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, 2019

☐ **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.)
6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL	**33487**
(Address of Principal Executive Offices)	(Zip Code)

(561) 961-1900
(Registrant's Telephone Number, including Area Code)

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

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

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

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

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

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

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

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of May 1, 2019 was 241,221,840.

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash	$ 122,883,852	$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of $678,886 and $596,602, respectively	14,944,750	11,063,821
Inventory	4,955,715	3,267,670
Other current assets	9,846,899	10,834,693
Total current assets	152,631,216	186,779,261
Fixed assets, net	668,607	472,683
Other Assets:		
License rights	20,000,000	20,000,000
Intangible assets, net	4,455,730	4,092,679
Other assets	3,821,566	324,855
Security deposit	314,446	314,446
Total other assets	28,591,742	24,731,980
Total assets	$ 181,891,565	$ 211,983,924
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 25,365,243	$ 22,743,841
Other current liabilities	19,607,439	18,334,948
Total current liabilities	44,972,682	41,078,789
Long-Term Liabilities:		
Long-term debt	73,501,160	73,381,014
Operating lease liability	2,724,501	—
Total liabilities	121,198,343	114,459,803
Commitments and Contingencies - See Note 15		
Stockholders' 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: 241,221,840 and 240,462,439 issued and outstanding, respectively	241,222	240,463
Additional paid-in capital	619,234,655	616,559,938
Accumulated deficit	(558,782,655)	(519,276,280)
Total stockholders' equity	60,693,222	97,524,121
Total liabilities and stockholders' equity	$ 181,891,565	$ 211,983,924

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, 2019	March 31, 2018
Revenues, net	$ 3,946,651	$ 3,773,392
Cost of goods sold	762,827	633,623
Gross profit	3,183,824	3,139,769
Operating expenses:		
Sales, general, and administrative	34,864,082	20,757,237
Research and development	6,317,882	7,039,297
Depreciation and amortization	106,938	59,621
Total operating expenses	41,288,902	27,856,155
Operating loss	(38,105,078)	(24,716,386)
Other (expense) income		
Miscellaneous income	688,721	314,557
Interest expense	(2,090,018)	—
Total other (expense) income	(1,401,297)	314,557
Loss before income taxes	(39,506,375)	(24,401,829)
Provision for income taxes	—	—
Net loss	$ (39,506,375)	$ (24,401,829)
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	$ (0.16)	$ (0.11)
Weighted average number of common shares outstanding, basic and diluted	241,006,032	216,525,316

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, 2019	March 31, 2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (39,506,375)	$ (24,401,829)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	66,494	38,424
Amortization of intangible assets	40,444	21,197
Non-cash operating lease expense	219,765	—
Provision for doubtful accounts	82,284	22,955
Share-based compensation	2,586,948	1,751,358
Amortization of deferred financing costs	120,146	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,963,214)	(790,885)
Inventory	(1,688,045)	(135,514)
Other current assets	987,794	1,506,152
Accounts payable	2,621,402	2,186,224
Accrued expenses and other liabilities	268,939	152,223
Net cash used in operating activities	(38,163,418)	(19,649,695)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(403,496)	(142,136)
Purchase of fixed assets	(262,418)	(26,908)
Payment of security deposit	—	(11,486)
Net cash used in investing activities	(665,914)	(180,530)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options	100,107	44,057
Net cash provided by financing activities	100,107	44,057
Decrease in cash	(38,729,225)	(19,786,168)
Cash, beginning of period	161,613,077	127,135,628
Cash, end of period	$ 122,883,852	$ 107,349,460
Supplemental disclosure of cash flow information		
Interest paid	$ 1,913,956	—

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2019 AND 2018
(Unaudited)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2017	216,429,642	$ 216,430	$ 516,351,405	$ (386,659,120)	$ 129,908,715
Shares issued for exercise of options, net	154,632	154	43,902	—	44,056
Share-based compensation	—	—	1,751,358	—	1,751,358
Net loss	—	—	—	(24,401,829)	(24,401,829)
Balance, March 31, 2018	216,584,274	$ 216,584	$ 518,146,665	$ (411,060,949)	$ 107,302,300
Balance, December 31, 2018	240,462,439	$ 240,463	$ 616,559,938	$ (519,276,280)	$ 97,524,121
Shares issued for exercise of options, 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

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."

Nature of Business

We are a women's healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and 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 advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. Our track record of commercialization allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products.

During 2018, U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. 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 BIJUVA™, 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. We are also focused on commercialization activities necessary for launch of ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent unintended pregnancy for up to a full year, which was approved by the FDA on August 10, 2018. On July 30, 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 addition, on July 30, 2018, we entered into an exclusive license agreement, or the Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA™ in the U.S.

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, 2018, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2018. 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.

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 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 are currently evaluating the effect of this guidance on our disclosures.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. We adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a $3.8 million right of use asset and a $4.1 million liability related to adoption of this standard. Comparative financial information was not adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we did not assess (1) whether existing or expired contracts contain leases, (2) lease classification for any existing or expired leases, and (3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

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

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.

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 Accounting Standards Codification, or ASC, 820, *Fair Value Measurements.* 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 asset or liability.

At March 31, 2019 and 2018, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets or long-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with the Company's impairment test. There was no impairment of intangible assets or long-lived assets during the three months ended March 31, 2019 and 2018.

The carrying amount for the long-term debt as of March 31, 2019 (as disclosed in Note 9), approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk (Level 2).

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 charge-backs and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due for more than 90 days to be delinquent. 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.

Revenue Recognition

We adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. ASC 606 states that a contract is considered "completed" if all (or substantially all) of the revenue was recognized in accordance with revenue guidance that was in effect before the date of initial application. Because all (or substantially all) of the revenue related to sales of our products has been recognized under ASC 605 prior to the date of initial application of the new standard, the contracts are considered completed under ASC 606. Based on our evaluation of ASC 606, we concluded that a cumulative adjustment was not necessary upon implementation of ASC 606 on January 1, 2018. In accordance with 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, 2019, our products consisted primarily of prescription vitamins and our recently approved product IMVEXXY®, which we began selling during the third quarter of 2018. We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors. 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 pharmacy distributors, 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. All of our performance obligations, and associated revenue, are transferred to customers at a point in time. 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 prescription products currently have a shelf life of 24 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 the accrued expenses and 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 the commercial launch for IMVEXXY® during the third quarter of 2018, we introduced a co-pay assistance program where enrolled patients do not pay more than $35 for up to 12 IMVEXXY® prescription fills. This allows patients to access the product at a reasonable cost regardless of insurance coverage. We reimburse pharmacies for this discount through third-party vendors. We consider these payments as consideration paid to the customer and reflect such payments as a reduction of the transaction price as we do not receive a distinct good or service related to these payments. 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 IMVEXXY® 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 IMVEXXY® is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain revenue recognized for IMVEXXY® to an amount that will not result in a significant revenue reversal in future periods. Our ability to estimate the net transaction price for IMVEXXY® is constrained by our estimates of the amount to be paid for the co-pay assistance program for IMVEXXY® 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 any constraint each reporting period.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the three months ended March 31, 2019 and 2018:

	For the Three Months Ended March 31,	
	2019	2018
Prescription vitamins	$ 1,935,971	$ 3,773,392
IMVEXXY®	2,010,680	—
Net revenue	$ 3,946,651	$ 3,773,392

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. Prior to January 1, 2017, the expected volatility of share options was estimated based on a historical volatility analysis of peer entities whose stock prices were publicly available that were similar to the Company with respect to industry, stage of life cycle, market capitalization, and financial leverage. 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. The average expected life is 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. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. 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 nonemployees 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 nonemployees 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.

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 legal fees and 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. Legal activities that were classified as R&D expenses include professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal 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 expense in the period in which the facts that give rise to the revision become known.

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.

NOTE 4 – INVENTORY

Inventory consists of the following:

	March 31, 2019	December 31, 2018
Finished product	$ 3,217,706	$ 2,908,958
Work in process	808,694	339,312
Raw material	929,315	19,400
TOTAL INVENTORY	$ 4,955,715	$ 3,267,670

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	March 31, 2019	December 31, 2018
Prepaid sales and marketing costs	$ 3,774,437	$ 5,148,789
Debt financing fees (Note 9)	1,898,074	1,898,074
Prepaid insurance	455,929	790,465
Other prepaid costs	3,718,459	2,997,365
TOTAL OTHER CURRENT ASSETS	$ 9,846,899	$ 10,834,693

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	March 31, 2019	December 31, 2018
Accounting system	$ 301,096	$ 301,096
Equipment	560,772	490,576
Furniture and fixtures	271,864	116,542
Computer hardware	80,211	80,211
Leasehold improvements	74,788	37,888
	1,288,731	1,026,313
Accumulated depreciation	(620,124)	(553,630)
TOTAL FIXED ASSETS, NET	$ 668,607	$ 472,683

Depreciation expense for the three months ended March 31, 2019 and 2018 was $66,494 and $38,424, respectively.

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets as of March 31, 2019 and December 31, 2018:

	March 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (10,983)	$ 20,968	10.5
Approved hormone therapy drug candidate patents	2,519,316	(322,431)	2,196,885	13.75
Hormone therapy drug candidate patents (pending)	1,967,124	—	1,967,124	n/a
Non-amortizable intangible assets:				
Multiple trademarks	270,753	—	270,753	indefinite
Total	$ 4,789,144	$ (333,414)	$ 4,455,730	

	December 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (10,484)	$ 21,467	10.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	2,234,129	(282,485)	1,951,644	14
Hormone therapy drug candidate patents (pending)	1,855,279	—	1,855,279	n/a
Non-amortizable intangible assets:				
Multiple trademarks	264,289	—	264,289	indefinite
Total	$ 4,477,391	$ (384,712)	$ 4,092,679	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the three months ended March 31, 2019 and year ended December 31, 2018, there was no impairment recognized related to intangible assets.

As of March 31, 2019, we had 22 issued domestic, or U.S., patents and 27 issued foreign patents, including:

- 12 domestic patents and five foreign patents that relate to BIJUVA™ as well as three domestic patents that relate to non-approved doses of BIJUVA™. These patents establish an important intellectual property foundation for BIJUVA™ 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, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Four foreign patents that relate to our progesterone-only candidate, which are owned by us. The foreign patents will expire no earlier than 2033. In addition, we have pending patent applications with respect to our progesterone-only candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- Three domestic patents (two 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 jurisdictions, 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. We have pending patent applications with respect to our topical-cream candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;

- One domestic utility patent and five 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., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa;

- One domestic utility patent that relates to our OPERA® information-technology platform, which is owned by us and will expire in 2031; and

- One domestic utility patent that relates to TX-009HR, a progesterone and estradiol product candidate, which is owned by us and will expire in 2037. We have pending patent applications with respect to TX-009HR in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.

Amortization expense was $40,444 and $21,197 for the three months ended March 31, 2019 and 2018, respectively. Estimated amortization expense for the next five years for the patent costs currently being amortized is as follows:

Year Ending December 31,		Estimated Amortization
2019 (9 months)	$	121,333
2020	$	161,777
2021	$	161,777
2022	$	161,777
2023	$	161,777

License Agreement with the Population Council

On July 30, 2018, we entered into the Council License Agreement to commercialize in the U.S. ANNOVERA™. We currently estimate that ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned full commercial launch by the first quarter of 2020.

Under the terms of the Council License Agreement, we paid the Population Council a milestone payment of $20,000,000 within 30 days following approval by the FDA of the NDA for ANNOVERA™ and will be required to pay the Population Council $20,000,000 within 30 days following the release of the first commercial batch of ANNOVERA™. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™. We will assume responsibility for marketing expenses related to the commercialization of ANNOVERA™. The milestone payment of $20,000,000 upon the FDA's approval of ANNOVERA™ in the third quarter of 2018 was recorded as a finite-lived intangible asset in the consolidated balance sheet and will be amortized on a straight-line basis once it becomes available for use which is expected to be upon release of first commercial batch 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. 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 Council License Agreement. We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the 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 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.

We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. If impairment indicators are present or changes in circumstance suggest that impairment may exist, we perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, we would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. We also evaluate the remaining useful life of intangible assets subject to amortization on a periodic basis to determine whether events and circumstances would indicate impairment or warrant a revision to the remaining useful life. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

License Agreement with Knight Therapeutics Inc.

On July 30, 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 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. 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 and Israel 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. In connection with the Knight License Agreement, Knight entered into a subscription agreement with us, pursuant to which Knight purchased 3,921,568 shares of our Common Stock concurrent with the closing of the underwritten public offering of Common Stock at a price of $5.10, for proceeds of $20,000,000, on August 6, 2018.

NOTE 8 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	March 31, 2019	December 31, 2018
Accrued payroll, bonuses and commission costs	$ 5,200,009	$ 6,854,002
Allowance for coupons and returns	5,995,027	5,294,120
Accrued sales and marketing costs	1,590,746	2,288,028
Accrued compensated absences	1,390,396	1,178,110
Allowance for wholesale distributor fees	1,115,689	792,891
Operating lease liability - short term	1,158,286	—
Accrued legal and accounting expense	690,346	385,824
Accrued research and development	869,188	388,675
Accrued rent	—	365,155
Accrued rebates	929,022	412,570
Other accrued expenses	668,730	375,573
TOTAL OTHER CURRENT LIABILITIES	$ 19,607,439	$ 18,334,948

NOTE 9 – DEBT

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. Interest on amounts borrowed under the Term Loan was due and payable monthly in arrears. Interest expense related to the Term Loan for the three months ending March 31, 2019 was $1,969,872.

As of March 31, 2019, we had $75,000,000 in borrowings outstanding under the Term Loan, which are classified as long-term debt in the accompanying unaudited consolidated financial statements. We incurred $3,786,918 in debt issuance costs related to the Term Loan. Debt financing fees related to the entire Term Loan have been allocated pro rata between the funded and unfunded portions of each tranche. Allocated debt financing fees related to Tranche 1 of $1,888,844 have been reclassified to debt discount and are accreted to interest expense using the effective interest method. Debt financing fees associated with unfunded tranches were deferred as assets until the Tranche 2 and Tranche 3 milestones have been met. As of March 31, 2019, deferred financing fees related to Tranche 2 and Tranche 3 were included in other current assets in the accompanying consolidated financial statements. During the three months ended March 31, 2019, we amortized $120,146 of debt issuance costs related to Tranche 1 as interest expense in the accompanying unaudited consolidated financial statements. The overall effective interest rate was approximately 11% as of March 31, 2019. As of March 31, 2019, the carrying value of debt consisted of the following:

	March 31, 2019	December 31, 2018
Term Loan	$ 75,000,000	$ 75,000,000
Debt discount and financing fees	(1,498,840)	(1,618,986)
TOTAL LONG-TERM DEBT	$ 73,501,160	$ 73,381,014

On April 24, 2019, we entered into a Financing Agreement, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or Administration Agent, various lenders from time to time party thereto, and certain of our subsidiaries party thereto from time to time as guarantors, which provides a $300,000,000 first lien secured term loan credit facility, or the Facility, to the Company. See Note 16 - Subsequent Events.

On April 24, 2019, we terminated the Credit Agreement. 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 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.

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 antidilutive 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.

	Three Months Ended	
	March 31, 2019	March 31, 2018
Stock options	21,447,719	25,196,684
Warrants	1,832,571	3,290,905
Restricted stock awards	1,040,000	—
	24,320,290	28,487,589

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At March 31, 2019, 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, 2019, we had 350,000,000 shares of Common Stock authorized for issuance, of which 241,221,840 shares of Common Stock were issued and outstanding.

Issuances During the Three Months Ended March 31, 2019

During the three months ended March 31, 2019, certain individuals exercised stock options to purchase 276,383 shares of Common Stock for $100,107 in cash. Also, during the same period, stock options to purchase 12,097 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 11,834 shares of Common Stock were issued.

Issuances During the Three Months Ended March 31, 2018

During the three months ended March 31, 2018, certain individuals exercised stock options to purchase 144,791 shares of Common Stock for $44,057 in cash. Also, during the same period, stock options to purchase 10,000 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 9,841 shares of Common Stock were issued.

Warrants to Purchase Common Stock

As of March 31, 2019, 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 2.70 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 rate and the term of the warrant.

During the three months ended March 31, 2019, we granted warrants to purchase 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 5 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 are vesting ratably over a 12-month period and have an expiration date of February 12, 2024.

During the three months ended March 31, 2018, we granted warrants to purchase 175,000 shares of Common Stock to outside consultants at an exercise price of $5.16. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of 5 years; volatility of 62.1%; risk free rate of 2.36%; and dividend yield of 0%. The grant date fair value of the warrants was $2.79 per share. The warrants are vesting ratably over a 12-month period and have an expiration date of March 15, 2023.

During the three months ended March 31, 2019 and 2018, we recorded $85,716 and $91,475, respectively, as share-based compensation expense in the accompanying consolidated financial statements related to warrants. As of March 31, 2019, total unrecognized estimated compensation expense related to the unvested portion of these warrants was approximately $196,000, which is expected to be recognized over a weighted-average period of 0.9 years.

During the three months ended March 31, 2019, warrants to purchase 1,250,000 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 471,184 shares of Common Stock were issued.

During the three months ended March 31, 2018, no warrants were exercised.

Options to Purchase Common Stock

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 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 2009 Plan. There are 25,000,000 shares of Common Stock authorized for issuance thereunder. 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, 2019, there were non-qualified stock options to purchase 15,128,745 shares of Common Stock outstanding under the 2009 Plan. As of March 31, 2019, there were 44,300 shares of Common Stock available to be issued under 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. The Awards available under the 2012 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 2012 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. There are 10,000,000 shares of Common Stock authorized for issuance thereunder. As of March 31, 2019, there were non-qualified stock options to purchase 6,318,974 shares of Common Stock outstanding and 1,040,000 restricted stock awards under the 2012 Plan. As of March 31, 2019, there were 2,392,833 shares of Common Stock available to be issued under 2012 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 assumptions used in the Black-Scholes Model for options granted during the three months ended March 31, 2019 and 2018 are set forth in the table below.

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Risk-free interest rate	2.54%	2.38-2.60%
Volatility	61.85%	63.59-64.04%
Term (in years)	6.25	6-6.25
Dividend yield	0.00%	0.00%

A summary of activity under the 2009 and 2012 Plans and related information follows:

	Number of Shares Underlying Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2018	20,872,824	$ 4.93	5.94	$ 12,239,876
Granted	907,000	$ 5.63		
Exercised	(288,480)	$ 0.35		$ 1,315,238
Expired/Forfeited	(43,625)	$ 5.69		
Balance at March 31, 2019	21,447,719	$ 5.02	5.93	$ 19,747,182
Vested and Exercisable at March 31, 2019	16,995,263	$ 4.78	5.16	$ 19,747,182
Unvested at March 31, 2019	4,452,456	$ 5.93	8.83	$ 0

At March 31, 2019, our outstanding stock options had exercise prices ranging from $0.10 to $8.92 per share. The weighted average grant date fair value per share of options granted was $3.35 and $3.11 during the three months ended March 31, 2019 and 2018, respectively. Share-based compensation expense for options recognized in our results of operations for the three months ended March 31, 2019 and 2018 ($2,143,239 and $1,659,883, respectively) is based on vested awards. At March 31, 2019, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $12,942,820 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.30 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock

Restricted stock awards granted under our 2009 and 2012 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.

On December 13, 2018, we granted 1,040,000 restricted stock units to certain executive employees which will vest at the end of the third year. The grant date fair value was $4.06 per unit. During the three months ended March 31, 2019 we recorded $346,414 in share-based compensation expense related to restricted stock units. At March 31, 2019, total unrecognized estimated compensation expense related to unvested restricted stock units was approximately $3,800,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.7 years. At March 31, 2019, 1,040,000 restricted stock awards remained outstanding.

Cash-Settled Stock Appreciation Rights (SARs)

On July 1, 2018, we issued cash-settled SARs to certain consultants and employees. The SARs plan year begins on July 1 and ends on or immediately following June 30, 2019. SARs are granted with a grant price equal to the market value of a share of our Common Stock on the date of grant. Cash-settled SARs provide for the cash payment of the excess of the fair market value of our Common Stock on June 30, 2019 over the grant price. Cash-settled SARs have no effect on dilutive shares or shares outstanding as any appreciation of our Common Stock over the grant price is paid in cash and not in Common Stock.

Cash settled SARs are recorded in our consolidated balance sheets as a liability until the date of exercise. The fair value of each SAR award is estimated using the Black-Scholes valuation model. In accordance with ASC Topic 718, “Stock Compensation,” the fair value of each SAR award is recalculated at the end of each reporting period and the liability and expense adjusted based on the new fair value and the percent vested. At March 31, 2019, we had 97,000 SARs outstanding and the liability related to SAR calculation was approximately $11,579.

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 2019 as a result of (i) the losses recorded during the three months ended March 31, 2019, (ii) additional losses expected for the remainder of 2019, 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, 2019, 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, 2019 and 2018, we were billed by Catalent approximately $1,397,000 and $338,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of March 31, 2019 and December 31, 2018, there were amounts due to Catalent of approximately $937,000 and $88,000, respectively.

NOTE 14 – BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 33%, 29%, 27% and 11% of our purchases were supplied by four vendors each, respectively, during the three months ended March 31, 2019 and 100% of our purchases were supplied by one vendor for the three months ended March 31, 2018.

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, 2019, five customers each generated more than 10% of our net revenues. During the three months ended March 31, 2018, five customers each generated more than 10% of our net revenues. Revenue generated from the five customers combined accounted for approximately 83% of our net revenue for the three months ended March 31, 2019 and revenue generated from five customers combined accounted for approximately 80% of our net revenue for the three months ended March 31, 2018.

During the three months ended March 31, 2019, PI Services accounted for approximately $967,000 of our net revenue, Pillpack, Inc. accounted for approximately $534,000 of our net revenue, AmerisourceBergen accounted for approximately $787,000 of our net revenue, Cardinal Health accounted for approximately $525,000 of our net revenue and McKesson Corporation accounted for approximately $457,000 of our net revenues. During the three months ended March 31, 2018, PI Services generated approximately $557,000 of our revenue, Pillpack, Inc. generated approximately $905,000 of our revenue, AmerisourceBergen generated approximately $668,000 of our revenue, Cardinal Health generated approximately $493,000 of our revenue and McKesson Corporation generated approximately $385,000 of our revenue.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

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 have 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 is 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 lease on 7,561 square feet has commenced in 2018 and the lease on the remaining 48,651 square feet will commence no earlier than June 1, 2019, or the full premises commencement date. The lease will expire 11 years after 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 addition, we will be entitled to reimbursement from the landlord of up to $1,800,000 for tenant improvements.

Supplemental lease information at March 31, 2019:		
Right of use asset	$	3,540,407
Short-term operating lease liability	$	1,158,286
Long-term operating lease liability	$	2,724,501
Weighted average remaining term		5.3 years
Weighted average discount rate		8.25 %

Supplemental cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities for operating lease	$	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, 2019 to the operating lease liabilities recorded on the balance sheet:

Years Ending December 31,		
2019 (9 months)	$	879,998
2020		1,292,914
2021		1,135,467
2022		172,651
2023		176,968
Thereafter		1,228,504
Total undiscounted lease payments		4,886,502
Less: Imputed interest		(1,003,715)
Present value of lease payments	$	3,882,787

As of March 31, 2019, we estimated fixed future minimum rental commitments of approximately $11.6 million and estimated variable future minimum rental commitments of approximately $5.7 million over the term of the lease related to the operating lease for the new corporate office that we entered into in October 2018 that had not commenced yet, as disclosed above.

During the three months ended March 31, 2019, operating lease expense was $295,109 and variable lease expense was $11,786 related to our real estate leases. Rent expense totaled $257,301 during the three months ended March 31, 2018.

NOTE 16 – SUBSEQUENT EVENTS

In April 2019, we launched BIJUVA™, our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of VMS due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. BIJUVA™ will follow a similar commercialization model to IMVEXXY®.

On April 24, 2019, we entered into the Financing Agreement with the Administrative Agent, various lenders from time to time party thereto, and certain of our Company's subsidiaries party thereto from time to time as guarantors.

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 upon the designation of our ANNOVERA™ product as a new category of birth control by the FDA on or prior to December 31, 2019 and satisfaction (or waiver) of other customary conditions precedent; and (iii) $50,000,000 will be available to us upon our achieving $11,000,000 in net revenues, as defined in the Financing Agreement, from our IMVEXXY®, BIJUVA™ and ANNOVERA™ products for the fourth quarter of 2019 and satisfaction (or waiver) of other customary conditions precedent.

Borrowings under the Facility 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%. Interest on amounts borrowed under the Facility will be payable quarterly. The outstanding principal amount of the Facility will be payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. We will 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 will also be 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 will be required to (i) maintain a minimum unrestricted cash balance of $50,000,000, which will increase to $60,000,000 if we draw either the second or third tranche of the Facility, 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.

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 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, 2018 filed with the Securities and Exchange Commission, or the SEC, on February 27, 2019, or the 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: our ability to maintain or increase sales of our approved products; our ability to develop and commercialize IMVEXXY®, BIJUVA™, ANNOVERA™ and 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 agreement; 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; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the ability of our licensees to commercialize and distribute IMVEXXY® and BIJUVA™; 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.

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.

Overview

We are a women's healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and 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 advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. Our commercialization plan allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. 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™, 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 on October 28, 2018. We are also focused on commercialization activities necessary for launch of ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent unintended pregnancy for up to a full year, which was approved by the FDA on August 10, 2018. 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 with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY® and BIJUVA™ in 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 a corporate website 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.

IMVEXXY®

On May 30, 2018, we announced that the FDA had 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.

On July 9, 2018, we launched IMVEXXY® 10-µg with our early experience program to a targeted sample of healthcare providers, or HCPs, throughout the U.S. The national launch of the 10-µg dose of IMVEXXY® began in August 2018, and the 4-µg dose of IMVEXXY® launched on September 13, 2018. Since FDA approval of our NDA for IMVEXXY®, we have been focused on executing our launch plan. The key objectives of our launch plan include: (i) providing broad commercial access at the retail level and with commercial payers, (ii) increasing awareness and appreciation of the clinical and patient features of IMVEXXY® amongst HCPs, (iii) designing and deploying our customer facing model, and (iv) developing our internal capabilities (for example, in the areas of finance, human resources, medical affairs, information technology, data analytics, pharmacovigilance capacity and compliance) to support our commercial-stage company. We have made progress in each of these key strategic areas:

Commercial Access:

- Both the 4-µg and 10-µg doses of IMVEXXY® 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.

- We have aggressively sought commercial payer coverage as many commercial payers employ "new-to-market blocks" for newly launched brands until the payers make a coverage decision based upon their internal review 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 that involves affordable access for patients.

- Through March 31, 2019, we achieved unrestricted coverage with seven of the top ten commercial payers of VVA products and we continue to sign new agreements with payers to cover IMVEXXY®. In addition, as of March 31, 2019, two of the top six Medicare Part D payers of VVA products were adjudicating IMVEXXY®.

- Beginning at launch, we instituted a patient education and affordability program that allows all eligible patients who enroll to receive IMVEXXY® at a reasonable cost. When a product is not covered, 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. With our co-pay assistance program, enrolled patients do not pay more than $35 for a prescription of IMVEXXY®.

Brand Awareness and Adoption:

- In addition to our focus on direct selling from our sales organization, we have executed a branded multichannel awareness campaign for HCPs leveraging digital, non-personal promotion and journal advertising and have already reached most of the active writing HCPs within the VVA category with IMVEXXY® branded messages. The focus of our interactions with HCPs included: (i) introducing IMVEXXY® and highlighting the unmet medical that IMVEXXY® can fulfill for many women, (ii) increasing awareness of the clinical data and patient features of IMVEXXY®, and (iii) familiarizing HCPs with our patient support services for IMVEXXY®. Based on our early sales effectiveness research, more than 90% of HCPs that responded to our surveys indicated that they have prescribed or intend to prescribe IMVEXXY®. As of March 31, 2019, more than 10,700 HCPs had sent an IMVEXXY® prescription to a pharmacy for at least one patient.

Patient Affordability and Adherence Programs:

- We believe the patient affordability and adherence programs that we created and piloted around our prescription prenatal vitamin business have the potential to improve patient compliance for IMVEXXY®, compared to other products in the VVA category. We launched our patient affordability and adherence program for IMVEXXY® to help patients manage out-of-pocket costs (eligible patients pay no more than $35 per prescription) and improve education regarding VVA and IMVEXXY® with the goal of increasing patient adherence and compliance for an improved treatment experience. As of March 31, 2019, 93% of our total IMVEXXY® fills have utilized the patient savings programs. We plan to launch print and digital direct-to-consumer marketing for IMVEXXY® in the second half of 2019. As of March 31, 2019, we have approximately 44,900 patients who have received at least one paid IMVEXXY® prescription filled at a pharmacy.

Customer Model:

- As of March 31, 2019, we had a sales force targeting approximately 200 territories, covering approximately 37,000 HCPs, and deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our customer universe. Additionally, we have an internal sales team that covers areas of the U.S. where key HCPs are located but where we do not have defined territories and have launched our Key Account Managers (KAMs) to engage with our BIO-IGNITE™ partners.

Infrastructure:

- We continue to develop our internal capabilities and sales force to support the launch of IMVEXXY®. We have launched KAMs to support our BIO-IGNITE™ 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.

Regulatory:

- 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 also 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. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we submitted to FDA.

BIJUVA™

On October 28, 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 vasomotor symptoms, or 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 chemical and molecular structure as the hormones that are naturally produced in a woman's body.

We launched BIJUVA™ on April 17, 2019 with a similar model to IMVEXXY®. The key objectives of our launch plan include: (i) broad commercial access at the retail level and with commercial payers, (ii) increasing awareness and appreciation of the clinical and patient features of BIJUVA™ amongst HCPs, (iii) expanding and leveraging our existing customer facing model, and (iv) leverage our internal capabilities (for example, in the areas of finance, human resources, information technology, data analytics and compliance) to support launch of BIJUVA™.

Our focus will first be on key OB/GYN targets, particularly those that have already adopted IMVEXXY®, to deliver the core clinical messages as well as provide information on our patient affordability and adherence programs. In support of BIJUVA™, our field force is expanding to approximately 200 territories. In addition, we will continue to expand our BIO-IGNITE program throughout 2019 with a fuller expansion towards the end of 2019 when the six month payer block for BIJUVA™ is expected to lift.

We believe that the successful launch of IMVEXXY® will allow us to leverage existing contracts with our third-party logistics partner and our distribution partners. With regards to payer coverage, we anticipate similar timing as experienced with IMVEXXY® as many commercial payers employ "new-to-market blocks" for newly launched brands until they have the opportunity to make a coverage decision based upon their internal review. However, our ability to leverage existing payer contracts by amending to include BIJUVA™ along with our recent experience with the payers may simplify the process. With the approval of BIJUVA™, the FDA required a postapproval 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 FDA as required in our approval.

ANNOVERA™

On July 30, 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up a full year, which was approved by the FDA on August 10, 2018.

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 NES, and ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal products. Segesterone acetate, a new chemical entity, is a potent progestin that is not active orally but is active when administered via non-oral routes such as vaginal rings, implants, and transdermal systems. NES 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, or OCs, ANNOVERA™ does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA™ for 7 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 (1 year). ANNOVERA™ releases daily vaginal doses of both active ingredients (NES and EE). The claimed release rate of 150 µg/day NES 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.

We currently estimate that ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned full commercial launch by the first quarter of 2020. We intend to leverage our existing infrastructure, including our sales force, to commercialize ANNOVERA™, together with our recently approved IMVEXXY® and BIJUVA™. ANNOVERA™ will also follow the same commercialization model as IMVEXXY® and BIJUVA™.

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 also 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. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we submitted to FDA.

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. A protocol submission for the study is due 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.

As of March 31, 2019, we had 27 issued foreign patents and 22 issued domestic or, U.S., patents, which included 15 domestic utility patents that relate to BIJUVA™, three domestic utility 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, one domestic utility patent that relates to our OPERA® information technology platform and one domestic utility patent that relates to TX-009HR, our progesterone and estradiol drug candidate.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug candidates. Our business model is dependent upon our company continuing to conduct research and development. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our 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 IND application approval from the FDA.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

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

	Three Months Ended March 31,	
	2019	2018
	(000s)	
TX 001-HR (BIJUVA™)	$ 1,510	$ 3,353
TX 002-HR	—	—
TX 004-HR (IMVEXXY®)	765	1,400
ANNOVERA™	874	—
Other research and development	3,169	2,286
Total	$ 6,318	$ 7,039

Research and development expenditures will continue to be incurred as we continue development of our drug candidates and advance the development of our proprietary pipeline of novel drug candidates. We expect to incur ongoing research and development costs as we develop our drug pipeline, continue stability testing and validation on our drug candidates, 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 factors that include, but are not limited to, the following: per patient trial costs; the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial; the duration of patient follow-up; and the efficacy and safety profile of the drug candidate. 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.

Results of Operations

Three months ended March 31, 2019 compared with three months ended March 31, 2018

	Three Months Ended March 31,		
	2019	2018	Change
	(000s)		
Revenues, net	$ 3,947	$ 3,773	$ 174
Cost of goods sold	763	634	129
Operating expenses	41,289	27,856	13,433
Operating loss	(38,105)	(24,717)	(13,388)
Other (expense) income, net	(1,401)	315	(1,716)
Net loss	$ (39,506)	$ (24,402)	$ (15,104)

Revenues and Cost of Goods Sold

Revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Revenues for the three months ended March 31, 2019 increased approximately $174,000, or 4.6%, to approximately $3,947,000, compared with approximately $3,773,000 for the three months ended March 31, 2018. Revenues increased primarily due to sales of approximately $2,011,000 of IMVEXXY® in the current period partially offset by a decrease in prenatal vitamin sales of approximately $1,837,000. The revenue decrease related to our prenatal vitamins was primarily affected by lower number of units sold and higher utilization of coupons offered to customers as compared to the prior year. The lower number of units sold was primarily due to a price increase in the first quarter of 2019, causing some customers to increase purchases of our prescription prenatal vitamins in the fourth quarter of 2018. We launched IMVEXXY® in the third quarter of 2018. Since the launch, revenues related to our newly approved drug have been greatly affected by the co-pay assistance program that we introduced to launch IMVEXXY®, which allowed patients to access the product at a reasonable cost of no more than $35 per prescription regardless of insurance coverage. We expect our revenues related to IMVEXXY® to improve as commercial and Medicare payer coverage for IMVEXXY® increases and plans complete the process needed to adjudicate IMVEXXY® prescriptions at pharmacies.

Cost of goods sold increased approximately $129,000, or 20.3%, to approximately $763,000 for the three months ended March 31, 2019, compared with approximately $634,000 for the three months ended March 31, 2018 primarily related to product costs attributable to IMVEXXY® unit sales, partially offset by lower shipping costs. Our gross margin was approximately 81% and 83% for the three-month periods ended March 31, 2019 and 2018.

Operating Expenses

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

	Three Months Ended March 31,	
	2019	2018
Sales and marketing costs, excluding human resource costs	41.2%	37.7%
Human resource related costs, including salaries, benefits and taxes	26.9%	23.0%
Product research and development costs	15.3%	25.3%
Professional fees and consulting costs	6.1%	6.4%
Other operating expenses	10.5%	7.6%

Operating expenses increased by approximately $13,433,000, or 48.2%, to approximately $41,289,000 for the three months ended March 31, 2019, from approximately $27,856,000 for the three months ended March 31, 2018 as a result of the following items:

	Three Months Ended March 31,		
	2019	2018	Change
	(000s)		
Sales and marketing, excluding human resources costs	$ 17,012	$ 10,495	$ 6,517
Human resources related costs	11,108	6,418	4,690
Product research and development costs	6,318	7,039	(721)
Professional fees and consulting costs	2,535	1,795	740
Other operating expenses	4,316	2,109	2,207
Total operating expenses	$ 41,289	$ 27,856	$ 13,433

Sales and marketing costs for the three months ended March 31, 2019 increased by approximately $6,517,000, or 62.1%, to approximately $17,012,000, compared with approximately $10,495,000 for the three months ended March 31, 2018, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of IMVEXXY® and BIJUVA™, including costs related to outsourced sales personnel and their related expenses, physician education and product samples, advertising and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue the launch of BIJUVA™, prepare for the launch of ANNOVERA™ and continue to support our growing business and commercialization of our products.

Human resource costs, including salaries, benefits and taxes, for the three months ended March 31, 2019 increased by approximately $4,690,000, or 73.1%, to approximately $11,108,000, compared with approximately $6,418,000 for the three months ended March 31, 2018, primarily as a result of an increase of approximately $3,828,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our new drugs and an increase of approximately $862,000 in non-cash compensation expense included in this category related to employee stock based compensation during 2019 as compared to 2018.

Research and development costs for the three months ended March 31, 2019 decreased by approximately $721,000, or 10.2%, to approximately $6,318,000, compared with approximately $7,039,000 for the three months ended March 31, 2018. Research and development costs include costs related to clinical trials as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased primarily as a result of the completion of the REPLENISH Trial for BIJUVA™ and FDA approval of IMVEXXY® and BIJUVA™, partially offset by scale-up and manufacturing activities for BIJUVA™ before FDA approval as well as increased pre-clinical work to support our product pipeline. Research and development costs during the three months ended March 31, 2019 included the following research and development projects.

During the three months ended March 31, 2019 and since the project's inception in February 2013, we have incurred approximately $1,510,000 and $128,697,000, respectively, in research and development costs with respect to BIJUVA™.

During the three months ended March 31, 2019 and since the project's inception in April 2013, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR.

During the three months ended March 31, 2019 and since the project's inception in August 2014, we have incurred approximately $765,000 and $46,504,000, respectively, in research and development costs with respect to IMVEXXY®.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Research and Development" in our Annual Report on Form 10-K. For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business" in our Annual Report on Form 10-K. For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources." For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drugs," "Item 1. Business — Pipeline for Our Hormone Therapy Drug Candidates" and "Item 1. Business — Pharmaceutical Regulation" in our Annual Report on Form 10-K. Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Professional fees for the three months ended March 31, 2019 increased by approximately $740,000, or 41.2%, to approximately $2,535,000, compared with approximately $1,795,000 for the three months ended March 31, 2018, primarily as a result of increased legal, recruiting and consulting fees.

All other operating expense for the three months ended March 31, 2019 increased by approximately $2,207,000, or 104.6%, to approximately $4,316,000, compared with approximately $2,109,000 for the three months ended March 31, 2018, as a result of increased information technology, travel, dues and subscriptions, rent, allowance for bad debt expense, insurance and other office expenses primarily to support commercialization of our new drugs.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $13,388,000, or 54.2%, to approximately $38,105,000 for the three months ended March 31, 2019, compared with approximately $24,717,000 for the three months ended March 31, 2018 primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of IMVEXXY® and BIJUVA™, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, partially offset by a decrease in research and development costs.

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

Other (Expense) Income

Other non-operating (expense) income changed by approximately $1,716,000, or 544.8%, to an expense of approximately $1,401,000 for the three months ended March 31, 2019 compared with an income of approximately $315,000 for the three months ended March 31, 2018, primarily as a result of increased interest expense related to our term loan that we obtained subsequent to the first quarter of 2018.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately $15,104,000, or 61.9%, to approximately $39,506,000 for the three months ended March 31, 2019, compared with approximately $24,402,000 for the three months ended March 31, 2018. Net loss per share of Common Stock, basic and diluted, was ($0.16) and ($0.11) for the three months ended March 31, 2019 and 2018, respectively.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our common stock and private placements of equity and debt securities. For the three-year period ended December 31, 2018, we received approximately $293,344,000 in net proceeds from the issuance of shares of our common stock. As of March 31, 2019, we had a cash balance of approximately $122,884,000, 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 divided by the average daily net revenues during the quarter. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross revenues to distributors during the quarter. For the quarter ended March 31, 2019, our gross DSO was 74 days compared to 77 days for the quarter ended December 31, 2018 and our net DSO was 341 days for the quarter ended March 31, 2019 compared to 200 days for the quarter ended December 31, 2018. Our net DSO was affected by extended terms and increased coupons and discounts given to our customers in connection with the launch of IMVEXXY® and timing of cash receipts after March 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 launch of IMVEXXY®, BIJUVA™ and ANNOVERA™ and changes in the healthcare industry.

On April 24, 2019, we entered into a Financing Agreement, 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 the Company's subsidiaries party thereto from time to time as guarantors, which provided 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 upon the designation of ANNOVERA™ as a new category of birth control by the FDA on or prior to December 31, 2019 and satisfaction (or waiver) of other customary conditions precedent; and (iii) $50,000,000 will be available to us upon our achieving $11,000,000 in net revenues from our IMVEXXY®, BIJUVA™ and ANNOVERA™ products for the fourth quarter of 2019 and satisfaction (or waiver) of other customary conditions precedent. 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.

We believe that our existing cash and availability under the Facility will allow us to fund our operating plan through at least the next 12 months from the date of this Quarterly Report. However, if the commercialization of IMVEXXY®, BIJUVA™ or ANNOVERA™ is delayed, our existing cash 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 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 and pre-commercialization efforts and we may seek to sell additional equity or debt securities. 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 shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. 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 drugs. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of (Uses) and Sources of Cash

	Three Months Ended March 31,	
	2019	2018
	(000 s)	
Net cash used in operating activities	$ (38,163)	$ (19,650)
Net cash used in investing activities	$ (666)	$ (180)
Net cash provided by financing activities	$ 100	$ 44

Operating Activities

The principal use of cash in operating activities for the three months ended March 31, 2019 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 $18,513,000 in cash used in operating activities for the three months ended March 31, 2019 compared with the comparable period in the prior year was due primarily to an increase in our net loss net of non-cash items coupled with changes in the components of working capital.

Investing Activities

An increase in spending on patent and trademarks as well as purchase of fixed assets resulted in an increase in cash used in investing activities for the three months ended March 31, 2019 compared with the same period in 2018.

Financing Activities

Financing activities represent the principal source of our cash flow. 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. The cash provided by financing activities during the three months ended March 31, 2018 included approximately $44,000 in proceeds from 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 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 are currently evaluating the effect of this guidance on our disclosures.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. We adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a $3.8 million right of use asset and a $4.1 million liability related to adoption of this standard. Comparative financial information was not adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we did not assess (1) whether existing or expired contracts contain leases, (2) lease classification for any existing or expired leases, and (3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

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.

As of March 31, 2019, we were also subject to market risk in connection with borrowings under the MidCap Agreement. Amounts borrowed under the MidCap 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. At March 31, 2019, the outstanding principal balance under the MidCap Agreement, net of issuance costs, was approximately $73,501,000. Considering the total outstanding balance of approximately $75,000,000, as of March 31, 2019, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately $750,000 per year.

As of April 24, 2019, we repaid all amounts outstanding under the MidCap Agreement and became subject to market risk in connection with borrowings under the Financing Agreement. 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 approximately $200,000,000 at April 24, 2019, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately $2,000,000 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 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, 2019, 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

We have been informed by the staff ("Staff") of the Securities and Exchange Commission (the "SEC") that the Staff is conducting a formal investigation concerning whether certain of our communications during 2017 regarding TX-004HR may have violated Regulation FD. We are cooperating with the Staff in connection with the investigation. Any determination that our actions violated Regulation FD could result in penalties or other remedies being imposed. While we believe that any such penalties and other remedies would be immaterial from a financial perspective, no assurance can be made about the ultimate outcome of the investigation, and there can be no assurance that any such penalties and remedies would not have a material adverse effect on our business.

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

There have been no material changes to the risk factors previously disclosed in our Annual Report.

Item 6. Exhibits

Exhibit	Date	Description
31.1*	May 8, 2019	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	May 8, 2019	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	May 8, 2019	Section 1350 Certification of Chief Executive Officer
32.2*	May 8, 2019	Section 1350 Certification of Chief Financial Officer
101.INS*	n/a	XBRL Instance 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

* Filed herewith.

SIGNATURES

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

DATE: May 8, 2019

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 8, 2019

/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 8, 2019

/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, 2019 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 8, 2019

/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, 2019 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 8, 2019

/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.