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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 October 30, 2017 was 216,429,642.

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current Assets:		
Cash	$ 148,292,654	$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of $377,929 and $376,374, respectively	4,392,635	4,500,699
Inventory	1,293,517	1,076,321
Other current assets	3,001,777	2,299,052
Total current assets	156,980,583	139,410,173
Fixed assets, net	448,066	516,839
Other Assets:		
Intangible assets, net	2,793,421	2,405,972
Security deposit	139,036	139,036
Total other assets	2,932,457	2,545,008
Total assets	$ 160,361,106	$ 142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 4,199,369	$ 7,358,514
Other current liabilities	6,677,232	7,624,085
Total current liabilities	10,876,601	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; 216,429,642 and 196,688,222 issued and outstanding, respectively	216,430	196,688
Additional paid in capital	514,499,865	436,995,052
Accumulated deficit	(365,231,790)	(309,702,319)
Total stockholders' equity	149,484,505	127,489,421
Total liabilities and stockholders' equity	$ 160,361,106	$ 142,472,020

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues, net	$ 4,417,598	$ 5,535,685	$ 12,653,495	$ 14,869,023
Cost of goods sold	700,814	1,237,446	2,042,174	3,475,997
Gross profit	3,716,784	4,298,239	10,611,321	11,393,026
Operating expenses:				
Sales, general, and administration	12,057,868	14,721,710	43,524,412	35,019,268
Research and development	6,436,802	14,664,123	22,878,037	43,602,333
Depreciation and amortization	54,055	40,460	156,943	84,319
Total operating expense	18,548,725	29,426,293	66,559,392	78,705,920
Operating loss	(14,831,941)	(25,128,054)	(55,948,071)	(67,312,894)
Other income:				
Miscellaneous income	167,300	109,942	442,322	265,879
Accreted interest	—	2,451	7,699	7,850
Total other income	167,300	112,393	450,021	273,729
Loss before taxes	(14,664,641)	(25,015,661)	(55,498,050)	(67,039,165)
Provision for income taxes	—	—	—	—
Net loss	$ (14,664,641)	$ (25,015,661)	$ (55,498,050)	$ (67,039,165)
Net loss per share, basic and diluted	$ (0.07)	$ (0.13)	$ (0.27)	$ (0.34)
Weighted average number of common shares outstanding	207,938,338	196,502,327	203,282,335	195,912,173

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

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

	Nine Months Ended	
	September 30, 2017	September 30, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (55,498,050)	$ (67,039,165)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	104,622	45,759
Amortization of intangible assets	52,321	38,560
Provision for doubtful accounts	1,555	2,261,568
Share-based compensation	5,037,783	13,385,215
Changes in operating assets and liabilities:		
Accounts receivable	106,509	(4,245,151)
Inventory	(217,196)	(153,245)
Other current assets	(831,623)	379,930
Accounts payable	(3,159,145)	1,098,245
Other current liabilities	(946,853)	703,895
Net cash used in operating activities	(55,350,077)	(53,524,389)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(439,770)	(541,686)
Purchase of fixed assets	(35,849)	(307,714)
Payment of security deposit	—	(14,036)
Net cash used in investing activities	(475,619)	(863,436)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	68,572,635	134,863,475
Proceeds from exercise of warrants	3,798,999	1,373,000
Proceeds from exercise of options	212,615	979,060
Net cash provided by financing activities	72,584,249	137,215,535
Increase in cash	16,758,553	82,827,710
Cash, beginning of period	131,534,101	64,706,355
Cash, end of period	$ 148,292,654	$ 147,534,065

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

NOTE 1 – THE COMPANY

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

Nature of Business

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

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 May 2017, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, that clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. The new guidance will allow companies to make certain changes to awards without accounting for them as modifications. This guidance does not change the accounting for modifications. The guidance will be applied prospectively to awards modified on or after the adoption date and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including in an interim period. We do not expect that adoption of this guidance will have a material effect on our consolidated financial statements.

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

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 September 30, 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 our impairment test. There was no impairment of intangible assets or long-lived assets during the three and nine months ended September 30, 2017 and 2016.

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card charge-backs and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due for more than 90 days to be delinquent. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off when received as an increase in the allowance for doubtful accounts. To the extent data we use to calculate these estimates does not accurately reflect bad debts, adjustments to these reserves may be required.

Revenue Recognition

We 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 (Iron 21/7). 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.

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. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. 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 may include options, restricted stock, restricted stock units, performance-based awards, and share appreciation rights. 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 our 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 our company. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. The average expected life 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.

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 $0 at September 30, 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 U.S. Food and Drug Administration, or the FDA, submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities include professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

Segment Reporting

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

NOTE 4 – INVENTORY

Inventory consists of the following:

	September 30, 2017	December 31, 2016
Finished product	$ 1,293,517	$ 1,062,285
Raw material	—	14,036
TOTAL INVENTORY	$ 1,293,517	$ 1,076,321

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2017	December 31, 2016
Prepaid manufacturing costs	$ 999,508	$ 991,809
Prepaid sales and marketing costs	535,936	—
Prepaid insurance	953,792	628,039
Prepaid research and development costs	—	100,035
Prepaid consulting	—	128,898
Prepaid vendor deposits	5,000	44,311
Other prepaid costs	507,541	405,960
TOTAL OTHER CURRENT ASSETS	$ 3,001,777	$ 2,299,052

NOTE 6 – FIXED ASSETS

Fixed assets consist of the following:

	September 30, 2017	December 31, 2016
Accounting system	$ 301,096	$ 301,096
Equipment	247,568	215,182
Computer hardware	80,211	80,211
Furniture and fixtures	116,542	113,079
Leasehold improvements	37,888	37,888
	783,305	747,456
Accumulated depreciation	(335,239)	(230,617)
TOTAL FIXED ASSETS	$ 448,066	$ 516,839

Depreciation expense for the three months ended September 30, 2017 and 2016 was $35,622 and $26,543 respectively, and $104,622 and $45,759 for the nine months ended September 30, 2017 and 2016, respectively.

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of September 30, 2017 and December 31, 2016:

	September 30, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$ 31,951	$ (7,988)	$ 23,963	12
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,247,181	(153,216)	1,093,965	15.25
Hormone therapy drug candidate patents (pending)	1,474,061	—	1,474,061	n/a
Non-amortizing intangible assets:				
Multiple trademarks	201,432	—	201,432	indefinite
Total	$ 3,046,368	$ (252,947)	$ 2,793,421	

	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	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the nine months ended September 30, 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 September 30, 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 patents that relate 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 $18,433 and $13,917 for the three months ended September 30, 2017 and 2016, respectively, and $52,321 and $38,560 for the nine months ended September 30, 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(3 months)	$ 18,433
2018	$ 73,732
2019	$ 73,732
2020	$ 73,732
2021	$ 73,732
Thereafter	$ 804,567

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2017	December 31, 2016
Accrued clinical trial costs	$ 556,048	$ 1,281,080
Accrued payroll, bonuses and commission costs	2,662,359	3,531,440
Accrued compensated absences	952,587	665,561
Accrued legal and accounting expense	366,828	176,518
Accrued sales and marketing costs	69,041	665,773
Other accrued expenses	319,015	224,865
Allowance for wholesale distributor fees	145,563	76,510
Accrued royalties	93,870	26,507
Allowance for coupons and returns	1,218,249	794,816
Accrued rent	293,672	181,015
TOTAL OTHER CURRENT LIABILITIES	$ 6,677,232	$ 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 Common Stock outstanding plus all potentially dilutive shares of Common Stock outstanding during the period. Such potentially dilutive shares of 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.

	Nine Months Ended September 30,	
	2017	2016
Stock options	23,383,100	20,705,923
Warrants	3,115,905	12,060,571
	26,499,005	32,766,494

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 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.

Common Stock

At September 30, 2017, we had 350,000,000 shares of Common Stock authorized for issuance, of which 216,429,642 shares of Common Stock were issued and outstanding.

Issuances During 2017

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our Common Stock at a price of $5.55 per share. The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of Common Stock.

During the three months ended September 30, 2017, certain individuals exercised stock options to purchase 2,500 shares of Common Stock for $255 in cash. During the nine months ended September 30, 2017, certain individuals exercised stock options to purchase 102,546 shares of Common Stock for $212,615 in cash.

Issuances During 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 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 Common Stock.

During the three months ended September 30, 2016, certain individuals exercised stock options to purchase 127,109 shares of Common Stock. Stock options to purchase shares of Common Stock were exercised as follows: (i) 10,000 options for $1,018 in cash and (ii) 117,109 options, pursuant to the stock options' cashless provision, wherein 78,017 shares of Common Stock were issued. During the nine months ended September 30, 2016, certain individuals exercised stock options to purchase 544,277 shares of Common Stock. Stock options to purchase shares of Common Stock were exercised as follows: (i) 427,168 options for $979,060 in cash and (ii) 117,109 options, pursuant to the stock options' cashless provision, wherein 78,017 shares of Common Stock were issued.

Warrants to Purchase Common Stock

As of September 30, 2017, we had warrants outstanding to purchase an aggregate of 3,115,905 shares of Common Stock with a weighted-average contractual remaining life of approximately 2.08 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.58 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the warrant. During the nine months ended September 30, 2017, we granted warrants to purchase 125,000 shares of Common Stock to outside consultants at an exercise price of $6.83 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 63.24%; risk free rate of 1.47%; and dividend yield of 0%. The grant date fair value of the warrants was $3.67 per share. The warrants are vesting ratably over a 12-month period and have an expiration date of March 15, 2022. During the nine months ended September 30, 2016, we granted warrants to purchase 245,000 shares of Common Stock to outside consultants at a weighted average exercise price of $7.90 per share. The weighted average grant date fair value of these warrants was $4.78 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 74.10%-74.15%; risk free rate of 1.04%-1.28%; and dividend yield of 0%. These warrants vest and have expiration dates as follows: warrants to purchase 75,000 shares of Common Stock vested on April 21, 2016 and have an expiration date of April 21, 2021, warrants to purchase 50,000 shares of Common Stock vest ratably over a 24-month period and have an expiration date of April 21, 2021, and warrants to purchase 120,000 shares of Common Stock vest ratable over a 12-month period and have an expiration date of January 21, 2021.

During the three months ended September 30, 2017 and 2016, we recorded $101,376 and $137,161, respectively, and during the nine months ended September 30, 2017 and 2016 we recorded $217,150 and $820,751, respectively, as share-based compensation expense in the accompanying consolidated financial statements related to warrants. As of September 30, 2017, unamortized costs associated with these warrants totaled approximately $279,000.

In May 2013, we entered into a consulting agreement with Sancilio and Company, Inc., or SCI, to develop drug platforms to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain FDA approval for our drug candidates, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of 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 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 both the three months ended September 30, 2017 and 2016, we did not record any non-cash compensation related to this warrant in the accompanying consolidated financial statements. During the nine months ended September 30, 2017 and 2016, we recorded $0 and $77,026, 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 occur in the near future.

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to SCI for services to be rendered over approximately five years beginning in May 2012. The warrants vested upon issuance. Services provided are to include (a) services in support of our drug development efforts, including services in support of our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain New Drug Approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. During the three months ended September 30, 2017 and 2016, we recorded $0 and $64,449, respectively, and during the nine months ended September 30, 2017 and 2016, we recorded $128,898 and $193,347, respectively, 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 September 30, 2017, the SCI warrants issued in 2013 and 2012 were fully amortized.

During both the three months ended September 30, 2017 and 2016, no warrants were exercised. During the nine months ended September 30, 2017, certain individuals exercised warrants to purchase 2,476,666 shares of Common Stock for $3,798,999 in cash. In addition, during the nine months ended September 30, 2017, certain individuals 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. During the nine months ended September 30, 2016, certain individuals exercised warrants to purchase 722,744 shares of Common Stock for $1,373,000 in cash.

Options to Purchase Common Stock

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares 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 September 30, 2017, there were non-qualified stock options to purchase 18,592,959 shares of Common Stock outstanding under the 2009 Plan. As of September 30, 2017, there were 2,156,003 shares of Common Stock 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 September 30, 2017, there were non-qualified stock options to purchase 4,790,141 shares of Common Stock outstanding under the 2012 Plan. As of September 30, 2017, there were 5,128,333 shares of Common Stock 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 nine months ended September 30, 2017 and 2016 are set forth in the table below.

	Nine Months Ended	
	September 30, 2017	September 30, 2016
Risk-free interest rate	1.84-2.01%	1.13-1.70%
Volatility	61.56-63.95%	70.26-71.22%
Term (in years)	5.5-6.25	6.00-6.25
Dividend yield	0.00%	0.00%

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

	Number of Shares Underlying Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2016	21,767,854	$ 3.56	5.8	$ 60,495,730
Granted	2,184,500	$ 6.61		
Exercised	(102,546)	$ 2.07		$ 452,287
Expired/Forfeited	(466,708)	$ 6.52		
Balance at September 30, 2017	23,383,100	$ 3.79	5.4	$ 52,467,444
Vested and Exercisable at September 30, 2017	18,883,183	$ 3.15	4.6	$ 52,059,288
Unvested at September 30, 2017	4,499,917	$ 6.46	8.6	$ 408,156

At September 30, 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 $3.82 and $4.70 during the nine months ended September 30, 2017 and 2016, respectively. Share-based compensation expense for options recognized in our results of operations is based on vested awards. Share-based compensation expense related to options for the three months ended September 30, 2017 and 2016 was $1,885,050 and $3,982,759, respectively, and for the nine months ended September 30, 2017 and 2016 was $4,691,735 and $12,294,089, respectively. At September 30, 2017, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $12,419,000. This cost is expected to be recognized over a weighted-average period of 2.2 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 (a) the losses recorded during the nine months ended September 30, 2017, (b) additional losses expected for the remainder of 2017, and/or (c) net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is “more likely than not” that some component or all of the benefits of deferred tax assets will not be realized. As of September 30, 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 September 30, 2017 and 2016, we were billed by Catalent approximately $186,000 and $828,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. During the nine months ended September 30, 2017 and 2016, we were billed by Catalent approximately $2,646,000 and $2,907,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of September 30, 2017 and December 31, 2016, there were amounts due to Catalent of approximately $26,000 and $57,000, respectively.

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 100% and 97% of our purchases supplied from one vendor for both the three and nine months ended September 30, 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 both the nine months ended September 30, 2017 and 2016, four customers each generated more than 10% of our total revenue. Revenue generated from four major customers combined accounted for approximately 60% of our revenue for both the nine months ended September 30, 2017 and 2016. During the nine months ended September 30, 2017, Pharmacy Innovations PA generated approximately $2,715,000 of our revenue, AmerisourceBergen generated approximately $1,716,000 of our revenue, Cardinal Health generated approximately $1,764,000 of our revenue and McKesson Corporation generated approximately $1,458,000 of our revenue. During the nine months ended September 30, 2016, Woodstock Pharmaceutical and Compounding generated approximately $2,247,000 of our revenue, Medical Center Pharmacy generated approximately $2,683,000 of our revenue, Due West Pharmacy generated approximately $1,890,000 of our revenue and Pharmacy Innovations generated approximately $2,113,000 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 September 30, 2017 and 2016 was approximately $257,000 and $182,000, respectively. The rental expense related to our current lease during the nine months ended September 30, 2017 and 2016 was approximately $772,000 and $482,000, respectively.

As of September 30, 2017, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,		
2017 (3 months)	$	224,632
2018		951,194
2019		1,094,116
2020		1,113,069
2021		943,127
Total minimum lease payments	$	4,326,138

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 purported 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 promulgated thereunder, based on statements made by the defendants concerning the NDA for TX-004HR. The complaint sought unspecified damages, interest, attorneys' fees and other costs. On July 18, 2017, the complaint was voluntarily dismissed by the lead plaintiff without prejudice. We and certain of our officers and directors were are also subject to two shareholder derivative lawsuits regarding the NDA for TX-004HR, one filed in the U.S. District Court for the Southern District of Florida on May 30, 2017 (Case No. 9:17-cv-80686-RLR) and one filed in Florida state court in Palm Beach County on June 5, 2017 (Case No. 502017CA006289XXXXMB). These complaints were both voluntarily dismissed by the lead plaintiffs without prejudice on August 14, 2017.

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 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," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are made as of the date of this Quarterly Report on Form 10-Q and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our Annual Report, and include the following: our ability to resolve the deficiencies identified by the U.S. Food and Drug Administration, or FDA, in our new drug application, or NDA, for our TX-004HR product candidate and the time frame associated with such resolution; whether we will be able to prepare an amended NDA for our TX-004HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; our ability to maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to prepare an NDA for our TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; the length, cost and uncertain results of our clinical trials, including any additional clinical trials that the FDA may require in connection with TX-004HR; the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

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

Overview

We are a women's health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of our advanced hormone therapy pharmaceutical products. Our drug candidates that have completed clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, 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 the Common Stock, has been listed on the Nasdaq Global Select Market of The Nasdaq Stock Market LLC since October 9, 2017. Our Common Stock was previously listed on the NYSE American, LLC. 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 FDA acceptance of our Investigational New Drug, or 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 applications for TX-002HR and TX-003HR are 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. In the fourth quarter of 2016 we submitted an IND application 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 as early as 2018. 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. Our IND is currently in inactive status.We have no current plans to conduct clinical trials for TX-003HR, our oral estradiol alone drug candidate, and the IND application 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 FDA's draft guidance.

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

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

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

MITT = Modified intent to treat

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

We had a pre-NDA meeting for TX-001HR with the FDA on August 28, 2017. We anticipate that we will submit an NDA for TX-001HR to the FDA in the fourth 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 the fourth quarter of 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 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. Our IND is currently in inactive status. 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 applicator 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 was sufficiently complete to permit a substantive review and accepted the NDA for filing with the PDUFA target action date for the completion of the FDA's review of May 7, 2017. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the phase 3 REJOICE Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA.

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

On June 14, 2017, we participated in a Type A Post-Action Meeting with the Division of Bone, Reproductive, and Urologic Products (DBRUP) of the FDA to discuss the CRL. The meeting enabled us to present new information that we believe could address concerns raised by the FDA in the CRL and positively affect the status of the NDA for TX-004HR. We have received the minutes of the meeting and, per the FDA's request, on July 5, 2017 formally submitted the new information for consideration related to the NDA for TX-004HR.

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

On November 3, 2017, we participated in an in-person meeting with DBRUP. At the meeting, DBRUP agreed to the resubmission of the NDA for the 4 mcg and 10 mcg doses of TX-004HR without the need for an additional pre-approval study. We will commit to conduct a post-approval observational study. We believe that we will be in a position to resubmit the NDA for TX-004HR within the coming weeks, with a potential approval of the NDA within two to six months after resubmission, depending on the classification of the review of the NDA.

As of September 30, 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 application approval from the FDA.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future research and development activities are capitalized, and were $0 at September 30, 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(000s)		(000s)	
TX 001-HR	$ 3,066	$ 7,751	$ 11,971	$ 25,101
TX 002-HR	—	—	—	—
TX 004-HR	1,580	2,611	6,292	7,724
Other research and development	1,791	4,302	4,615	10,777
Total	$ 6,437	$ 14,664	$ 22,878	$ 43,602

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 September 30, 2017 compared with three months ended September 30, 2016

	Three Months Ended September 30,		
	2017	2016	Change
	(000s)		
Revenues, net	$ 4,417	$ 5,536	$ (1,119)
Cost of goods sold	701	1,237	(536)
Operating expenses	18,548	29,427	(10,879)
Operating loss	(14,832)	(25,128)	(10,296)
Other income, net	167	113	54
Net loss	$ (14,665)	$ (25,015)	$ (10,350)

Revenues and Cost of Goods Sold

Revenues for the three months ended September 30, 2017 decreased approximately $1,119,000, or 20%, to approximately $4,417,000, compared with approximately $5,536,000 for the three months ended September 30, 2016. This decrease was attributable to a decrease in the average net revenue per unit of our products and a slight decrease in the number of units sold. Cost of goods sold decreased approximately $536,000, or 43%, to approximately $701,000 for the three months ended September 30, 2017, compared with approximately $1,237,000 for the three months ended September 30, 2016. Our gross margin was approximately 84% and 78% for the three months ended September 30, 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, which, among other things, lowered the cost to package, prepare and deliver our products to customers.

Operating Expenses

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

	Three Months Ended September 30,	
	2017	2016
Research and development costs	34.7%	49.8%
Human resource related costs including salaries, benefits and taxes	32.2%	20.3%
Sales and marketing costs, excluding human resource costs	17.0%	14.3%
Professional fees for legal, accounting and consulting	6.9%	4.9%
Other operating expenses	9.2%	10.7%

Operating expenses decreased by approximately $10,879,000, or 37%, to approximately $18,548,000 for the three months ended September 30, 2017, from approximately $29,427,000 for the three months ended September 30, 2016 as a result of the following items:

	Three Months Ended September 30,		
	2017	2016	Change
	(000s)		
Research and development costs	$ 6,437	$ 14,664	$ (8,227)
Human resources related costs, including salaries, benefits and taxes	5,966	5,965	1
Sales and marketing, excluding human resource costs	3,163	4,201	(1,038)
Professional fees for legal, accounting and consulting	1,271	1,450	(179)
Other operating expenses	1,711	3,147	(1,436)
Total operating expenses	$ 18,548	$ 29,427	$ (10,879)

Research and development costs for the three months ended September 30, 2017 decreased by approximately $8,227,000, or 56%, to approximately $6,437,000, compared with $14,664,000 for the three months ended September 30, 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 September 30, 2017 included the following research and development projects.

During the three months ended September 30, 2017 and the period from February 2013 (project inception) through September 30, 2017, we have incurred approximately $3,066,000 and $107,987,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the three months ended September 30, 2017 and the period April 2013 (project inception) through September 30, 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 September 30, 2017 and the period from August 2014 (project inception) through September 30, 2017, we have incurred approximately $1,580,000 and $39,098,000, 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.

Human resource costs, including salaries, benefits and taxes, for the three months ended September 30, 2017 increased by approximately $1,000, or less than 1%, to approximately $5,966,000, compared with approximately $5,965,000 for the three months ended September 30, 2016, primarily as a result of a an increase of approximately $1,042,000 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 $1,041,000 in non-cash compensation expense included in this category related to employee stock option amortization.

Sales and marketing costs for the three months ended September 30, 2017 decreased by approximately $1,038,000, or 25%, to approximately $3,163,000, compared with approximately $4,201,000 for the three months ended September 30, 2016, primarily as a result reduced spending associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates, partially offset by higher costs related to outsourced sales personnel and their related expenses together with an increase in employee incentives.

Professional fees for the three months ended September 30, 2017 decreased by approximately $179,000, or 12%, to approximately $1,271,000, compared with approximately $1,450,000 for the three months ended September 30, 2016, primarily as a result of decreased consulting expenses partially offset by a slight increase in legal expenses.

Other operating expense for the three months ended September 30, 2017 decreased by approximately $1,436,000, or 46%, to approximately $1,711,000, compared with approximately $3,147,000 for the three months ended September 30, 2016, as a result of decrease in bad debt expense, partially offset by increased rent, information technology and other office expenses.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $10,296,000, or 41%, to approximately $14,832,000 for the three months ended September 30, 2017, compared with approximately $25,128,000 for the three months ended September 30, 2016, primarily as a result of decreased research and development costs and reduced spending associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates, partially offset by higher costs related to outsourced sales personnel and their related expenses, professional fees, and other operating expenses, as well a decrease in revenue.

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 $54,000, or 48%, to approximately $167,000 for the three months ended September 30, 2017 compared with approximately $113,000 for the comparable period in 2016, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss decreased approximately $10,350,000, or 41%, to approximately $14,665,000 for the three months ended September 30, 2017, compared with approximately $25,015,000 for the three months ended September 30, 2016. Net loss per share of Common Stock, basic and diluted, was ($0.07) for the three months ended September 30, 2017, compared with ($0.13) for the three months ended September 30, 2016.

Nine months ended September 30, 2017 compared with nine months ended September 30, 2016

	Nine Months Ended September 30,		
	2017	2016	Change
	(000s)		
Revenues, net	$ 12,653	$ 14,869	$ (2,216)
Cost of goods sold	2,042	3,476	(1,434)
Operating expenses	66,559	78,706	(12,147)
Operating loss	(55,948)	(67,313)	(11,365)
Other income, net	450	274	176
Net loss	$ (55,498)	$ (67,039)	$ (11,541)

Revenues and Cost of Goods Sold

Revenues for the nine months ended September 30, 2017 decreased approximately $2,216,000, or 15%, to approximately $12,653,000, compared with approximately $14,869,000 for the nine months ended September 30, 2016. This decrease was attributable to a decrease in the average net revenue per unit of our products, primarily related to higher estimates related to discounts and returns in 2017, partially offset by a slight increase in the number of units sold. Cost of goods sold decreased approximately $1,434,000, or 41%, to approximately $2,042,000 for the nine months ended September 30, 2017, compared with approximately $3,476,000 for the nine months ended September 30, 2016. Our gross margin was approximately 84% and 77% for the nine months ended September 30, 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 which, among other things, lowered the cost to package, prepare and deliver our products to customers.

Operating Expenses

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

	Nine Months Ended September 30,	
	2017	2016
Research and development costs	34.4%	55.4%
Human resource related costs, including salaries, benefits and taxes	26.2%	22.0%
Sales and marketing costs, excluding human resource costs	24.9%	9.9%
Professional fees for legal, accounting and consulting	6.1%	4.6%
Other operating expenses	8.4%	8.1%

Operating expenses decreased by approximately $12,147,000, or 15%, to approximately $66,559,000 for the nine months ended September 30, 2017, from approximately $78,706,000 for the nine months ended September 30, 2016 as a result of the following items:

	Nine Months Ended September 30,		
	2017	2016	Change
	(000s)		
Research and development costs	$ 22,878	$ 43,602	$ (20,724)
Human resources related costs, including salaries, benefits and taxes	17,415	17,309	106
Sales and marketing costs, excluding human resource costs	16,590	7,796	8,794
Professional fees for legal, accounting and consulting	4,062	3,615	447
Other operating expenses	5,614	6,384	(770)
Total operating expenses	$ 66,559	$ 78,706	$ (12,147)

Research and development costs for the nine months ended September 30, 2017 decreased by approximately $20,724,000, or 48%, to approximately $22,878,000, compared with $43,602,000 for the nine months ended September 30, 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 nine months ended September 30, 2017 included the following research and development projects.

During the nine months ended September 30, 2017 and the period from February 2013 (project inception) through September 30, 2017, we have incurred approximately $11,971,000 and $107,987,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the nine months ended September 30, 2017 and the period April 2013 (project inception) through September 30, 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 nine months ended September 30, 2017 and the period from August 2014 (project inception) through September 30, 2017, we have incurred approximately $6,292,000 and $39,098,000, 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.

Human resource costs, including salaries, benefits and taxes, for the nine months ended September 30, 2017 increased by approximately $106,000, or less than 1%, to approximately $17,415,000, compared with approximately $17,309,000 for the nine months ended September 30, 2016, primarily as a result of an increase of approximately $4,636,000 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 $4,530,000 in non-cash compensation expense included in this category related to employee stock option amortization.

Sales and marketing costs for the nine months ended September 30, 2017 increased by approximately $8,794,000, or 113%, to approximately $16,590,000, compared with approximately $7,796,000 for the nine months ended September 30, 2016, primarily as a result of increased expenses in the first half of 2017 associated with sales and marketing efforts to support commercialization of our hormone therapy drug candidates, which were curtailed in the third quarter of 2017 due to the status of the NDA for TX-004HR, higher costs related to outsourced sales personnel and their related expenses which started in the fourth quarter of 2016, together with an increase in employee incentives.

Professional fees for the nine months ended September 30, 2017 increased by approximately $447,000, or 12%, to approximately $4,062,000, compared with approximately $3,615,000 for the nine months ended September 30, 2016, primarily as a result of increased legal and other professional expenses, partially offset by a decrease in consulting expenses.

Other operating expense for the nine months ended September 30, 2017 decreased by approximately $770,000, or 12%, to approximately $5,614,000, compared with approximately $6,384,000 for the nine months ended September 30, 2016, as a result of a decrease in bad debt expense as well as decreased investor relations expenses, partially offset by increased rent, information technology and other office expenses.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $11,365,000, or 17%, to approximately $55,948,000 for the nine months ended September 30, 2017, compared with approximately $67,313,000 for the nine months ended September 30, 2016, primarily as a result of decreased research and development costs and other operating expenses, partially offset by increased personnel costs, sales and marketing expenses to support commercialization of our hormone therapy drug candidates, higher costs related to outsourced sales personnel and their related expenses and professional fees as well a decrease in revenue.

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 $176,000, or 64%, to approximately $450,000 for the nine months ended September 30, 2017, compared with approximately $274,000 for the comparable period in 2016, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss decreased approximately $11,541,000, or 17%, to approximately $55,498,000 for the nine months ended September 30, 2017, compared with approximately $67,039,000 for the nine months ended September 30, 2016. Net loss per share of Common Stock, basic and diluted, was ($0.27) for the nine months ended September 30, 2017, compared with ($0.34) for the nine months ended September 30, 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. Since 2014 , we received approximately $337,582,000 in net proceeds from the issuance of shares of Common Stock. As of September 30, 2017, we had cash and cash equivalents totaling approximately $148,293,000, 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.

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our Common Stock at a price of $5.55 per share . The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of our Common Stock. We intend to use a majority of the net proceeds from this offering to fund pre-commercialization and commercialization activities for our TX-004HR and TX-001HR drug candidates. We currently intend to fund the remainder of our pre-commercialization and commercialization expenses for our TX-004HR and TX-001HR drug candidates through debt financing and are currently engaged in discussions to secure debt financing commitments during the fourth quarter of 2017. If we are successful in obtaining these commitments, we currently anticipate we would begin to draw on them following approval of either TX-004HR or TX-001HR.

During the nine months ended September 30, 2017, certain individuals exercised warrants to purchase 2,476,666 shares of Common Stock for $3,798,999 in cash. During the nine months ended September 30, 2017, certain individuals exercised stock options to purchase 102,546 shares of Common Stock for $212,615 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 September 30, 2017, our days sales outstanding, or DSO, was 91 days compared to 92 days for the year ended December 31, 2016. 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

	Nine Months Ended September 30,	
	2017	2016
	(000s)	
Net cash used in operating activities	$ (55,350)	$ (53,524)
Net cash used in investing activities	$ (476)	$ (863)
Net cash provided by financing activities	$ 72,584	$ 137,216

Operating Activities

The principal use of cash in operating activities for the nine months ended September 30, 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 $1,826,000 in cash used in operating activities for the nine months ended September 30, 2017 compared with the comparable period in the prior year was due primarily to lower non-cash compensation expense coupled with changes in the components of working capital and decreased net loss.

Investing Activities

A decrease in spending on patent and trademarks and fixed assets resulted in a decrease in cash used in investing activities for the nine months ended September 30, 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 nine months ended September 30, 2017 included approximately $68,573,000 in proceeds from the sale of Common Stock and approximately $4,011,000 in proceeds from the exercise of options and warrants. The cash provided by financing activities during the nine months ended September 30, 2016, included approximately $134,864,000 in proceeds from the sale of Common Stock and approximately $2,352,000 in proceeds from the exercise of options and warrants.

Recently Issued Accounting Pronouncements

In May 2017, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, that clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. The new guidance will allow companies to make certain changes to awards without accounting for them as modifications. This guidance does not change the accounting for modifications. The guidance will be applied prospectively to awards modified on or after the adoption date and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including in an interim period. We do not expect that adoption of this guidance will have a material effect on our consolidated financial statements.

In August 2016, the FASB issued 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 do not expect that adoption of this guidance will have a material effect on our 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 the 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 issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We 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. We are currently in the process of drafting disclosures required by the new standard. 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 September 30, 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 purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on statements made by the defendants concerning the NDA for TX-004HR. The complaint sought unspecified damages, interest, attorneys' fees and other costs. On July 18, 2017, the complaint was voluntarily dismissed by the lead plaintiff without prejudice. We and certain of our officers and directors are also subject to two shareholder derivative lawsuits regarding the NDA for TX-004HR, one filed in the U.S. District Court for the Southern District of Florida on May 30, 2017 (Case No. 9:17-cv-80686-RLR) and one filed in Florida state court in Palm Beach County on June 5, 2017 (Case No. 502017CA006289XXXXMB). These complaints were both voluntarily dismissed by the lead plaintiffs without prejudice on August 14, 2017.

Item 1A. Risk Factors

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

Item 6. Exhibits

Exhibit	Date	Description
10.1	September 25, 2017	Underwriting Agreement by and between the Company and J.P. Morgan Securities LLC(1)
31.1*	November 7, 2017	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	November 7, 2017	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	November 7, 2017	Section 1350 Certification of Chief Executive Officer
32.2*	November 7, 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

1) Filed as Exhibit 1.1 to Form 8-K filed with the SEC on September 25, 2017 and incorporated herein by reference
* 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: November 7, 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)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

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

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

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

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

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

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

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

November 7, 2017

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daniel A. Cartwright, certify that:

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

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

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

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

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

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

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

November 7, 2017

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

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert G. Finizio, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

November 7, 2017

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

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

Exhibit 32.2

SECTION 1350 CERTIFICATION OF CHIEF FINANCIAL OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel A. Cartwright, Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

November 7, 2017

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer

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