PPP Loan") was disbursed by Bank of America, NA, a national banking association, pursuant to a promissory note issued by the Company. Although we believed, in good faith, we were qualified for the PPP Loan under the available regulations, as a result of newly-issued guidance, particularly with respect to publicly traded companies receiving funding under the CARES Act, we voluntarily returned the PPP Loan proceeds on May 14, 2020.

NOTE 10 – NET LOSS PER SHARE

We calculate earnings per share, or EPS, in accordance with ASC 260, *Earnings Per Share*, which requires the computation and disclosure of two EPS amounts: basic and diluted. We compute basic EPS based on the weighted-average number of shares of Common Stock outstanding during the period. We compute diluted EPS based on the weighted-average number of shares of our Common Stock outstanding plus all potentially dilutive shares of our Common Stock outstanding during the period. Such potentially dilutive shares of our Common Stock consist of options, warrants and restricted stock units and were excluded from the calculation of diluted earnings per share because their effect would have been anti-dilutive due to the net loss reported by us. The table below presents potentially dilutive securities that could affect our calculation of diluted net loss per share allocable to common stockholders for the periods presented.

	September 30, 2020	September 30, 2019
Stock options	23,893,180	24,849,984
Warrants	6,534,687	1,832,571
Performance stock units	2,422,885	—
Restricted stock units	6,029,957	1,240,000
	38,880,709	27,922,555

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 2020, we had 10,000,000 shares of preferred stock, par value $0.001 per share, authorized for issuance, of which no shares were issued or outstanding.

Common Stock

At September 30, 2020, we had 600,000,000 shares of Common Stock authorized for issuance, of which 272,812,271 shares of Common Stock were issued and outstanding.

Issuances During the Three and Nine Months ended September 30, 2020

During the three months ended September 30, 2020, stock options to purchase an aggregate of 517,891 shares of Common Stock were exercised for $105,494 in cash. During the nine months ended September 30, 2020, stock options to purchase an aggregate of 1,182,195 shares of Common Stock were exercised for $271,678 in cash.

Issuances During the Three and Nine Months ended September 30, 2019

During the three months ended September 30, 2019, certain individuals exercised stock options to purchase an aggregate of 55,236 shares of Common Stock for $8,549 in cash. During the nine months ended September 30, 2019, certain individuals exercised stock options to purchase an aggregate of 331,619 shares of Common Stock for $108,656 in cash. Also, during the same period, stock options to purchase an aggregate of 12,097 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein an aggregate of 11,834 shares of Common Stock were issued.

Warrants to Purchase Common Stock

As of September 30, 2020, we had warrants outstanding to purchase an aggregate of 6,534,687 shares of Common Stock with a weighted-average contractual remaining life of approximately 7.5 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $1.83 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate, dividend yield and the term of the warrant.

In connection with Amendment No. 5 and in lieu of a cash amendment fee, we issued to the Administrative Agent and the lenders under the Financing Agreement the Lender Warrants. The fair value for the Lender Warrants was determined by using the Black-Scholes Model on the date of the grant using a term of ten years, volatility of 68.8%, risk-free interest rate of 0.34% and dividend yield of 0%. The grant date fair value of the warrants was $1.56 per share. The warrants vested upon issuance. We concluded that the modification accounting model is applicable to this warrant issuance and recognized the fair value of the warrants as a debt discount. As a result, the fair value of the Lender Warrants is being amortized to interest expense over the term of the Financing Agreement.

We recorded share-based compensation expense related to warrants previously issued of $0 and $56,418 for the three months ended September 30, 2020 and 2019, respectively, and $26,446 and $198,306 for the nine months ended September 30, 2020 and 2019, respectively, in the accompanying consolidated financial statements. At September 30, 2020, there was no unrecognized compensation expense remaining related to unvested warrants.

During the nine months ended September 30, 2019, we granted warrants to purchase an aggregate of 75,000 shares of Common Stock to outside consultants at an exercise price of $5.63. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years, volatility of 60.8%, risk-free interest rate of 2.52%, and dividend yield of 0%. The grant date fair value of the warrants was $3.00 per share. The warrants are vesting ratably over a 12-month period and have an expiration date of February 12, 2024.

During the nine months ended September 30, 2020, no warrants were exercised. During the nine months ended September 30, 2019, warrants to purchase an aggregate of 1,250,000 shares of Common Stock were exercised pursuant to the warrants' cashless exercise provisions, wherein an aggregate of 471,184 shares of Common Stock were issued.

Options to Purchase Common Stock

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. As of September 30, 2020, there were non-qualified stock options to purchase an aggregate of 13,346,455 shares of Common Stock outstanding under the 2009 Plan. Effective upon our adoption of the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, or the 2019 Plan, on June 20, 2019, no future awards may be made under the 2009 Plan.

In 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. As of September 30, 2020, there were non-qualified stock options to purchase an aggregate of 6,305,974 shares of Common Stock outstanding and an aggregate of 890,000 restricted stock units under the 2012 Plan. Effective upon our adoption of the 2019 Plan, no future awards may be made under the 2012 Plan.

On June 20, 2019, we adopted the 2019 Plan to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. The Awards available under the 2019 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2019 Plan. Generally, the options vest annually over four years or as determined by our board of directors, upon each option grant. Options may be exercised by paying the price for shares or on a cashless exercise basis after they have vested and prior to the specified expiration date provided and applicable exercise conditions are met, if any. The expiration date is generally ten years from the date the option is issued.

As of September 30, 2020, there were 3,465,514 shares of Common Stock available for issuance under the 2019 Plan, consisting of (i) 470,522 new shares, (ii) 2,405,833 unallocated shares previously available for issuance under the 2012 Plan that were not then subject to outstanding "Awards" (as defined in the 2012 Plan), and (iii) 589,159 unallocated shares previously available for issuance under the 2009 Plan that were not then subject to outstanding "Awards" (as defined in the 2009 Plan). Any shares subject to outstanding options or other equity "Awards" under the 2019 Plan, the 2012 Plan and the 2009 Plan that are forfeited, expire or otherwise terminate without issuance of the underlying shares, or if any such Award is settled for cash or otherwise does not result in the issuance of all or a portion of the shares subject to such Award (other than shares tendered or withheld in connection with the exercise of an Award or the satisfaction of withholding tax liabilities), the shares to which those Awards were subject, shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, again be available for delivery with respect to Awards under the 2019 Plan. As of September 30, 2020, there were non-qualified stock options to purchase an aggregate of 4,240,751 shares of Common Stock outstanding under the 2019 Plan and an aggregate of 5,139,957 restricted stock units and 2,422,885 performance stock units outstanding under the 2019 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The ranges of assumptions used in the Black-Scholes Model during the nine months ended September 30, 2020 and 2019 are set forth in the table below.

	September 30, 2020	September 30, 2019
Weighted average grant date fair value	$ 0.95	$ 1.84
Risk-free interest rate	0.34-1.68%	1.83-2.54%
Volatility	63.53-67.92%	61.25-64.49%
Term (in years)	6-6.8	5.5-6.5
Dividend yield	0.00%	0.00%

A summary of option activity under the 2009, 2012 and 2019 Plans and related information during the nine months ended September 30, 2020 is as follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2019	25,030,234	$ 4.65	5.84	$ 3,668,171
Granted	736,500	$ 1.58		
Exercised	(1,182,195)	$ 0.23		$ 1,738,740
Expired	(361,109)	$ 3.66		
Cancelled/Forfeited	(330,250)	$ 3.69		
Balance at September 30, 2020	23,893,180	$ 4.80	5.46	$ 379,535
Vested and Exercisable at September 30, 2020	19,827,306	$ 5.06	4.83	$ 218,370
Unvested at September 30, 2020	4,065,874	$ 3.55	8.53	$ 161,165

At September 30, 2020, our outstanding options had exercise prices ranging from $0.38 to $8.92 per share. Share-based compensation expense related to options recognized in our results of operations for the three months ended September 30, 2020 and 2019 was $1,143,920 and $2,194,667, respectively, and for the nine months ended September 30, 2020 and 2019 was $4,141,061 and $6,568,736, respectively, and it is based on awards vested. At September 30, 2020, total unrecognized estimated compensation expense related to unvested options was approximately $6,500,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.0 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock units granted under our 2009, 2012 and 2019 Plans entitle the holder to receive, at the end of vesting period, a specified number of shares of our Common Stock. Share-based compensation expense is measured by the market value of our Common Stock on the day of the grant. The shares vest ratably over the period specified in the grant. There is no partial vesting and any unvested portion is forfeited.

Performance stock units will vest if certain performance targets are achieved. If minimum performance thresholds are achieved, each award will convert into Common Stock at a defined ratio depending on the degree of achievement of the performance target designated by each individual award. If minimum performance thresholds are not achieved, then no shares will be issued. We recognize performance-based restricted stock as compensation expense based on the most likely probability of attaining the prescribed performance and over the requisite service period beginning at its grant date and through the date the restricted stock vests. The expected levels of achievement are reassessed over the requisite service periods and, to the extent that the expected levels of achievement change, stock-based compensation is adjusted and recorded on the consolidated statements of income and the remaining unrecognized stock-based compensation is recognized over the remaining requisite service period.

During the three and nine months ended September 30, 2020 we recorded $1,988,844 and $4,334,537, respectively, and during the three and nine months ended September 30, 2019 we recorded $84,061 and $1,080,738, respectively, in share-based compensation expense related to restricted stock units and performance stock units. As of September 30, 2020, we recognized performance-based compensation expense using our assessment of the most likely probability of attaining EBITDA break-even which would result in vesting two times the base number of performance stock units. At September 30, 2020, total unrecognized estimated compensation expense related to unvested restricted stock units and performance stock units was approximately $11,000,000, which may be adjusted if certain performance targets are achieved or for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 1.6 years.

Schedule of restricted stock units and performance stock units

	Restricted Stock Units		Performance Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2019	1,240,000	$ 3.56	—	$ —
Granted	5,102,817	$ 1.40	2,585,745	$ 1.08
Vested/Released	(301,500)	$ 1.78	(151,500)	$ 1.14
Forfeited	(11,360)	$ 1.07	(11,360)	$ 1.07
Balance at September 30, 2020	6,029,957	$ 1.83	2,422,885*	$ 1.08

* The number of performance stock units (PSUs) represents the base number of PSUs that may vest. The actual number of PSUs that will vest will be between zero and two times the base number of PSUs depending on the Company's achievement of break-even quarterly EBITDA.

Employee Stock Purchase Plan

On June 18, 2020, our stockholders approved the TherapeuticsMD, Inc. 2020 Employee Stock Purchase Plan (the “ESPP”), which reserved 5,400,000 shares of Common Stock for purchase. The ESPP permits eligible employee participants to purchase Common Stock at a price per share which is equal to 85% of the lesser of (a) the fair market value of the shares on the offering date of the offering period or (b) the fair market value of the shares on the purchase date.

NOTE 12 – INCOME TAXES

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We do not expect to pay any significant federal or state income tax for 2020 as a result of (i) the losses recorded during the nine months ended September 30, 2020, (ii) additional losses expected for the remainder of 2020, and/or (iii) net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is “more likely than not” that some component or all of the benefits of deferred tax assets will not be realized. As of September 30, 2020, we maintain a full valuation allowance for all deferred tax assets. Based on these requirements, no provision or benefit for income taxes has been recorded. There were no recorded unrecognized tax benefits at the end of the reporting period.

NOTE 13 – RELATED PARTIES

In July 2015, J. Martin Carroll, a director of our company, was appointed to the board of directors of Catalent, Inc. From time to time, we have entered into agreements with Catalent, Inc. and its affiliates, or Catalent, in the normal course of business. Agreements with Catalent have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our company, since July 2015. During the three months ended September 30, 2020 and 2019, we were billed by Catalent approximately $520,000 and $2,196,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. During the nine months ended September 30, 2020 and 2019, we were billed by Catalent approximately $2,563,000 and $4,118,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of September 30, 2020 and December 31, 2019, there were amounts due to Catalent of approximately $147,000 and $35,000, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 15, Commitments and Contingencies.

In April 2020, Karen L. Ling, Executive Vice President and Chief Human Resources Officer of American International Group, Inc., or AIG, was appointed to our board of directors. From time to time, we have entered into agreements with AIG in the normal course of business. Agreements with AIG have been reviewed by independent directors of our Company, or a committee consisting of independent directors of our Company, since April 2020. During the three and nine months ended September 30, 2020, we were billed by AIG approximately $52,000 and $195,000, respectively, for various insurance coverage for our Company.

NOTE 14 - BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 42%, 25% and 24% of our purchases supplied by three vendors each, respectively, during the nine months ended September 30, 2020, and 36%, 28%, and 26% of our purchases supplied by three vendors each, respectively, during the nine months ended September 30, 2019.

We sell our prescription products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. During the nine months ended September 30, 2020, three customers each accounted for more than 10% of our total product revenues. Product revenue from the three customers combined accounted for approximately 56% of our product revenue for the nine months ended September 30, 2020. During the nine months ended September 30, 2019, four customers each generated more than 10% of our product revenues. Revenue generated from the four customers combined accounted for approximately 68% of our product revenue for the nine months ended September 30, 2019.

During the nine months ended September 30, 2020, Pillpack, Inc. accounted for approximately $9,319,000 of our product revenue, Cardinal Health accounted for approximately $7,415,000 of our product revenue, and McKesson Corporation accounted for approximately $6,009,000 of our product revenue. During the nine months ended September 30, 2019, Pillpack, Inc. accounted for approximately $6,397,000 of our product revenue, AmerisourceBergen accounted for approximately $2,226,000 of our product revenue, PI Services accounted for approximately $1,935,000 of our product revenue and Cardinal Health accounted for approximately $1,863,000 of our product revenue.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Operating Leases

We adopted ASC 842, Leases, effective January 1, 2019. Substantially all our operating lease right-of-use assets and operating lease liabilities represent leases for office space used to conduct our business. Upon adoption, we recognized a right-of-use asset and a lease liability for all leases that have commenced as of January 1, 2019. The right-of-use assets represent the right to use the leased asset for the lease term. The lease liabilities represent the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using our secured incremental borrowing rate for the same term as the underlying lease because the rates are not implicit in the leases. Some of our leases contain variable lease payments, including payments based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement. Additional payments based on the change in an index or rate, or payments based on a change in our portion of the operating expenses are recorded as a period expense when incurred. Lease modifications result in remeasurement of the lease liability. Included in lease expense are any variable lease payments incurred in the period that were not included in the initial lease liability.

We lease administrative office space in Boca Raton, Florida pursuant to a non-cancelable operating lease that commenced on July 1, 2013 and originally provided for a 63-month term. On February 18, 2015, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. In addition, on April 26, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location. This agreement was effective beginning May 1, 2016 and extended the original expiration of the lease term to October 31, 2021. On October 4, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. This addendum became effective beginning November 1, 2016.

In October 2018, we entered into a lease for new corporate offices in Boca Raton, Florida. The lease includes 56,212 rentable square feet, or the full premises, of which the lease on 7,561 square feet commenced in 2018 and the lease on the remaining 48,651 square feet commenced in August 2019, or the full premises commencement date. The lease will expire 11 years after the full premises commencement date, unless terminated earlier in accordance with the terms of the lease. We have the option to extend the term of the lease for two additional consecutive periods of five years. The extension option is not included in the determination of the lease term as it is not reasonably certain to be exercised. The term of the lease includes escalating rent and free rent periods. We are also responsible for certain other operating costs under the lease, including electricity and utility expenses. In June 2019, we entered into an agreement with the same lessors to lease additional 6,536 square feet of administrative office space in the same location, pursuant to an addendum to such lease, which commenced in May 2020.

Supplemental lease information:	September 30, 2020	December 31, 2019
Right-of-use asset	$ 9,975,725	$ 10,109,154
Short-term operating lease liability (included in Other current liabilities)	$ 2,404,286	$ 1,501,539
Long-term operating lease liability	$ 8,907,995	$ 9,145,049
Weighted average remaining term	8.8 years	9 years
Weighted average discount rate	8.3%	8.25%

Supplemental cash flow information for the nine months ended	September 30, 2020	September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities for operating lease	$ 1,006,970	$ 849,440
Right-of-use assets obtained in exchange for lease obligation	$ 998,821	$ 11,171,471

The following table reconciles the undiscounted cash flows for all operating leases at September 30, 2020 to the operating lease liabilities recorded on the balance sheet:

Years Ended December 31,	
2020 (3 months)	$ 610,675
2021	2,334,582
2022	1,413,289
2023	1,443,143
2024	1,476,534
Thereafter	8,947,869
Total undiscounted lease payments	16,226,092
Less: imputed interest	(4,913,811)
Present value of lease payments	$ 11,312,281

During the three and nine months ended September 30, 2020, operating lease expense related to our real estate leases was approximately $590,000 and $1,749,000, respectively, and variable lease expense was approximately $148,000 and $226,000, respectively, for the same periods. During the three and nine months ended September 30, 2019, operating lease expense related to our real estate leases was approximately $458,000 and $1,062,000, respectively, and variable lease expense was insignificant for the same periods.

Intellectual Property Licenses

The Population Council License Agreement provides for future milestone payments to be paid by us for access to certain technologies. In addition, we pay royalties as a percent of product revenue as described in Note 7, Intangible Assets, to these consolidated financial statements.

Purchase Commitments

We have manufacturing and supply agreements whereby we are required to purchase from Catalent a minimum number of softgels during the first contract year and a higher number of softgels after the first contract year. If the minimum order quantities of specific products are not met, we are required to pay Catalent 50% of the difference between the total amount we would have paid to Catalent if the minimum requirement had been fulfilled and the sum of all purchases of our products from Catalent during the contract year. The updated minimum purchase commitments for Catalent for the next five years are as follows: 2020 - $3,719,000, 2021 - $2,150,000, 2022 - $2,991,000, 2023 - $3,347,000, and 2024 - $3,786,000. In addition, we have a manufacturing and supply agreement whereby we are required to purchase a minimum number of units of ANNOVERA during a contract year. As of September 30, 2020, we have met our contract year purchase commitments.

Legal Proceedings

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

Off-Balance Sheet Arrangements

As of September 30, 2020 and 2019, we had no off-balance sheet arrangements that have had or are reasonably likely to have current or future effects on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Employment Agreements

We have entered into employment agreements with certain of our executives that provide for compensation and certain other benefits. Under certain circumstances, including a change in control, some of these agreements provide for severance or other payments, if those circumstances occur during the term of the employment agreement.

NOTE 16 – SUBSEQUENT EVENTS

On November 8, 2020, we entered into Amendment No. 6 which temporarily lowered the minimum required cash balance under the Financing Agreement from $60 million to $45 million through December 31, 2020. After December 31, 2020, the minimum required cash balance will revert to $60 million. On November 8, 2020, in connection with entering into Amendment No. 6 to the Financing Agreement, we amended the Lender Warrants to provide for an adjustment to the exercise price if we conduct certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 is lower than the then-current exercise price.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

General

The following discussion and analysis provides information that we believe to be relevant to an assessment and understanding of our results of operations and financial condition for the periods described. This discussion should be read together with our unaudited consolidated financial statements and the notes to the financial statements, which are included in this Quarterly Report on Form 10-Q. This information should also be read in conjunction with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission, or the SEC, on February 24, 2020, or our Annual Report, including the audited financial statements and notes included therein. The reported results will not necessarily reflect future results of operations or financial condition.

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

Throughout this Quarterly Report on Form 10-Q, the terms “we,” “us,” “our,” “TherapeuticsMD,” or “our company” refer to TherapeuticsMD, Inc., a Nevada corporation, and unless specified otherwise, include our wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and vitaCare Prescription Services, Inc., a Florida corporation, or vitaCare.

This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA® which are protected under applicable intellectual property laws and are the property of, or licensed to, our company. Solely for convenience, trademarks, trade names and service marks referred to in this Quarterly Report on Form 10-Q may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Overview

TherapeuticsMD is 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.

Our portfolio of products focused on women's health allows us to efficiently leverage our sales and marketing plans to grow our recently approved products. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our pharmaceutical products has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our pharmaceutical products.

- In July 2018, we launched our FDA-approved product, IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause, which was approved by the FDA in May 2018.
- In April 2019, we launched our FDA-approved product, BIJUVA (estradiol and progesterone) capsules, our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA in October 2018.
- In October 2019, we began a "test and learn" market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual patient-controlled, procedure-free, reversible prescription contraceptive option for women, which was approved by the FDA in August 2018 and which we have licensed for commercialization in the U.S. pursuant to an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative on July 1, 2020.

We have also entered into license agreements with strategic partners to commercialize IMVEXXY and BIJUVA outside of the U.S.

- In July 2018, we entered into a license and supply agreement with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel.
- In June 2019, we entered into an exclusive license and supply agreement, or the Theramex License Agreement, with Theramex HQ UK Limited, or Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercial BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel.

Our common stock, par value $0.001 per share, or the Common Stock, is traded on the Nasdaq Global Select Market of The Nasdaq Stock Market LLC, or the Nasdaq, under the symbol "TXMD." We maintain websites at www.therapeuticsmd.com as well as various product websites. The information contained on our websites or that can be accessed through our websites does not constitute part of this Quarterly Report on Form 10-Q.

Impact of COVID-19 on our Business

Our business has been, and we anticipate that it will continue to be, impacted by the coronavirus (COVID-19) pandemic. Despite the ongoing COVID-19 pandemic, we remain committed to the execution of our corporate goals, demonstrated in part by the increase of our third quarter 2020 product revenue as compared to our second quarter of 2020 product revenue. During the third quarter of 2020, our product revenue increased primarily due to our sales force being able to visit more healthcare providers, or HCPs, as their offices opened. We resumed the full launch of ANNOVERA on July 1, 2020 and launched the new consumer marketing campaign for IMVEXXY in August 2020.

At this time, the extent of the impact of the COVID-19 pandemic on our business continues to be highly uncertain and difficult to predict. We developed a comprehensive COVID-19 contingency plan designed to preserve the value of our investments in our sales and marketing infrastructure, protect our balance sheet during this period of market disruption, and meet the needs of our patients and prescribers. This contingency plan was designed to be implemented in stages as we continue to evaluate the length of time that COVID-19 may impact our business, which is intended to allow us to conserve our financial resources during the COVID-19 pandemic and re-scale our sales and marketing activity when conditions warrant.

Our COVID-19 contingency plan is designed to support our strategy of driving product revenue by prioritizing ANNOVERA as the lead product, IMVEXXY in the second position and BIJUVA in the third position. As part of this plan, we reduced our marketing focus on BIJUVA so that we can prioritize driving our product revenue growth for ANNOVERA and IMVEXXY. Our COVID-19 contingency plan includes containing costs and cutting spending, preparing for a potential longer-term impact throughout the year, leveraging vitaCare to continue to meet the needs of our patients and prescribers, and ensuring continued availability of our products to patients.

Cost Containment and Spending Cuts

We reduced our operating expenses during the COVID-19 pandemic and we continue to identify areas in which we can further reduce operating expenses in the future. These cost cuts and reductions included permanent cost savings that had been identified by management, as well as the interim cessation of certain spending that may be restarted in future quarters. These cost cuts included:

- Negotiating lower fees or suspending services from third party vendors;
- Implementing certain hiring restrictions;
- Delaying or cancelling non-critical information technology projects;
- Eliminating travel, entertainment, meeting, and event expenses; and
- Reducing the size of our sales force and eliminating certain staff positions.

Employees and Sales Force

As live interactions with HCPs resumed during the third quarter of 2020, when healthcare professional offices opened, we continue to utilize digital engagement tools and tactics and virtual detailing to remain engaged with prescribers and distribution channels to supplement live interactions.

- Our sales force continues to support HCPs remotely, when it is necessary, including the sales forces' ability to continue to provide HCPs with access to patient product samples, product marketing information, and information regarding patient affordability programs and support services.
- Our sales force is in regular interaction with HCPs, including conducting live and "virtual" lunch and learn programs with providers.
- Our sales force also continues product training, including sharing best practices, in advance of our anticipated future sales and marketing ramp.

Remote Pharmacy and At-Home Delivery Options

As of the date of this Quarterly Report on Form 10-Q, we are providing continued access to our products for patients.

- Our products have broad distribution at all major retail pharmacy chains across the country.
- vitaCare patient model assists patients in obtaining easy and convenient access to their prescriptions for products at a retail pharmacy of their choice, including via home delivery retail pharmacy options. We anticipate that home delivery pharmacy options will continue to be attractive to patients during the COVID-19 pandemic.
- We anticipate that vitaCare will support continued patient access to our products during the COVID-19 pandemic and will help sustain refill trends for our products given vitaCare's broad use by our patients.
- We have also engaged with independent community pharmacies and multiple third-party online pharmacies and telemedicine providers that focus on contraception or menopause to help ensure patients have real-time access to both diagnosis and treatment.
- We have developed relationships with industry leaders and emerging technology companies in the telehealth sector, a sector that has seen accelerated growth as a result of COVID-19. Recognizing the importance of telehealth particularly in the contraception category, we began developing various telehealth partnerships in 2019. Among those partnerships are leading online telemedicine platforms which focus on directly prescribing and filling birth control directly to patients.

Supply of Products

As of the date of this Quarterly Report on Form 10-Q, we do not anticipate a shortage of our products due to the COVID-19 pandemic.

- We currently have sufficient inventory of finished product in our contracted warehouses to meet anticipated demand through the next six months.
- We currently do not foresee any interruption in our contract manufacturers' abilities to continue to manufacture additional products to be used. Our contract manufacturers have sufficient active pharmaceutical ingredients on hand for the continued manufacture of our products and there is currently no interruption in the supply chain for the active pharmaceutical ingredients for our products.
- We currently have uninterrupted wholesale and retail distribution of our products and are actively working to ensure that there continues to be an adequate supply of our products at pharmacies for sales to patients.

While we currently believe that our COVID-19 contingency plan has the ability to mitigate the effect of the COVID-19 pandemic on our business, the severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, the duration of "stay at home," quarantine or "social distancing" orders, the ability of our sales force to access healthcare providers to promote our products, increases in unemployment, which could reduce access to commercial health insurance for our patients, thus limiting payer coverage for our products, and the impact of the pandemic on our global supply chain, all of which are uncertain and cannot be predicted. 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.

Our business may also be affected by negative impacts of the COVID-19 pandemic on capital markets and economies worldwide, and it is possible that the pandemic could cause a local and/or global economic recession. While policymakers globally have responded with fiscal policy actions to support the healthcare industry and economy as a whole, the magnitude and overall effectiveness of these actions remains uncertain.

Our Products

IMVEXXY

In May 2018, the FDA approved the 4-µg and 10-µg doses of IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause. The 4-µg formulation of IMVEXXY represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY 10-µg became available for commercial distribution in July 2018 and both doses were commercially available in September 2018.

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

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

BIJUVA

In October 2018, the FDA approved BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg, 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 VMS (commonly known as hot flashes or flushes), due to menopause in women with a uterus. The estrogen and progesterone in BIJUVA have the same molecular structure as the hormones that are naturally produced in a woman's body. We launched BIJUVA in April 2019.

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

In late January 2020, we submitted a New Drug Application, or NDA, efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA for review and potential approval. The NDA efficacy supplement used existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. On November 5, 2020, we withdrew the NDA efficacy supplement. We currently intend to file a Formal Dispute Resolution Request, or FDRR, with the FDA that disputes the FDA's requirement that the efficacy supplement meet approval standards that have not been required of other approved drugs in BIJUVA's therapeutic class. There can be no assurance that we will prevail with respect to the FDRR, if filed, or that the 0.5/100 mg dose of BIJUVA will be approved.

With the approval of BIJUVA, the FDA required a post-approval commitment to further develop and validate our in-vitro dissolution method to show how BIJUVA is released from the capsule in an in-vitro setting for quality control assessments. The development of this method and validation were completed and submitted to the FDA as required in our approval.

Our hormone therapy pharmaceutical products are characterized by safety and efficacy profiles that can be consistently manufactured to target specifications. This provides an alternative to the non-FDA approved compounded bio-identical market. We believe that our FDA-approved pharmaceutical products offer advantages in terms of demonstrated safety and efficacy, consistency in the hormone dose, lower patient cost due to the increased likelihood of insurance coverage and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

ANNOVERA

In July 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only annual patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up to a total of 13 cycles (one year), which was approved by the FDA in August 2018. In October 2019, we began a "test and learn" market introduction phase of launch for ANNOVERA. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative on July 1, 2020.

ANNOVERA was classified by the FDA as a "new chemical entity," or NCE, and thus has five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. ANNOVERA is a one-year ring-shaped contraceptive vaginal system, or CVS. ANNOVERA, which is made with a silicone elastomer, contains segesterone acetate, a 19-nor progesterone derivative also known as Nestorone®, or SA, and ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, an NCE, is a potent progestin that, based on pharmacological studies in animals and *in vitro*, does not bind to the androgen or estrogen receptors and has no glucocorticoid activity at contraceptive doses. SA has been evaluated in 51 clinical studies across these delivery systems with more than 26,794 cycles of exposure.

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

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. In accordance with the post-marketing requirements, the full protocol for the study was submitted to the FDA in August 2019. 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 million, half of such excess will offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

We believe that ANNOVERA will compete across all the contraception options for women with focus on those women seeking a long-lasting option without a procedure.

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

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

Commercialization Model

We are commercializing the products in our portfolio through a common model focused on the belief that providing good experiences for both HCPs and patients will drive profitability for TherapeuticsMD. Given that our portfolio focus is exclusively in women's health, we believe that each new product launch will allow us to further leverage our existing infrastructure and build out our reputation as the premier women's health organization in the U.S. Below is more detail on our commercialization model:

HCP Education - Initially, we focus on the high writing and high potential HCPs in each territory to gain a full understanding of their prescribing behavior and practices. Our focus is on driving initial prescriptions of these writers for each new product launch and utilizing the time to also pull through on our portfolio of existing products. Once regular writing is established with the initial group of HCPs, we expand our reach to a larger set of HCPs writing in the category. We educate HCPs on our products primarily with our field sales organization supplemented by non-personal promotion. Our sales force currently targets approximately 130 territories, which includes the most significant part of the addressable markets across our product portfolio. As of September 30, 2020, more than 20,400 HCPs had written at least one prescription for IMVEXXY and more than 6,600 HCPs had written at least one prescription for BIJUVA, the majority of whom are also IMVEXXY writers demonstrating the value of portfolio and focus. In addition, as of September 30, 2020, more than 3,500 HCPs had written at least one prescription for ANNOVERA. In addition to our sales organization, we leverage non-personal promotion (multi-channel advertising) to targets and non-targets designed to drive awareness, education, and action. These efforts are designed to allow for pull through of the sales organization's efforts and identification of new targets that have interest in writing prescriptions for one or more of our products. We believe this will drive increased prescribing for our products and lift the overall writing universe and our products to top of mind in the HCP community.

BIO-IGNITE - In addition to our sales organization calling on HCPs, we have a Key Account Management, or KAM, team to support our existing BIO-IGNITE pharmacy partners and additional pharmacies that wish to enroll in the BIO-IGNITE program. Additionally, KAMs are focusing on supporting current prescribers of BIJUVA as well as high decile prescribers of hormone therapy for menopause.

Payer Access - With the ever-changing payer environment, we believe it is critical to maximize breadth of coverage as quickly as possible to not inhibit patient access to product. We do this while working to negotiate the best possible contracts for us. Many commercial payers employ "new-to-market blocks" for newly launched products until the payers have the opportunity to make a coverage decision based upon their internal review of the product. When a product is not covered, the patient is responsible to pay the full price for the medication, which can significantly limit utilization of the product. As we seek to increase the number of lives covered by commercial payers, it is our objective to continue to seek unrestricted coverage. As of September 30, 2020, we have obtained coverage for the majority of commercial payers by commercial payer lives for IMVEXXY and BIJUVA and continue to seek unrestricted coverage from the remaining commercial insurance plans that we have not yet contracted with to provide affordable access for patients. For IMVEXXY, we achieved unrestricted coverage with the top ten commercial payers of VVA products by commercial payer lives and we continue to sign new agreements with other payers to cover IMVEXXY. In addition, as of September 30, 2020, four of the top eight Medicare Part D payers of VVA products, based on covered lives, were adjudicating IMVEXXY, with additional decisions for other Medicare Part D payers expected during the second half of 2020. For BIJUVA, through September 30, 2020, we have achieved unrestricted coverage with nine of the top ten commercial payers of VMS products by commercial payer lives and we continue to sign new agreements with payers to cover BIJUVA. Although Medicare is a small percentage of the VMS market, as of September 30, 2020, two of the top six Medicare Part D payers of VMS products, based on covered lives, were adjudicating BIJUVA.

For ANNOVERA, we believe that its unique characteristics will assist us in pursuing favorable commercial payer coverage, including only one pharmacy fill fee per year and no office visit or procedure fees. We have made substantial progress in achieving unrestricted access to ANNOVERA through commercial payers, including having achieved adjudication with six of the top ten commercial payers by commercial payer lives as of September 30, 2020, and we continue to pursue discussions with several of the country's largest commercial insurers to further expand coverage. As of September 30, 2020, approximately 61% of the commercial payer market covered ANNOVERA with unrestricted access under pharmacy benefits and approximately 73% covered ANNOVERA with step or prior authorization access.

In February 2020, we entered into an agreement with Afaxys Pharma, LLC, a pharmaceutical company focused on serving women in the public health system, to market ANNOVERA in the U.S. public health sector. As part of the Population Council License Agreement, we have agreed to provide significantly reduced pricing to federally designated Title X family planning clinics serving underrepresented women. We also have agreements to market ANNOVERA to the U.S. Department of Defense, the U.S. Department of Veteran's Affairs, and in Puerto Rico.

Supply - We want to ensure our products are available in all classes of trade and delivery systems. We offer our products through traditional chain wholesalers (Cardinal, McKesson and AmerisourceBergen) and independent retail pharmacies, community compounding pharmacies with our BIO-IGNITE program, and online pharmacies. We continue to develop unique opportunities to sell direct to pharmacies to streamline distribution and better control costs.

Patient Affordability Programs - We have affordability and adherence programs in place for patients so that we can support appropriate use of our products by patients. Our co-pay assistance programs allow all patients to access our products at a reasonable cost.

- We continue to support our patient education and affordability program that allows all eligible patients who enroll to receive IMVEXXY and BIJUVA at a reasonable cost. When a product is not covered by a patient's commercial insurance, the patient is responsible to pay the full price for the medication, which can significantly limit a patient's ability to pay and subsequent utilization of the product. For IMVEXXY and BIJUVA, enrolled patients pay as little as $35 for a prescription with commercial insurance coverage and pay as little as $50 for a prescription without commercial insurance coverage. For ANNOVERA, for commercially insured patients, we offer patients assistance for as low as $60 for an annual prescription. Many patients will not need a co-pay assistance program for ANNOVERA given the requirements of the Affordable Care Act, or ACA, at the federal level and similar laws at the state level.

- We continue to dialogue with the FDA regarding the potential inclusion of ANNOVERA as a new class of contraception for women in the FDA's Birth Control Guide, which would require private health plans to cover ANNOVERA with no patient out-of-pocket costs as part of the ACA. There is no assurance that the FDA will make such a determination and it is possible that other FDA-approved products could also be included in such a new class. The FDA may also find that ANNOVERA fits into the vaginal contraceptive ring class, which it would share with NuvaRing and its generic equivalents, and potentially others. Eight states require insurance coverage of prescription contraception with co-pay regardless of inclusion in the FDA's Birth Control Guide and 11 states, plus Washington D.C., require coverage of prescription contraception with no co-pay regardless of inclusion in the FDA's Birth Control Guide.

Patient Adherence - Establishing compliance and adherence programs that make getting on a prescription medication and obtaining prescribed refills easy and convenient for the patient and HCPs is a critical lever in our commercial model. Our focus is on minimizing complications in patients filling their first prescription and engaging with them throughout the life of their treatment to ensure patients stay on and use therapy for the appropriate length of time. We have delivered effective patient engagement programs for all of our products.

Consumer Communication - Another critical level in the commercial model is consumer outreach. Our initial focus is on those patients who are already predisposed to seek treatment, such as those patients new to therapy, and those patients dissatisfied with their current therapy. Next, we are focused on expanding the market by energizing patients who are experiencing bothersome symptoms but who have not been motived to seek treatment. Methods of communication include online and offline media and span branded and unbranded communication to ensure we drive action from awareness of symptoms to desire to speak to an HCP to acquire a prescription.

License Agreements

License Agreement with the Population Council

Under the terms of the Population Council License Agreement, we paid the Population Council a milestone payment of $20 million within 30 days following approval by the FDA of the NDA for ANNOVERA. The first commercial batch of ANNOVERA was released during the third quarter of 2019, and we paid the Population Council a second milestone payment of $20 million as a result of the commercial batch release. The Population Council is eligible to receive additional milestone payments and royalties from commercial sales of ANNOVERA, as detailed below. We assumed responsibility for marketing expenses related to the commercialization of ANNOVERA. We are required to pay the Population Council additional milestone payments of $40 million upon cumulative net sales of ANNOVERA in the U.S. by us and our affiliates and permitted sublicensees of each of $200 million, $400 million and $1.0 billion.

In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA in the U.S. by us and our affiliates and permitted sublicensees as follows:

Annual Net Sales	Royalty Rate
Less than or equal to $50.0 million	5%
Greater than $50.0 million and less than or equal to $150.0 million	10%
Greater than $150.0 million	15%

The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of ANNOVERA that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate.

The Population Council has agreed to perform and pay the costs and expenses associated with two post-approval studies required by the FDA for ANNOVERA and we have agreed to perform and pay the costs and expenses associated with a post-approval study required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will be offset against royalties or other payments owed by us to the Population Council under the Population Council License Agreement. We and the Population Council formed a joint product committee responsible for overseeing activities under the Population Council License Agreement. We are responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee.

Unless earlier terminated, the Population Council License Agreement will remain in effect until the later of the expiration of the last-to-expire of the Population Council's U.S. patents that are licensed to us, or the date following such expiration that follows a continuous period of six months during which we and our affiliates have not made a commercial sale of ANNOVERA in the U.S. The Population Council License Agreement may also be terminated for certain breach and bankruptcy-related events and by us on 180 days' prior notice to the Population Council.

As part of the Population Council License Agreement, we have the exclusive right to negotiate co-development and U.S. marketing rights for two other investigational vaginal contraceptive systems in development by the Population Council.

License Agreement with Knight

In July 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and BIJUVA in Canada and Israel. Pursuant to the terms of the Knight License Agreement, Knight paid us $2 million in milestone fees upon the first regulatory approval in Canada for IMVEXXY and BIJUVA in the third quarter of 2020, and is also required to pay us sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY and BIJUVA and royalties based on aggregate annual sales of each of IMVEXXY and BIJUVA in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY and BIJUVA. We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY and BIJUVA in Canada within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters. As part of the Knight License Agreement, Knight is prohibited from exporting IMVEXXY and BIJUVA to the United States.

License Agreement with Theramex

In June 2019, we entered into a licensing and supply agreement, or the Theramex License Agreement, with Theramex pursuant to which we granted Theramex an exclusive, perpetual license to commercialize BIJUVA and IMVEXXY for human use outside of the U.S., except for Canada and Israel, or the Theramex Territory. Pursuant to the terms of the Theramex License Agreement, Theramex paid us an upfront fee of EUR 14 million in cash. We are also eligible to receive up to an additional EUR 29.5 million in cash milestone payments, comprised of (i) an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for each of BIJUVA and IMVEXXY in certain specified markets and (ii) an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones in the Theramex Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments based on net sales of BIJUVA and IMVEXXY in the Theramex Territory. Theramex has agreed to submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY in certain specified markets within certain specified time periods and we may terminate the Theramex License Agreement if Theramex does not submit certain of such regulatory applications, submissions and/or registrations. We may also terminate the Theramex License Agreement if Theramex challenges our patents. Either party may terminate the Theramex License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Theramex Territory, except for certain specified markets. Pursuant to the terms of the Theramex License Agreement, we agreed to supply, or cause to be supplied, BIJUVA and IMVEXXY to Theramex. We and Theramex have agreed to form a joint product committee responsible for advising and overseeing activities under the Theramex License Agreement.

Intellectual Property

As of September 30, 2020, we had 35 issued foreign patents and 35 issued domestic or, U.S., patents, which included 14 domestic utility patents that relate to BIJUVA, three domestic patents that relate to estradiol and progesterone product candidates, ten domestic patents that relate to IMVEXXY, which establish an important intellectual property foundation for IMVEXXY, one domestic utility patent that relates to a pipeline transdermal patch technology, one domestic utility patent that relates to our topical-cream candidates, two domestic patents that relate to formulations containing progesterone, one domestic utility patent that relates to our OPERA® information technology platform, that we wrote off, and three domestic utility patents that relate to TX-009HR, our progesterone and estradiol drug candidate. During the nine months ended September 30, 2020 and 2019, we wrote off $584,509 and $78,864, respectively, in costs related to trademarks and patents.

Research and Development Expenses

A significant portion of our historical operating expenses have been incurred in research and development activities. Research and development expenses relate primarily to the development, support and maintenance of our drug candidates. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, and consultants that conduct our clinical and preclinical studies; employee related expenses, which include salaries and benefits, and non-cash share-based compensation; the cost of developing our chemistry, manufacturing, and controls capabilities, and costs associated with other research activities and regulatory approvals. Other research and development costs listed below consist of costs incurred with respect to drug candidates that have not received Investigational New Drug Application approval from the FDA.

The following table indicates our research and development expense by project for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(000s)		(000s)	
TX 001-HR(BIJUVA)	$ 563	$ 454	$ 1,680	$ 2,869
TX 004-HR(IMVEXXY)	248	527	1,004	1,869
ANNOVERA	439	396	1,308	2,109
Other research and development	777	2,701	4,046	8,513
Total	$ 2,027	$ 4,078	$ 8,038	$ 15,360

Research and development expenditures have been reduced as we refocused our resources towards the commercialization of our approved pharmaceutical products. We will continue to deploy limited resources as we develop our drug pipeline, continue stability testing and validation on our pharmaceutical products, develop and validate secondary manufacturers, prepare regulatory submissions and work with regulatory authorities on existing submissions.

The costs of clinical trials may vary significantly over the life of a project owing to a variety of factors. We base our expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties. Research and development expenditures for the drug candidates will continue after the trial completes for on-going stability and laboratory testing, regulatory submission and response work. For a discussion of the nature of efforts, steps and costs necessary to complete these projects, see “Item 1. Business — Research and Development” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses” contained in our Annual Report.

Results of Operations

Three months ended September 30, 2020 compared with three months ended September 30, 2019

	Three Months Ended September 30,		
	2020	2019	Change
		(000s)	
Product revenue, net	$ 17,343	$ 8,213	$ 9,130
License revenue	2,000	15,506	(13,506)
Cost of goods sold	3,279	1,444	1,835
Operating expenses	41,037	49,347	(8,310)
Operating loss	(24,973)	(27,072)	2,099
Other expense, net	(7,638)	(4,895)	(2,743)
Net loss	$ (32,611)	$ (31,967)	$ (644)

Revenue and Cost of Goods Sold

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. We launched IMVEXXY in the third quarter of 2018 and BIJUVA in the second quarter of 2019. We started selling ANNOVERA in the third quarter of 2019. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative on July 1, 2020. Product revenue for the three months ended September 30, 2020 increased approximately $9,130,000, or 111%, to approximately $17,343,000, compared with approximately $8,213,000 for the three months ended September 30, 2019. Product revenue increased primarily due to continued ramping of sales of IMVEXXY, BIJUVA and ANNOVERA during the three months ended September 30, 2020, as compared to the prior period, partially offset by a decrease in prenatal vitamins sales and slower than anticipated growth of our product revenue due to the impact of the COVID-19 pandemic.

Sales of IMVEXXY increased approximately $2,069,000 as compared to the prior period, primarily due to increased net product revenue per unit partially offset by a lower number of units sold. Sales of BIJUVA increased approximately $1,156,000 as compared to the prior period, primarily due to a higher number of units sold and increased net product revenue per unit. Sales of ANNOVERA increased approximately $6,019,000 as compared to the prior period, primarily due to a higher number of units sold and increased net product revenue per unit. In addition, during the three months ended September 30, 2020, our prenatal vitamin sales decreased approximately $114,000 due to a decreased number of units sold, partially offset by increased net product revenue per unit as compared to the prior period. In addition to our product revenue, during the three months ended September 30, 2020, we recognized license revenue of $2,000,000 from two non-refundable milestone payments from Knight under the terms of the Knight License Agreement, which we recognized at the point in time upon the regulatory approvals in Canada of each of IMVEXXY and BIJUVA. During the three months ended September 30, 2019, we recognized license revenue of approximately $15,506,000 from the upfront fee, which was a non-refundable payment, payable to us by Theramex under the terms of the Theramex License Agreement, which we recognized at the point in time when Theramex was able to use and benefit from the license, which was when the knowledge transfer of regulatory documents occurred.

During the launches of IMVEXXY and BIJUVA we introduced co-pay assistance programs which allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect that our product revenue will improve in the long term as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA, and ANNOVERA prescriptions at pharmacies.

Cost of goods sold increased approximately $1,835,000, or 127%, to approximately $3,279,000 for the three months ended September 30, 2020, as compared with approximately $1,444,000 for the three months ended September 30, 2019. This increase in cost of goods sold is attributable to the 111% increase in product revenue as compared to the prior period, an increase in the amortization of our license fee related to ANNOVERA of approximately $746,000, an increase in royalty fees of approximately $301,000, as well as approximately $152,000 of inventory obsolescence expense recorded during the three months ended September 30, 2020 as compared to the prior period. Our gross margin related to prescription products was approximately 81% and 82% for the three-month periods ended September 30, 2020 and 2019, respectively. The change in our gross margin between the two periods is primarily related to the change in product mix and its related costs.

Operating Expenses

Our principal operating costs include the following items as a percentage of total operating expenses.

	Three Months Ended September 30,	
	2020	**2019**
Sales and marketing costs, excluding human resources costs	39.4%	45.7%
Human resources related costs, including salaries, benefits and taxes	35.2%	27.4%
Product research and development costs	4.9%	8.3%
Professional fees and consulting costs	6.1%	8.3%
Other operating expenses	14.4%	10.3%

Our principal operating costs include the following items.

	Three Months Ended September 30,		
	2020	2019	Change
	(000s)		
Sales and marketing costs, excluding human resources costs	$ 16,182	$ 22,547	$ (6,365)
Human resources related costs	14,434	13,507	927
Product research and development costs	2,027	4,078	(2,051)
Professional fees and consulting costs	2,512	4,100	(1,588)
Other operating expenses	5,882	5,115	767
Total operating expenses	$ 41,037	$ 49,347	$ (8,310)

Sales and marketing costs, excluding human resources costs, for the three months ended September 30, 2020 decreased by approximately $6,365,000, or 28%, to approximately $16,182,000, compared with approximately $22,547,000 for the three months ended September 30, 2019. The sales and marketing costs, excluding human resources costs, decreased due to cost cutting initiatives put in place at the beginning of the COVID-19 pandemic, including reducing consulting and agency fees, reduced travel and lower physician education and training expenses caused by restrictions on in-person speaker programs due to the COVID-19 pandemic, which was partially offset by higher advertising expense and higher incentives during the three months ended September 30, 2020 as compared to the prior period.

Human resources costs, including salaries, benefits and taxes, for the three months ended September 30, 2020 increased by approximately $927,000, or 7%, to approximately $14,434,000, compared with approximately $13,507,000 for the three months ended September 30, 2019, as a result of an increase of approximately $725,000 in non-cash compensation expense included in this category related to employee stock-based compensation and an increase of approximately $202,000 in personnel costs due to continued commercialization of our prescription products.

Product research and development costs for the three months ended September 30, 2020 decreased by approximately $2,051,000, or 50%, to approximately $2,027,000, compared with approximately $4,078,000 for the three months ended September 30, 2019. Product research and development costs include costs related to manufacturing validation and early development trials, as well as salaries, wages, non-cash compensation, and benefits of personnel involved in research and development activities. Product research and development expenditures have been reduced as we refocused our resources towards the commercialization of our approved pharmaceutical products. We continue to deploy limited resources as we develop our drug pipeline, continue stability testing and validation on our pharmaceutical products, develop and validate secondary manufacturers, prepare regulatory submissions and work with regulatory authorities on existing submissions.

- Since the project's inception in February 2013, we have incurred approximately $132,715,000 in research and development costs with respect to BIJUVA.
- Since the project's inception in August 2014, we have incurred approximately $49,266,000 in research and development costs with respect to IMVEXXY.

For a discussion of the nature of efforts, steps and costs related to our research and development projects, see "Item 1. Business — Research and Development" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses" contained in our Annual Report.

Professional fees and consulting costs for the three months ended September 30, 2020 decreased by approximately $1,588,000, or 39%, to approximately $2,512,000, compared with approximately $4,100,000 for the three months ended September 30, 2019, primarily as a result of decreased recruiting and consulting fees, partially offset by increased legal fees.

All other operating expenses for the three months ended September 30, 2020 increased by approximately $767,000, or 15%, to approximately $5,882,000, compared with approximately $5,115,000 for the three months ended September 30, 2019, primarily as a result of increased dues and subscriptions, rent, and insurance, partially offset by decreased information technology, other office and travel expenses in part due to travel restrictions caused by the COVID-19 pandemic.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $2,099,000, or 8%, to approximately $24,973,000 for the three months ended September 30, 2020, compared with approximately $27,072,000 for the three months ended September 30, 2019, primarily as a result of a decrease in total operating expenses due to cost cutting initiatives put in place due to the COVID-19 pandemic and an increase in product revenue partially offset by increased cost of goods sold and decreased license revenue as compared to the prior period.

We anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that any commercialization of IMVEXXY, BIJUVA and ANNOVERA will be successful.

Other expense, net

Other non-operating expenses, net increased by approximately $2,743,000, or 56%, to an expense of approximately $7,638,000 for the three months ended September 30, 2020, compared with an expense of approximately $4,895,000 for the three months ended September 30, 2019, primarily as a result of increased interest expense related to our Financing Agreement. For more information regarding our Financing Agreement, see "Liquidity and Capital Resources" below.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately $644,000, or 2%, to approximately $32,611,000 for the three months ended September 30, 2020, compared with approximately $31,967,000 for the three months ended September 30, 2019. Net loss per share of Common Stock, basic and diluted, was ($0.12) and ($0.13) for the three months ended September 30, 2020 and 2019, respectively.

Nine months ended September 30, 2020 compared with nine months ended September 30, 2019

	Nine Months Ended September 30,		
	2020	2019	Change
		(000s)	
Product revenue, net	$ 40,294	$ 18,239	$ 22,055
License revenue	2,000	15,506	(13,506)
Cost of goods sold	10,394	3,456	6,938
Operating expenses	152,834	137,102	15,732
Operating loss	(120,934)	(106,813)	(14,121)
Other expense, net	(20,503)	(19,896)	(607)
Net loss	$ (141,437)	$ (126,709)	$ (14,728)

Revenue and Cost of Goods Sold

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. We launched IMVEXXY in the third quarter of 2018 and BIJUVA in the second quarter of 2019. We started selling ANNOVERA in the third quarter of 2019. We paused the planned full commercial launch of ANNOVERA in March 2020 due to the impact of the COVID-19 pandemic and resumed this initiative on July 1, 2020. Product revenue for the nine months ended September 30, 2020 increased approximately $22,055,000, or 121%, to approximately $40,294,000, compared with approximately $18,239,000 for the nine months ended September 30, 2019. Product revenue increased primarily due to continued ramping of sales of IMVEXXY, BIJUVA and ANNOVERA, partially offset by slower than anticipated growth of our product revenue due to the impact of the COVID-19 pandemic.

Sales of IMVEXXY increased approximately $8,414,000 as compared to the prior period, sales of BIJUVA increased approximately $3,485,000 as compared to the prior period, and sales of ANNOVERA increased approximately $10,127,000 as compared to the prior period, in each case primarily due to a higher number of units sold and increased net product revenue per unit. In addition, during the nine months ended September 30, 2020, our prenatal vitamin sales increased approximately $29,000 due to increased net product revenue per unit as compared to the prior period, partially offset by a decreased number of units sold. In addition to our product revenue, during the nine months ended September 30, 2020, we recognized aggregate license revenue of $2,000,000 from two non-refundable milestone payments from Knight under the terms of the Knight License Agreement, which we recognized at the point in time upon the regulatory approvals in Canada of each of IMVEXXY and BIJUVA. During the nine months ended September 30, 2019, we recognized license revenue of approximately $15,506,000 from the upfront fee, which was a non-refundable payment, payable to us by Theramex under the terms of the Theramex License Agreement, which we recognized at the point in time when Theramex was able to use and benefit from the license, which was when the knowledge transfer of regulatory documents occurred.

During the launches of IMVEXXY and BIJUVA, we introduced co-pay assistance programs which allow eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect that our product revenue will improve in the long term as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA, and ANNOVERA prescriptions at pharmacies.

Cost of goods sold increased approximately $6,938,000, or 201%, to approximately $10,394,000 for the nine months ended September 30, 2020, compared with approximately $3,456,000 for the nine months ended September 30, 2019. This increase is attributable to a 121% increase in product revenue as compared to the prior period, an increase in royalty fees of approximately $506,000, and an increase in amortization of our license fee related to ANNOVERA of approximately $2,246,000, as well as an increase of $2,232,000 inventory obsolescence expense, primarily related to BIJUVA, as compared to the prior period. Our gross margin related to prescription products was approximately 74% and 81% for the nine-month periods ended September 30, 2020 and 2019, respectively. The change in our gross margin between the two periods is primarily related to the change in product mix and its related costs, as well as inventory obsolescence expense described above.

Operating Expenses

Our principal operating costs include the following items as a percentage of total operating expenses.

	Nine Months Ended September 30,	
	2020	2019
Sales and marketing costs, excluding human resources costs	46.5%	44.2%
Human resources related costs, including salaries, benefits and taxes	30.6%	27.1%
Product research and development costs	5.3%	11.2%
Professional fees and consulting costs	5.7%	7.3%
Other operating expenses	11.9%	10.2%

Our principal operating costs include the following items:

	Nine Months Ended September 30,		
	2020	2019	Change
	(000s)		
Sales and marketing costs, excluding human resources costs	$ 71,051	$ 60,537	$ 10,514
Human resources related costs	46,779	37,162	9,617
Product research and development costs	8,038	15,360	(7,322)
Professional fees and consulting costs	8,734	10,025	(1,291)
Other operating expenses	18,232	14,018	4,214
Total operating expenses	$ 152,834	$ 137,102	$ 15,732

Sales and marketing costs, excluding human resources costs, for the nine months ended September 30, 2020 increased by approximately $10,514,000, or 17%, to approximately $71,051,000, compared with approximately $60,537,000 for the nine months ended September 30, 2019. This increase was primarily due to higher expenses associated with sales and marketing efforts to support the significant initiative related to the launch of ANNOVERA in March 2020, which was subsequently paused as a result of the COVID-19 pandemic and relaunched on July 1, 2020, as well as continuing to support the commercialization of BIJUVA and IMVEXXY, which was partially offset by cost cutting initiatives put in place at the beginning of the COVID-19 pandemic, including reducing consulting and agency fees. Sales and marketing costs, excluding human resources costs, also increased as compared to the prior period as a result of higher sales incentives due to the increase in product revenue, which was partially offset by lower physician education, training and travel expenses caused by restrictions on in-person speaker programs due to the COVID-19 pandemic. In addition, we recorded the write down of product samples of approximately $5,100,000, during the nine months ended September 30, 2020, primarily related to BIJUVA.

Human resources costs, including salaries, benefits and taxes, for the nine months ended September 30, 2020 increased by approximately $9,617,000, or 26%, to approximately $46,779,000, compared with approximately $37,162,000 for the nine months ended September 30, 2019, as a result of an increase of approximately $8,180,000 in personnel costs primarily in sales, marketing and regulatory areas to support commercialization of our prescription products, partially offset by cost cutting measures implemented due to the COVID-19 pandemic, and an increase of approximately $1,437,000 in non-cash compensation expense included in this category related to employee stock-based compensation during 2020 as compared to 2019.

Product research and development costs for the nine months ended September 30, 2020 decreased by approximately $7,322,000, or 48%, to approximately $8,038,000, compared with approximately $15,360,000 for the nine months ended September 30, 2019. Product research and development costs include costs related to manufacturing validation and early development trials, as well as salaries, wages, non-cash compensation, and benefits of personnel involved in research and development activities. Product research and development expenditures have been reduced as we refocused our resources towards the commercialization of our approved pharmaceutical products. We continue to deploy limited resources as we develop our drug pipeline, continue stability testing and validation on our pharmaceutical products, develop and validate secondary manufacturers, prepare regulatory submissions and work with regulatory authorities on existing submissions.

- Since the project's inception in February 2013, we have incurred approximately $132,715,000 in research and development costs with respect to BIJUVA.
- Since the project's inception in August 2014, we have incurred approximately $49,266,000 in research and development costs with respect to IMVEXXY.

For a discussion of the nature of efforts, steps and costs related to our research and development projects, see "Item 1. Business — Research and Development" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses" contained in our Annual Report.

Professional fees and consulting costs for the nine months ended September 30, 2020 decreased by approximately $1,291,000, or 13%, to approximately $8,734,000, compared with approximately $10,025,000 for the nine months ended September 30, 2019, primarily as a result of reduced recruiting and consulting fees partially offset by increased legal, accounting and other professional fees.

All other operating expense for the nine months ended September 30, 2020 increased by approximately $4,214,000, or 30%, to approximately $18,232,000, compared with approximately $14,018,000 for the nine months ended September 30, 2019, primarily as a result of increased insurance, dues and subscriptions, rent, and information technology expenses, partially offset by lower other office and travel expenses due to travel restrictions caused by the COVID-19 pandemic.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $14,121,000, or 13%, to approximately $120,934,000 for the nine months ended September 30, 2020, compared with approximately $106,813,000 for the nine months ended September 30, 2019, primarily as a result of an increase in total operating expenses to support commercialization and launch efforts related to our pharmaceutical products, as well as write off of product samples and inventory due to the COVID-19 pandemic, as described above, partially offset by increased total net product revenue.

We anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that any commercialization of IMVEXXY, BIJUVA, and ANNOVERA will be successful.

Other expense, net

Other non-operating expense, net increased by approximately $607,000, or 3%, to an expense of approximately $20,503,000 for the nine months ended September 30, 2020, compared with an expense of approximately $19,896,000 for the nine months ended September 30, 2019, primarily as a result of increased interest expense related to our Financing Agreement partially offset by the loss on extinguishment of debt of $10,058,000 incurred during the nine months ended September 30, 2019. For more information regarding our Financing Agreement, see "Liquidity and Capital Resources" below.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately $14,728,000, or 12%, to approximately $141,437,000 for the nine months ended September 30, 2020, compared with approximately $126,709,000 for the nine months ended September 30, 2019. Net loss per share of Common Stock, basic and diluted, was ($0.52) and ($0.53) for the nine months ended September 30, 2020 and 2019, respectively.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our Common Stock and private placements of equity and debt securities. For the three-year period ended December 31, 2019, we received approximately $236,000,000 in net proceeds from the issuance of shares of our Common Stock. As of September 30, 2020, we had cash and cash equivalents totaling approximately $79,634,000. However, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

Our net days sales outstanding, or net DSO, is calculated by dividing gross accounts receivable less the reserve for doubtful accounts, chargebacks and payment discounts by the average daily net product revenue during the quarter. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross product revenue to distributors during the quarter. For the three months ended September 30, 2020, our gross DSO was 56 days compared to 55 days for the three months ended December 31, 2019 and our net DSO was 128 days for the three months ended September 30, 2020 compared to 141 days for the three months ended December 31, 2019. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the launches of IMVEXXY, BIJUVA, and ANNOVERA and changes in the healthcare industry. Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the COVID-19 pandemic, or other customer-specific factors. Although we have historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade receivables in the future.

On April 24, 2019, we entered into a Financing Agreement, as amended, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which provides us with up to a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for fund availability in multiple tranches: $200,000,000 was drawn upon entering into the Financing Agreement while an additional $50,000,000 was drawn on February 18, 2020. An additional $50,000,000 was previously available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the quarter ended June 30, 2020 or at such earlier date as the Administrative Agent may have consented to. Due to the pause in the full launch of ANNOVERA caused by the COVID-19 pandemic, the undrawn $50,000,000 trance under the Financing Agreement is no longer available.

On August 5, 2020, we and our subsidiaries entered into Amendment No. 5 to the Financing Agreement, or Amendment No. 5, with the Administrative Agent and the lenders party thereto, pursuant to which we modified the minimum consolidated net product revenue requirements attributable to commercial sales of our IMVEXXY, BIJUVA, and ANNOVERA products, which requirements are effective beginning with the fiscal quarter ending December 31, 2020. In lieu of a cash amendment fee, to induce the lenders to enter into Amendment No. 5, on August 5, 2020, we issued warrants, or the Warrants, to the lenders under the Financing Agreement to purchase an aggregate of 4,752,116 shares of Common Stock, pursuant to a subscription agreement among the parties, or the Subscription Agreement. The Warrants have an exercise price of $1.58 per share of Common Stock and an expiration date of August 5, 2030. The Warrants may also be exercised via cashless exercise pursuant to the terms thereof. No registration rights were issued pursuant to the Warrants or Subscription Agreement. On November 8, 2020, in connection with entering into Amendment No. 6 to the Financing Agreement, we amended the Warrants to provide for an adjustment to the exercise price if we conduct certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 is lower than the then-current exercise price.

As of the filing date of this Quarterly Report on Form 10-Q, our cash balance was above the $60 million balance as required by the Financing Agreement. On November 8, 2020, we and our subsidiaries entered into Amendment No. 6 to the Financing Agreement, or Amendment No. 6, with the Administrative Agent and the lenders party thereto, pursuant to which we temporarily lowered the minimum required cash balance from $60 million to $45 million through December 31, 2020. After December 31, 2020, the minimum cash balance will revert to $60 million. Based on our current projections, we will need to raise additional capital to remain in compliance with this minimum cash balance covenant for the next twelve months from the issuance of these financial statements.

In order to address our projected capital needs, we are pursuing various equity financing and other alternatives including the sale of a controlling interest in vitaCare Prescription Services for which we commenced a sale process and received initial indications of interest. The equity financing alternatives may include the private placement of equity, equity-linked, or other similar instruments or obligations with one or more investors, lenders, or other institutional counterparties or an underwritten public equity or equity-linked securities offering. Our ability to sell equity securities may be limited by market conditions. To the extent that we raise additional capital through the sale of such securities, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders.

Along with considering additional financings, we have reviewed numerous potential scenarios in connection with the impact of COVID-19 on our business including the impact of the recent steps we have taken to reduce our operating expenses in response. Based on our analysis, we believe that our existing cash reserves along with potential proceeds from the sale of certain non-core assets of the Company and proceeds from potential future financings, if available to us, would be sufficient to meet our cash needs arising in the ordinary course of business for the next twelve months from the date of this Quarterly Report on Form 10-Q.

However, if we are unsuccessful with future financings and if the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the continued impact of the COVID-19 pandemic on our business is worse than we anticipate, our existing cash reserves would be insufficient to maintain compliance with the Financing Agreement covenants or satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA. 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 unaudited consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

We need substantial amounts of cash to complete the launch and commercialization of our hormone therapy and contraceptive drugs. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of (Uses) and Sources of Cash

	Nine Months Ended September 30,	
	2020	2019
	(000s)	
Net cash used in operating activities	$ (129,149)	$ (114,900)
Net cash used in investing activities	$ (1,069)	$ (3,178)
Net cash provided by financing activities	$ 49,022	$ 111,796

Operating Activities

The principal use of cash in operating activities for the nine months ended September 30, 2020 was to fund our current expenses primarily related to supporting commercialization activities for IMVEXXY, BIJUVA, and ANNOVERA, sales, marketing, scale-up and manufacturing activities and clinical development, adjusted for non-cash items. The increase of approximately $14,249,000 in cash used in operating activities for the nine months ended September 30, 2020 compared with the prior year was primarily due to an increase in our net loss and changes in the components of working capital partially offset by an increase in non-cash items.

Investing Activities

Investing activities include costs related to patents and fixed assets. Net cash used in investing activities for the nine months ended September 30, 2020 decreased by approximately $2,109,000 primarily due to lower costs related to the purchase of fixed assets during the nine months ended September 30, 2020 compared with the prior period.

Financing Activities

Financing activities currently represent the principal source of our cash flow. Our financing activities for the nine months ended September 30, 2020 provided net cash of approximately $49,022,000 which consisted of the funding from our Financing Agreement of $50,000,000 and the exercise of options to purchase Common Stock of approximately $272,000, partially offset by the payment of deferred financing fees of $1,250,000. Our financing activities for the nine months ended September 30, 2019 provided net cash of approximately $111,796,000, which consisted of the net funding from our Facility of approximately $193,348,000 and the exercise of options and warrants to purchase Common Stock of approximately $109,000, partially offset by the repayment of the MidCap Agreement of approximately $81,661,000.

New Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2018-13 which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The FASB developed the amendments to Accounting Standards Codification, or ASC, 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. The new guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. We adopted this standard on January 1, 2020, and the adoption did not have a material effect on our disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected based on historical experience, current conditions, and reasonable supportable forecasts. The amendments in this update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted no sooner than the first quarter of 2019. A modified retrospective approach is required for all investments, except debt securities for which an other-than-temporary impairment had been recognized prior to the effective date, which will require a prospective transition approach and should be applied either prospectively or retrospectively depending on the nature of the disclosure. The adoption of ASU 2016-13 requires expanded quantitative and qualitative disclosures about the Company’s expected credit losses. Effective January 1, 2020, we adopted ASU 2016-13 under a modified retrospective approach for all financial assets measured at amortized cost. There was no adjustment recorded for the cumulative effect of adopting ASU 2016-13. The adoption expanded disclosures about our credit losses.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain an investment portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Amounts borrowed under the Financing Agreement accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.20%. Considering the total outstanding principal balance under the Financing Agreement of $250,000,000 at September 30, 2020, a 1.0% change in interest rates would result in an impact to loss before income taxes of $2,500,000 per year.

Item 4. 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, or the Exchange Act, is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, in order to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Controls

During the three months ended September 30, 2020, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are involved in litigation and proceedings in the ordinary course of our business.

On February 20, 2020, we received a Paragraph IV certification notice letter, or the IMVEXXY Notice Letter, regarding an Abbreviated New Drug Application, or ANDA, submitted to the FDA by Teva Pharmaceuticals USA, Inc., or 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, or 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. On April 1, 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. A trial date has not been set.

On March 17, 2020, we received a Paragraph IV certification notice letter, or the BIJUVA Notice Letter, regarding an ANDA submitted to the FDA by Amneal Pharmaceuticals, or Amneal. The ANDA seeks approval from the FDA to commercially manufacture, use, or sell a generic version of BIJUVA. In the BIJUVA Notice Letter, Amneal alleges that TherapeuticsMD patents listed in the FDA's Orange Book that claim compositions and methods of BIJUVA, or the BIJUVA Patents, are invalid, unenforceable, and/or will not be infringed by Amneal's commercial manufacture, use, or sale of its proposed generic drug product. The BIJUVA Patents identified in the BIJUVA Notice Letter expire in 2032. On April 29, 2020, we filed a complaint for patent infringement against Amneal in the United States District Court for the District of New Jersey arising from Amneal's ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Amneal's ANDA would be a date no earlier than the expiration of the BIJUVA Patents and equitable relief enjoining Amneal from infringing the BIJUVA Patents. Amneal has filed its answer and counterclaim to the complaint, alleging that the BIJUVA Patents are invalid and not infringed. A trial date has not been set.

Item 1A. Risk Factors

Except as set forth below, there have been no material changes with respect to those risk factors previously disclosed in Item 1A "Risk Factors" in Part I of our Annual Report.

Our financial condition and results of operations for fiscal year 2020 and beyond may be materially adversely affected by the ongoing COVID-19 (coronavirus) pandemic.

The outbreak of the novel COVID-19 has evolved into a global pandemic. COVID-19 has spread to many regions of the world, including virtually all of the United States. Our business has been, and we anticipate that it will continue to be, impacted by the COVID-19 pandemic. During the third quarter of 2020, all of our products remained affected by the COVID-19 pandemic, primarily due to our sales force having limited access to healthcare professionals and our patients deferring visits to healthcare professionals in certain areas. While we have developed a comprehensive COVID-19 contingency plan designed to preserve the value of our investments in our sales and marketing infrastructure, protect our balance sheet during this period of market disruption and meet the needs of our patients and prescribers, the severity of the impact of the COVID-19 pandemic on our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted.

Stay at home, quarantine and social distancing orders and closures and restrictions on travel have negatively affected the ability of our sales force to access healthcare providers to promote our products and the ability of patients to visit their healthcare professionals for non-emergent matters. Our sales force is continuing to use a hybrid model of office visits when necessary and digital engagement tools and tactics and virtual detailing, which may be less effective than our ordinary course sales and marketing programs. Increases in unemployment could reduce access to commercial health insurance for our patients, thus limiting payer coverage for our products, which could lead to increased use of our co-pay assistance programs and negatively affect our results of operations.

Our future results of operations and liquidity could be materially adversely affected by, and we may require an increased level of working capital as a result of, extended billing and collection cycles as a result of displaced employees at our company, payers, revenue cycle management contractors, or otherwise; 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.

Additionally, although we currently continue to have uninterrupted wholesale and retail distribution of our products and we do not anticipate a shortage of our products due to COVID-19 at this time, disruptions may occur for our customers or suppliers that may materially affect our ability to obtain supplies or other components for our products, manufacture additional products or deliver inventory in a timely manner. This would result in lost sales, additional costs, or penalties, or damage to our reputation.

Our business may also be affected by negative impacts of the COVID-19 pandemic on capital markets and economies worldwide, and it is possible that the pandemic could cause a local and/or global economic recession. While policymakers globally have responded with fiscal policy actions to support the healthcare industry and economy as a whole, the magnitude and overall effectiveness of these actions remains uncertain.

We may also experience other unknown impacts from COVID-19 that cannot be predicted. Accordingly, disruptions to our business as a result of COVID-19 could result in a material adverse effect on our business, results of operations, financial condition and prospects in the near-term and beyond 2020.

Our level of indebtedness and the terms of the Financing Agreement could adversely affect our operations and limit our ability to plan for or respond to changes in our business. If we are unable to comply with certain actual net revenue covenants and other restrictions in the Financing Agreement, the repayment of our existing indebtedness could be accelerated.

Under the Financing Agreement, we have incurred a substantial amount of debt, which could adversely affect our business. In April 2019, we drew down the first tranche of $200.0 million under the Financing Agreement and in February 2020 we drew down the second tranche of $50.0 million under the Financing Agreement. Our high level of indebtedness 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; 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 requires us to make certain payments of principal and interest over time and contains certain minimum quarterly product revenue requirements and several other restrictive covenants. We are required to achieve total minimum net revenue requirement for ANNOVERA, IMVEXXY, and BIJUVA equal to (i) $20 million for the fiscal quarter ending December 31, 2020, (ii) $25 million, $37.5 million, $47.5 million, and $57.5 million for the first, second, third, and fourth quarters of 2021, respectively, (iii) $65.0 million, $75.0 million, $85.0 million and $95.0 million for the first, second, third, and fourth quarters of 2022, respectively, and (iv) $95.0 million for each fiscal quarter thereafter. Among other requirements of the Financing Agreement, we and our subsidiaries party to the Financing Agreement must maintain a minimum unrestricted cash balance of $60.0 million (which, pursuant to Amendment No. 6, is being temporarily lowered to a minimum required cash balance of $45.0 million through December 31, 2020). 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, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) 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. In order to maintain compliance with the minimum unrestricted cash balance requirement of the Financing Agreement, we anticipate that we will 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, achieve any of the total minimum net revenue requirements or otherwise comply with any other covenant of the Financing Agreement, all or a portion of our obligations under the Financing Agreement may be declared immediately due and payable, which would have a material adverse effect on our business, results of operations and financial condition.

Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies, especially in light of the COVID-19 pandemic. If we are unable to generate such cash flow, 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 our current debt obligations.

We may not recognize any anticipated benefits of the proposed disposition of vitaCare Prescription Services or any other divestitures we may pursue in the future.

We have commenced a process for the divestiture of vitaCare Prescription Services. Additionally, we may evaluate other potential divestiture opportunities with respect to portions of our business from time to time, and may determine to proceed with a divestiture opportunity if and when we believe such opportunity is consistent with our business strategy and we would be able to realize value for our stockholders in so doing. There can be no assurance that we will be able to sell vitaCare Prescription Services. Any divestiture or disposition, including the planned disposition of vitaCare Prescription Services, could expose us to significant risks, including, without limitation, fees for legal and transaction-related services, diversion of management resources, transaction execution risks (including risks resulting from buyer financing and due diligence contingencies and other closing conditions), loss of key personnel and reduction in revenue. Further, we may be required to retain or indemnify a buyer against certain liabilities and obligations in connection with any such divestiture, and we may also become subject to third-party claims arising out of such divestiture. In addition, we may not achieve the expected price in a divestiture transaction, including the proposed sale of vitaCare Prescription Services, which could result in additional losses being recorded. If we do not realize the expected strategic, economic, or other benefits of any divestiture transaction, it could adversely affect our financial condition and results of operations. A divesture of vitaCare Prescription Services may be subject to various third party consents. There can be no assurances that we will obtain any necessary consents of governmental authorities or other third parties that might be required in order for us to sell vitaCare Prescription Services or effectuate any other divesture. If we are unable to consummate the divestiture of vitaCare Prescription Services for any reason, our business and financial position could be adversely impacted.

Item 5. Other Information

On November 8, 2020, we entered into indemnification agreements with each of our directors and executive officers which may be, in some cases, broader than the specific indemnification provisions under Nevada law. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Nevada law, including indemnification of expenses (including, but not limited to, as attorneys' fees and other litigation-related expenses), judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or executive officer, or on the director or executive officer, in connection with such proceeding or any claim, issue, or matter therein, if such director or executive officer either (i) is not liable under Section 78.138 of the Nevada Revised Statutes, or (ii) acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of our company, and with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful in any action or proceeding, including any action or proceeding by or in right of our company, arising out of the person's services as a director or executive officer. Pursuant to the indemnification agreements, we have agreed to advance all expenses incurred by or on behalf of the director or executive officer in connection with defending any proceeding, which amounts shall be repaid to our company if it is ultimately determined by a court of competent jurisdiction that the director or executive officer is not entitled to be indemnified by our company. The foregoing summary of the indemnification agreements does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the form of indemnification agreement, a copy of which is filed as Exhibit 10.3 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

On November 8, 2020, we and our subsidiaries entered into Amendment No. 6 to the Financing Agreement with the Administrative Agent and the lenders party thereto, pursuant to which we temporarily lowered the minimum required cash balance under the Financing Agreement from $60 million to $45 million through December 31, 2020. After December 31, 2020, the minimum cash balance will revert to $60 million. The foregoing summary of Amendment No. 6 does not purport to be complete and is subject to, and qualified in its entirety by, the full text of Amendment No. 6, a copy of which is filed as Exhibit 10.4 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

On November 8, 2020, in connection with entering into Amendment No. 6 to the Financing Agreement, we amended the Warrants to provide for an adjustment to the exercise price if we conduct certain dilutive issuances prior to December 31, 2020, or if the volume-weighted average price of our Common Stock for the fifteen trading days ending December 31, 2020 is lower than the then-current exercise price. The foregoing summary of the Warrant amendments does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Warrant amendments, a copy of which is filed as Exhibit 4.2 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 6. Exhibits

Exhibit	Date	Description
4.1	August 5, 2020	Form of Warrant to Purchase Common Stock issued by TherapeuticsMD, Inc. to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020.(1)
4.2*	November 8, 2020	Amendment to Form of Warrant to Purchase Common Stock issued by TherapeuticsMD, Inc. to the Subscribers party to that certain Subscription Agreement, dated as of August 5, 2020.
10.1	August 5, 2020	Amendment No. 5 to Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., VitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., and the lenders thereto.(1)
10.2	August 5, 2020	Subscription Agreement, by and among TherapeuticsMD, Inc. and the Subscribers identified on the Schedule of Subscribers attached hereto.(1)
10.3*	n/a	Form of Indemnification Agreement between TherapeuticsMD, Inc. and each of its executive officers and directors.
10.4*	November 8, 2020	Amendment No. 6 to Financing Agreement, by and among TherapeuticsMD, Inc., VitaMedMD, LLC, BocagreenMD, Inc., vitaCare Prescription Services, Inc., Sixth Street Specialty Lending, Inc., and the lenders thereto.
10.5*+	December 1, 2017	Amendment No. 1 to the Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC.
10.6*+	September 29, 2020	Amendment No. 2 to the Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC.
10.7*+	September 29, 2020	Amendment No. 2 to the Softgel Commercial Supply Agreement, between TherapeuticsMD, Inc. and Catalent Pharma Solutions, LLC.
31.1*	November 9, 2020	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a).
31.2*	November 9, 2020	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a).
32.1**	November 9, 2020	Section 1350 Certification of Chief Executive Officer.
32.2**	November 9, 2020	Section 1350 Certification of Chief Financial Officer.
101.INS*	n/a	XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	n/a	XBRL Taxonomy Extension Schema Document.
101.CAL*	n/a	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document.
101.LAB*	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document.
101.PRE*	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document.
104*	n/a	Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

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

(1) Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 filed with the Commission on August 7, 2020 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: November 9, 2020

THERAPEUTICSMD, INC.

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

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

By: /*s/ Michael Donegan*
Michael Donegan
Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 4.2

AMENDMENT TO COMPANY WARRANT

This AMENDMENT TO THE COMPANY WARRANT (this "**Amendment**"), dated as of November 8, 2020, is by and among TherapeuticsMD, Inc., a Nevada corporation (the "**Company**"), Tao Finance 1, LLC, a Delaware limited liability company ("**Tao Finance**"), Redwood IV Finance 1, LLC, a Delaware limited liability company ("**Redwood IV**") and Sixth Street Specialty Lending, Inc., a Delaware corporation ("**Sixth Street**" and together with Tao Finance and Redwood IV, collectively the "**Holders**").

WHEREAS, the Company issued Warrant No. 1 to Sixth Street on August 5, 2020 convertible into 712,817 shares of Company Common Stock (the "**Sixth Street Warrant**");

WHEREAS, the Company issued Warrant No. 2 to Redwood IV on August 5, 2020 convertible into 1,188,029 shares of Company Common Stock (the "**Redwood IV Warrant**");

WHEREAS, the Company issued Warrant No. 3 to Tao Finance on August 5, 2020 convertible into 2,851,270 shares of Company Common Stock (the "**Tao Finance Warrant**" and together with the Sixth Street Warrant and Redwood IV Warrant collectively, the "**Warrants**"); and

WHEREAS, the Company and the Holders wish to amend the Warrants on the terms set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Holders agree as follows:

1. Amendment to Warrant: Adjustment to Exercise Price For Subsequent Issuances. Section 3 of each Warrant is hereby amended and restated in its entirety to read as follows:

3. Adjustment to Exercise Price For Subsequent Issuances. In order to prevent dilution of the purchase rights granted under this Warrant, the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant shall be subject to adjustment from time to time as provided in this Section 3 (in each case, after taking into consideration any prior adjustments pursuant to this Section 3 or otherwise), with any such adjustment automatically becoming effective without further action of any person required; *provided*, that there shall be no adjustment to the number of Warrant Shares acquirable upon exercise of the Warrant, as provided in this Section 3 (an "**Adjustment**"), unless and until such Adjustment, together with any previous Adjustments to the number of Warrant Shares so acquirable which would otherwise have resulted in an Adjustment were it not for this proviso, would require an increase or decrease of at least 5% of the total number of Warrant Shares so acquirable at the time of such Adjustment, in which event such Adjustment and all such previous Adjustments shall immediately occur.

(a) Definitions. For the purposes of this Section 3, the following terms shall have the following meanings:

"**Excluded Issuances**" means any issuance or sale (or deemed issuance or sale in accordance with Section 3(d)) by the Company after the Adjustment Date of: (a) shares of Common Stock issued upon the exercise of the Warrants; (b) shares of Common Stock issued upon the conversion or exercise of options or convertible securities issued prior to the Adjustment Date, *provided* that such securities are not amended after the Adjustment Date to increase the number of shares of Common Stock issuable thereunder or to lower the exercise or conversion price thereof; or (c) shares of Common Stock under the Company's 2019 Stock Incentive Plan.

"**Independent Financial Expert**" shall mean a nationally recognized accounting, investment banking or consultant firm, which firm does not have a material financial interest or other material economic relationship with either the Company or any of its Affiliates or the Holder or any of its Affiliates that is, in the good faith judgment of the Company's board of directors (the "**Board**"), qualified to perform the task for which it has been engaged.

"**Trading Day**" shall mean a day on which trading in the shares of Common Stock (or other applicable security) generally occurs on the principal exchange or market on which the shares of Common Stock (or other applicable security) are then listed or traded; provided that if the shares of Common Stock (or other applicable security) are not so listed or traded, "Trading Day" means a Business Day.

"**VWAP**" shall mean, as of any date of determination, the average per share volume-weighted average price as displayed under the heading "Bloomberg VWAP" on Bloomberg page "TXMD<equity> AQR" (or its equivalent successor if such Bloomberg page is not available) in respect of the period from the open of trading on the relevant Trading Day until the close of trading on such Trading Day (or if such volume-weighted average price is unavailable, the market value of one share of Common Stock on such Trading Day reasonably determined, using a volume-weighted average method, by an Independent Financial Expert appointed (and compensated by the Company) for such purpose). The VWAP will be determined without regard to after-hours trading or any other trading outside of the regular trading session trading hours.

(b) Adjustment to Exercise Price. If the Company shall, at any time or from time to time after November 8, 2020 (the "**Adjustment Date**") and on or prior to December 31, 2020, issue or sell, or in accordance with Section 3(e) is deemed to have issued or sold, any shares of Common Stock for consideration per share less than the Exercise Price in effect immediately prior to such issuance or sale (or deemed issuance or sale) ("**Adjustment Trigger Shares**"), then immediately upon such issuance or sale (or deemed issuance or sale), the Exercise Price shall be reduced to the weighted average per share consideration received by the Company for all Adjustment Trigger Shares so issued or sold (or deemed issued or sold) from and after the Adjustment Date and on or prior to December 31, 2020, as determined in good faith by the Board. If the Company does not issue or sell, or in accordance with Section 3(e) is not deemed to have issued or sold, any Adjustment Trigger Shares from and after the Amendment Date and on or prior to December 31, 2020, then on December 31, 2020 the Exercise Price shall be reduced to the average of the VWAP for 15 consecutive Trading Days ending on December 31, 2020 (if and only if such average VWAP is lower than the Exercise Price otherwise in effect on December 31, 2020). Notwithstanding the forgoing, if the Company receives aggregate consideration equal to or less than $10,000,000 in exchange for all Adjustment Trigger Shares issued or sold (or deemed issued or sold in accordance with Section 3(e)) after the Adjustment Date and on or prior to December 31, 2020, then the Holder may, at its option delivered in writing to the Company within five (5) Business Days of December 31, 2020, elect to adjust the Exercise Price based on the VWAP calculation provided in the second sentence of this Section 3(b) as if no Adjustment Trigger Shares were issued.

(c) Exceptions to Adjustment Upon Issuance of Common Stock. Anything herein to the contrary notwithstanding, there shall be no adjustment to the Exercise Price or the number of Warrant Shares issuable upon exercise of this Warrant with respect to any Excluded Issuance.

(d) Effect of Certain Events on Adjustment to Exercise Price. For purposes of determining the adjusted Exercise Price under Section 1(a) hereof, the following shall be applicable:

(i) *Issuance of Options*. If the Company shall, at any time or from time to time after the Adjustment Date, grant or sell any options, whether or not such options or the right to convert or exchange any convertible securities issuable upon the exercise of such options are immediately exercisable, and the price per share (determined as provided in this paragraph and in Section 1(d)(iii)) for which Common Stock is issuable upon the exercise of such options or upon the conversion or exchange of convertible securities issuable upon the exercise of such options is less than the Exercise Price in effect immediately prior to the time of the granting or sale of such options, then the total maximum number of shares of Common Stock issuable upon the exercise of such options or upon conversion or exchange of the total maximum amount of convertible securities issuable upon the exercise of such options shall be deemed to have been issued as of the date of granting or sale of such options at a price per share equal to the quotient obtained by dividing of (A) the total amount, if any, received or receivable by the Company as consideration for the granting, sale, or exercise of all such options (which sum shall constitute the applicable consideration received for purposes of Section 1(a)), by (B) the total maximum number of shares of Common Stock issuable upon the exercise of all such options or upon the conversion or exchange of all convertible securities issuable upon the exercise of all such options. No further adjustment of the Exercise Price of Warrant Shares shall be made upon the actual issuance of Common Stock or of convertible securities upon exercise of such options or upon the actual issuance of Common Stock upon conversion or exchange of convertible securities issuable upon exercise of such options.

(ii) *Issuance of Convertible Securities*. If the Company shall, at any time or from time to time after the Adjustment Date, grant or sell any convertible securities, whether or not the right to convert or exchange any such convertible securities is immediately exercisable, and the price per share (determined as provided in this paragraph and in Section 1(d)(iii)) for which Common Stock is issuable upon the conversion or exchange of such convertible securities is less than the Exercise Price in effect immediately prior to the time of the granting or sale of such convertible securities, then the total maximum number of shares of Common Stock issuable upon conversion or exchange of the total maximum amount of such convertible securities shall be deemed to have been issued as of the date of granting or sale of such convertible securities at a price per share equal to the quotient obtained by dividing (A) the total amount, if any, received or receivable by the Company as consideration for the granting, sale, or exercise of such convertible securities (which sum shall constitute the applicable consideration received for purposes of Section 1(a)), by (B) the total maximum number of shares of Common Stock issuable upon the conversion or exchange of all such convertible securities. No further adjustment of the Exercise Price shall be made upon the actual issuance of Common Stock upon conversion or exchange of such convertible securities or by reason of the issue or sale of convertible securities upon exercise of any options to purchase any such convertible securities for which adjustments of the Exercise Price have been made pursuant to the other provisions of this Section 1(d).

(iii) *Calculation of Consideration Received*. If the Company shall, at any time or from time to time after the Adjustment Date, issue or sell, or is deemed to have issued or sold in accordance with Section 1(d), any shares of Common Stock, options or convertible securities: (A) for cash, the consideration received therefor shall be deemed to be the net amount received or receivable by the Company therefor; (B) for consideration other than cash, the amount of the consideration other than cash received or receivable by the Company shall be the fair market value of such consideration, except where such consideration consists of marketable securities, in which case the amount of consideration received or receivable by the Company shall be the market price (as reflected on any securities exchange, quotation system or association or similar pricing system covering such security) for such securities as of the end of business on the date of receipt of such securities; or (C) for no specifically allocated consideration in connection with an issuance or sale of other securities of the Company, together comprising one integrated transaction, the amount of the consideration therefor shall be deemed to be the fair market value of such portion of the aggregate consideration received or receivable by the Company in such transaction as is attributable to such shares of Common Stock, options or convertible securities, as the case may be, issued in such transaction. The net amount of any cash consideration and the fair market value of any consideration other than cash or marketable securities shall be determined in good faith by the Board.

(e) Certificate as to Adjustment.

(i) As promptly as reasonably practicable following any adjustment of the Exercise Price, but in any event not later than 15 Business Days thereafter, the Company shall furnish to the Holder a certificate of an executive officer setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof. All calculations under this Section 3 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be.

(ii) As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than 15 Business Days thereafter, the Company shall furnish to the Holder a certificate of an executive officer certifying the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of the Warrant.

2. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of New York, without regard to principles of conflict of laws.

3. No Other Amendments. Except as expressly amended herein, each of the Warrants remains in full force and effect in accordance with its terms.

4. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be an original, but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment by telefacsimile or other electronic means (including email with a "pdf") shall have the same force and effect as the delivery of an original executed counterpart of this Amendment.

[*Signature Page to Follow*]

IN WITNESS WHEREOF, each of the undersigned has duly executed this Amendment as of the day and year first above written.

COMPANY:

TherapeuticsMD, Inc.

By: /s/ James D'Arecca
Name: James D'Arecca
Title: Chief Financial Officer

HOLDERS:

Tao Finance 1, LLC

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Redwood IV Finance 1, LLC

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Sixth Street Specialty Lending, Inc.

By: /s/ Joshua Easterly
Name: Joshua Easterly
Title: Chief Executive Officer

Exhibit 10.3

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "***Agreement***"), dated as of [●] [●], 20[__] ("***Effective Date***"), is by and between TherapeuticsMD, Inc., a Nevada corporation (the "***Company***"), and [NAME OF DIRECTOR/OFFICER] (the "***Indemnitee***").

RECITALS

WHEREAS, Indemnitee is a director or officer of the Company;

WHEREAS, both the Company and Indemnitee recognize the increased risk of litigation and other claims being asserted against directors and officers of public companies;

WHEREAS, the board of directors of the Company (the "***Board***") has determined that enhancing the ability of the Company to retain and attract as directors and officers the most capable persons is in the best interests of the Company and its stockholders and that the Company therefore should seek to assure such persons that indemnification and insurance coverage is available; and

WHEREAS, Chapter 78 of the Nevada Revised Statutes (the "***NRS***") authorizes a Nevada corporation to indemnify directors, officers, employees, and agents of such a corporation and the Amended and Restated Articles of Incorporation of the Company, as amended (the "***Articles***"), provides that the Company will indemnify any and all persons whom it has power to indemnify under the NRS.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and Indemnitee's agreement to continue to provide services to the Company, the parties agree as follows:

1. Definitions and Construction. For purposes of this Agreement:

(a) "***Change in Control***" means the occurrence of any one of the following events:

i. any "person" (as such term is defined in Section 3(a)(9) of the Exchange Act and as used in Sections 13(d)(3) and 14(d)(2) of the Exchange Act) is or becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 30% or more of the combined voting power of the Company's then outstanding securities eligible to vote for the election of the Board (the "***Company Voting Securities***"); provided, however, that the event described in this paragraph (i) will not be deemed to be a Change in Control by virtue of any of the following acquisitions: (A) by the Company or any subsidiary; (B) by any employee benefit plan (or related trust) sponsored or maintained by the Company or any subsidiary; (C) pursuant to a Non-Control Transaction (as defined in paragraph (iii) below); or (D) a transaction (other than one described in paragraph (iii) below) in which Company Voting Securities are acquired from the Company, if a majority of the Incumbent Board (as defined in paragraph (ii) below) approves a resolution providing expressly that the acquisition under this clause (D) does not constitute a Change in Control under this paragraph (i);

ii. individuals who, as of the Effective Date, constitute the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority thereof, provided that any person becoming a director subsequent to the Effective Date, whose election or nomination for election was approved by a vote of at least two-thirds of the directors comprising the Incumbent Board (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for director, without objection to such nomination) will be considered a member of the Incumbent Board (other than any individual designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 1(a)(i), (iii), (iv) or (v));

iii. the consummation of a merger, consolidation, share exchange or similar form of corporate transaction involving the Company or any of its subsidiaries that requires the approval of the Company's stockholders (whether for such transaction or the issuance of securities in the transaction or otherwise) (a "***Reorganization***"), unless immediately following such Reorganization more than 50% of the total combined voting power of the entity that controls, directly or indirectly, the entity resulting from such Reorganization (the "***Surviving Company***") is represented by Company Voting Securities that were outstanding immediately prior to such Reorganization (or, if applicable, is represented by shares into which such Company Voting Securities were converted pursuant to such Reorganization), and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Company (a "***Non-Control Transaction***"); or

iv. the stockholders of the Company approve a plan of complete liquidation or dissolution; or the consummation of a sale (or series of sales) of all or substantially all of the assets of the Company and its subsidiaries to an entity that is not an affiliate of the Company.

Notwithstanding the foregoing, a Change in Control will not be deemed to occur solely because any person acquires beneficial ownership of 30% or more of the Company Voting Securities as a result of the acquisition of Company Voting Securities by the Company which reduces the number of Company Voting Securities outstanding; provided that, if, after such acquisition by the Company, such person becomes the beneficial owner of additional Company Voting Securities that increases the percentage of outstanding Company Voting Securities beneficially owned by such person, a Change in Control will then be deemed to have occurred.

(b) "***Corporate Status***" means the fact that a person is or was a director, officer, employee, or agent of the Company or is or was serving at the request of the Company as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise.

(c) "***Disinterested Director***" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(d) "***Enterprise***" will mean the Company and any other corporation, partnership, joint venture, trust, or other enterprise that Indemnitee is or was serving at the request of the Company as a director, officer, employee, or agent.

(e) "***Expenses***" will include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred or actually incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in a Proceeding. Expenses also will include Expenses incurred in connection with any appeal resulting from any Proceeding, including, without limitation, the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent. Should any payments by the Company to or for the account of Indemnitee under this Agreement be determined to be subject to any federal, state, or local income or excise tax, Expenses will also include such amounts as are necessary to place Indemnitee in the same after-tax position (after giving effect to all applicable taxes) Indemnitee would have been in had no such tax been determined to apply to those payments. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable in the good faith judgment of such counsel will be presumed conclusively to be reasonable. Expenses, however, will not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(f) "***Independent Counsel***" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five (5) years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" will not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities, and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(g) "***Proceeding***" includes any threatened, pending, or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing, or any other actual, threatened, or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative, legislative, or investigative (formal or informal), in each case whether or not Indemnitee's Corporate Status existed at the time any liability or expense is incurred for which indemnification can be provided under this Agreement, including one pending on or before the Effective Date, but excluding one initiated by an Indemnitee under Section 8 to enforce Indemnitee's rights under this Agreement.

(h) Unless otherwise explicitly specified, this Agreement is to be interpreted such that (i) words denoting the singular will include the plural and vice versa; (ii) the terms "include," "including," "comprise," "comprises," and words of similar effect are used in the inclusive sense of "including, without limitation; (iii) "or" is used in the inclusive sense of "and/or" unless used in connection with the word "either," "unless," "alternatively," and words of similar effect; (iv) "any" is used in the sense of "any and/or all"; (v) "herein," "hereof," "hereunder," and words of similar effect refer to the entirety of this Agreement; and (vi) "days" refer to calendar days. The language of this Agreement will be construed according to its fair meaning and not strictly against either Party.

2. Indemnity of Indemnitee. The Company will hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof:

(a) Proceedings Other Than Proceedings by or in the Right of the Company. Indemnitee will be entitled to the rights of indemnification provided in this Section 2(a) if, by reason of Indemnitee's Corporate Status, Indemnitee was or is a party, or is threatened to be made a party, to any Proceeding other than a Proceeding by or in the right of the Company. Under this Section 2(a), the Company will indemnify Indemnitee against all Expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection with such Proceeding or any claim, issue, or matter therein, if Indemnitee either (i) is not liable under NRS 78.138, or (ii) acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe Indemnitee's conduct was unlawful.

(b) Proceedings by or in the Right of the Company. Indemnitee will be entitled to the rights of indemnification provided in this Section 2(b) if, by reason of Indemnitee's Corporate Status, Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company to procure a judgment in its favor. Under this Section 2(b), the Company will indemnify Indemnitee against all Expenses and amounts paid in settlement actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection with such Proceeding or any claim, issue, or matters therein, if Indemnitee either (i) is not liable under NRS 78.138, or (ii) acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, if applicable law so provides, no indemnification against such Expenses or other amounts will be made in respect of any claim, issue, or matter as to which Indemnitee will have been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the Company or for amounts paid in settlement to the Company, unless and only to the extent that the court in which the Proceeding was brought or other court of competent jurisdiction will determine that in view of all the circumstances in the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

(c) Termination of Proceeding. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, will not, of itself, create a presumption that the Indemnitee is liable under NRS 78.138 or did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe that the conduct was unlawful.

(d) Indemnification for Expenses of a Successful Party. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a party to and is successful on the merits or otherwise in any Proceeding, the Company will indemnify Indemnitee to the maximum extent permitted by law, as such may be amended from time to time, against all Expenses actually and reasonably incurred by Indemnitee in connection with the defense of the Proceeding. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues, or matters in such Proceeding, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred Indemnitee, or on Indemnitee's behalf, in connection with each successfully resolved claim, issue, or matter. For purposes of this Section 2(d) and without limitation, the termination of any claim, issue, or matter in such a Proceeding by dismissal, with or without prejudice, will be deemed to be a successful result as to such claim, issue, or matter.

3. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1, the Company will and hereby does indemnify and hold harmless Indemnitee, to the fullest extent permitted by law, as may be amended from time to time, against all Expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, if, by reason of Indemnitee's Corporate Status, Indemnitee was or is a party, or is threatened to be made a party, to any Proceeding (including a Proceeding by or in the right of the Company). The only limitation that will exist upon the Company's obligations under this Agreement will be that the Company will not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Section 7 and Section 8) to be unlawful.

4. Contribution.

(a) Whether or not the indemnification provided herein is available, in respect of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company will pay the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company will not enter into any settlement of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee elects to or be required to pay all or any portion of any judgment or settlement in any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company will contribute to the amount of Expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors, or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the events that resulted in such expenses, judgments, fines, or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, will be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.

(c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors, or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.

(d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, will contribute to the amount incurred by Indemnitee, whether for judgments, fines, amounts paid or to be paid in settlement, or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) or transaction(s) giving cause to such Proceeding; or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) or transaction(s).

(e) The Company hereby acknowledges that Indemnitee may have rights to indemnification for payment of the judgment or settlement amount, or the advancement of Expenses provided by another entity ("***Other Indemnitor(s)***"). The Company agrees with Indemnitee that the Company is the indemnitor of first resort of Indemnitee with respect to matters for which indemnification or advancement of Expenses is provided under this Agreement and that the Company will be obligated to make all payments due to or for the benefit of Indemnitee under this agreement without regard to any rights that Indemnitee may have against the Other Indemnitor(s). The Company hereby waives any equitable rights to contribution or indemnification from the Other Indemnitor in respect of any amounts paid or advanced to Indemnitee hereunder. The Company further agrees that no payment of Expenses or losses by the Other Indemnitor(s) to or for the benefit of Indemnitee will affect the obligations of the Company hereunder, and that the Company will be obligated to repay the Other Indemnitor(s) for all amounts so paid or reimbursed to the extent that the Company has an obligation to indemnify Indemnitee for such Expenses or losses hereunder.

5. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee, by reason of Indemnitee's Corporate Status, is a witness, or is made (or asked) to respond to discovery requests or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection therewith.

6. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company will advance all Expenses incurred by or on behalf of Indemnitee in connection with defending any Proceeding within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements will reasonably evidence the Expenses incurred by Indemnitee and, if required by law, at the time of such advance. Indemnitee will also submit an undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it is ultimately be determined by a court of competent jurisdiction that Indemnitee is not entitled to be indemnified by the Company against such Expenses. Any advances and undertakings to repay under this Section 6 will be unsecured and interest free. In furtherance of the foregoing, Indemnitee hereby undertakes to repay such amounts advanced only if, and to the extent that, it will ultimately be determined by a court of competent jurisdiction that Indemnitee is not entitled to be indemnified by the Company as authorized by this Agreement.

7. Procedures and Presumptions for Determination of Entitlement to Indemnification. It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under the NRS and public policy of the State of Nevada. Accordingly, the parties agree that the following procedures and presumptions will apply if of any question as to whether Indemnitee is entitled to indemnification under this Agreement:

(a) To obtain indemnification under this Agreement, Indemnitee will submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The General Counsel will, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, will not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, the Company is actually and materially prejudiced as a direct result of such failure.

(b) Upon written request by Indemnitee for indemnification under the first sentence of Section 7(a), a determination with respect to Indemnitee's entitlement thereto will be made in the specific case by one of the following three methods, which will be at the election of the Board: (i) by a majority vote of a quorum consisting of Disinterested Directors (as hereinafter defined), (ii) if a majority vote of a quorum consisting of Disinterested Directors so orders, or if a quorum of Disinterested Directors cannot be obtained, by Independent Counsel (as hereinafter defined) in a written opinion to the Board, a copy of which will be delivered to Indemnitee, or (iii) by the stockholders of the Company.

(c) Notwithstanding anything to the contrary set forth in this Agreement, if a request for indemnification is made after a Change in Control, at the election of Indemnitee made in writing to the Company, and if the Board by a majority vote of a quorum consisting of Disinterested Directors orders the determination of Indemnitee's entitlement to indemnification to be made by an Independent Counsel, or if a quorum of Disinterested Directors cannot be obtained, any determination required to be made under Section 7(b) as to whether Indemnitee is entitled to indemnification will be made by Independent Counsel selected as provided in this Section 7(c). The Independent Counsel will be selected by Indemnitee, unless Indemnitee requests that such selection be made by the Board. The party making the selection will give written notice to the other party advising it of the identity of the Independent Counsel so selected. The party receiving such notice may, within seven (7) days after such written notice of selection is received, deliver to the other party a written objection to such selection. Such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1, and the objection sets forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected will act as Independent Counsel. If a written objection is made, the Independent Counsel so selected may not serve as Independent Counsel unless and until a court has determined that such objection is without merit. If, within twenty (20) days after submission by Indemnitee of a written request for indemnification under Section 7(a), no Independent Counsel has been selected (or, if selected, such selection has been objected to) in accordance with this paragraph, then either the Company or Indemnitee may petition the courts of the State of Nevada or other court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court designates, and the person with respect to whom an objection is favorably resolved or the person so appointed will act as Independent Counsel under this Section. The Company will pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting under Section 7(b). The Company will pay any and all reasonable and necessary fees and expenses incident to the procedures of this Section 7(c), regardless of the manner in which such Independent Counsel was selected or appointed.

(d) Except as set forth in Section 7(c), if the determination of entitlement to indemnification is to be made by Independent Counsel under Section 7(b), the Independent Counsel will be selected by the Board. Indemnitee may, within ten (10) days after such written notice of selection is given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1, and the objection will set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected will act as Independent Counsel. If a written objection is made and substantiated, the Independent Counsel selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within twenty (20) days after submission by Indemnitee of a written request for indemnification under Section 7(a), no Independent Counsel has been selected (or, if selected, such selection has been objected to) in accordance with this paragraph, then either the Company or Indemnitee may petition the appropriate courts of the State of Nevada or other court of competent jurisdiction for resolution of any objection made by Indemnitee to the Company's selection of Independent Counsel or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court will designate, and the person with respect to whom an objection is favorably resolved or the person so appointed will act as Independent Counsel under Section 7(b). The Company will pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting under Section 7(b), and the Company will pay any and all reasonable fees and expenses incident to the procedures of this Section 7(d), regardless of the manner in which such Independent Counsel was selected or appointed.

(e) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination will presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption will have the burden of proof and the burden of persuasion by clear and convincing evidence. Neither the failure of the Company (including by its directors or independent legal counsel) to have made a determination prior to the commencement of any action under this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, will be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(f) Indemnitee will be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. In addition, the knowledge or actions, or failure to act, of any director, officer, agent, or employee of the Enterprise will not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section 7(f) are satisfied, Indemnitee will be presumed to have at all times acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. Anyone seeking to overcome this presumption will have the burden of proof and the burden of persuasion by clear and convincing evidence. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(g) Notwithstanding anything to the contrary set forth in this Agreement, if the person, persons, or entity empowered or selected under Section 7 to determine whether Indemnitee is entitled to indemnification will not have been appointed or will not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification will be deemed to have been made and Indemnitee will be entitled to such indemnification, unless the Company establishes by written opinion of Independent Counsel that (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such sixty (60)-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons, or entity making such determination with respect to entitlement to indemnification in good faith requires such additional time to obtain or evaluate documentation or information relating thereto; and provided, further, that the foregoing provisions of this Section 7(g) will not apply if the determination of entitlement to indemnification is to be made by the stockholders under Section 7(b) and if (A) within fifteen (15) days after receipt by the Company of the request for such determination, the Disinterested Directors resolve as required by Section 7(b)(iii) to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within ninety (90) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within ninety (90) days after having been so called and such determination is made thereat.

(h) Indemnitee will cooperate with the person, persons, or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons, or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Independent Counsel or member of the Board or stockholder of the Company will act reasonably and in good faith in making a determination regarding Indemnitee's entitlement to indemnification under this Agreement. Any costs or expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons, or entity making such determination will be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(i) The Company acknowledges that a settlement or other disposition, including a conviction or a plea of nolo contendere short of final judgment, may be successful if it permits a party to avoid expense, delay, distraction, disruption, or uncertainty. If any Proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such Proceeding with or without payment of money or other consideration) it will be presumed that Indemnitee has been successful on the merits or otherwise in such Proceeding and will not create a presumption that (i) Indemnitee did not act in good faith or in a manner reasonably believed to be in or not opposed to the best interests of the Company or (ii) that, with respect to any criminal Proceeding, Indemnitee did not have reasonable cause to believe that Indemnitee's conduct was unlawful. Anyone seeking to overcome this presumption will have the burden of proof and the burden of persuasion by clear and convincing evidence.

(j) The termination of any Proceeding or of any claim, issue, or matter therein, by judgment, order, settlement, or conviction, or upon a plea of nolo contendere or its equivalent, will not of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

8. Remedies of Indemnitee.

(a) If (i) a determination is made under Section 7 that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made under Section 6, (iii) no determination of entitlement to indemnification is made under Sections 7(b) or 7(c) within sixty (60) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made under this Agreement within ten (10) days after receipt by the Company of a written request therefor, or (v) payment of indemnification is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made under Section 6, Indemnitee will be entitled to an adjudication of Indemnitee's entitlement thereto, at Indemnitee's sole option, in (1) an appropriate court of the State of Nevada, or any other court of competent jurisdiction, or (2) an arbitration to be conducted by a single arbitrator, selected by mutual agreement of the Company and Indemnitee, under the rules of the American Arbitration Association. The Company will not oppose Indemnitee's right to seek any such adjudication.

(b) If a determination has been made under Sections 7(b) or 7(c) that Indemnitee is not entitled to indemnification, (i) any judicial proceeding or arbitration commenced under this Section 8 will be conducted in all respects *de novo* on the merits, and Indemnitee will not be prejudiced by reason of the adverse determination under Sections 7(b) or 7(c); and (ii) in any such judicial proceeding or arbitration, the Company will have the burden of proving that Indemnitee is not entitled to indemnification under this Agreement.

(c) If a determination is made under Sections 7(b) or 7(c), or deemed to have been made pursuant to Section 7(g), that Indemnitee is legally entitled to indemnification, the Company will be obligated to pay the amounts constituting such indemnification within five (5) days after such determination has been made or has been deemed to have been made and will be conclusively bound by such determination in any judicial proceeding commenced under this Section 8.

(d) If Indemnitee, under this Section 8, seeks a judicial adjudication of or arbitration to enforce Indemnitee's rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company will pay to Indemnitee, or on Indemnitee's behalf, in advance, and will indemnify Indemnitee against any and all Expenses actually and reasonably incurred by Indemnitee in such judicial adjudication or arbitration, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses, or insurance recovery. The Company will indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, will (within ten (10) days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses, or insurance recovery, as the case may be.

(e) The Company will be precluded from asserting in any judicial proceeding or arbitration commenced under Section 8 that the procedures and presumptions of this Agreement are not valid, binding, or enforceable and will stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement.

9. Non-Exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and advancement of Expenses as provided by this Agreement will not be deemed exclusive of and will be in addition to any other rights to which Indemnitee may at any time be entitled under applicable law, the Articles, or the Bylaws of the Company, as amended (the "***Bylaws***"), any agreement, a vote of stockholders, a resolution of directors, or otherwise, and nothing in this Agreement will diminish or otherwise restrict Indemnitee's rights to indemnification or advancement of expenses under any of the foregoing. No amendment, alteration, or repeal of this Agreement or of any provision hereof will limit or restrict any right of Indemnitee with respect to any action taken or omitted by such Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration, or repeal. To the extent that a change in the NRS, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the Articles, the Bylaws, or this Agreement, it is the intent of the parties hereto that Indemnitee will be entitled to the greater benefits so afforded by such change and Indemnitee will be deemed to have such greater benefits hereunder. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy will be cumulative and in addition to every other right and remedy hereunder or now or hereafter existing at law or in equity or otherwise. The assertion of any right or remedy hereunder, or otherwise, will not prevent the concurrent assertion or employment of any other right or remedy. The Company will not adopt any amendments to its Articles or Bylaws, the effect of which would be to deny, diminish, or encumber Indemnitee's right to indemnification or advancement of expenses under this Agreement, any other agreement or otherwise.

(b) To the extent that the Company maintains insurance providing liability insurance for directors, officers, employees, agents, or fiduciaries of the Company, or of any other corporation, partnership, joint venture, or other enterprise that such person serves at the request of the Company, Indemnitee will be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent, or fiduciary under such policy or policies. The Company will use commercially reasonable efforts (taking into account the scope and amount of coverage available relative to the cost thereof) to maintain in effect for the duration of the Indemnitee's service to the Company (and thereafter for so long as Indemnitee will be subject to any pending Proceeding) such insurance policy or policies providing coverage that is at least substantially comparable in scope and amount to that provided by the Company's current such policies. If, at the time of the receipt of a notice of a claim under the terms hereof, the Company has or had director and officer liability insurance in effect, the Company will give prompt notice of the commencement of such Proceeding to the relevant insurers in accordance with the procedures set forth in the respective policies. The Company will thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) If the Company makes any payment under this Agreement, the Company will be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who will execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights (with all of Indemnitee's Expenses related thereto reimbursed by or, at the option of Indemnitee, advanced by the Company).

(d) The Company will not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement, or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee, or agent of any other corporation, partnership, joint venture, trust, or other enterprise will be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, or other enterprise.

10. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company will not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision;

(b) on account of Indemnitee's conduct that is established by a final, non-appealable judgment of a court of competent jurisdiction as intentional misconduct, fraud, or a knowing violation of law, provided such misconduct, fraud, or violation was or is material to the cause of action;

(c) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or similar provisions of state statutory law or common law;

(d) if and to the extent indemnification is contrary to law, including specifically the provisions of the Securities Act of 1933, as amended, or the Exchange Act, the NRS;

(e) for any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company under Section 304 of the Sarbanes-Oxley Act of 2002 (the "***Sarbanes-Oxley Act***"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act);

(f) for any reimbursement of the Company by Indemnitee of any compensation under any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(g) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees, or other indemnitees, unless (i) the Board authorized the Proceeding (or such part of the Proceeding) prior to its initiation, or (ii) the Company indemnifies Indemnitee, in its sole discretion, independently of this Agreement under the powers vested in the Company under applicable law.

The Company will have the burden of proof by clear and convincing evidence to set forth facts supporting an assertion that the Company is not obligated under this Agreement to make any indemnity as a result of any of Sections 10(a) to 10(g).

11. Retroactive Effect; Duration of Agreement; Successors and Binding Agreement. All agreements and obligations of the Company contained herein will be deemed to have become effective upon the date Indemnitee first had Corporate Status, will continue during the period Indemnitee has Corporate Status, and will continue thereafter so long as Indemnitee may be subject to any Proceeding (or any action commenced under Section 8) by reason of Indemnitee's Corporate Status, whether or not Indemnitee is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement will be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation, reorganization, or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors, and personal and legal representatives. The Company will require any such successor to all or substantially all of the business or assets of the Company, by agreement in form and substance satisfactory to Indemnitee and Indemnitee's counsel, to expressly assume and agree to perform this Agreement in the same manner and to the same extent the Company would be required to perform if no such succession had taken place. Except as otherwise set forth in this Section 11, this Agreement will not be assignable or delegable by the Company.

12. Security. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust, or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of Indemnitee.

13. Enforcement. The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby to induce Indemnitee to serve, or continue to serve, as an officer or a director of the Company. The Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as an officer or a director of the Company.

14. Severability. The invalidity or unenforceability of any provision hereof will in no way affect the validity or enforceability of any other provision. Without limiting the generality of the foregoing, this Agreement intends to confer upon Indemnitee indemnification rights to the fullest extent permitted by applicable laws. If any provision hereof conflicts with any applicable law, such provision will be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.

15. Modification and Waiver. No supplement, modification, termination, or amendment of this Agreement will be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement will be deemed or will constitute a waiver of any other provisions hereof (whether or not similar) nor will such waiver constitute a continuing waiver.

16. Notice by Indemnitee; Defense of Claims. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information, or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company will not relieve the Company of any obligation which it may have to Indemnitee under this Agreement unless, and only to the extent that, the Company is actually and materially prejudiced as a direct result of such delay or failure. The Company will be entitled to participate in the defense of any Proceeding giving rise to a claim for indemnification hereunder at its own expense and, except as otherwise provided below, to the extent the Company so wishes, it may assume the defense thereof with counsel reasonably satisfactory to Indemnitee. After notice from the Company to Indemnitee of its election to assume the defense of any such Proceeding, the Company will not be liable to Indemnitee under this Agreement or otherwise for any Expenses subsequently directly incurred by Indemnitee in connection with Indemnitee's defense of such Proceeding other than reasonable costs of investigation or as otherwise provided below. Indemnitee will have the right to employ Indemnitee's own legal counsel in such Proceeding, but all Expenses related to such counsel incurred after notice from the Company of its assumption of the defense will be at Indemnitee's own expense; provided, however, that if (a) Indemnitee's employment of its own legal counsel has been authorized by the Company, (b) Indemnitee has reasonably determined that there may be a conflict of interest between Indemnitee and the Company in the defense of such Proceeding, (c) after a Change in Control, Indemnitee's employment of Indemnitee's own counsel has been approved by the Independent Counsel, or (d) the Company will not in fact have employed counsel to assume the defense of such Proceeding, then Indemnitee will be entitled to retain Indemnitee's own separate counsel and all Expenses related to such separate counsel will be borne by the Company.

17. Notices. All notices and other communications given or made under this Agreement will be in writing and will be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when confirmed by a non-automated reply if sent by electronic mail, or (c) when received or delivery is refused by the recipient when sent by registered or certified mail, return receipt requested, postage prepaid, or via a nationally recognized overnight courier. All communications will be sent:

(a) To Indemnitee at the address set forth below Indemnitee's signature hereto.

(b) To the Company at:
TherapeuticsMD, Inc.
951 Yamato Road, Suite 220
Boca Raton, Florida 33431
Attention: General Counsel

or to such other address as may have been provided to Indemnitee by the Company or to the Company by Indemnitee.

18. Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same Agreement. Executed counterparts may be delivered by electronic transmission and will be deemed an original, but all of such counterparts together will constitute the same instrument.

19. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and will not be deemed to constitute part of this Agreement or to affect the construction thereof.

20. Successors and Assigns. The terms of this Agreement will be binding upon the Company and its successors and assigns and will inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors, administrators, and other legal representatives.

21. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties will be governed by, and construed and enforced in accordance with, the laws of the State of Nevada, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (a) agree that any action or proceeding arising out of or in connection with this Agreement (other than an arbitration under Section 8) will be brought in the appropriate court of the State of Nevada (the "***Nevada Court***"), and not in any other state or federal court in the United States of America or any court in any other country, (b) consent to submit to the exclusive jurisdiction of the Nevada Court for purposes of such action or proceeding, (c) waive any objection to the laying of venue of any such action or proceeding in the Nevada Court, (d) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Nevada Court has been brought in an improper or inconvenient forum, and (e) appoint, to the extent such party is not otherwise subject to service of process in the State of Nevada, Paracorp Incorporated, 318 N. Carson St., Ste. 208, Carson City, Nevada 87901, as its agent in the State of Nevada for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Nevada.

22. Entire Agreement. This Agreement, and any exhibits or schedules attached hereto, constitutes the full and entire understanding and agreement between the parties with regard to the subjects hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties with regard to the subjects hereof. No party hereto will be liable or bound to any other party in any manner with regard to the subjects hereof or thereof by any warranties, representations or covenants except as specifically set forth herein.

(*Signature page to follow*)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

THERAPEUTICSMD, INC.

By: _____

Name: _____

Title: _____

INDEMNITEE

_____

Name: _____

Exhibit 10.4

AMENDMENT NO. 6
TO FINANCING AGREEMENT

AMENDMENT NO. 6 TO FINANCING AGREEMENT, dated as of November 8, 2020 (this "Amendment"), to the Financing Agreement, dated as of April 24, 2019 (as amended, restated, supplemented or otherwise modified from time to time, the "Financing Agreement"), by and among THERAPEUTICSMD, INC., a Nevada corporation ("Company" or "Borrower"), certain Subsidiaries of Borrower, as Guarantors, the Lenders from time to time party thereto, and SIXTH STREET SPECIALTY LENDING, INC., a Delaware corporation ("Sixth Street"), as administrative agent for the Lenders (in such capacity, together with its successors and assigns in such capacity, the "Administrative Agent").

WHEREAS, the Loan Parties have requested that the Administrative Agent and the Lenders amend certain terms and conditions of the Financing Agreement; and

WHEREAS, the Administrative Agent and the Lenders are willing to amend such terms and conditions of the Financing Agreement on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Definitions. All terms used herein that are defined in the Financing Agreement and not otherwise defined herein shall have the meanings assigned to them in the Financing Agreement.

2. Amendments.

(a) New Definitions. Section 1.01 of the Financing Agreement is hereby amended by adding the following definitions, in appropriate alphabetical order:

(i) ""Amendment No. 6" means Amendment No. 6 to Financing Agreement, dated as of November 8, 2020, by and among the Loan Parties, the Administrative Agent and the Lenders."

(ii) ""Amendment No. 6 Effective Date" means the "Amendment Effective Date" as set forth in Amendment No. 6."

(b) Section 6.8(a) (Minimum Qualified Cash). Section 6.8(a) of the Financing Agreement is hereby amended and restated in its entirety to read as follows:

"(b) Minimum Qualified Cash. At all times, Borrower shall not permit Qualified Cash to be less than $60,000,000; provided, that, Borrower shall not permit Qualified Cash to be less than $45,000,000 from and after the Amendment No. 6 Effective Date through and including December 31, 2020."

3. Conditions to Effectiveness. This Amendment shall become effective only upon satisfaction in full, in a manner satisfactory to the Administrative Agent, of the following conditions precedent (the first date upon which all such conditions shall have been satisfied being hereinafter referred to as the "Amendment Effective Date"):

(a) Payment of Fees, Etc. The Borrowers shall have paid on or before the Amendment Effective Date all fees, costs, expenses and taxes then payable, if any, pursuant to Section 2.7 or 10.2 of the Financing Agreement.

(b) Representations and Warranties. The representations and warranties contained in this Amendment and in Article IV of the Financing Agreement and in each other Loan Document shall be true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as the Amendment Effective Date to the same extent as though made on and as of that date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date.

(c) No Default; Event of Default. No Default or Event of Default shall have occurred and be continuing on the Amendment Effective Date or result from this Amendment becoming effective in accordance with its terms.

(d) Delivery of Documents. The Administrative Agent shall have received on or before the Amendment Effective Date:

(i) this Amendment, duly executed by the Loan Parties, the Administrative Agent and the Lenders; and

(ii) an amendment to each Warrant to Purchase Common Stock dated August 5, 2020 issued by the Borrower to Sixth Street, Redwood IV Finance 1, LLC and TAO Finance 1, LLC, in each case in form and substance satisfactory to the Administrative Agent and duly executed by the Borrower.

(e) Material Adverse Effect. The Administrative Agent shall have determined, in its reasonable judgment, that no event or development shall have occurred since December 31, 2019, which could reasonably be expected to have a Material Adverse Effect.

(f) Liens; Priority. The Administrative Agent shall be satisfied that the Administrative Agent has been granted, and holds, for the benefit of the Administrative Agent and the Lenders, a perfected, first priority Lien on and security interest in all of the Collateral, subject only to Permitted Liens, to the extent such Liens and security interests are required pursuant to the Loan Documents to be granted or perfected on or before the Amendment Effective Date.

(g) Approvals. All consents, authorizations and approvals of, and filings and registrations with, and all other actions in respect of, any Governmental Authority or other Person required in connection with any Loan Document or the transactions contemplated thereby or the conduct of the Loan Parties' business shall have been obtained or made and shall be in full force and effect. There shall exist no claim, action, suit, investigation, litigation or proceeding (including, without limitation, shareholder or derivative litigation) pending or, to the knowledge of any Loan Party, threatened in any court or before any arbitrator or Governmental Authority which (i) relates to the Loan Documents or the transactions contemplated thereby or (ii) could reasonably be expected to have a Material Adverse Effect.

4. Continued Effectiveness of the Financing Agreement and Other Loan Documents. Each Loan Party hereby (a) acknowledges and consents to this Amendment, (b) confirms and agrees that the Financing Agreement and each other Loan Document to which it is a party is, and shall continue to be, in full force and effect and is hereby ratified and confirmed in all respects, except that on and after the Amendment Effective Date, all references in any such Loan Document to "the Financing Agreement", the "Agreement", "thereto", "thereof", "thereunder" or words of like import referring to the Financing Agreement shall mean the Financing Agreement as amended by this Amendment, and (c) confirms and agrees that, to the extent that any such Loan Document purports to assign or pledge to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, or to grant to the Administrative Agent, for the benefit of the Administrative Agent and the Lenders, a security interest in or Lien on any Collateral as security for the Obligations of the Loan Parties from time to time existing in respect of the Financing Agreement (as amended hereby) and the other Loan Documents, such pledge, assignment and/or grant of the security interest or Lien is hereby ratified and confirmed in all respects. This Amendment does not and shall not affect any of the obligations of the Loan Parties, other than as expressly provided herein, including, without limitation, the Loan Parties' obligations to repay the Loans in accordance with the terms of Financing Agreement or the obligations of the Loan Parties under any Loan Document to which they are a party, all of which obligations shall remain in full force and effect. Except as expressly provided herein, the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of Administrative Agent or any Lender under the Financing Agreement or any other Loan Document nor constitute a waiver of any provision of the Financing Agreement or any other Loan Document.

5. No Novation. Nothing herein contained shall be construed as a substitution or novation of the Obligations outstanding under the Financing Agreement or instruments securing the same, which shall remain in full force and effect, except as modified hereby.

6. No Representations by Administrative Agent or Lenders. Each Loan Party hereby acknowledges that it has not relied on any representation, written or oral, express or implied, by Administrative Agent or any Lender, other than those expressly contained herein, in entering into this Amendment.

7. Release. Each Loan Party hereby acknowledges and agrees that: (a) neither it nor any of its Subsidiaries has any claim or cause of action against Administrative Agent or any Lender (or any of the directors, officers, employees, agents, attorneys or consultants of any of the foregoing) and (b) the Administrative Agent and the Lenders have heretofore properly performed and satisfied in a timely manner all of their obligations to the Loan Parties, and all of their Subsidiaries and Affiliates. Notwithstanding the foregoing, the Administrative Agent and the Lenders wish (and the Loan Parties agree) to eliminate any possibility that any past conditions, acts, omissions, events or circumstances would impair or otherwise adversely affect any of their rights, interests, security and/or remedies. Accordingly, for and in consideration of the agreements contained in this Amendment and other good and valuable consideration, each Loan Party (for itself and its Subsidiaries and Affiliates and the successors, assigns, heirs and representatives of each of the foregoing) (collectively, the "Releasors") does hereby fully, finally, unconditionally and irrevocably release, waive and forever discharge the Administrative Agent and the Lenders, together with their respective Affiliates and Related Funds, and each of the directors, officers, employees, agents, attorneys and consultants of each of the foregoing (collectively, the "Released Parties"), from any and all debts, claims, allegations, obligations, damages, costs, attorneys' fees, suits, demands, liabilities, actions, proceedings and causes of action, in each case, whether known or unknown, contingent or fixed, direct or indirect, and of whatever nature or description, and whether in law or in equity, under contract, tort, statute or otherwise, which any Releasor has heretofore had or now or hereafter can, shall or may have against any Released Party by reason of any act, omission or thing whatsoever done or omitted to be done, in each case, on or prior to the Amendment Effective Date directly arising out of, connected with or related to this Amendment, the Financing Agreement or any other Loan Document, or any act, event or transaction related or attendant thereto, or the agreements of Administrative Agent or any Lender contained therein, or the possession, use, operation or control of any of the assets of any Loan Party, or the making of any Loans or other advances, or the management of such Loans or other advances or the Collateral. Each Loan Party represents and warrants that it has no knowledge of any claim by any Releasor against any Released Party or of any facts or acts or omissions of any Released Party which on the date hereof would be the basis of a claim by any Releasor against any Released Party which would not be released hereby.

8. Further Assurances. The Loan Parties shall execute any and all further documents, agreements and instruments, and take all further actions, as may be required under applicable law or as Administrative Agent may reasonably request, in order to effect the purposes of this Amendment.

9. Miscellaneous.

(a) This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment by facsimile or electronic mail shall be equally effective as delivery of an original executed counterpart of this Amendment.

(b) Section and paragraph headings herein are included for convenience of reference only and shall not constitute a part of this Amendment for any other purpose.

(c) This Amendment shall be governed by, and construed in accordance with, the laws of the State of New York.

(d) Each Loan Party hereby acknowledges and agrees that this Amendment constitutes a "Loan Document" under the Financing Agreement. Accordingly, it shall be an immediate Event of Default under the Financing Agreement if (i) any representation or warranty made by any Loan Party under or in connection with this Amendment shall have been incorrect in any respect when made or deemed made, or (ii) any Loan Party shall fail to perform or observe any term, covenant or agreement contained in this Amendment.

(e) Any provision of this Amendment that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining portions hereof or affecting the validity or enforceability of such provision in any other jurisdiction.

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date set forth on the first page hereof.

BORROWER:

THERAPEUTICSMD, INC.

By: /s/ James D'Arecca
Name: James D'Arecca
Title: Chief Financial Officer

GUARANTORS:

VITAMEDMD, LLC

By: /s/ James D'Arecca
Name: James D'Arecca
Title: Chief Financial Officer

BOCAGREENMD, INC.

By: /s/ James D'Arecca
Name: James D'Arecca
Title: Chief Financial Officer

VITACARE PRESCRIPTION SERVICES, INC.

By: /s/ John Milligan
Name: John Milligan
Title: President

SIXTH STREET SPECIALTY LENDING, INC.,
as Administrative Agent and Lender

By: /s/ Joshua Easterly
Name: Joshua Easterly
Title: Chief Executive Officer

TOP IV TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

TAO TALENTS, LLC, as Lender

By: /s/ Joshua Peck
Name: Joshua Peck
Title: Vice President

Exhibit 10.5

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

EXECUTION VERSION

AMENDMENT NO. 1 TO THE COMMERCIAL SUPPLY AGREEMENT BETWEEN THERAPEUTICSMD, INC. AND CATALENT PHARMA SOLUTIONS, LLC (Estradiol and Progesterone softgel capsules)

This Amendment No. 1 (the "First Amendment") by and between **THERAPEUTICSMD, INC. ("TXMD") and CATALENT PHARMA SOLUTIONS, LLC** ("CATALENT"), to the Agreement (as defined below), is made as of this 1st day of December, 2017 (the "First Amendment Effective Date"). TXMD and CATALENT are sometimes herein referred to individually as a "Party" and collectively as the "Parties".

Unless otherwise defined herein, capitalized terms used in this First Amendment shall have the meaning provided to such terms in the Agreement.

The following sets forth the background for this First Amendment:

WHEREAS, TXMD and CATALENT entered into that certain Commercial Supply Agreement, dated June 24, 2016 (the "Agreement"); and

WHEREAS, TXMD and CATALENT wish to amend the Agreement as provided herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants and obligations set forth in this First Amendment, the Parties hereby agree as follows:

1. The foregoing recitals are hereby incorporated into this First Amendment and made a part hereof. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to them in the Agreement.

2. The following definitions shall be added to the Agreement.

"Qualification Conditions" shall mean that (A) each Access Fee Payment has been made by the earlier of (i) June 30, 2018 or (ii) within sixty (60) days of invoice date for such Access Fee Payment, (B) the Summary Report Payment is made within sixty (60) days of invoice for such payment, and (C) the Qualification Quote has not been terminated prior to completion of, or payment for, all Access Fee Payments and the Summary Report Payment listed in Section 3.1 of the Qualification Quote. For the avoidance of doubt, the Access Fee Payments do not include the Summary Report Payment.

"Access Fee Payment(s)" shall mean all Manufacturing Process Development Access Fee payments listed in Section 3.1 of the Qualification Quote and all costs, fees and expenses payable by Client pursuant to, or incurred by Client under, the Qualification Quote.

"Summary Report Payment" shall mean the payment listed in Section 3.1 of the Qualification Quote that is due upon completion of the Summary Report.

"Qualification Quote" shall mean Quotation SPQ-TIZ-2310.00, between the Parties and dated as of October 19, 2017, and attached hereto as Attachment C.

3. Section 4.1 shall be amended by adding the following sentence at the end of the section:

"If the Qualification Conditions have not been met, the Minimum Requirements set forth in Attachment B shall revert to the minimum amounts in place prior to the First Amendment Effective Date."

4. The following language shall be added to the Agreement as Section 4.8:

"4.8 Additional Equipment. Subject to the terms of the Qualification Quote, Catalent shall procure, at its sole expense, any additional equipment required to ensure that it is capable of providing to Client [***] ([***]) softgels of Product (in the aggregate across all strengths) per Contract Year; provided, however, that such [***] ([***]) annual figure assumes that Purchase Orders for Product shall be spread out across the Contract Year."

5. Section 7.2 of the Agreement is amended by replacing the following PPI calculation language:

"The initial base period for comparison shall be the twelve (12) month period ending on the date most closely preceding July 1, 2017, but which allows enough time for Catalent to provide to Client the notice required by this Section 7.2."

With the following language:

"The initial base period for comparison shall be the twelve (12) month period ending on the date most closely preceding the effective date of the first price increase, but which allows enough time for Catalent to provide to Client the notice required by this Section 7.2."

6. Section 7.2 of the Agreement is amended by adding the following language at the end of the section:

"If the Qualification Conditions have been met, the first annual price adjustment shall be effective on July 1, 2018. If any Product is sold by Catalent to Client at the Unit Pricing set forth in Attachment B, and the Qualification Conditions are not met, then Catalent shall have the right to retroactively increase the Unit Pricing for Product, effective July 1, 2017, and invoice Client for any additional amounts that Client would have had to pay for such Product if the retroactively increased pricing had been in effect at the time of original invoice for such Product."

7. The MINIMUM REQUIREMENT table in Attachment B of the Agreement is hereby deleted and replaced with the following:

MINIMUM REQUIREMENT		
Contract Year	**Product**	**Minimum Requirement***
Contract Year 1	Across all three strengths	[***] Softgels
Contract Year 2	Across all three strengths	[***] Softgels
Contract Year 3	Across all three strengths	[***] Softgels
Contract Year 4	Across all three strengths	[***] Softgels
Contract Year 5	Across all three strengths	[***] Softgels
Each additional Contract Year	Across all three strengths	[***] Softgels

*Softgels shipped per Contract Year qualify towards the Minimum Requirement

8. Exhibit 1 attached to this First Amendment shall be attached to the Agreement as Attachment C.

9. This First Amendment shall be governed by the laws of the State of Delaware, as such laws are applied to contracts entered into and to be performed within such state as though made and to be fully performed therein without regard to conflict of laws principles.

10. The Parties hereby agree that, except as expressly modified herein, all terms and provisions of the Agreement shall remain unmodified and in full force and effect.

11. This First Amendment may be executed in facsimile counterparts, each of which shall be deemed an original but all of which shall constitute the same First Amendment.

[SIGNATURE PAGE ON NEXT PAGE]

IN WITNESS WHEREOF, the parties have caused this First Amendment to be executed by their duly authorized representatives as of the day and year first indicated above.

THERAPEUTICSMD, INC.

By: /s/ John Milligan
Name: John Milligan
Title: President

CATALENT PHARMA SOLUTIONS, LLC

By: /s/ Aris Gennadios, Ph.D
Name: Aris Gennadios, Ph.D
Title: President, Softgel Technologies

Exhibit 10.6

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

EXECUTION VERSION

AMENDMENT NO. 2 TO THE COMMERCIAL SUPPLY AGREEMENT BETWEEN THERAPEUTCSMD, INC. AND CATALENT PHARMA SOLUTIONS, LLC
(Estradiol softgel capsules)

This Amendment No. 2 to the Commercial Supply Agreement (**"Second Amendment"**) is made as of this 29th day of September, 2020 ("**Second Amendment Effective Date**") by and between TherapeuticsMD, Inc., a Nevada corporation, with a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873 ("**Catalent**").

WHEREAS, Client and Catalent entered into that certain Commercial Supply Agreement dated April 20, 2016, as amended (the "**Agreement**").

WHEREAS, Client and Catalent desire to amend the Agreement as more fully set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

1. Capitalized Terms. All capitalized terms used in this Second Amendment and not otherwise defined herein shall have the meanings given to them in the Agreement. For clarity, the term "Agreement" as used in the Agreement and herein shall mean the Agreement as amended hereby.

2. Section 1.53 of the Agreement, is hereby deleted and replaced with the following:

> "**Territory**" means worldwide, except shall not include countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation, those imposed by the U.S. Office of Foreign Asset Control.

"**ROW**" means any country in the Territory excluding the United States, Canada, and Israel.

3. The following definition shall be added to Section 1 of the Agreement:

"**Authorized Generic(s)**" means any drug sold, licensed, or marketed under the Product's New Drug Application that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the Product.

4. Section 2.1 of the Agreement is hereby amended by adding the following to the end of the Section:

"Client and its Affiliates shall purchase exclusively from Catalent all of Client's and its Affiliates' requirements of Product for sale in the United States, Canada, and Israel. In the event Client or its Affiliate(s), alone or in partnership with a third party, launches an Authorized Generic, then Client and its Affiliates shall purchase exclusively from Catalent all of Client's and Client's Affiliate's requirements of the Authorized Generic in the Territory so long as Catalent's pricing for the Authorized Generic is competitive with the pricing requirements for the Authorized Generic."

5. Section 4.1 of the Agreement, as amended, is hereby deleted in its entirety and replaced with the following:

Minimum Requirement. During each Contract Year, Client shall purchase the minimum number of units of Product set forth on Attachment B ("**Minimum Requirement**"). If Client does not purchase such Minimum Requirement during any Contract Year, then within [***] ([***]) days after the end of such Contract Year, Client shall pay Catalent [***] percent ([***]%) of the difference between (A) the total amount Client would have paid to Catalent if the Minimum Requirement had been fulfilled for the Product and (B) the sum of all purchases of Product from Catalent during such Contract Year.

6. Article 2 of the Agreement is hereby amended by adding the following as a new Section 2.5:

Stability Studies. During the Term, Catalent shall have the right, but not the obligation, to perform all annual stability studies (including testing and storage) for Product to be sold in the United States at the pricing set forth on Attachment D. If Catalent is unable to perform the annual stability studies, Client may contract with a Third Party for the performance of the annual stability studies. Price increases for such stability services shall not exceed [***] percent ([***]%) per year.

7. Section 7.1 of the Agreement is hereby amended by including the following as a new subsection D:

Beginning January 1, 2021, Client shall pay Catalent the annual Hormone Suite Occupancy fees set forth on Attachment B. Catalent shall submit an invoice to Client for such fees on January 1, 2021 and each January 1st thereafter during the Term.

8. Section 7.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on each July 1st (with the first Unit Pricing adjustment to be effective on July 1, 2017), upon sixty (60) days' prior written notice from Catalent to Client, to reflect increases in labor, utilities and overhead and shall be in an amount equal to the change in the Producer Price Index ("PPI"), "Pharmaceutical Preparation Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics; provided that beginning July 1, 2021 the annual increase to the Unit Pricing for the PPI for Product to be sold in the United States, Canada, and Israel shall be capped at [***] percent ([***]%) per year. The initial base period for comparison shall be the twelve (12) month period ending on the date most closely preceding the effective date of the first Unit Pricing increase, but which allows enough time for Catalent to provide to Client the notice required by this Section 7.2. In addition, notwithstanding the foregoing, price increases for raw materials, and components shall be passed through to Client annually.

9. Section 16.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

Term. This Agreement shall commence on the Effective Date and shall continue until through July 22, 2028, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). The Term shall automatically be extended for successive two (2)-year periods unless and until one party gives the other party at least twelve (12) months' prior written notice of its desire to terminate as of the end of the then-current Term.

10. Attachment B of the Agreement, as amended, is hereby deleted in its entirety and replaced with the revised Attachment B, attached hereto.

11. The Agreement is hereby amended by adding Attachment D, attached hereto.

12. Governing Law. This Second Amendment shall be governed by and construed under the laws of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Second Amendment.

13. No Other Variations. Except as specifically amended herein, all other terms and conditions of the Agreement remain in full force and effect and shall apply to the construction of this Second Amendment.

14. Counterparts. This Second Amendment may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Second Amendment shall constitute an original.

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Second Amendment effective as of the Second Amendment Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**THERAPEUTICSMD, INC.**
By: /s/ Louis B. Weiner	By: /s/ James D'Arecca
Name: Louis B. Weiner	Name: James D'Arecca
Title: VP Business Development, NA Softgel	Title: Chief Financial Officer

ATTACHMENT B

UNIT PRICING, FEES AND MINIMUM REQUIREMENT FOR US MARKET*

UNIT PRICING Effective through June 30, 2021** Theoretical Batch Size of [***] softgels per strength		
Product	**Unit Strength**	**Unit Pricing per [***] softgels (USD)**
Estradiol Softgel Ovule	Estradiol 10 mcg	$[***]
Estradiol Softgel Ovule	Estradiol 4 mcg	$[***]

UNIT PRICING Effective Through June 30, 2021** Theoretical Batch Size of [***] softgels per strength		
Tier 1 Volume: [***] to [***] Total Softgels Shipped between July 1, 2020 and June 30, 2021		
Product	**Unit Strength**	**Unit Pricing per 1,000 softgels (USD)**
Estradiol Softgel Ovule	Estradiol 10 mcg	$[***]
Estradiol Softgel Ovule	Estradiol 4 mcg	$[***]
Tier 2 Volume: [***] and over Total Softgels Shipped between July 1, 2020 and June 30, 2021		
Product	**Unit Strength**	**Unit Pricing per [***] softgels (USD) for all incremental volume over [***] softgels**
Estradiol Softgel Ovule	Estradiol 10 mcg	$[***]
Estradiol Softgel Ovule	Estradiol 4 mcg	$[***]

* For ROW markets, initial Unit Pricing and annual Unit Pricing increases will be negotiated in good faith between Catalent and Client to be less than or equal to the Unit Pricing for the United States as required by the Client's licensee partner's pricing requirements for the ROW markets. For the Canada and Israel markets, initial Unit Pricing and annual Unit Pricing increases will be negotiated in good faith between Catalent and Client to be less than or equal to the Unit Pricing for the United States as required by the Client's licensee partner's pricing requirements for the Canada and Israel markets.

** One unit is [***] softgel capsules. Unit Pricing includes full API release testing, cost of Processed softgels, Product full release testing and bulk packaging. Unit Pricing does not include cost of API, tooling or other Product-specific capital items, artwork, shipping, insurance or duty.

Unit Pricing also does not include any testing, retesting or testing supplies other than as expressly set forth in the Specifications. Unit Pricing is based on certain assumptions as to manufacturing processes, storage conditions, etc. Accordingly, Unit Pricing is subject to adjustment in the event any such assumptions are subject to revision in connection with the validation of the Product.

MINIMUM REQUIREMENT		
Contract Year	**Product**	**Minimums Requirement**
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules

ADDITIONAL FEES		
Type of Fee	**Amount**	**Payable**
Product Maintenance Fee	$[***] for the first strength; $[***] for each additional strength	[***]
Hormone Suite Occupancy Fee	$[***]	[***]

ATTACHMENT D

STABILITY STUDY PRICING

[***]

Exhibit 10.7

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

EXECUTION VERSION

AMENDMENT NO. 2 TO THE SOFTGEL COMMERCIAL SUPPLY AGREEMENT BETWEEN THERAPEUTCSMD, INC. AND CATALENT PHARMA SOLUTIONS, LLC

(Estradiol and Progesterone softgel capsules)

This Amendment No. 2 to the Softgel Commercial Supply Agreement (**"Second Amendment"**) is made as of this 29th day of September, 2020 ("**Second Amendment Effective Date**") by and between TherapeuticsMD, Inc., a Nevada corporation, with a place of business at 951 Yamato Road, Suite 220, Boca Raton, Florida 33431 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873 ("**Catalent**").

WHEREAS, Client and Catalent entered into that certain Softgel Commercial Supply Agreement dated June 24, 2016, as amended (the "**Agreement**").

WHEREAS, Client and Catalent desire to amend the Agreement as more fully set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

1. Capitalized Terms. All capitalized terms used in this Second Amendment and not otherwise defined herein shall have the meanings given to them in the Agreement. For clarity, the term "Agreement" as used in the Agreement and herein shall mean the Agreement as amended hereby.

2. Section 1.53 of the Agreement, is hereby deleted and replaced with the following:

> "**Territory**" means worldwide, except shall not include countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation, those imposed by the U.S. Office of Foreign Asset Control.

3. The following definitions shall be added to Section 1 of the Agreement:

"**Authorized Generic(s)**" means any drug sold, licensed, or marketed under the Product's New Drug Application that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the Product.

"**ROW**" means any country in the Territory excluding the United States.

4. Section 2.1 of the Agreement is hereby amended by adding the following to the end of the Section:

"Client and its Affiliates shall purchase from Catalent: (1) at least [***] percent ([***]%) of Client's and its Affiliates' requirements of Product in the United States, and (2) at least [***] percent ([***]%) of Client's and its Affiliates' requirements of Product in the ROW as supplied by, through, or on behalf of Client. In the event Client or its Affiliate(s), alone or in partnership with a third party, launches an Authorized Generic, then Client and its Affiliates shall purchase exclusively from Catalent all of Client's and its Affiliates' requirements of the Authorized Generic in the Territory so long as Catalent's pricing for the Authorized Generic is competitive with the pricing requirements for the Authorized Generic."

5. Article 2 of the Agreement is hereby amended by adding the following as a new Section 2.5:

Stability Studies. During the Term, Catalent shall have the right, but not the obligation, to perform all annual stability studies (including testing and storage) for Product to be sold in the United States at the pricing set forth on Attachment D. If Catalent is unable to perform the annual stability studies, Client may contract with a Third Party for the performance of the annual stability studies. Price increases for such stability services shall not exceed [***] percent ([***]%) per year.

6. Section 7.1 of the Agreement is hereby amended by including the following as a new subsection D:

Beginning January 1, 2021, Client shall pay Catalent the annual Hormone Suite Occupancy fees as set forth on Attachment B. Catalent shall submit an invoice to Client for such fees on January 1, 2021 and each January 1st thereafter during the Term.

7. Section 7.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

> Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on each July 1st (with the first Unit Pricing adjustment to be effective on July 1, 2017), upon sixty (60) days' prior written notice from Catalent to Client, to reflect increases in labor, utilities and overhead and shall be in an amount equal to the change in the Producer Price Index ("PPI"), "Pharmaceutical Preparation Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics; provided that beginning July 1, 2021 (a) the annual increase to the Unit Pricing for the PPI for Product to be sold in United States, Canada, and Israel shall be capped at [***] percent ([***]%) per year, and (b) the annual increase to the Unit Pricing for the PPI for Product to be sold in the ROW shall be capped at [***] percent ([***]%) per year. The initial base period for comparison shall be the twelve (12) month period ending on the date most closely preceding the effective date of the first Unit Pricing increase, but which allows enough time for Catalent to provide to Client the notice required by this Section 7.2. In addition, notwithstanding the foregoing, price increases for raw materials, and components shall be passed through to Client annually.

8. Section 16.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

> Term. This Agreement shall commence on the Effective Date and shall continue through April 2, 2029, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). The Term shall automatically be extended for successive two (2)-year periods unless and until one party gives the other party at least twelve (12) months' prior written notice of its desire to terminate as of the end of the then-current Term.

9. Attachment B of the Agreement, as amended, is hereby deleted in its entirety and replaced with the revised Attachment B, attached hereto.

10. The Agreement is hereby amended by adding Attachment D, attached hereto.

11. Governing Law. This Second Amendment shall be governed by and construed under the laws of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Second Amendment.

12. No Other Variations. Except as specifically amended herein, all other terms and conditions of the Agreement remain in full force and effect and shall apply to the construction of this Second Amendment.

13. Counterparts. This Second Amendment may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Second Amendment shall constitute an original.

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Second Amendment effective as of the Second Amendment Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**THERAPEUTICSMD, INC.**
By: /s/ Louis B. Weiner	By: /s/ James D'Arecca
Name: Louis B. Weiner	Name: James D'Arecca
Title: VP Business Development, NA Softgel	Title: Chief Financial Officer

ATTACHMENT B

UNIT PRICING, FEES AND MINIMUM REQUIREMENT

UNIT PRICING FOR THE UNITED STATES
Effective Through June 30, 2021

Product Unit Strength	Product Size	Batch Size	Unit* Pricing for Total Softgels Shipped between July 1, 2020 and June 30, 2021			
			First [***] softgels	Between [***] and [***] softgels	Between [***] and [***] softgels	[***] and more softgels
100mg Progesterone + 1mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]
100mg Progesterone + 0.5mg Estradiol	[***] oval	[***]	$[***]	$[***]	$[***]	$[***]

UNIT PRICING FOR ROW
Effective Through June 30, 2021

Product Unit Strength	Product Size	Batch Size	Unit* Pricing per [***] Softgels
100mg Progesterone + 1mg Estradiol	[***] oval	[***]	$[***]
100mg Progesterone + 0.5mg Estradiol	[***] oval	[***]	$[***]

* One unit is [***] softgel capsules. Unit Pricing includes full API release testing, cost of Processed softgels, Product full release testing and bulk packaging. Unit Pricing does not include cost of API, tooling or other Product-specific capital items, artwork, shipping, insurance or duty. Unit Pricing also does not include any testing, retesting or testing supplies other than as expressly set forth in the Specifications. Unit Pricing is based on certain assumptions as to manufacturing processes, storage conditions, etc. Accordingly, Unit Pricing is subject to adjustment in the event any such assumptions are subject to revision in connection with the validation of the Product.

MINIMUM REQUIREMENT		
Contract Year	**Product**	**Minimums Requirement**
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules
[***]	Across all strengths	[***] capsules

ADDITIONAL FEES		
Type of Fee	**Amount**	**Payable**
Product Maintenance Fee	$[***] for the first Product strength; $[***] for each additional Product strength	[***]
Hormone Suite Occupancy Fee	$[***]	[***]

ATTACHMENT D

STABILITY STUDIES PRICING
[***]

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2020

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, James C. D'Arecca, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2020

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

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert G. Finizio, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

November 9, 2020

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

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

SECTION 1350 CERTIFICATION OF CHIEF FINANCIAL OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James C. D'Arecca, Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

November 9, 2020

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

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.