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, 2018

☐ **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. **001-001000**

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	**(561) 961-1900**
(Address of Principal Executive Offices)	(Issuer's Telephone Number)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	Emerging growth company ☐

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

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

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of April 30, 2018 was 216,584,274.

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash	$ 107,349,460	$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of $403,535 and $380,580, respectively	5,096,731	4,328,802
Inventory	1,620,872	1,485,358
Other current assets	5,098,132	6,604,284
Total current assets	119,165,195	139,554,072
Fixed assets, net	425,539	437,055
Other Assets:		
Intangible assets, net	3,220,686	3,099,747
Security deposit	150,522	139,036
Total other assets	3,371,208	3,238,783
Total assets	$ 122,961,942	$ 143,229,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 6,283,824	$ 4,097,600
Other current liabilities	9,375,818	9,223,595
Total current liabilities	15,659,642	13,321,195
Commitments and Contingencies - See Note 14		
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:		
216,584,274 and 216,429,642 issued and outstanding, respectively	216,584	216,430
Additional paid-in capital	518,146,665	516,351,405
Accumulated deficit	(411,060,949)	(386,659,120)
Total stockholders' equity	107,302,300	129,908,715
Total liabilities and stockholders' equity	$ 122,961,942	$ 143,229,910

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, 2018	March 31, 2017
Revenues, net	$ 3,773,392	$ 3,985,464
Cost of goods sold	633,623	659,635
Gross profit	3,139,769	3,325,829
Operating expenses:		
Sales, general, and administrative	20,757,237	16,837,617
Research and development	7,039,297	7,724,840
Depreciation and amortization	59,621	49,699
Total operating expenses	27,856,155	24,612,156
Operating loss	(24,716,386)	(21,286,327)
Other income		
Miscellaneous income	314,557	125,968
Accreted interest	—	3,867
Total other income	314,557	129,835
Loss before income taxes	(24,401,829)	(21,156,492)
Provision for income taxes	—	—
Net loss	$ (24,401,829)	$ (21,156,492)
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	$ (0.11)	$ (0.11)
Weighted average number of common shares outstanding, basic and diluted	216,525,316	197,790,040

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, 2018	March 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (24,401,829)	$ (21,156,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	38,424	33,600
Amortization of intangible assets	21,197	16,099
Provision for (recovery of) doubtful accounts	22,955	(1,603)
Share-based compensation	1,751,358	1,413,195
Changes in operating assets and liabilities:		
Accounts receivable	(790,885)	580,943
Inventory	(135,514)	(262,297)
Other current assets	1,506,152	(253,518)
Accounts payable	2,186,224	(1,212,236)
Other current liabilities	152,223	316,638
Net cash used in operating activities	(19,649,695)	(20,525,671)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(142,136)	(107,487)
Purchase of fixed assets	(26,908)	(27,834)
Payment of security deposit	(11,486)	—
Net cash used in investing activities	(180,530)	(135,321)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options	44,057	192,310
Proceeds from exercise of warrants	—	2,460,000
Net cash provided by financing activities	44,057	2,652,310
Decrease in cash	(19,786,168)	(18,008,682)
Cash, beginning of period	127,135,628	131,534,101
Cash, end of period	$ 107,349,460	$ 113,525,419

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 health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. With our SYMBODA™ technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, iron supplements, which we ceased manufacturing in October 2017.

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, 2017, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2017. 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 February 2016, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize 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. We are in the process of analyzing the quantitative impact of this guidance on our results of operations and financial position. While we are continuing to assess all potential impacts of the standard, we currently believe the impact of this standard will be primarily related to the accounting for our operating lease.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We adopted this standard under the modified retrospective method to all contracts not completed as of January 1, 2018 and the adoption did not have a material effect on our financial statements but we expanded our disclosures related to contracts with customers in Note 3.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable and accrued expenses. 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, 2018 and 2017, 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, 2018 and 2017.

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 Accounting Standards Codification, or 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 the 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

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. 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 to which the we expect to be entitled 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. 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. We include amounts of variable consideration in a contract's transaction price only to the extent that we have a relatively high level of confidence that the amounts will not be subject to significant reversals, that is, downward adjustments to revenue recognized for satisfied performance obligations. 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. When determining if variable consideration should be constrained, we consider whether there are factors outside our control that could result in a significant reversal of revenue. In making these assessments, we consider the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

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 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 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. Rebates estimates are recorded in accrued expenses and coupon estimates and distributor fees are recorded in the other current liabilities on the consolidated balance sheet. We estimate chargebacks based on prices stated in contracts based the number of units sold each period. We provide invoice discounts to our customers for prompt payment. We deduct invoice discounts and chargebacks from our gross product revenues at the time such discounts are earned by customers.

OTC Products

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing in October 2017. We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound shipping and handling fees, if any, in revenues, net, and bill them upon shipment. We include shipping expenses in cost of goods sold. A majority of our OTC customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to OTC sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce OTC customers. We recognize revenue from OTC sales, net of estimated returns and sales discounts.

Disaggregation of revenue

We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors which accounted for all sales during 2018 and the vast majority of sales during 2017. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing in October 2017. The sales of Iron 21/7 during the three months ended March 31, 2018 and 2017 were approximately $0 and $8,000.

Contract assets and contract liabilities

Based on our contracts, we invoice customers once our performance obligations have been satisfied, at which point payment is unconditional. Accordingly, our contracts do not give rise to contract assets or liabilities under ASC 606. Accounts receivable are recorded when the right to consideration becomes unconditional. We disclose receivables from contracts with customers separately in the statement of financial position. Estimates related to cash discounts and chargebacks are included in net accounts receivable. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 8.

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. 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, including forfeiture rates, 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.

Equity instruments (“instruments”) issued to non-employees are recorded on the basis of the fair value of the instruments, as required by ASC 505, Equity - Based Payments to Non-Employees, or ASC 505. ASC 505 defines the measurement date and recognition period for such instruments. In general, the measurement date is when either (a) a performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The estimated expense is recognized each period based on the current fair value of the award. As a result, the amount of expense related to awards to non-employees can fluctuate significantly during the period from the date of the grant through the final measurement date. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in ASC 505.

We recognize the compensation expense for all 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.

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 U.S. Food and Drug Administration, or the 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, 2018	December 31, 2017
Finished product	$ 1,620,872	$ 1,485,358
TOTAL INVENTORY	$ 1,620,872	$ 1,485,358

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	March 31, 2018	December 31, 2017
Prepaid sales and marketing costs	$ 4,037,107	$ 5,335,936
Prepaid insurance	403,059	680,243
Other prepaid costs	657,966	523,694
Prepaid vendor deposits	—	64,411
TOTAL OTHER CURRENT ASSETS	$ 5,098,132	$ 6,604,284

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	March 31, 2018	December 31, 2017
Accounting system	$ 301,096	$ 301,096
Equipment	300,445	273,536
Furniture and fixtures	116,542	116,542
Computer hardware	80,211	80,211
Leasehold improvements	37,888	37,888
	836,182	809,273
Accumulated depreciation	(410,643)	(372,218)
TOTAL FIXED ASSETS, NET	$ 425,539	$ 437,055

Depreciation expense for the three months ended March 31, 2018 and 2017 was $38,424 and $33,600 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, 2018 and December 31, 2017:

	March 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (8,986)	$ 22,965	11.50
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,413,755	(192,609)	1,221,146	14.75
Hormone therapy drug candidate patents (pending)	1,738,417	—	1,738,417	n/a
Non-amortizable intangible assets:				
Multiple trademarks	238,158	—	238,158	indefinite
Total	$ 3,514,024	$ (293,338)	$ 3,220,686	

	December 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (8,487)	$ 23,464	11.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,293,614	(171,911)	1,121,703	15
Hormone therapy drug candidate patents (pending)	1,721,305	—	1,721,305	n/a
Non-amortizable intangible assets:				
Multiple trademarks	233,275	—	233,275	indefinite
Total	$ 3,371,888	$ (272,141)	$ 3,099,747	

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, 2018 and year ended December 31, 2017, there was no impairment recognized related to intangible assets.

We have numerous pending foreign and domestic patent applications. As of March 31, 2018, we had 16 issued foreign patents and 18 issued domestic, or U.S., patents including:

- 13 domestic utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us. These domestic utility patents will expire in 2032. In addition, we have pending patent applications with respect to our combination progesterone and estradiol product candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- Three domestic patents that relate to TX-004HR, our applicator-free vaginal estradiol softgel product candidate. These patents establish an important intellectual property foundation for TX-004HR and are owned by us. These domestic patents will expire in 2033 or 2032. In addition, we have pending patent applications related to our applicator-free vaginal estradiol softgel product candidate in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- One domestic utility patent that relates to our pipeline transdermal patch technology, which is owned by us. The domestic utility patent will expire in 2032. We have pending patent applications with respect to this technology in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa; and
- One utility patent that relates to our OPERA® information-technology platform, which is owned by us and is a domestic patent that will expire in 2029.

Amortization expense was $21,197 and $16,099 for the three months ended March 31, 2018 and 2017, respectively. Estimated amortization expense for the next five years for the patent cost currently being amortized is as follows:

Year Ending December 31,	Estimated Amortization
2018(9 months)	$ 63,590
2019	$ 84,786
2020	$ 84,786
2021	$ 84,786
2022	$ 84,786
Thereafter	$ 841,377

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	March 31, 2018	December 31, 2017
Accrued payroll, bonuses and commission costs	$ 2,650,124	$ 4,240,379
Allowance for coupons and returns	1,860,205	1,432,846
Accrued compensated absences	956,331	945,457
Other accrued expenses	144,940	525,999
Accrued rebates	36,988	76,917
Accrued legal and accounting expense	363,804	600,350
Accrued sales and marketing costs	1,845,900	420,162
Accrued research and development	944,757	366,933
Accrued rent	360,019	327,099
Allowance for wholesale distributor fees	81,741	172,973
Accrued royalties	131,009	114,480
TOTAL OTHER CURRENT LIABILITIES	$ 9,375,818	$ 9,223,595

NOTE 9 – 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 and warrants and were excluded from the calculation of diluted earnings per share because their effect would have been anti-dilutive due to the net loss reported by us. The table below presents potentially dilutive securities that could affect our calculation of diluted net loss per share allocable to common stockholders for the periods presented.

	Three months ended	
	March 31, 2018	March 31, 2017
Stock options	25,196,684	23,286,933
Warrants	3,290,905	10,374,071
	28,487,589	33,661,004

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

At March 31, 2018, 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, 2018, we had 350,000,000 shares of Common Stock authorized for issuance, of which 216,584,274 shares of Common Stock were issued and outstanding.

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.

Issuances During the Three Months Ended March 31, 2017

During the three months ended March 31, 2017, certain individuals exercised stock options to purchase 95,046 shares of Common Stock for $192,310 in cash.

Warrants to Purchase Common Stock

As of March 31, 2018, we had warrants outstanding to purchase an aggregate of 3,290,905 shares of Common Stock with a weighted-average contractual remaining life of approximately 2.1 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.72 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, 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, 2017, we granted warrants to purchase 125,000 shares of Common Stock to outside consultants at an exercise price of $6.83 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 63.24%; risk free rate of 1.47%; and dividend yield of 0%. The grant date fair value of the warrants was $3.67 per share. The warrants vest ratably over a 12-month period and have an expiration date of March 15, 2022.

During the three months ended March 31, 2018 and 2017, we recorded $91,475 and $47,686, respectively, as share based compensation expense in the accompanying consolidated financial statements related to warrants. As of March 31, 2018, total unrecognized estimated compensation expense related to the unvested portion of these warrants was approximately $478,000 which is expected to be recognized over a weighted-average period of 0.9 years.

In May 2013, we entered into a consulting agreement with Sancilio and Company, Inc., or SCI, to develop drug platforms to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain FDA approval for our drug candidates, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of our Common Stock that were to be granted pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the agreement, we agreed to issue to SCI a warrant to purchase 850,000 shares of our Common Stock at $2.01 per share that has vested or will vest, as applicable, as follows:

1. 283,333 shares were earned on May 11, 2013 upon acceptance of an Investigational New Drug application by the FDA for an estradiol-based drug candidate in a softgel vaginal capsule for the treatment of VVA; however, pursuant to the terms of the consulting agreement, the shares did not vest until June 30, 2013. The fair value of $405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of vesting using a term of 5 years; a volatility of 45.89%; risk free rate of 1.12%; and a dividend yield of 0%. We recorded the entire $405,066 as non-cash compensation as of June 30, 2013. These shares were exercised in 2017.

2. 283,333 shares vested on June 30, 2013. The fair value of $462,196 for these shares was determined by using the Black-Scholes Model on the date of vesting using a term of 5 years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. As of June 30, 2016, this warrant was fully amortized. These shares were exercised in 2017; and

3. 283,334 shares would have vested upon the receipt by us, prior to the warrant expiration date of April 30, 2018, of any final FDA approval of a drug candidate that SCI helped us design. Since the receipt of such approval did not occur before the warrant’s expiration date, the warrant expired on April 30, 2018.

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to SCI for services to be rendered over approximately five years beginning in May 2012. The warrants vested upon issuance. Services provided are to include (a) services in support of our drug development efforts, including services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain new drug approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. During the three months ended March 31, 2018 and 2017, we recorded $0 and $64,449, respectively, as non-cash compensation with respect to these warrants in the accompanying consolidated financial statements. This warrant was fully exercised, of which 800,000 shares were exercised in 2017 and 500,000 shares were exercised in 2016. As of March 31, 2018, the SCI warrants issued in 2013 and 2012 were fully amortized.

During the three months ended March 31, 2018, no warrants were exercised. During the three months ended March 31, 2017, certain individuals exercised warrants to purchase 1,810,000 shares of our Common Stock for $2,460,000 in cash.

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, 2018, there were non-qualified stock options to purchase 18,751,543 shares of Common Stock outstanding under the 2009 Plan. As of March 31, 2018, there were 1,842,787 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, 2018, there were non-qualified stock options to purchase 6,445,141 shares of Common Stock outstanding under the 2012 Plan. As of March 31, 2018, there were 3,473,333 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, 2018 and 2017 are set forth in the table below.

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Risk-free interest rate	2.38-2.60%	1.90%
Volatility	63.59-64.04%	61.56-62.83%
Term (in years)	6-6.25	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, 2017	23,365,225	$ 3.78	5.13	$ 64,664,821
Granted	2,025,500	$ 5.19		
Exercised	(154,791)	$ 0.29		$ 795,224
Expired/Forfeited	(39,250)	$ 7.70		
Balance at March 31, 2018	25,196,684	$ 3.91	5.3	$ 45,463,554
Vested and Exercisable at March 31, 2018	20,244,060	$ 3.40	4.4	$ 45,405,774
Unvested at March 31, 2018	4,952,624	$ 5.99	9.1	$ 57,780

At March 31, 2018, 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 $3.11 and $3.96 during the three months ended March 31, 2018 and 2017, respectively. Share-based compensation expense for options recognized in our results of operations for the three months ended March 31, 2018 and 2017 ($1,659,883 and $1,301,060, respectively) is based on vested awards. At March 31, 2018, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $15,066,000 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.5 years. No tax benefit was realized due to a continued pattern of operating losses.

NOTE 11 – 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 2018 as a result of (i) the losses recorded during the three months ended March 31, 2018, (ii) additional losses expected for the remainder of 2018, 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, 2018, 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 12 – 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, 2018 and 2017, we were billed by Catalent approximately $338,000 and $705,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of March 31, 2018 and December 31, 2017, there were amounts due to Catalent of approximately $157,000 and $523,000, respectively.

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 100% of our purchases supplied from one vendor for the both three months ended March 31, 2018 and 2017.

We sell our prescription prenatal vitamin 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, 2018 and 2017, five customers each generated more than 10% of our total revenues. Revenue generated from five major customers combined accounted for approximately 80% of our recognized revenue for the three months ended March 31, 2017 and revenue generated from five major customers combined accounted for approximately 72% of our recognized revenue for the three months ended March 31, 2017.

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. During the three months ended March 31, 2017, Pharmacy Innovations TX generated approximately $440,000 of our revenue, Pharmacy Innovations PA generated approximately $937,000 of our revenue, AmerisourceBergen generated approximately $526,000 of our revenue, Cardinal Health generated approximately $553,000 of our revenue and McKesson Corporation generated approximately $428,000 of our revenue.

As a result of developments in the pharmaceutical industry that negatively affected independent pharmacies, including such pharmacies' reliance on third party payors, in 2016, we identified that payment periods for our retail pharmacy distributors were becoming longer than in prior years. As a result, during the third quarter of 2016, we centralized the distribution channel for both our retail pharmacy distributors and wholesale distributors, in order to facilitate sales to a broader population of retail pharmacies and minimize business risk exposure to any one retail pharmacy. During the third quarter of 2016, we entered into new distribution agreements with our retail pharmacy distributors to effectuate this centralization which were effective September 1, 2016.

NOTE 14– COMMITMENTS AND CONTINGENCIES

Operating Lease

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.

The rental expense related to our current lease during the three months ended March 31, 2018 and 2017 was $257,301 and $250,067, respectively.

As of March 31, 2018, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,		
2018 (9 months)	$	726,562
2019		1,094,116
2020		1,113,069
2021		943,127
2022		—
Total minimum lease payments	$	3,876,874

NOTE 15 – SUBSEQUENT EVENTS

On May 1, 2018, we entered into a Credit and Security Agreement (the "Credit Agreement"), by and among us and our subsidiaries party thereto from time to time, each as a borrower (the "Borrowers"), MidCap Financial Trust ("MidCap"), as agent ("Agent") and as lender, and the additional lenders party thereto from time to time (together with MidCap as a lender, the "Lenders").

The Credit Agreement provides a secured term loan facility in an aggregate principal amount of up to $200 million (the "Term Loan"). Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches (each, a "Tranche"), with each Tranche to be made available to us, at our option, upon our achievement of certain milestones. The first Tranche of $75.0 million ("Tranche 1") may be drawn by us on or before July 31, 2018, provided that we satisfy certain conditions described in the Credit Agreement, including approval by the FDA of the New Drug Application ("NDA") for our TX-004HR drug candidate. The second Tranche of $75.0 million ("Tranche 2") may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for our TX-001HR drug candidate and (iii) we have consummated our first commercial sale in the United States of TX-001HR. The third Tranche of $50.0 million ("Tranche 3") may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) the Borrowers have generated at least $75.0 million of consolidated net revenue attributable to commercial sales of TX-001HR and TX-004HR during the twelve-month period ending immediately prior to the funding of Tranche 3.

Amounts borrowed under the Term Loan will bear 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 will be due and payable monthly in arrears. Principal on each Tranche will be payable in 36 equal monthly installments beginning May 1, 2020 until paid in full on May 1, 2023 (the "Maturity Date"), *provided*, *however*, that if the Borrowers generate at least $95.0 million of consolidated net revenue attributable to commercial sales of TX-001HR and TX-004HR by December 31, 2019, the Borrowers may extend the interest-only period by an additional 12 months to May 1, 2021.

The Term Loan may be prepaid, in whole or in part, subject to a prepayment fee on the amount being prepaid (or required to be prepaid, if such amount is greater) of (i) 4.0% for the first year following the Tranche 1 funding date, (ii) 3.0% for the second year following the Tranche 1 funding date and (iii) 2.0% thereafter. Upon repayment of the Term Loan at the Maturity Date or prepayment on any earlier date, we will be required to pay a termination payment based on the principal amount paid or prepaid. In connection with the execution of the Credit Agreement, we paid Agent, for the benefit of all Lenders, an origination fee equal to 1.00% of the maximum potential amount of the Term Loan. The Borrowers will also pay Agent an annual administration fee based on the amounts borrowed under the Term Loan, in addition to other fees and expenses.

The obligations of the Borrowers under the Credit 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 the Borrowers. The obligations under the Credit Agreement will be guaranteed by each of our future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of ours and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions).

The Credit Agreement contains customary restrictions and covenants applicable to the Borrowers. Among other requirements, the Borrowers must (i) maintain a minimum cash balance of $50.0 million and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products. The Credit Agreement also contains customary covenants that limit, among other things, the ability of the Borrowers to (i) incur indebtedness, (ii) incur liens on their property, (iii) pay dividends or make other distributions, (iv) sell their assets, (v) make certain loans or investments, (vi) merge or consolidate,

(vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions.

The Credit Agreement contains customary representations and warranties and events of default relating to, among other things, payment defaults, breaches of covenants, the occurrence of any fact, event or circumstance that could reasonably be expected to result in a Material Adverse Effect (as defined in the Credit Agreement), delisting of the our Common Stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments and inaccuracies of representations and warranties. Upon or after an event of default, Agent and the Lenders may declare all or a portion of our obligations under the Credit Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Credit Agreement.

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, 2017 filed with the Securities and Exchange Commission, or the SEC, on February 23, 2018, 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. 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 resolve the deficiencies identified by the U.S. Food and Drug Administration, or FDA, in our new drug application, or NDA, for our TX-004HR product candidate and the time frame associated with such resolution; whether the FDA will approve the amended NDA for the company's TX-004HR product candidate and whether such approval will occur by the PDUFA target action date; whether the FDA will approve the NDA for the company's TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; our ability to maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan, the length, cost and uncertain results of our clinical trials, including any additional clinical trials that the FDA may require in connection with TX-004HR; the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; 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 health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating clinical efficacy at lower doses, thereby enabling an enhanced side-effect profile compared with competing products. With our SYMBODA™ technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins.

Our common stock, par value $0.001 per share, or the Common Stock, is traded on the Nasdaq Global Select Market of The Nasdaq Stock Market LLC, or the Nasdaq, under the symbol "TXMD." We maintain websites at www.therapeuticsmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com. 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.

Research and Development

We have submitted two NDAs to the FDA. In December 2017, we submitted our NDA for TX-001HR, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe vasomotor symptoms, or VMS, due to menopause in menopausal women with an intact uterus. In November 2017, we re-submitted our NDA for TX-004HR, our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy, or VVA, in menopausal women with vaginal linings that do not receive enough estrogen. The NDA for our TX-004HR drug candidate has a Prescription Drug User Fee Act, or PDUFA, target action date for the completion of the FDA's review of May 29, 2018 and, if approved on that date, the drug candidate could be launched as early as the third quarter of 2018. The PDUFA target action date for our TX-001HR drug candidate is October 28, 2018. We intend to leverage and grow our current marketing and sales organization to commercialize our advanced hormone therapy drug candidates in the United States assuming the successful completion of the FDA regulatory process. We believe that our national sales force has developed strong relationships in the OB/GYN market to sell our current prescription prenatal vitamin products and that by delivering additional products through the same sales channel we can leverage our already deployed assets.

TX-001HR

TX-001HR is our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate for the treatment of moderate to severe VMS due to menopause, including hot flashes, night sweats and sleep disturbances for menopausal women with an intact uterus. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone bioidentical to the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product.

On September 5, 2013, we began enrollment in the REPLENISH Trial, a multicenter, double-blind, placebo-controlled, phase 3 clinical trial of TX-001HR in menopausal women with an intact uterus. The trial was designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe VMS due to menopause and the endometrial safety of TX-001HR. Patients were assigned to one of five arms, four active and one placebo, and received study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia was an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe VMS was the mean change of frequency and severity of moderate to severe VMS at weeks four and 12 compared to placebo, as measured by the number and severity of hot flashes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flashes at screening were included in the VMS analysis, while all subjects were included in the endometrial hyperplasia analysis. The secondary endpoints included reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. The trial evaluated 1,835 patients between 40 and 65 years old at 111 sites. On December 5, 2016, we announced positive topline data for the REPLENISH Trial.

The REPLENISH Trial evaluated four doses of TX-001HR and placebo; the doses studied were:

- 17ß-estradiol 1 mg/progesterone 100 mg (n = 416)
- 17ß-estradiol 0.5 mg/progesterone 100 mg (n = 423)
- 17ß-estradiol 0.5 mg/progesterone 50 mg (n = 421)
- 17ß-estradiol 0.25 mg/progesterone 50 mg (n = 424)
- Placebo (n = 151)

The REPLENISH Trial results demonstrated:

- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both achieved all four of the co-primary efficacy endpoints and the primary safety endpoint.
- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both demonstrated a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo.
- TX-001HR estradiol 0.5 mg/progesterone 50 mg and TX-001HR estradiol 0.25 mg/progesterone 50 mg were not statistically significant at all of the co-primary efficacy endpoints. The estradiol 0.25 mg/progesterone 50 mg dose was included in the clinical trial as a non-effective dose to meet the recommendation of the FDA guidance to identify the lowest effective dose.
- The incidence of consensus endometrial hyperplasia or malignancy was 0 percent across all four TX-001HR doses, meeting the recommendations established by the FDA's draft guidance.

As outlined in the FDA guidance, the co-primary efficacy endpoints in the REPLENISH Trial were the change from baseline in the number and severity of hot flashes at weeks four and 12 as compared to placebo. The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. General safety was also evaluated.

The results of the REPLENISH Trial are summarized in the table below (p-values of < 0.05 meet FDA guidance and support evidence of efficacy):

Replenish Trial Co-Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-MITT Population					
Estradiol/Progesterone	1 mg/100 mg (n = 141)	0.5 mg/100 mg (n = 149)	0.5 mg/50 mg (n = 147)	0.25 mg/50 mg (n = 154)	Placebo (n = 135)
			Frequency		
Week 4 P-value versus placebo	<0.001	0.013	0.141	0.001	—
Week 12 P-value versus placebo	<0.001	<0.001	0.002	<0.001	—
			Severity		
Week 4 P-value versus placebo	0.031	0.005	0.401	0.100	—
Week 12 P-value versus placebo	<0.001	<0.001	0.018	0.096	—
Replenish Trial Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population₸					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

₸Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

We submitted the NDA for TX-001HR to the FDA on December 28, 2017. In March 2018, the FDA, in its 74-day letter, stated that the application was sufficiently complete to permit a substantive review and that, as of the date of the letter, the FDA had not identified any potential review issues. The FDA noted that the filing review was only a preliminary evaluation of the application and was not indicative of deficiencies that may be identified during the FDA's review. The PDUFA target action date for the completion of the FDA's review is October 28, 2018.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial, our phase 3 clinical trial for TX-002HR, to update the phase 3 protocol based on discussions with the FDA. Our Investigational New Drug Application, or IND, related to TX-002HR is currently in inactive status. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bioidentical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. Our IND related to TX-003HR is currently inactive.

TX-004HR

TX-004HR is our applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia, a symptom of VVA in menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. We initiated the REJOICE Trial, a randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of three doses – 25 mcg, 10 mcg and 4 mcg (compared to placebo) – of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. In December 2015, we announced positive top-line results from the REJOICE Trial, our phase 3 clinical trial of TX-004HR. In November 2017, we re-submitted our NDA for TX-004HR. The NDA has a PDUFA target action date for the completion of the FDA's review of May 29, 2018, and, if approved on that date, the drug candidate could be launched as early as the third quarter of 2018.

On December 7, 2015, we announced positive top-line results from the REJOICE Trial. The pre-specified four co-primary efficacy endpoints were the changes from baseline to week 12 versus placebo in the percentage of vaginal superficial cells, percentage of vaginal parabasal cells, vaginal pH and severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA. The trial enrolled 764 menopausal women (40 to 75 years old) experiencing moderate to severe dyspareunia at approximately 89 sites across the United States and Canada. Trial participants were randomized to receive either TX-004HR at 25 mcg (n=190), 10 mcg (n=191), or 4 mcg (n=191) doses or placebo (n=192) for a total of 12 weeks, all administered once daily for two weeks and then twice weekly (approximately three to four days apart) for ten weeks. The 25 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 10 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo across all four co-primary endpoints. The 4 mcg dose of TX-004HR also demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoints of vaginal superficial cells, vaginal parabasal cells, and vaginal pH; the change from baseline compared to placebo in the severity of dyspareunia was statistically significant at the $p = 0.0149$ level. The FDA has previously indicated to us that in order to approve the drug based on a single trial, the trial would need to show statistical significance at the 0.01 level or lower for each endpoint, and that a trial that is merely statistically significant at a higher level may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial. Statistical improvement over placebo was also observed for all three doses at the first assessment at week two and sustained through week 12. Vaginal dryness was a pre-specified key secondary endpoint. The 25 mcg and 10 mcg doses of TX-004HR demonstrated highly statistically significant results at the $p < 0.0001$ level compared to placebo for the endpoint of vaginal dryness. The 4 mcg dose of TX-004HR demonstrated statistically significant results at the $p = 0.0014$ level compared to placebo. The pharmacokinetic data for all three doses demonstrated negligible to very low systemic absorption of 17 beta estradiol, estrone and estrone conjugated, supporting the previous phase 1 trial data. TX-004HR was well tolerated, and there were no clinically significant differences compared to placebo-treated participants with respect to adverse events. There were no drug-related serious adverse events reported.

We submitted the NDA for TX-004HR with the FDA on July 7, 2016. The FDA determined that the NDA was sufficiently complete to permit a substantive review and accepted the NDA for filing with the PDUFA target action date for the completion of the FDA's review of May 7, 2017. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the phase 3 REJOICE Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial.

On May 5, 2017, we received a Complete Response Letter, or CRL, from the FDA regarding the NDA for TX-004HR. In the CRL, the only approvability concern raised by the FDA was the lack of long-term safety data for TX-004HR beyond the 12 weeks studied in the phase 3 REJOICE Trial. The CRL did not identify any issues related to the efficacy of TX-004HR and did not identify any approvability issues related to chemistry, manufacturing and controls.

On June 14, 2017, we participated in a Type A Post-Action Meeting with the Division of Bone, Reproductive, and Urologic Products (DBRUP) of the FDA to discuss the CRL. At the meeting, we presented information that we believed could address concerns raised by the FDA in the CRL and positively affect the status of the NDA for TX-004HR. On July 5, 2017, we received the official minutes of the meeting from the FDA, which provided the FDA's response to the information presented at the Type A meeting. Per the FDA's request, we formally submitted the information presented at the Type A meeting for consideration related to the NDA for TX-004HR.

On August 3, 2017, we received a formal General Advice Letter from the FDA stating that an initial review of this information has been completed and requesting that we submit the additional endometrial safety information to the NDA for TX-004HR on or before September 18, 2017. On September 14, 2017, we submitted the additional endometrial safety information that was requested by the FDA in the General Advice Letter to the NDA for TX-004HR. The submission included a comprehensive, systematic review of the medical literature on the use of vaginal estrogen products and the risk of endometrial hyperplasia or cancer, including the safety data from the recently published Women's Health Initiative Observational Study, or WHI Study, of vaginal estrogen use in postmenopausal women and information on the relevance of the first uterine pass effect for low-dose vaginal estrogen products. The WHI Study demonstrated no significant difference in the risk of invasive breast cancer, stroke, colorectal cancer, endometrial cancer and venous thromboembolism in vaginal estrogen users versus non-users. The WHI Study also shows that, among women with an intact uterus, there was a decreased risk of cardiovascular disease, hip fracture and all-cause mortality in vaginal estrogen users versus non-users. The WHI Study evaluated over 4,000 women who used vaginal estrogens for a median duration of two to three years.

On November 3, 2017, we participated in an in-person meeting with DBRUP. At the meeting, DBRUP agreed to the resubmission of the NDA for the 4 mcg and 10 mcg doses of TX-004HR without the need for an additional pre-approval study.

On November 29, 2017, we resubmitted the NDA for the 4 mcg and 10 mcg doses of TX-004HR with the FDA. We have committed to conduct a post-approval observational study. The FDA has acknowledged that the resubmission is a complete, class 2 response to the CRL received on May 5, 2017 for TX-004HR. The PDUFA target action date for the completion of the FDA's review is May 29, 2018. If approved, the 4 mcg formulation of TX-004HR would represent a lower effective dose than the currently available VVA therapies approved by the FDA. We entered into negotiations with the FDA regarding the proposed label for TX-004HR on April 11, 2018.

As of March 31, 2018, we had 16 issued foreign patents and 18 issued domestic or U.S. patents, which included 13 domestic utility patents that relate to our combination progesterone and estradiol formulations, three domestic utility patents that relate to TX-004HR, which establish an important intellectual property foundation for TX-004HR, one domestic utility patent that relates to a pipeline transdermal patch technology, and one domestic utility patent that relates to our OPERA® information technology platform.

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 a significant amount of 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.

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

	Three Months Ended March 31,	
	2018	2017
	(000s)	
TX 001-HR	$ 3,353	$ 3,528
TX 002-HR	—	—
TX 004-HR	1,400	1,945
Other research and development	2,286	2,252
Total	$ 7,039	$ 7,725

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, 2018 compared with three months ended March 31, 2017

	Three Months Ended March 31,		
	2018	2017	Change
	(000s)		
Revenues, net	$ 3,773	$ 3,985	$ (212)
Cost of goods sold	634	659	(25)
Operating expenses	27,856	24,612	3,244
Operating loss	(24,717)	(21,286)	(3,431)
Other income, net	315	130	185
Net loss	$ (24,402)	$ (21,156)	$ (3,246)

Revenues and Cost of Goods Sold

Revenues for the three months ended March 31, 2018 decreased approximately $212,000, or 5%, to approximately $3,773,000, compared with approximately $3,985,000 for the three months ended March 31, 2017. This decrease was primarily attributable to a decrease in the average net revenue per unit of our products, which was primarily related to higher estimates related to discounts in 2018, partially offset by an increase in the number of units sold. Cost of goods sold decreased approximately $25,000, or 4%, to approximately $634,000 for the three months ended March 31, 2018, compared with approximately $659,000 for the three months ended March 31, 2017. Our gross margin was approximately 83% for both of the three-month periods ended March 31, 2018 and 2017.

Operating Expenses

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

	Three Months Ended March 31,	
	2018	2017
Research and development costs	25.3%	31.4%
Human resource related costs, including salaries, benefits and taxes	23.0%	23.0%
Sales and marketing costs, excluding human resource costs	37.7%	31.3%
Professional fees for legal, accounting and consulting	6.4%	6.5%
Other operating expenses	7.6%	7.8%

Operating expenses increased by approximately $3,244,000, or 13%, to approximately $27,856,000 for the three months ended March 31, 2018, from approximately $24,612,000 for the three months ended March 31, 2017 as a result of the following items:

	Three Months Ended March 31,		
	2018	2017	Change
	(000s)		
Research and development costs	$ 7,039	$ 7,725	$ (686)
Human resources related costs	6,418	5,664	754
Sales and marketing, excluding human resources costs	10,495	7,699	2,796
Professional fees for legal, accounting and consulting	1,795	1,606	189
Other operating expenses	2,109	1,918	191
Total operating expenses	$ 27,856	$ 24,612	$ 3,244

Research and development costs for the three months ended March 31, 2018 decreased by approximately $686,000, or 9%, to approximately $7,039,000, compared with $7,725,000 for the three months ended March 31, 2017. 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 as a direct result of the completion of the REPLENISH Trial for TX-001HR, our combination estradiol and progesterone drug candidate. Research and developments costs during the three months ended March 31, 2018 included the following research and development projects.

During the three months ended March 31, 2018 and the period from February 2013 (project inception) through March 31, 2018, we have incurred approximately $3,353,000 and $118,750,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the three months ended March 31, 2018 and the period April 2013 (project inception) through March 31, 2018, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the three months ended March 31, 2018 and the period from August 2014 (project inception) through March 31, 2018, we have incurred approximately $1,400,000 and $42,249,000, respectively, in research and development costs with respect to TX-004HR, our applicator-free vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Pharmaceutical Regulation” in our Annual Report and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development” above. 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. 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” below. 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 Drug Candidates,” and “Item 1. Business — Pharmaceutical Regulation” in our Annual Report. Future milestones, including NDA submission dates and potential approval dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, scale-up and manufacturing activities.

Sales and marketing costs for the three months ended March 31, 2018 increased by approximately $2,796,000, or 36%, to approximately $10,495,000, compared with approximately $7,699,000 for the three months ended March 31, 2017, primarily as a result of increased expenses associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates, including costs related to outsourced sales personnel and their related expenses. We expect sales and marketing expenses to continue to increase as we continue to support our growing business and prepare for commercialization.

Other operating expense for the three months ended March 31, 2018 increased by approximately $191,000, or 10%, to approximately $2,109,000, compared with approximately $1,918,000 for the three months ended March 31, 2017, as a result of increased information technology and other office expenses partially offset by decreased investor relations expenses.

Human resource costs, including salaries, benefits and taxes, for the three months ended March 31, 2018 increased by approximately $754,000, or 13%, to approximately $6,418,000, compared with approximately $5,664,000 for the three months ended March 31, 2017, primarily as a result of an increase of approximately $329,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our hormone therapy drug candidates and an increase of approximately $425,000 in non-cash compensation expense included in this category related to employee stock based compensation during 2018 as compared to 2017.

Professional fees for the three months ended March 31, 2018 increased by approximately $189,000, or 12%, to approximately $1,795,000, compared with approximately $1,606,000 for the three months ended March 31, 2017, primarily as a result of increased legal expenses and recruiting costs partially offset by decreased consulting expenses.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $3,431,000, or 16%, to approximately $24,717,000 for the three months ended March 31, 2018, compared with approximately $21,286,000 for the three months ended March 31, 2017, primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of our hormone therapy drug candidates, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, as well a decrease in revenue, partially offset by a decrease in research and development costs.

As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Other Income

Other non-operating income increased by approximately $185,000, or 142%, to approximately $315,000 for the three months ended March 31, 2018 compared with approximately $130,000 for the comparable period in 2017, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $3,246,000, or 15%, to approximately $24,402,000 for the three months ended March 31, 2018, compared with approximately $21,156,000 for the three months ended March 31, 2017. Net loss per share of Common Stock, basic and diluted, was ($0.11) for both the three months ended March 31, 2018 and 2017.

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 year ended December 31, 2017, we received approximately $68,573,000 in net proceeds from the issuance of shares of our Common Stock. As of March 31, 2018, we had cash and cash equivalents totaling approximately $107,349,000, 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. We currently intend to fund the next phase of our pre-commercialization and commercialization expenses for our TX-004HR and TX-001HR drug candidates through debt financing. On May 1, 2018, we entered into a Credit and Security Agreement, or the Credit Agreement, by and among us and our subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time, which provides a secured term loan facility in an aggregate principal amount of up to $200 million, or the Term Loan. For more information regarding the Credit Agreement, see Note 15 to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

For the three months ended March 31, 2018, our days sales outstanding, or DSO, was 122 days compared to 97 days for the year ended December 31, 2017. The increase in our DSO as of March 31, 2018 was partially related to increased coupons and discounts which lowered our net revenues, as well as to the timing of payments received from our customers subsequent to March 31, 2018. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors, as compared to the terms previously provided to our retail pharmacy distributors, changes in the healthcare industry and specific terms that may be extended in connection with the launch of our hormone therapy drug candidates, if approved.

We believe that our existing cash and funds available under the Term Loan 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 our hormone therapy drug candidates is delayed, our existing cash may be insufficient to satisfy our liquidity requirements until we are able to commercialize our hormone therapy drug candidates and we may not be able to access funds under the Term Loan. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing and other pre-commercialization efforts and we may seek to sell additional equity or debt securities. Our ability to obtain additional debt financing is restricted pursuant to the Credit Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Credit 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 Credit Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Credit 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 clinical development of and commercialize of our hormone therapy drug candidates. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of (Uses) and Sources of Cash

	Three Months Ended March 31,	
	2018	2017
	(000s)	
Net cash used in operating activities	$ (19,650)	$ (20,526)
Net cash used in investing activities	$ (180)	$ (135)
Net cash provided by financing activities	$ 44	$ 2,652

Operating Activities

The principal use of cash in operating activities for the three months ended March 31, 2018 was to fund our current expenses primarily related to supporting clinical development, scale-up and manufacturing activities and future commercial activities, adjusted for non-cash items. The decrease of approximately $876,000 in cash used in operating activities for the three months ended March 31, 2018 compared with the comparable period in the prior year was due primarily to an increase in our net loss and non-cash compensation expense coupled with changes in the components of working capital.

Investing Activities

An increase in spending on patent and trademarks resulted in an increase in cash used in investing activities for the three months ended March 31, 2018 compared with the same period in 2017.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the three months ended March 31, 2018 provided net cash of approximately $44,000 which was related to exercise of options. The cash provided by financing activities during the three months ended March 31, 2017 included approximately $2,652,000 in proceeds from the exercise of options and warrants.

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize 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. We are in the process of analyzing the quantitative impact of this guidance on our results of operations and financial position. While we are continuing to assess all potential impacts of the standard, we currently believe the impact of this standard will be primarily related to the accounting for our operating lease.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We adopted this standard under the modified retrospective method to all contracts not completed as of January 1, 2018 and the adoption did not have an impact on our financial statements but we expanded our disclosures related to contracts with customers in Note 3 to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our market risk has not changed materially from the interest rate risk disclosed in Item 7A of our Annual Report.

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, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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 7, 2018	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	May 7, 2018	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	May 7, 2018	Section 1350 Certification of Chief Executive Officer
32.2*	May 7, 2018	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 7, 2018

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 7, 2018

/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 7, 2018

/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, 2018 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 7, 2018

/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, 2018 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 7, 2018

/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.