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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 May 1, 2020 was 271,683,266.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
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PART I - FINANCIAL INFORMATION

Item. 1 Financial Statements

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash	$ 170,097,813	$ 160,829,713
Accounts receivable, net of allowance for doubtful accounts of $781,419 and $904,040, respectively	20,664,009	24,395,958
Inventory	14,607,453	11,860,716
Other current assets	6,618,367	11,329,793
Total current assets	211,987,642	208,416,180
Fixed assets, net	2,330,190	2,507,775
Other Assets:		
License rights, net	38,475,797	39,221,308
Intangible assets, net	5,616,832	5,258,211
Right of use assets	9,757,167	10,109,154
Other assets	473,009	473,009
Total other assets	54,322,805	55,061,682
Total assets	$ 268,640,637	$ 265,985,637
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 28,714,327	$ 19,181,212
Other current liabilities	32,924,485	33,823,613
Total current liabilities	61,638,812	53,004,825
Long-Term Liabilities:		
Long-term debt	243,428,671	194,634,643
Operating lease liability	8,782,274	9,145,049
Total long-term liabilities	252,210,945	203,779,692
Total liabilities	313,849,757	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; 350,000,000 shares authorized: 271,677,742 and 271,177,076 issued and outstanding, respectively	271,678	271,177
Additional paid-in capital	706,789,283	704,351,222
Accumulated deficit	(752,270,081)	(695,421,279)
Total stockholders' (deficit) equity	(45,209,120)	9,201,120
Total liabilities and stockholders' equity	$ 268,640,637	$ 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 March 31,	
	2020	**2019**
Product revenue, net	$ 12,250,657	$ 3,946,651
Cost of goods sold	2,715,051	762,827
Gross profit	9,535,606	3,183,824
Operating expenses:		
Sales, general, and administrative	56,927,021	34,864,082
Research and development	3,268,829	6,317,882
Depreciation and amortization	261,994	106,938
Total operating expenses	60,457,844	41,288,902
Operating loss	(50,922,238)	(38,105,078)
Other income (expense)		
Miscellaneous income	335,482	688,721
Interest expense	(6,262,046)	(2,090,018)
Total other expense	(5,926,564)	(1,401,297)
Loss before income taxes	(56,848,802)	(39,506,375)
Provision for income taxes	—	—
Net loss	$ (56,848,802)	$ (39,506,375)
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	$ (0.21)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	271,459,522	241,006,032

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019
(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, December 31, 2019	271,177,076	$ 271,177	$ 704,351,222	$ (695,421,279)	$ 9,201,120
Shares issued for exercise of options, 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)

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

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

	Three Months Ended March 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (56,848,802)	$ (39,506,375)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	198,839	66,494
Amortization of intangible assets	63,155	40,444
Non-cash operating lease expense	351,987	219,765
(Recovery of) provision for doubtful accounts	(122,621)	82,284
Share-based compensation	2,366,453	2,586,948
Amortization of deferred financing fees	319,408	120,146
Amortization of license fee	745,511	—
Changes in operating assets and liabilities:		
Accounts receivable	3,854,569	(3,963,214)
Inventory	(2,746,737)	(1,688,045)
Other current assets	4,436,047	987,794
Accounts payable	9,533,115	2,621,402
Accrued expenses and other current liabilities	(1,261,904)	268,939
Net cash used in operating activities	(39,110,980)	(38,163,418)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(421,775)	(403,496)
Purchase of fixed assets	(21,254)	(262,418)
Net cash used in investing activities	(443,029)	(665,914)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options and warrants	72,109	100,107
Proceeds from Financing Agreement	50,000,000	—
Payment of deferred financing fees	(1,250,000)	—
Net cash provided by financing activities	48,822,109	100,107
Increase (decrease) in cash	9,268,100	(38,729,225)
Cash, beginning of period	160,829,713	161,613,077
Cash, end of period	$ 170,097,813	$ 122,883,852
Supplemental disclosure of cash flow information		
Interest paid	$ 5,892,639	$ 1,913,956

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® and BIJUVA® are registered trademarks of our company and ANNOVERA™ is a licensed trademark 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 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. 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 are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the response to the pandemic is in its incipient stages and information is rapidly evolving. At this time, we continue to provide an uninterrupted supply of our portfolio of products for patients. 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.

We have activated 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 currently have mailing options in place for these materials. We also have business continuity plans and infrastructure in place that allows for virtual detailing.

We have also implemented measures to cut planned marketing expenses for 2020. However, we have the ability to re-accelerate our planned marketing spend for ANNOVERA and IMVEXXY should market conditions improve, or to extend or expand the cost cuts throughout 2020. We have also implemented cost savings which include negotiating lower fees or suspending services from third party vendors; implementing a company-wide hiring freeze; delaying or cancelling non-critical IT projects; and eliminating travel, entertainment, meeting, and event expenses.

These savings can be extended further throughout 2020 or expanded depending on the impact of the COVID-19 pandemic. We already have sufficient inventory of finished product in our warehouses to meet anticipated demand through at least early third quarter of 2020. However, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a local and/or global economic recession. Such economic disruption could have a material adverse effect on our business. 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.

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 and the extent and severity of the impact on our customers, all of which are uncertain and cannot be predicted. Our future results of operations and liquidity could be adversely impacted by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions and uncertain demand, and the impact of any initiatives or programs that we may undertake to address financial and operations challenges that we may face. As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact our financial condition, liquidity, or results of operations is uncertain.

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 for the three months ended March 31, 2020.

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 March 31, 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 March 31, 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. There was no impairment of intangible assets during the three months ended March 31, 2020 and 2019.

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 share-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 awards and restricted stock awards for shares of common stock to employees. We value our restricted stock awards and our performance-based stock awards by reference to our stock price on the date of grant. We have elected to recognize compensation expense on a straight-line basis over the requisite service period of the entire award. 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. 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 the grant date and through the date the restricted stock vests.

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 March 31, 2020, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, and BIJUVA, which we began selling in the second quarter of 2019. We started selling ANNOVERA 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 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 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 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 revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a 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 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 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 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 revenues are recognized. We record distributor fees based on amounts stated in contracts. Rebate and coupon estimates and distributor fees are recorded in accrued expenses and 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 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 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 months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Prescription vitamins	$ 2,473,691	$ 1,935,971
IMVEXXY	6,392,601	2,010,680
BIJUVA	1,111,604	—
ANNOVERA	2,272,761	—
Net revenue	$ 12,250,657	$ 3,946,651

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.

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 months ended March 31, 2020, we recorded $745,511 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.

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.

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 management team that reports to the President of our company. 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

Inventory consists of the following:

	March 31, 2020	December 31, 2019
Finished products	$ 6,956,900	$ 4,976,910
Work in process	2,554,891	1,182,059
Raw materials	5,095,662	5,701,747
TOTAL INVENTORY	$ 14,607,453	$ 11,860,716

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	March 31, 2020	December 31, 2019
Prepaid sales and marketing costs	$ 553,789	$ 1,583,698
Debt financing fees on undrawn tranches (Note 9)	275,378	550,757
Prepaid insurance	1,064,468	1,812,135
Prepaid manufacturing	955,659	2,595,721
Other prepaid costs	3,769,073	4,787,482
TOTAL OTHER CURRENT ASSETS	$ 6,618,367	$ 11,329,793

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	March 31, 2020	December 31, 2019
Accounting system	$ 301,096	$ 301,096
Equipment	1,640,900	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	3,497,853	3,476,599
Accumulated depreciation	(1,167,663)	(968,824)
TOTAL FIXED ASSETS, NET	$ 2,330,190	$ 2,507,775

Depreciation expense for the three months ended March 31, 2020 and 2019 was $198,839, and $66,494, 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 March 31, 2020 and December 31, 2019:

	March 31, 2020			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	$ 3,763,022	$ (542,235)	$ 3,220,787	12.75
Hormone therapy drug candidate patents (pending)	2,070,397	—	2,070,397	n/a
Non-amortizable intangible assets:				
Multiple trademarks	325,648	—	325,648	indefinite
TOTAL	$ 6,159,067	$ (542,235)	$ 5,616,832	

	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 remaining 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 three months ended March 31, 2020 and 2019, there was no impairment recognized related to intangible assets.

As of March 31, 2020, we had 31 issued domestic patents and 30 issued foreign patents, including:

- 12 domestic patents and six 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, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.
- Eight domestic patents (seven utility and one design) and 13 foreign patents (three 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, 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 seven 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. In addition, we have pending patent applications with respect formulations containing progesterone in the U.S., Australia, Brazil, Canada, Europe, and Mexico.
- 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 $63,155 and $40,444 for the three months ended March 31, 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 (9 months)	$ 189,464
2021	$ 252,618
2022	$ 252,618
2023	$ 252,618
2024	$ 252,618

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	March 31, 2020	December 31, 2019
Accrued payroll, bonuses and commission costs	$ 6,087,359	$ 8,040,278
Allowance for coupons and returns	10,712,171	10,316,298
Accrued sales and marketing costs	893,332	3,285,662
Accrued compensated absences	1,874,036	1,463,878
Accrued wholesale distributor fees	3,897,398	2,347,122
Accrued legal and accounting expense	909,137	422,336
Accrued research and development	1,179,065	1,049,603
Operating lease liability	1,753,499	1,501,539
Accrued rebates	4,794,794	3,916,672
Other accrued expenses	823,694	1,480,225
TOTAL OTHER CURRENT LIABILITIES	$ 32,924,485	$ 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 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 will be available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as the Administrative Agent shall have consented to; and (iii) $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. 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. 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 on amounts borrowed under the Term Loan was due and payable monthly in arrears. Interest expense for the three months ended March 31, 2019 related to the Credit Agreement was $1,969,872. During the three months ended March 31, 2019, we amortized $120,146 of debt issuance costs as interest expense in the accompanying unaudited consolidated financial statements.

As of March 31, 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 and are accreted to interest expense using the effective interest method. Deferred financing fees associated with an unfunded tranche are deferred as assets until such tranche has been drawn. As of March 31, 2020, deferred financing fees related to the unfunded tranche of $50,000,000 were included in other current assets in the accompanying consolidated financial statements. During the three months ended March 31, 2020, we amortized $319,408 of deferred financing fees related to the two tranches that have been received 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 months ended March 31, 2020 was $5,942,639. The overall effective interest rate under the Financing Agreement was approximately 11% as of March 31, 2020.

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

	March 31, 2020	December 31, 2019
Financing Agreement	$ 250,000,000	$ 200,000,000
Debt discount and financing fees	(6,571,329)	(5,365,357)
TOTAL LONG-TERM DEBT	$ 243,428,671	$ 194,634,643

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, par value $0.001 per share, or 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 awards 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.

	March 31, 2020	March 31, 2019
Stock options	25,155,221	21,447,719
Warrants	1,832,571	1,832,571
Restricted stock awards	6,858,490	1,040,000
	33,846,282	24,320,290

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At March 31, 2020, we had 10,000,000 shares of Preferred Stock, par value $0.001, authorized for issuance, of which no shares of Preferred Stock were issued or outstanding.

Common Stock

At March 31, 2020, we had 350,000,000 shares of Common Stock authorized for issuance, of which 271,677,742 shares of Common Stock were issued and outstanding.

Issuances During the Three Months ended March 31, 2020

During the three months ended March 31, 2020, certain individuals exercised stock options to purchase an aggregate of 350,666 shares of Common Stock for $72,109 in cash.

Issuances During the Three Months ended March 31, 2019

During the three months ended March 31, 2019, certain individuals exercised stock options to purchase an aggregate of 276,383 shares of Common Stock for $100,107 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 March 31, 2020, we had warrants outstanding to purchase an aggregate of 1,832,571 shares of Common Stock with a weighted-average contractual remaining life of approximately 1.70 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.62 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.

During the three months ended March 31, 2020, no warrants were granted. During the three months ended March 31, 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 rate of 2.52%; and dividend yield of 0%. The grant date fair value of the warrants was $3.00 per share. The warrants vested ratably over a 12-month period and have an expiration date of February 12, 2024.

During the three months ended March 31, 2020, no warrants were exercised. During the three months ended March 31, 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.

We recorded share-based compensation expense related to warrants previously issued of $26,446 and $85,716 for the three months ended March 31, 2020 and 2019, respectively, in the accompanying consolidated financial statements. At March 31, 2020, there was no unrecognized estimated compensation expense related to unvested warrants.

Options to Purchase Common Stock of the Company

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 March 31, 2020, there were non-qualified stock options to purchase an aggregate of 14,546,246 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 March 31, 2020, there were non-qualified stock options to purchase an aggregate of 6,316,474 shares of Common Stock outstanding and an aggregate of 890,000 restricted stock awards 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 March 31, 2020, there were 4,970,994 shares of Common Stock available for issuance under the 2019 Plan, consisting of (i) 2,354,764 new shares, (ii) 2,395,333 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) 220,897 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 March 31, 2020, there were non-qualified stock options to purchase 4,292,501 shares of Common Stock outstanding under the 2019 Plan, 3,584,245 restricted stock awards and 2,384,245 performance stock awards 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 three months ended March 31, 2020 and 2019 are set forth in the table below.

	March 31, 2020	March 31, 2019
Weighted average grant date fair value	$ 0.98	$ 3.35
Risk-free interest rate	1.32-1.68 %	2.54%
Volatility	63.53-65.72 %	61.85%
Term (in years)	6-6.7	6.25
Dividend yield	0.00%	0.00%

A summary of activity under the 2009, 2012 and 2019 Plans and related information during the three months ended March 31, 2019 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	636,500	$ 1.64		
Exercised	(350,666)	$ 0.21		$ 725,199
Expired	(50,472)	$ 0.41		
Cancelled/Forfeited	(110,375)	$ 4.48		
Balance at March 31, 2020	25,155,221	$ 4.65	5.77	$ 787,178
Vested and Exercisable at March 31, 2020	19,258,556	$ 5.02	4.77	$ 787,178
Unvested at March 31, 2020	5,896,665	$ 3.42	9.05	$ —

At March 31, 2020, our outstanding options had exercise prices ranging from $0.19 to $8.92 per share. Share-based compensation expense related to options recognized in our results of operations for the three months ended March 31, 2020 and 2019 was approximately $1,836,630 and $2,143,239, respectively, and it is based on awards vested. At March 31, 2020, total unrecognized estimated compensation expense related to unvested options was approximately $9,800,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.3 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock awards 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 awards 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. Based upon the expected levels of achievement, stock-based compensation is recognized on a straight-line basis over the awards' requisite service periods. 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 months ended March 31, 2020 and 2019, we recorded $503,377 and $346,414, respectively, in share-based compensation expense related to restricted stock units and performance stock awards. At March 31, 2020, total unrecognized estimated compensation expense related to unvested restricted stock units and performance stock awards was approximately $9,830,000, 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 2.6 years.

	Restricted Stock Awards		Performance Stock Awards	
	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	3,384,245	$ 1.50	2,384,245	$ 1.07
Vested/Released	(150,000)	$ 2.42	—	—
Forfeited	—	—	—	—
Balance at March 31, 2020	4,474,245	$ 2.04	2,384,245	$ 1.07

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 three months ended March 31, 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 March 31, 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 March 31, 2020 and 2019, we were billed by Catalent approximately $1,303,000 and $1,397,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of March 31, 2020 and December 31, 2019, there were amounts due to Catalent of approximately $755,000 and $35,000, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 15, Commitments and Contingencies.

NOTE 14 – BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 32%, 28%, 24% and 13% of our purchases supplied by four vendors each, respectively, during the three months ended March 31, 2020 and 33%, 29%, 27% and 11% of our purchases supplied by four vendors each, respectively, during the three months ended March 31, 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 three months ended March 31, 2020, four customers each accounted for more than 10% of our total prescription revenues. Prescription revenue from the four customers combined accounted for approximately 70% of our prescription revenue for the three months ended March 31, 2020. During the three months ended March 31, 2019, five customers each generated more than 10% of our prescription revenues. Revenue generated from the five customers combined accounted for approximately 83% of our prescription revenue for the three months ended March 31, 2019.

During the three months ended March 31, 2020, Pillpack, Inc. accounted for approximately $3,199,000 of our prescription revenue, McKesson Corporation accounted for approximately $2,259,000 of our prescription revenue, Cardinal Health accounted for approximately $1,886,000 of our prescription revenue and Pharmacy Innovation PA accounted for approximately $1,234,000 of our prescription revenue. During the three months ended March 31, 2019, PI Services accounted for approximately $967,000 of our prescription revenue, AmerisourceBergen accounted for approximately $787,000 of our prescription revenue, Pillpack, Inc. accounted for approximately $534,000 of our prescription revenue, Cardinal Health accounted for approximately $525,000 of our prescription revenue and McKesson Corporation accounted for approximately $457,000 of our prescription revenue.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Operating Leases

We adopted ASC 842 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 is expected to commence as soon as the second quarter of 2020.

Supplemental lease information at:	March 31, 2020	December 31, 2019
Right-of-use asset	$ 9,757,167	$10,109,154
Short-term operating lease liability (included in Other current liabilities)	$ 1,753,499	$ 1,501,539
Long-term operating lease liability	$ 8,782,274	$ 9,145,049
Weighted average remaining term	9 years	9 years
Weighted average discount rate	8.25%	8.25%

Supplemental cash flow information for the three months ended:	March 31, 2020	March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities for operating lease	$ 327,386	$ 279,742
Right-of-use assets obtained in exchange for lease obligation	$ —	$ 3,760,171

The following table reconciles the undiscounted cash flows for all operating leases at March 31, 2020 to the operating lease liabilities recorded on the balance sheet:

Year Ended December 31,	
2020 (9 months)	$ 1,239,230
2021	2,198,541
2022	1,262,302
2023	1,293,859
2024	1,326,206
Thereafter	8,036,931
Total undiscounted lease payments	15,357,069
Less: imputed interest	(4,821,296)
Present value of lease payments	$ 10,535,773

During the three months ended March 31, 2020 and 2019, operating lease expense related to our real estate leases was $563,764 and $295,109, respectively, and variable lease expense was insignificant.

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 revenue as described in Note 3, Summary of Significant Accounting Policies, 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. 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 March 31, 2020, we have met our purchase commitments with Catalent.

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 March 31, 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

Paycheck Protection Program Loan

On April 27, 2020, we received a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, as administered by the U.S. Small Business Administration, or the SBA. The loan in the principal amount of $6,477,094, or the PPP Loan, was disbursed by Bank of America, NA, a national banking association, or BofA, pursuant to a promissory note issued by the Company, or the Promissory Note.

The PPP Loan matures on the two-year anniversary of the funding date and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), will commence after the six-month anniversary of the funding date. We did not provide any collateral or guarantees for the PPP Loan, nor did we pay any facility charge to obtain the PPP Loan. The Promissory Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. We may prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the PPP Loan may be forgiven by the SBA and BofA upon application by us beginning 60 days but not later than 90 days after the funding date of the PPP Loan. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 25% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. Although we currently believe that our use of the PPP Loan will meet the conditions for forgiveness of the loan, we cannot assure that the PPP Loan will be forgiven, in whole or in part.

Amendment No. 2 to Financing Agreement

In connection with incurring the PPP Loan, we, together with our subsidiaries, amended the Financing Agreement to, among other things, permit us to incur the PPP Loan and add certain affirmative covenants relating thereto.

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 include the following: the effects of the COVID-19 pandemic; our ability to maintain or increase sales of our approved products; our ability to successfully commercialize IMVEXXY®, BIJUVA®, and ANNOVERA® and to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; 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, including the conditions to draw an additional tranche thereunder, and whether the lender will make such tranche available; whether we will be able to comply with the covenants and conditions under the loan we received pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration (SBA), including the conditions for forgiveness of the loan; 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; and 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 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. 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 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 commercialize 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. 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. At this time, the extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict.

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. This contingency plan is designed to be implemented in stages over the second and third quarters of 2020 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 focuses on five key areas:

- Containing costs and cutting spending.
- Addressing impacts and trends for the second quarter of 2020.
- Preparing for a potential longer-term impact throughout the year.
- Leveraging vitaCare Prescription Services to continue to meet the needs of our patients and prescribers.
- Ensuring continued availability of our products to patients.

Cost Containment and Spending Cuts

We have implemented measures to initially cut or defer more than $30 million in annual spending. This includes the deferral of approximately $10 million in planned second quarter consumer and healthcare practitioner marketing spend for ANNOVERA and IMVEXXY and cuts of approximately $20 million in other planned expenses for the remainder of 2020. We believe that we have the ability to re-accelerate our planned marketing spend for ANNOVERA and IMVEXXY should market conditions improve, or to extend or expand the cost deferrals throughout 2020. These cost cuts and reductions include permanent cost savings that have been identified by management, as well as the interim cessation of certain spending that may be restarted in future quarters. These cost cuts include:

- Negotiating lower fees or suspending services from third party vendors;
- Implementing a Company-wide hiring freeze;
- Delaying or cancelling non-critical IT projects; and
- Eliminating travel, entertainment, meeting, and event expenses.

We anticipate that these savings can be extended further throughout 2020 or expanded depending on the impact of the COVID-19 pandemic.

Employees and Sales Force

Our sales force currently continues to function utilizing digital engagement tools and tactics and virtual detailing to remain engaged with prescribers and distribution channels.

- We have enhanced the ability of our sales force to support healthcare providers remotely, including the sales forces' ability to continue to provide healthcare practitioners 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 healthcare providers, including conducting "virtual" lunch and learn seminars 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 continue to provide continued access to our products for patients.

- 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 anticipate that home delivery pharmacy options will be attractive to patients during the COVID-19 pandemic.
- Through vitaCare, we have connected with more than 80% of our patients. We anticipate that vitaCare will support continued patient access to our products during the COVID-19 pandemic and will help sustain the strong 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.

Supply of Products

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

- We currently have sufficient inventory of finished product in our contracted warehouses to meet anticipated demand through at least the early part of the third quarter of this year.
- We currently do not foresee any interruption in our contract manufacturers' abilities to continue to manufacture additional product to be used beyond the third quarter of this year. 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" and "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 patents, 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.

We submitted a New Drug Application, or NDA, efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA in late January 2020 for review and potential approval. The NDA efficacy supplement uses existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. The REPLENISH trial was the first time that a combination of bio-identical estradiol and bio-identical progesterone used in a continuous combined daily fashion demonstrated safety and efficacy data to support FDA-approval. We do not anticipate that the FDA will require any new clinical trials in connection with our submission of the NDA efficacy supplement, however, there is no assurance that will be the case. If accepted for review by the FDA, we expect that the NDA efficacy supplement will be reviewed, under current Prescription Drug User Fee Act timeline goals, within ten months of receipt by the FDA.

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 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 and we launched ANNOVERA commercially in March 2020. Due to the impact of the COVID-19 pandemic, we had to pause our launch initiative and we expect to resume the ANNOVERA launch later in 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 EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, an NCE, is a potent progestin that, based on pharmacopogical 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 rapid 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 a generic equivalent has not been established. As part of this strategy, we are pursuing distribution opportunities for ANNOVERA with multiple direct-to-consumer contraceptive platforms that are both low cost to TherapeuticsMD and offer an attractive return to the platforms. However, as a result of the COVID-19 pandemic, we have deferred a significant portion of our planned 2020 marketing spend for ANNOVERA.

Commercialization Model

We are commercializing the products in our portfolio through a common model focused on the belief that providing good experiences for both health care practitioners, or 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. We have defined a sales force targeting approximately 200 territories, which includes the most significant part of the addressable markets across our product portfolio. We are deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target HCPs. As of March 31, 2020, at least 19,500 HCPs had written at least one prescription of IMVEXXY and at least 5,900 HCPs had written at least one prescription of BIJUVA, the majority of which are also IMVEXXY writers demonstrating the value of portfolio and focus. In addition, as of March 31, 2020, at least 2,000 HCPs had written at least one prescription of ANNOVERA. In addition to our sales organization, we leverage non-personal promotion (multi-channel advertising) to targets and non-targets that drive awareness, education, and action. These efforts allow for pull through of the sales organization 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 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 BIO-IGNITE pharmacy partners and continue to build our internal capabilities to support both organizations, including compliance professionals and programs and key data support systems that provide real-time data for the sales force and KAMs. Our KAMs have national coverage and target over 1,900 community pharmacies that have a focus on compounded bio-identical hormones and the over 2,000 additional HCPs that are affiliated with these pharmacies. As of March 31, 2020, there were over 220 BIO-IGNITE compounding pharmacies that were dispensing BIJUVA.

Payer Access - With the ever-changing payer environment, 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. Currently, both IMVEXXY and BIJUVA are broadly available in major pharmacy chains in the U.S., as well as with our BIO-IGNITE partners, via our third-party logistics and our distribution partners. As of March 31, 2020, we have obtained coverage for the majority of commercial payers for both products 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 March 31, 2020, two of the top six (or three of the top eight) Medicare Part D payers of VVA products were adjudicating IMVEXXY, with additional decisions for other Medicare Part D payers expected during the second half of 2020. For BIJUVA, through March 31, 2020, we have achieved unrestricted coverage with seven 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 March 31, 2020, two of the top six Medicare Part D payers of VMS products 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 five of the top ten commercial payers by commercial payer lives as of March 31, 2020, and we continue to pursue discussions with several of the country’s largest commercial insurers to further expand coverage. As of March 31, 2020, approximately 64% of the commercial payer market covered ANNOVERA with unrestricted access under pharmacy benefits and approximately 76% 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. Veteran's Administration, 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 mail order. 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. Starting October 1, 2019, enrolled patients pay as little as $35 for a prescription of IMVEXXY with commercial insurance coverage and pay as little as $50 for a prescription of IMVEXXY 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 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. While we are optimistic about our chances to secure a new contraception class for ANNOVERA, 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 both our prescription prenatal line and for IMVEXXY with average adherence rates above the averages in their respective categories.

Consumer Communication - Another critical level in the commercial model is consumer communication. 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 will pay us a milestone fee upon the first regulatory approval in Canada of each of IMVEXXY and BIJUVA, 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. In October 2019 and November 2019, Knight's New Drug Submissions for Joyesta (IMVEXXY) and BIJUVA, respectively, were accepted for review by Health Canada. 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.

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.

As of March 31, 2020, we had 30 issued foreign patents and 31 issued domestic or, U.S., patents, which included 12 domestic utility patents that relate to BIJUVA, three domestic patents that relate to estradiol and progesterone product candidates, eight 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 in the second quarter of 2019, and three domestic utility patents that relate to TX-009HR, our progesterone and estradiol drug candidate.

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 discovery and development 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 March 31,	
	2020	2019
	(000s)	
TX 001-HR (BIJUVA)	$ 587	$ 1,510
TX 004-HR (IMVEXXY)	381	765
ANNOVERA	375	874
Other research and development	1,926	3,169
Total	$ 3,269	$ 6,318

Research and development expenditures have been reduced as we refocus 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 March 31, 2020 compared with three months ended March 31, 2019

	Three Months Ended March 31,		
	2020	2019	Change
	(000s)		
Revenue, net	$ 12,251	$ 3,947	$ 8,304
Cost of goods sold	2,715	763	1,952
Operating expenses	60,458	41,289	19,169
Operating loss	(50,922)	(38,105)	(12,817)
Other expense, net	(5,927)	(1,401)	(4,526)
Net loss	$ (56,849)	$ (39,506)	$ (17,343)

Revenues and Cost of Goods Sold

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 and although we commercially launched ANNOVERA in early March 2020, we subsequently paused the launch due to the COVID-19 pandemic. Revenue for the three months ended March 31, 2020 increased approximately $8,304,000, or 210%, to approximately $12,251,000, compared with approximately $3,947,000 for the three months ended March 31, 2019. Revenue increased primarily due to continued ramping of sales of IMMVEXXY, sales of BIJUVA, and pre-launch sales of ANNOVERA during the three months ended March 31, 2020 as compared to the prior year period. Our revenue in the prior year period only consisted of sales of IMVEXXY and our prenatal vitamins.

Sales of IMMVEXXY increased approximately $4,382,000 as compared to the prior period, which was primarily due to a higher number of units sold and increased net revenue per unit. Revenue for the three months ended March 31, 2020 also included sales of BIJUVA of approximately $1,111,000, which was commercially launched in the second quarter of 2019, and sales of ANNOVERA of approximately $2,273,000, which were affected by the recent COVID-19 pandemic. In addition, during the three months ended March 31, 2020, our prenatal vitamin sales increased approximately $538,000 due to increased net revenue per unit as compared to the prior year period, partially offset by a decreased number of units sold.

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 $1,952,000, or 256%, to approximately $2,715,000 for the three months ended March 31, 2020, compared with approximately $763,000 for the three months ended March 31, 2019, most of which is attributable to the 210% increase in revenue. A portion of the increase is due to royalty fees of approximately $114,000 and the amortization of our license fee of approximately $746,000 related to ANNOVERA. Our gross margin related to prescription products was approximately 78% and 81% for the three-month periods ended March 31, 2020 and 2019, respectively. The change in our gross margin is primarily related to the change in product mix between the two periods.

Operating Expenses

Our operating costs have increased substantially as we continue to support the launch of our new pharmaceutical products in the market. BIJUVA was launched in the second quarter of 2019. We commercially launched ANNOVERA in early March 2020, which was subsequently paused due to the outbreak of the COVID-19 pandemic. During the three months ended March 31, 2019, we were primarily focused on growing sales of IMVEXXY and prenatal vitamins. Our principal operating costs include the following items as a percentage of total operating expenses:

	Three Months Ended March 31,	
	2020	**2019**
Sales and marketing costs, excluding human resources costs	52.2%	41.2%
Human resources related costs, including salaries, benefits and taxes	26.9%	26.9%
Product research and development costs	5.4%	15.3%
Professional fees and consulting costs	5.3%	6.1%
Other operating expenses	10.2%	10.5%

Operating expenses increased by approximately $19,169,000, or 46%, to approximately $60,458,000 for the three months ended March 31, 2020, from approximately $41,289,000 for the three months ended March 31, 2019 as a result of the following items:

	Three Months Ended March 31,		
	2020	2019	Change
	(000s)		
Sales and marketing, excluding human resources costs	$ 31,530	$ 17,012	$ 14,518
Human resources related costs	16,230	11,108	5,122
Product research and development costs	3,269	6,318	(3,049)
Professional fees and consulting costs	3,231	2,535	696
Other operating expenses	6,198	4,316	1,882
Total operating expenses	$ 60,458	$ 41,289	$ 19,169

Sales and marketing costs, excluding human resources costs, for the three months ended March 31, 2020 increased by approximately $14,518,000, or 85%, to approximately $31,530,000, compared with approximately $17,012,000 for the three months ended March 31, 2019. This increase was primarily due to higher expenses associated with sales and marketing efforts to support the significant initiatives related to the launch of ANNOVERA in March 2020, which was subsequently paused as a result of the outbreak of the COVID-19 pandemic, as well as continuing to support the commercialization of BIJUVA and IMVEXXY. The sales and marketing increase includes a change of approximately $9,900,000 related to advertising expenses related primarily to the preparation of the launch of ANNOVERA and increased spend on consumer media to support growth of sales for IMVEXXY and BIJUVA, an increase of approximately $1,700,000 in consulting projects including costs for outsourced sales personnel and their related expenses, and an increase of approximately $1,200,000 in incentives related to increased sales of our products. The sales and marketing expenses also increased due to higher costs related to product samples, physician education and training expenses related to product commercialization. As noted in the COVID-19 discussion above, we have implemented measures to cut or defer spending, including sales and marketing costs, as a result of the COVID-19 pandemic.

Human resources related costs, including salaries, benefits and taxes, for the three months ended March 31, 2020 increased by approximately $5,122,000, or 46%, to approximately $16,230,000, compared with approximately $11,108,000 for the three months ended March 31, 2019, primarily as a result of an increase in personnel costs in sales, marketing and regulatory areas to support the commercialization of our pharmaceutical products in 2020 as compared to 2019.

Product research and development costs for the three months ended March 31, 2020 decreased by approximately $3,049,000, or 48%, to approximately $3,269,000, compared with approximately $6,318,000 for the three months ended March 31, 2019. 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. Research and development expenditures have been reduced as we refocus 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 $131,622,000 in research and development costs with respect to BIJUVA.
- Since the project's inception in August 2014, we have incurred approximately $48,642,000 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 March 31, 2020 increased by approximately $696,000, or 27%, to approximately $3,231,000, compared with approximately $2,535,000 for the three months ended March 31, 2019, primarily as a result of increased legal and other professional fees.

Other operating expense for the three months ended March 31, 2020 increased by approximately $1,882,000, or 44%, to approximately $6,198,000, compared with approximately $4,316,000 for the three months ended March 31, 2019, as a result of increased information technology, rent and utilities expense, dues and subscriptions, insurance and other office expenses primarily to support commercialization of our pharmaceutical products.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $12,817,000, or 34%, to approximately $50,922,000 for the three months ended March 31, 2020, compared with approximately $38,105,000 for the three months ended March 31, 2019, primarily as a result of an increase in total operating expenses to support commercialization and launch efforts related to our pharmaceutical products, partially offset by increased total 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 our commercialization of IMVEXXY, BIJUVA, and ANNOVERA will be successful.

Other expense, net

Other expense, net increased by approximately $4,526,000, or 323%, to an expense of approximately $5,927,000 for the three months ended March 31, 2020, compared with an expense of approximately $1,401,000 for the three months ended March 31, 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 $17,343,000, or 44%, to approximately $56,849,000 for the three months ended March 31, 2020, compared with approximately $39,506,000 for the three months ended March 31, 2019. Net loss per share of common stock, basic and diluted, was ($0.21) and ($0.16) for the three months ended March 31, 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 ending December 31, 2019, we received approximately $236,000,000 in net proceeds from the issuance of shares of our common stock. As of March 31, 2020, we had cash totaling approximately $170,098,000. 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 revenues during the quarter. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross product revenues to distributors during the quarter. For the three months ended March 31, 2020, our gross DSO was 52 days compared to 55 days for the three months ended December 31, 2019, and our net DSO was 153 days for the three months ended March 31, 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.

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 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; and (iii) $50,000,000 will be available to us in the Administrative Agent's sole and absolute discretion either contemporaneously with the delivery of our financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as the Administrative Agent shall have consented to. 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 5.20% 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. A portion of the initial tranche of borrowing under the Facility in the amount of approximately $81,661,000 was used to repay all amounts outstanding under our prior financing agreement with MidCap Financial Trust, or the MidCap Agreement.

Although there is uncertainty related to the anticipated impact of the COVID-19 pandemic on our future results, we believe that our current cash reserves and the recent steps we have taken to reduce costs will help us to manage our business through the pandemic. We have reviewed numerous potential scenarios in connection with the impact of COVID-19 on our business and, based on our analysis, we believe our existing cash reserves, our currently anticipated operating cash flows, and availability under the Facility, if we are able to access such funds, will 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 the successful commercialization of IMVEXXY, BIJUVA, or ANNOVERA is delayed, or the impact of the COVID-19 pandemic is worse than we anticipate, our existing cash reserves and availability under the Facility, if we are able to access such funds, may be insufficient to satisfy our liquidity requirements until we are able to successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA and we may not be able to access funds under the Facility. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing, and other commercialization efforts and we may seek to sell additional equity or debt securities. Our ability to sell equity securities will be limited by the authorized shares that we have available to issue. Our ability to sell debt securities or obtain additional debt financing is restricted pursuant to the Financing Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Financing Agreement, the ownership interests of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, certain of which are restricted under the Financing Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Financing Agreement. Additionally, we may have to grant licenses on terms that may not be favorable to us.

We need substantial amounts of cash to complete the launch and commercialization of our hormone therapy and contraceptive products and product candidates. 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

	Three Months Ended March 31,	
	2020	2019
	(000s)	
Net cash used in operating activities	$ (39,111)	$ (38,163)
Net cash used in investing activities	$ (443)	$ (666)
Net cash provided by financing activities	$ 48,822	$ 100

Operating Activities

The principal use of cash in operating activities for the three months ended March 31, 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 $948,000 in cash used in operating activities for the three months ended March 31, 2020 compared with the comparable period in the prior year was due primarily to an increase in our net loss coupled with changes in the components of working capital which were primarily due to the launch and commercialization of our pharmaceutical products.

Investing Activities

Investing activities include costs related to patents and fixed assets. Investing activities for the three months ended March 31, 2020 decreased by $223,000 primarily due to lower amounts spent on fixed assets during the three months ended March 31, 2020 as compared to the three months ended March 31, 2019.

Financing Activities

Financing activities currently represent the principal source of our cash flow. Our financing activities for the three months ended March 31, 2020 provided net cash of approximately $48,822,000 which consisted of the funding from our Financing Agreement of approximately $50,000,000 and the exercise of options to purchase common stock of approximately $72,000, partially offset by the payment of deferred financing fees of approximately $1,250,000. Our financing activities for the three months ended March 31, 2019 provided net cash of approximately $100,000, which was related to the exercise of stock options.

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 for the three months ended March 31, 2020.

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 will 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 March 31, 2020, a 1.0% change in interest rates would result in an impact to income 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 in connection with 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 March 31, 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. We are not currently involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

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 (coronavirus) has evolved into a global pandemic. COVID-19 has spread to many regions of the world, including the United States and Europe. The full extent to COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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, including cost-containment and spending cuts in the second quarter of 2020 that can be extended through the rest of the year depending on the evolution of COVID-19, we have suspended our previously announced 2020 financial guidance due to the unknown impact of COVID-19 on our business and the rapidly evolving nature of the pandemic. As a result of COVID-19, we will, among other things, (i) defer approximately $10 million in consumer and healthcare practitioner marketing spending for ANNOVERA and IMVEXXY, (ii) make cuts of approximately $20 million in other planned expenses for the year, (iii) negotiate lower fees and/or suspend services from non-critical third party vendors, (iv) implement a hiring freeze, (v) delay or cancel any non-critical information technology projects and (vi) eliminate travel, entertainment, meeting and event expenses.

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. In addition, due to closures and restrictions on travel, our sales force is currently functioning largely utilizing digital engagement tools and tactics and virtual detailing, which may be less effective than our ordinary course sales and marketing programs. We may also require an increased level of working capital if we experience extended billing and collection cycles as a result of displaced employees at our company, payers, revenue cycle management contractors, or otherwise. 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.

Item 6. Exhibits

Exhibit	Date	Description
31.1*	May 6, 2020	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	May 6, 2020	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1**	May 6, 2020	Section 1350 Certification of Chief Executive Officer
32.2**	May 6, 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.

SIGNATURES

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

DATE: May 6, 2020

THERAPEUTICSMD, INC.

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

By: */s/ Daniel A. Cartwright*
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

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

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

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

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

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

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

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

May 6, 2020

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daniel A. Cartwright, 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.

May 6, 2020

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 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.

May 6, 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 March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel A. Cartwright, 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.

May 6, 2020

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting 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.