TherapeuticsMD, Inc.
Form 10-Q
May 03, 2017

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, 2017

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 27, 2017 was 203,927,142.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

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THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	March 31, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current Assets:		
Cash	$113,525,419	$131,534,101
Accounts receivable, net of allowance for doubtful accounts of $374,771 and $376,374, respectively	3,921,359	4,500,699
Inventory	1,338,618	1,076,321
Other current assets	2,488,121	2,299,052
Total current assets	121,273,517	139,410,173
Fixed assets, net	511,073	516,839
Other Assets:		
Intangible assets, net	2,497,360	2,405,972
Security deposit	139,036	139,036
Total other assets	2,636,396	2,545,008
Total assets	$124,420,986	$142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$6,146,278	$7,358,514
Other current liabilities	7,940,723	7,624,085
Total current liabilities	14,087,001	14,982,599
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:		
198,593,268 and 196,688,222 issued and outstanding, respectively	198,593	196,688
Additional paid-in capital	441,025,624	436,995,052
Accumulated deficit	(330,890,232)	(309,702,319)
Total stockholders' equity	110,333,985	127,489,421
Total liabilities and stockholders' equity	$124,420,986	$142,472,020

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

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended	
	March 31, 2017	March 31, 2016
Revenues, net	$3,985,464	$4,930,091
Cost of goods sold	659,635	1,108,443
Gross profit	3,325,829	3,821,648
Operating expenses:		
Sales, general, and administrative	16,837,617	9,678,552
Research and development	7,724,840	15,097,017
Depreciation and amortization	49,699	19,597
Total operating expenses	24,612,156	24,795,166
Operating loss	(21,286,327)	(20,973,518)
Other income		
Miscellaneous income	125,968	41,617
Accreted interest	3,867	2,536
Total other income	129,835	44,153
Loss before income taxes	(21,156,492)	(20,929,365)
Provision for income taxes	—	—
Net loss	$(21,156,492)	$(20,929,365)
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	197,790,040	194,901,560

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, 2017	March 31, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(21,156,492)	$(20,929,365)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	33,600	8,363
Amortization of intangible assets	16,099	11,234
(Recovery of) provision for doubtful accounts	(1,603)	236,151
Share-based compensation	1,413,195	4,381,690
Changes in operating assets and liabilities:		
Accounts receivable	580,943	(2,250,209)
Inventory	(262,297)	(267,281)
Other current assets	(253,518)	477,312
Other assets	—	(2,536)
Accounts payable	(1,212,236)	304,475
Other current liabilities	316,638	(1,373,762)
Net cash used in operating activities	(20,525,671)	(19,403,928)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(107,487)	(90,529)
Purchase of fixed assets	(27,834)	(74,478)
Net cash used in investing activities	(135,321)	(165,007)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	—	134,863,475
Proceeds from exercise of options	192,310	786,450
Proceeds from exercise of warrants	2,460,000	1,310,000
Net cash provided by financing activities	2,652,310	136,959,925
(Decrease) increase in cash	(18,008,682)	117,390,990
Cash, beginning of period	131,534,101	64,706,355
Cash, end of period	$113,525,419	$182,097,345

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

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THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED 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.

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, 2016, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance

sheet as of December 31, 2016. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited interim consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year or any other interim period in the future.

Recently Issued Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-15, Statement of Cash Flows (Topic 230). ASU 2016-15 is intended to reduce the diversity in practice regarding how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted with retrospective application. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We adopted ASU 2016-09 effective January 1, 2017, electing to account for forfeitures when they occur. The impact from adoption of the provisions related to forfeiture rates was reflected in our consolidated financial statements on a modified retrospective basis, resulting in an adjustment of approximately $31,000 to retained earnings. The impact from adoption of the provisions related to excess tax benefits or deficiencies in the provision for income taxes rather than paid-in capital was adopted on a modified retrospective basis. Since we have a full valuation allowance on our net deferred tax assets, an amount equal to the cumulative adjustment made to retained earnings to recognize the previously unrecognized net operating losses from prior periods, was made to the valuation allowance through retained earnings for first quarter financial statements. Adoption of all other changes did not have an impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets 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 and the International Accounting Standards Board (IASB) 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. These 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 obligations. 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 have performed a preliminary review of the requirements of the new revenue standard and are monitoring the activity

of the FASB and the transition resource group as it relates to specific interpretive guidance. We have reviewed customer contracts and applied the five-step model of the new standard to our contracts as well as compared the results to our current accounting practices. At this point of our analysis, we do not believe that the adoption of this standard will have a material effect on our financial statements but will potentially expand our disclosures related to contracts with customers.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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, 2017 and 2016, 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, 2017 and 2016.

Revenue Recognition

We recognize revenue on arrangements in accordance with ASC 605, Revenue Recognition. We recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed, and collectability is reasonably assured.

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product primarily via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques. As of January 1, 2017, we ceased manufacturing and distributing our OTC product lines, except for Iron 21/7, which have declined steadily over time resulting in immaterial sales. The revenue that is generated by us from major customers is all generated from sales of our prescription prenatal vitamin products which is disclosed in Note 13. There are no major customers for our OTC prenatal vitamin or other products.

Over-the-Counter Products

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. As of January 1, 2017, we ceased manufacturing and distributing our OTC product lines, except for Iron 21/7, which have declined steadily over time resulting in immaterial sales.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Prescription Products

We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacy distributors. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, wholesaler fees, customer rebates and estimated returns.

Revenue related to prescription products sold through wholesale distributors is recognized when the prescription products are shipped to the distributors and the control of the products passes to each distributor. 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.

Prior to September 1, 2016, we recognized revenue related to prescription products sold through retail pharmacy distributors when the product was dispensed by the retail pharmacy distributor, at which point all revenue and discounts related to such product were known or determinable and there was no right of return with respect to such product. On September 1, 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 mitigate exposure to any one retail pharmacy. Beginning on September 1, 2016, all of our prescription products are distributed under the wholesale distributor model described above.

We offer various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The consumer rebate program is designed to enable the end user to submit a coupon to us. If the coupon qualifies, we send a rebate check to the end user. We estimate the allowance for consumer rebates that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. We record distributor fees based on amounts stated in contracts and estimate chargebacks based on the number of units sold each period.

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 started using our own stock price in our volatility calculation along with two other peer entities whose stock prices were publicly available that were similar to the 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 of warrants is based on the contractual terms of the awards. The average expected life of options is based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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. We adopted ASU 2016-09, effective January 1, 2017, electing to account for forfeitures when they occur. Prior to that, we estimated the forfeiture rate based on our historical experience of forfeitures.

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, laboratory supplies, scale-up and validation costs, and other activities. Internal R&D activity expenses include salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future research and development activities are capitalized, and were $186,205 at March 31, 2017 and $228,933 at December 31, 2016, all of which were included in other current assets on the accompanying consolidated balance sheets. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal fees and costs. The activities undertaken by our regulatory consultants that were classified as R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as R&D expenses related to designing experiments to generate data for patents and to further the formulation development process for our pipeline technologies. Outside legal counsel also provided 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.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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, 2017	December 31, 2016
Finished product	$1,324,582	$1,062,285
Raw material	14,036	14,036
TOTAL INVENTORY	$1,338,618	$1,076,321

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	March 31, 2017	December 31, 2016
Prepaid manufacturing costs	$995,676	$991,809
Prepaid marketing costs	555,186	—
Prepaid insurance	377,460	628,039

Prepaid research and development costs	121,756	100,035
Prepaid consulting	64,449	128,898
Prepaid vendor deposits	5,000	44,311
Other prepaid costs	368,594	405,960
TOTAL OTHER CURRENT ASSETS	$2,488,121	$2,299,052

NOTE 6 – FIXED ASSETS

Fixed assets consist of the following:

	March 31, 2017	December 31, 2016
Accounting system	$301,096	$301,096
Equipment	239,553	215,182
Computer hardware	80,211	80,211
Furniture and fixtures	116,542	113,079
Leasehold improvements	37,888	37,888
	775,290	747,456
Accumulated depreciation	(264,217)	(230,617)
TOTAL FIXED ASSETS	$511,073	$516,839

Depreciation expense for the three months ended March 31, 2017 and 2016 was $33,600 and $8,363 respectively.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of March 31, 2017 and December 31, 2016:

	March 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$31,951	$ (6,989)	$24,962	12.5
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,100,784	(117,993)	$982,791	15.75
Hormone therapy drug candidate patents (pending)	1,298,667	—	1,298,667	n/a
Non-amortizing intangible assets:				
Multiple trademarks	190,940	—	190,940	indefinite
Total	$2,714,085	$ (216,725)	$2,497,360	

	December 31, 2016			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$31,951	$ (6,490)	$25,461	12.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,093,452	(102,393)	991,059	16
Hormone therapy drug candidate patents (pending)	1,203,987	—	1,203,987	n/a
Non-amortizing intangible assets:				
Multiple trademarks	185,465		185,465	indefinite
Total	$2,606,598	$ (200,626)	$2,405,972	

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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, 2017 and year ended December 31, 2016, there was no impairment recognized related to intangible assets.

In addition to numerous pending patent applications, as of March 31, 2017, we had 17 issued patents, including:

13 utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us and are U.S. jurisdiction patents with expiration dates in 2032. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea.

two utility patent that relates to TX-004HR, our applicator-free vaginal estradiol softgel product candidate, which establishes an important intellectual property foundation for TX-004HR, which are owned by us and are U.S. jurisdiction patents with an expiration date in 2033. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea.

one utility patent that relates to a pipeline transdermal patch technology, which is owned by us and is a U.S. jurisdiction patent with an expiration in 2032. We have pending patent application with respect to this patent in Australia, Brazil, Canada, Europe, Mexico, and Japan.

one utility patent that relates to our OPERA® information technology platform, which is owned by us and is a U.S. jurisdiction patent with an expiration date in 2029.

Amortization expense was $16,099 and $11,234 for the three months ended March 31, 2017 and 2016, 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
2017(9 months)	$ 48,297
2018	$ 64,396
2019	$ 64,396
2020	$ 64,396
2021	$ 64,396
Thereafter	$ 701,872

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THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	March 31, 2017	December 31, 2016
Accrued clinical trial costs	$1,350,659	$1,281,080
Accrued payroll, bonuses and commission costs	2,163,635	3,531,440
Accrued compensated absences	853,961	665,561
Accrued legal and accounting expense	287,016	176,518
Accrued sales and marketing costs	1,623,877	665,773
Other accrued expenses	295,086	224,865
Allowance for wholesale distributor fees	141,299	76,510
Accrued royalties	48,311	26,507
Allowance for coupons and returns	966,632	794,816
Accrued rent	210,247	181,015
TOTAL OTHER CURRENT LIABILITIES	$7,940,723	$7,624,085

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, 2017	March 31, 2016
Stock options	23,286,933	20,569,655
Warrants	10,374,071	12,281,059
	33,661,004	32,850,714

Subsequent to March 31, 2017, certain individuals and entities exercised warrants to purchase 6,590,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 4,762,208 shares of Common Stock were issued. In addition, warrants to purchase 566,666 shares of Common Stock were exercised for $1,139,000 in cash. See Note 15 - Subsequent Events for more details.

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

At March 31, 2017, 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.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Common Stock

At March 31, 2017, we had 350,000,000 shares of Common Stock authorized for issuance, of which 198,593,268 shares of Common Stock were issued and outstanding.

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.

Issuances During the Three Months Ended March 31, 2016

On January 6, 2016, we entered into an underwriting agreement with Goldman Sachs & Co. and Cowen and Company, LLC, as the representatives of the several underwriters, or the Underwriters, relating to an underwritten public offering of 15,151,515 shares of our Common Stock at a public offering price of $8.25 per share. Under the terms of the underwriting agreement, we granted the Underwriters a 30-day option to purchase up to an aggregate of 2,272,727 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $134,864,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on January 12, 2016 and we issued 17,424,242 shares of our Common Stock.

During the three months ended March 31, 2016, certain individuals exercised stock options to purchase 340,045 shares of Common Stock for $786,450 in cash.

Warrants to Purchase Common Stock

As of March 31, 2017, we had warrants outstanding to purchase an aggregate of 10,374,071 shares of Common Stock with a weighted-average contractual remaining life of approximately 1 year, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.27 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes-Merton valuation model, or 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 term of the warrant. 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. The fair value for these shares was determined by using the Black-Scholes Model on the date of the vesting 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 are vesting ratably over a 12-month period and have an expiration date of March 15, 2022. During the three months ended March 31, 2016, we granted warrants to purchase 120,000 shares of Common Stock to outside consultants at an exercise price of $7.59. The fair value for these shares was determined by using the Black-Scholes Model on the date of the vesting using a term of five years; volatility of 74.15%; risk free rate of 1.28%; and dividend yield of 0%. The grant date fair value of the warrants was $4.60 per share. The warrants are vesting ratably over a 12-month period and have an expiration date of January 21, 2021.

During the three months ended March 31, 2017 and 2016, we recorded $47,686 and $127,465, respectively, as share based compensation expense in the accompanying consolidated financial statements related to warrants. As of March 31, 2017, unamortized costs associated with these warrants totaled approximately $569,000.

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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 U.S. Food and Drug Administration, or the 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;
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%. During the three months ended March 31 2017 and 2016, we recorded $0 and $38,517, respectively, as non-cash compensation in the accompanying consolidated financial statements related to this warrant. As of June 30, 2016 this warrant was fully amortized; and
3. 283,334 shares will vest upon the receipt by us of any final FDA approval of a drug candidate that SCI helped us design. It is anticipated that this event will not occur before May 2017.

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to an unaffiliated entity 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%. At March 31, 2017, we had $64,449 reported as prepaid expense-short term, associated with these warrants. During both the three months ended March 31, 2017 and 2016, we recorded $64,449 as non-cash compensation expense with respect to these warrants in the accompanying consolidated statements of operations. The contract will expire upon the commercial manufacture of a drug product. As of March 31, 2017, unamortized costs associated with the SCI warrants issued in 2013 and 2012 totaled approximately $64,449 and will be recognized over a period of three months.

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. During the three months ended March 31, 2016, certain individuals exercised warrants to purchase 561,372 shares of our Common Stock for $1,310,000 in cash.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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 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, 2017, there were non-qualified stock options to purchase 18,163,459 shares of Common Stock outstanding under the 2009 Plan. As of March 31, 2017, there were 2,593,003 shares available to be issued under the 2009 Plan.

In 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. 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, 2017, there were non-qualified stock options to purchase 5,123,474 shares of Common Stock outstanding under the 2012 Plan. As of March 31, 2017, there were 4,795,000 shares available to be issued under the 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, 2017 and 2016 are set forth in the table below.

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Risk-free interest rate	1.90%	1.70%
Volatility	61.56-62.83%	71.22%
Term (in years)	6-6.25	6.25
Dividend yield	0.00%	0.00%

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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, 2016	21,767,854	$ 3.56	5.8	$60,495,730
Granted	1,730,500	$ 6.83		
Exercised	(95,046)	$ 2.02		$421,767
Expired/Forfeited	(116,375)	$ 7.46		
Balance at March 31, 2017	23,286,933	$ 3.78	5.9	$85,606,859
Vested and Exercisable at March 31, 2017	18,514,058	$ 3.09	5.1	$81,091,380
Unvested at March 31, 2017	4,772,875	$ 6.48	9.2	$4,515,479

At March 31, 2017, 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 $3.96 and $4.91 during the three months ended March 31, 2017 and 2016, respectively. Share-based compensation expense for options recognized in our results for the three months ended March 31, 2017 and 2016 ($1,301,060 and $4,151,259, respectively) is based on vested awards. At March 31, 2017, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $16,173,000 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.7 years. 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 2017 as a result of (i) the losses recorded during the three months ended March 31, 2017, (ii) additional losses expected for the remainder of 2017, 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, 2017, 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, 2017 and 2016, we were billed by Catalent approximately $705,000 and $1,465,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of March 31, 2017 and December 31, 2016, there were amounts due to Catalent of approximately $93,000 and $57,000, respectively.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 100% and 95% of our purchases supplied from one vendor for the three months ended March 31, 2017 and 2016, respectively.

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. 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.

During the three months ended March 31, 2017, five customers each generated more than 10% of our total revenues and during the three months ended March 31, 2016 three customers each generated more than 10% of our total revenues. Revenue generated from five major customers combined accounted for approximately 72% of our recognized revenue for the three months ended March 31, 2017 and revenue generated from three major customers combined accounted for approximately 61% of our recognized revenue for the three months ended March 31, 2016. 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. During the three months ended March 31, 2016, Woodstock Pharmaceutical and Compounding generated approximately $1,336,000 of our revenue; Medical Center Pharmacy generated approximately $680,000 of our revenue and Due West Pharmacy generated approximately $1,104,000 of our revenue.

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, 2017 and 2016 was $250,067 and $118,550, respectively.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

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As of March 31, 2017, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,	
2017 (9 months)	$647,216
2018	942,305
2019	1,083,890
2020	1,102,667
2021	934,313
Total minimum lease payments	$4,710,391

NOTE 15 – SUBSEQUENT EVENTS

In April 2017, certain individuals and entities exercised warrants to purchase 6,590,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 4,762,208 shares of Common Stock were issued. In addition, warrants to purchase 566,666 shares of Common Stock were exercised for $1,139,000 in cash.

On April 17, 2017, a securities class action lawsuit was filed against our company and certain of our officers and directors in the U.S. District Court for the Southern District of Florida (Case No. 9:17-cv-80473-RLR) that purports to state a claim for alleged violations of Sections 10(b) and 20 (a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, based on statements made by the defendants concerning the NDA for TX-004HR. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. We believe this lawsuit to be without merit and intend to vigorously defend against it. The lawsuit is in the very early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

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, 2016 filed with the Securities and Exchange Commission, or the Commission or the SEC, on February 28, 2017, 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," "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 maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; our ability to resolve the deficiencies identified by the U.S. Food and Drug Administration, or FDA, in our New Drug Application, NDA, for our TX-004HR product candidate; whether the FDA will approve our NDA for our TX-004HR product candidate and whether any such approval will occur by the Prescription Drug User Fee Act, or PDUFA, date; the length, cost and uncertain results of our clinical trials; 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, 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.

Our common stock, par value $0.001 per share, or Common Stock, is traded on the NYSE MKT under the symbol "TXMD." We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmd.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 obtained the U.S. Food and Drug Administration, or FDA, acceptance of our IND applications to conduct clinical trials for five of our proposed hormone therapy drug products: TX-001HR, our oral combination of progesterone and estradiol; TX-002HR, our oral progesterone alone; TX-003HR, our oral estradiol alone; and TX-004HR, our applicator-free vaginal estradiol softgel with estradiol alone and TX-006HR our combination estradiol and progesterone product in a topical cream form. Our IND for TX-003HR is currently inactive.

In December 2016, we announced positive top-line results from the recently completed the REPLENISH Trial, our phase 3 clinical trial of 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 post-menopausal women with an intact uterus. In December 2015, we completed the REJOICE Trial, our phase 3 clinical of 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 post-menopausal women with vaginal linings that do not receive enough estrogen. On July 7, 2016, we submitted a New Drug Application, or NDA, for all three doses of TX-004HR that were evaluated in the REJOICE Trial. In the fourth quarter of 2016 we submitted an IND for TX-006HR, our combination estradiol and progesterone drug candidate in a topical cream form, and intend to commence phase 1 clinical trials of this drug candidate in 2017. In July 2014, we suspended enrollment in the SPRY Trial, our phase 3 clinical trial for TX-002HR, our oral progesterone alone drug candidate, and, in October 2014, we stopped the trial in order to update the phase 3 protocol based on discussions with the FDA. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates. We have no current plans to conduct clinical trials for TX-003HR, our oral estradiol alone drug candidate, and the IND for this drug candidate is currently inactive.

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 in post-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 postmenopausal 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 U.S. Food and Drug Agency’s (FDA) 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 anticipate that we will submit an NDA for TX-001HR to the FDA as early as the third quarter of 2017. Assuming that the NDA is accepted 60 days thereafter and an FDA review period of ten months from the receipt date to the Prescription Drug User Fee Act, or PDUFA, date for a non-new molecular entity, the NDA for TX-001HR could be approved by the FDA as soon as mid-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. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board, or IRB, approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. We are considering updating the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if proposed by us and approved by the FDA, would allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol if we propose it. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-004HR

TX-004HR is our appliclator free vaginal estradiol softgel drug candidate for the treatment of VVA in post-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, inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. TX-004HR features our SYMBODA™ technology. This allows for the production of cohesive, stable formulations and provides content uniformity and accuracy of dosing strengths for TX-004HR. 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.

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 postmenopausal 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 is sufficiently complete to permit a substantive review and accepted the NDA for filing. The PDUFA target action date for the completion of the FDA's review is 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. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The FDA previously set a target action date under PDUFA of May 7, 2017 to complete the FDA's review of the NDA and had communicated to us the FDA's target date of April 9, 2017 for communicating to us proposed labeling and/or post marketing requirements/commitments in accordance with FDA's PDUFA Reauthorization Performance Goals And Procedures – Fiscal Years 2013 Through 2017.

On April 7, 2017, we received a letter from the FDA stating that, as part of the FDA's ongoing review of our NDA for TX-004HR, the FDA had identified deficiencies that preclude discussion of labeling and post marketing requirements/commitments at that time. The letter stated that the notification did not reflect a final decision on the information under review. The letter did not specify the deficiencies identified by the FDA and at this time we are not aware of the nature of the deficiencies. We continue to communicate with the FDA to understand the nature of the deficiencies and intend to resolve them as quickly as possible. Based on continued correspondence with the FDA, we expect that the FDA will finalize an action on the NDA, including informing us of the deficiencies in the NDA identified by the FDA, on or before the originally scheduled PDUFA target action date of May 7, 2017.

As of March 31, 2017, we had 17 issued patents, which included 13 utility patents that relate to our combination progesterone and estradiol formulations, two utility patents that relate to TX-004HR, which establish an important intellectual property foundation for TX-004HR, one utility patent that relates to a pipeline transdermal patch technology, and one 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 acquiring clinical trial materials; 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 approval from the FDA.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future research and development activities are capitalized, and were $186,205 at March 31, 2017 and $228,933 at December 31, 2016 which were included in other current assets on the accompanying consolidated balance sheets. CRO activity expenses include preclinical laboratory experiments and clinical trial studies.

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

	Three Months Ended March 31,	
	2017	2016
	(000s)	
TX 001-HR	$3,528	$9,026
TX 002-HR	—	—
TX 004-HR	1,945	2,437
Other research and development	2,252	3,634
Total	$7,725	$15,097

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, 2017 compared with three months ended March 31, 2016

	Three Months Ended March 31, 2017	2016	Change
	(000s)		
Revenues, net	$3,985	$4,930	$ (945)
Cost of goods sold	659	1,108	(449)
Operating expenses	24,612	24,795	(183)
Operating loss	(21,286)	(20,973)	(313)
Other income, net	130	44	86
Net loss	$(21,156)	$(20,929)	$ (227)

Revenues and Cost of Goods Sold

Revenues for the three months ended March 31, 2017 decreased approximately $945,000 or 19%, to approximately $3,985,000, compared with approximately $4,930,000 for the three months ended March 31, 2016. 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 and returns in 2017, partially offset by an increase in the number of units sold. Cost of goods sold decreased approximately $449,000, or 41%, to approximately $659,000 for the three months ended March 31, 2017, compared with approximately $1,108,000 for the three months ended March 31, 2016. Our gross margin was approximately 83% and 78% for the three months ended March 31, 2017 and 2016, respectively. The increase in gross margin percentage was primarily attributable to the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors.

Operating Expenses

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

	Three Months Ended March 31,	
	2017	2016
Research and development costs	31.4%	60.9%
Human resource related costs, including salaries, benefits and taxes	23.0%	21.3%
Sales and marketing costs, excluding human resource costs	31.3%	6.5 %
Professional fees for legal, accounting and consulting	6.5 %	5.2 %
Other operating expenses	7.8 %	6.1 %

Operating expenses decreased by approximately $183,000, or less than 1%, to approximately $24,612,000 for the three months ended March 31, 2017, from approximately $24,795,000 for the three months ended March 31, 2016 as a result of the following items:

	Three Months Ended March 31,		
	2017	2016	Change
	(000s)		
Research and development costs	$7,725	$15,097	$(7,372)
Human resource related costs including salaries, benefits and taxes	5,664	5,270	394
Sales and marketing, excluding human resource costs	7,699	1,618	6,081
Professional fees for legal, accounting and consulting	1,606	1,301	305
Other operating expenses	1,918	1,509	409
Total operating expenses	$24,612	$24,795	$(183)

Research and development costs for the three months ended March 31, 2017 decreased by approximately $7,372,000, or 49%, to approximately $7,725,000, compared with $15,097,000 for the three months ended March 31, 2016. 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, 2017 included the following research and development projects.

During the three months ended March 31, 2017 and the period from February 2013 (project inception) through March 31, 2017, we have incurred approximately $3,528,000 and $99,544,000, 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, 2017 and the period April 2013 (project inception) through March 31, 2017, 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, 2017 and the period from August 2014 (project inception) through March 31, 2017, we have incurred approximately $1,945,000 and $34,751,000, 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, 2017 increased by approximately $6,081,000, or 376%, to approximately $7,699,000, compared with approximately $1,618,000 for the three months ended March 31, 2016, 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, coupled with an increase in employee incentives.

Other operating expense for the three months ended March 31, 2017 increased by approximately $409,000, or 27%, to approximately $1,918,000, compared with approximately $1,509,000 for the three months ended March 31, 2016, as a result of increased rent, information technology and other office expenses partially offset by decreased investor relations expenses and allowance for bad debt.

Human resource costs, including salaries, benefits and taxes, for the three months ended March 31, 2017 increased by approximately $394,000, or 7%, to approximately $5,664,000, compared with approximately $5,270,000 for the three months ended March 31, 2016, primarily as a result of an increase of approximately $2,066,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our hormone therapy drug candidates partially offset by a decrease of approximately $1,672,000 in non-cash compensation expense included in this category related to employee stock option amortization during 2017 as compared to 2016.

Professional fees for the three months ended March 31, 2017 increased by approximately $305,000, or 23%, to approximately $1,606,000, compared with approximately $1,301,000 for the three months ended March 31, 2016, primarily as a result of increased legal and consulting expenses.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $313,000 to approximately $21,286,000 for the three months ended March 31, 2017, compared with approximately $20,973,000 for the three months ended March 31, 2016, 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 $86,000 or 195%, to approximately $130,000 for the three months ended March 31, 2017 compared with approximately $44,000 for the comparable period in 2016, as a result of

increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $227,000 to approximately $21,156,000 for the three months ended March 31, 2017, compared with approximately $20,929,000 for the three months ended March 31, 2016. Net loss per share of Common Stock, basic and diluted, was ($0.11) for the three months ended March 31, 2017, compared with ($0.11) for the three months ended March 31, 2016.

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, 2016, we received approximately $134,864,000 in net proceeds from the issuance of shares of our Common Stock. As of March 31, 2017, we had cash and cash equivalents totaling approximately $113,525,000, 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.

In April 2017, certain individuals and entities exercised warrants to purchase 6,590,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 4,762,208 shares of Common Stock were issued. In addition, warrants to purchase 566,666 shares of Common Stock were exercised for $1,139,000 in cash.

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.

For the three months ended March 31, 2017, our days sales outstanding, or DSO, was 89 days compared to 92 days for the year ended December 31, 2016. This slight decline in DSO was primarily due to the paydown of receivables outstanding prior to the centralization of the distribution channel for both our retail pharmacy distributors and whole distributors. 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 in September 2016, 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 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. 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 or obtain a credit facility. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products. 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,	
	2017	2016
	(000s)	
Net cash used in operating activities	$(20,526)	$(19,404)
Net cash used in investing activities	$(135)	$(165)
Net cash provided by financing activities	$2,652	$136,960

Operating Activities

The principal use of cash in operating activities for the three months ended March 31, 2017 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 increase of approximately $1,122,000 in cash used in operating activities for the three months ended March 31, 2017 compared with the comparable period in the prior year was due primarily to an increase in our net loss and lower non-cash compensation expense coupled with changes in the components of working capital.

Investing Activities

An increase in spending on patent and trademarks and fixed assets resulted in an increase in cash used in investing activities for the three months ended March 31, 2017 compared with the same period in 2016.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the three months ended March 31, 2017 provided net cash of approximately $2,652,000 which was related to exercise of warrants and options. The cash provided by financing activities during the three months ended March 31, 2016, included approximately $134,864,000 in proceeds from sale of our Common Stock and approximately $2,096,000 in proceeds from the exercise of options and warrants.

New Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-15, Statement of Cash Flows (Topic 230). ASU 2016-15 is intended to reduce the diversity in practice regarding how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted with retrospective application. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We adopted ASU 2016-09 effective January 1, 2017, electing to account for forfeitures when they occur. The impact from adoption of the provisions related to forfeiture rates was reflected in our consolidated financial statements on a modified retrospective basis, resulting in an adjustment of approximately $31,000 to retained earnings. The impact from adoption of the provisions related to excess tax benefits or deficiencies in the provision for income taxes rather than paid-in capital was adopted on a modified retrospective basis. Since we have a full valuation allowance on our net deferred tax assets, an amount equal to the cumulative adjustment made to retained earnings to recognize the previously unrecognized net operating losses from prior periods, was made to the valuation allowance through retained earnings for first quarter financial statements. Adoption of all other changes did not have an impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets 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 and the International Accounting Standards Board (IASB) 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. These 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 obligations. 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 have performed a preliminary review of the requirements of the new revenue standard and are monitoring the activity of the FASB and the transition resource group as it relates to specific interpretive guidance. We have reviewed customer contracts and applied the five-step model of the new standard to our contracts as well as compared the results to our current accounting practices. At this point of our analysis, we do not believe that the adoption of this standard will have a material effect on our financial statements but will potentially expand our disclosures related to contracts with customers.

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, 2017, 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

On April 17, 2017, a securities class action lawsuit was filed against our company and certain of our officers and directors in the U.S. District Court for the Southern District of Florida (Case No. 9:17-cv-80473-RLR) that purports to state a claim for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, based on statements made by the defendants concerning the NDA for TX-004HR. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. We believe this lawsuit to be without merit and intend to vigorously defend against it. The lawsuit is in the very early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

Item 1A. Risk Factors

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

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

On January 24, 2017, we issued 800,000 shares of our Common Stock upon the exercise of warrants previously issued to an outside service provider and received proceeds of $2,056,000 in connection with this exercise. On February 17, 2017, we issued 1,000,000 shares of our Common Stock upon the exercise of warrants previously issued to an outside service provider and received proceeds of $380,000 in connection with this exercise. On March 14, 2017, we issued 10,000 shares of our Common Stock upon the exercise of warrants previously issued in connection with a loan agreement and received proceeds of $24,000 in connection with this exercise. Proceeds from these transactions were used in working capital. The shares of Common Stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

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Item 6. Exhibits

Exhibit	Date	Description
31.1*	May 3, 2017	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	May 3, 2017	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)and Rule 15d-14(a)
32.1*	May 3, 2017	Section 1350 Certification of Chief Executive Officer
32.2*	May 3, 2017	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 3, 2017

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)