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, 2015

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

For the transition period from_____ to _____

Commission File No. **001-00100**

THERAPEUTICSMD, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL 33487	**(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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)	

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 November 2, 2015 was 177,848,041.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
INDEX

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash	$ 81,123,988	$ 51,361,607
Accounts receivable, net of allowance for doubtful accounts of $96,916 and $59,753, respectively	3,666,586	2,154,217
Inventory	870,059	1,182,113
Other current assets	2,120,805	1,537,407
Total current assets	87,781,438	56,235,344
Fixed assets, net	56,748	63,293
Other Assets:		
Prepaid expense	1,172,051	1,427,263
Intangible assets, net	1,324,284	1,228,588
Security deposit	125,000	125,000
Total other assets	2,621,335	2,780,851
Total assets	$ 90,459,521	$ 59,079,488
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 5,301,625	$ 6,327,129
Other current liabilities	6,386,777	3,840,639
Deferred revenue	—	522,613
Total current liabilities	11,688,402	10,690,381
Long-Term Liabilities:		
Accrued expenses	1,213,874	—
Total liabilities	12,902,276	10,690,381
Commitments and Contingencies - See Note 15		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 350,000,000 and 250,000,000 shares authorized; 177,787,927 and 156,097,019 issued and outstanding, respectively	177,788	156,097
Additional paid-in capital	279,723,640	182,982,846
Accumulated deficit	(202,344,183)	(134,749,836)
Total stockholders' equity	77,557,245	48,389,107
Total liabilities and stockholders' equity	$ 90,459,521	$ 59,079,488

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues, net	$ 5,190,175	$ 4,186,261	$ 14,513,158	$ 10,768,572
Cost of goods sold	1,193,965	1,068,605	3,270,695	2,792,268
Gross profit	3,996,210	3,117,656	11,242,463	7,976,304
Operating expenses:				
Sales, general, and administration	7,060,944	6,043,354	20,089,998	16,610,015
Research and development	16,421,753	14,909,430	58,789,302	29,052,149
Depreciation and amortization	16,548	12,747	44,400	39,909
Total operating expenses	23,499,245	20,965,531	78,923,700	45,702,073
Operating loss	(19,503,035)	(17,847,875)	(67,681,237)	(37,725,769)
Other income (expense):				
Miscellaneous income	27,630	6,260	71,728	43,411
Interest income	2,760	9,364	15,162	27,756
Financing costs	—	—	—	(260,027)
Total other income (expense)	30,390	15,624	86,890	(188,860)
Loss before income taxes	(19,472,645)	(17,832,251)	(67,594,347)	(37,914,629)
Provision for income taxes	—	—	—	—
Net loss	$ (19,472,645)	$ (17,832,251)	$ (67,594,347)	$ (37,914,629)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	$ (0.11)	$ (0.12)	$ (0.39)	$ (0.26)
Weighted average number of common shares outstanding, basic and diluted	177,206,168	152,200,455	171,589,595	147,594,810

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, 2015	September 30, 2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (67,594,347)	$ (37,914,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	22,104	22,713
Amortization of intangible assets	22,296	17,196
Provision for doubtful accounts	37,163	2,594
Share-based compensation	4,740,906	3,934,836
Amortization of deferred financing costs	—	260,027
Changes in operating assets and liabilities:		
Accounts receivable	(1,549,532)	(460,565)
Inventory	312,054	31,673
Other current assets	(621,923)	197,569
Other assets	(15,162)	(17,069)
Accounts payable	(1,025,504)	3,534,462
Deferred revenue	(522,613)	(754,431)
Other current liabilities	2,546,138	909,890
Long term accrued expenses	1,213,874	—
Net cash used in operating activities	(62,434,546)	(30,235,734)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(117,992)	(193,349)
Purchase of property and equipment	(15,559)	(30,962)
Net cash used in investing activities	(133,551)	(224,311)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	91,374,649	42,771,353
Proceeds from exercise of options	589,829	315,546
Proceeds from exercise of warrants	366,000	181,000
Net cash provided by financing activities	92,330,478	43,267,899
Increase in cash	29,762,381	12,807,854
Cash, beginning of period	51,361,607	54,191,260
Cash, end of period	$ 81,123,988	$ 66,999,114

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 product company focused on creating and commercializing products targeted exclusively for women. As of the date of these unaudited consolidated financial statements, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of our advanced hormone therapy pharmaceutical products. The drug candidates used in our 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 equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins.

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, 2014, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2014. 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.

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS (Continued)

Recently Issued Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board, or FASB, issued final guidance that requires entities to measure inventory at the lower of cost or net realizable value rather than at the lower of cost or market (LOCOM). The guidance applies only to inventories for which cost is determined by methods other than last-in first-out (LIFO) or the retail inventory method (RIM). Entities that use LIFO or RIM will continue to use existing impairment models. The new guidance does not change the calculation of net realizable value that entities are required to calculate when applying existing LOCOM guidance. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Under the new guidance, however, entities will no longer need to calculate other measures of "market." The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In June 2015, the FASB issued Accounting Standards Update, or ASU, No. 2015-10, Technical Corrections and Improvements, to correct differences between original guidance and the Accounting Standards Codification, or ASC, clarify the guidance, correct references and make minor improvements affecting a variety of topics. Amendments that the FASB deemed more substantive are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The other amendments are effective immediately. We do not expect the adoption of ASU 2015-10 to have a material effect on our consolidated financial statements and disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of ASU 2014-15 to have a material effect on our consolidated financial statements and disclosures.

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. We are currently evaluating the impact of ASU 2014-09 on our consolidated financial statements and disclosures.

We do not believe there would have been a material effect on the accompanying consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Impairment of Long-Lived Assets

We review the carrying values of property and equipment and long-lived intangible assets for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. There was no impairment of any long-lived assets during the three and nine months ended September 30, 2015 and 2014.

Fair Value of Financial Instruments

Our financial instruments consist primarily of accounts receivable, accounts payable and accrued expenses. The carrying amount of accounts receivable, accounts payable and accrued expenses approximates their fair value because of the short-term maturity of such instruments.

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by ASC 820, *Fair Value Measurements*. 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, 2015 and December 31, 2014, 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 any required impairment test.

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 via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques.

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 in revenues, net, and bill them upon shipment. We include shipping expenses in cost of goods sold. A majority of our 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 sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce customers. We recognize our revenue from OTC sales, net of estimated returns, sales discounts, and eCommerce fees.

Prescription Products

We sell our name brand and generic prescription products primarily through drug wholesalers and retail pharmacies. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, and customer rebates.

We accept returns of unsalable product from customers 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. As of January 1, 2015, we started estimating returns based on historical return rates and recorded actual product returns against this reserve as received. Prior to January 1, 2015, we deferred the recognition of revenue on certain arrangements until the right of return no longer existed.

We maintain various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The consumer rebate program is designed to enable the end user to submit a coupon to us. If the coupon qualifies, we send a rebate check to the end user. We estimate the allowance for consumer rebates based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis.

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future research and development activities were $948,499 at September 30, 2015, of which $755,152 was included in Other current assets and $193,347 was included in long term Prepaid expense on the accompanying consolidated balance sheets. Advance payments to be expensed in future research and development activities were $1,175,082 at December 31, 2014, of which $711,362 was included in Other current assets and $463,720 was included in long term Prepaid expense 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 research and development expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as research and development expenses related to designing experiments to generate data for patents and to further the formulation development process for our pipeline technologies. Outside legal counsel also provided professional research and advice regarding research and development, 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. As of September 30, 2015, we classified $1,213,874 of the accrued clinical study costs as long term Accrued Expenses related to the costs that will be paid at the completion of one of our clinical trials. 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, 2015	December 31, 2014
Finished product	$ 787,232	$ 874,294
Raw material	82,827	155,341
Deferred costs	—	152,478
TOTAL INVENTORY	$ 870,059	$ 1,182,113

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2015	December 31, 2014
Prepaid insurance	$ 870,949	$ 394,878
Prepaid research and development costs	381,813	299,498
Prepaid consulting	373,339	411,864
Other receivables-related party (Note 13)	249,981	249,981
Other prepaid costs	219,086	181,186
Prepaid vendor deposits	25,637	—
TOTAL OTHER CURRENT ASSETS	$ 2,120,805	$ 1,537,407

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	September 30, 2015	December 31, 2014
Equipment	$ 132,150	$ 132,150
Furniture and fixtures	69,454	53,895
	201,604	186,045
Accumulated depreciation	(144,856)	(122,752)
TOTAL FIXED ASSETS, NET	$ 56,748	$ 63,293

Depreciation expense for the three months ended September 30, 2015 and 2014 was $7,856 and $7,122, respectively, and $22,104 and $22,713 for the nine months ended September 30, 2015 and 2014, respectively.

NOTE 7 – PREPAID EXPENSE

Prepaid expense (long-term) consists of the following:

	September 30, 2015	December 31, 2014
Prepaid manufacturing costs	$ 978,704	$ 963,543
Prepaid research and development costs	193,347	463,720
TOTAL PREPAID EXPENSE	$ 1,172,051	$ 1,427,263

NOTE 8 – INTANGIBLE ASSETS, NET

The following table sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets as of September 30, 2015 and December 31, 2014:

	September 30, 2015			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$ 31,951	$ (3,994)	$ 27,957	14
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	605,502	(40,199)	565,303	17.25
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents (pending)	585,241	—	585,241	n/a
Multiple trademarks for vitamins/supplements	145,783	—	145,783	indefinite
Total	$ 1,460,220	$ (135,936)	$ 1,324,284	

	December 31, 2014			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$ 31,951	$ (2,496)	$ 29,455	14.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	439,184	(19,401)	419,783	18
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents (pending)	675,982	—	675,982	n/a
Multiple trademarks for vitamins/supplements	103,368	—	103,368	indefinite
Total	$ 1,342,228	$ (113,640)	$ 1,228,588	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, we write-off any capitalized patent costs at that time.

Trademarks are perpetual and are not amortized. As of September 30, 2015, the remaining life related to OPERA® patent was approximately 14 years and the remaining life related to the approved hormone therapy drug candidate patents was approximately 17 years. During the three and nine months ended September 30, 2015 and 2014, there was no impairment recognized.

In addition to numerous pending patent applications, as of September 30, 2015, we had 13 issued patents, including:

- one method 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;
- twelve utility patents that relate to our combination progesterone and estradiol formulations, 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, Canada, the European Union, Israel, Mexico, Brazil, Japan, Russia, South Africa and South Korea.

Amortization expense was $8,692 and $5,625 for the three months ended September 30, 2015 and 2014, respectively and $22,296 and $17,196 for the nine months ended September 30, 2015 and 2014, respectively. Estimated amortization expense for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2015 (3 months)	$ 8,692
2016	$ 34,768
2017	$ 34,768
2018	$ 34,768
2019	$ 34,768

NOTE 9 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2015	December 31, 2014
Accrued clinical trial costs	$ 3,528,061	$ 1,706,542
Accrued payroll, bonuses and commission costs	930,913	814,205
Accrued legal and accounting expense	615,946	276,470
Accrued compensated absences	490,170	442,430
Other accrued expenses	388,268	185,965
Allowance for coupons and returns	208,361	90,446
Allowance for wholesale distributor fees	96,440	160,503
Accrued rent	86,998	91,368
Accrued royalties	41,620	72,710
TOTAL OTHER CURRENT LIABILITIES	$ 6,386,777	$ 3,840,639

NOTE 10 – NET LOSS PER SHARE

We calculate basic and diluted net loss per share allocable to common stockholders using the weighted-average number of shares of common stock, par value $0.001 per share, or Common Stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of our Common Stock outstanding subject to repurchase or forfeiture for the three and nine months ended September 30, 2015 and 2014.

Since we are in a net loss position, we have excluded outstanding stock options, all of which are subject to forfeiture, as well as warrants for the purchase of our Common Stock from our calculation of diluted net loss per share.

The table below presents the potentially dilutive securities that would have been included in our calculation of diluted net loss per share allocable to common stockholders if they were not antidilutive for the periods presented.

	As of September 30,	
	2015	2014
Stock options	17,414,242	16,851,943
Warrants	12,722,431	13,927,916
	30,136,673	30,779,859

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 2015, 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, 2015, we had 350,000,000 shares of Common Stock authorized, of which 177,787,927 shares of Common Stock were issued and outstanding.

On July 9, 2015, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC, as the representatives of the several underwriters, or the Stifel Underwriters, relating to an underwritten public offering of 3,846,154 shares of Common Stock at a public offering price of $7.80 per share. Under the terms of the underwriting agreement, we granted the Stifel Underwriters a 30-day option to purchase up to an aggregate of 576,923 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $32.2 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on July 15, 2015 and we issued 4,423,077 shares of our Common Stock.

On February 10, 2015, we entered into an underwriting agreement, or the Cowen Agreement, with Cowen and Company, LLC, as the representative of the several underwriters, or the Cowen Underwriters, relating to an underwritten public offering of 13,580,246 shares of Common Stock, at a public offering price of $4.05 per share. Under the terms of the Cowen Agreement, we granted the Cowen Underwriters a 30-day option to purchase up to an aggregate of 2,037,036 additional shares of Common Stock, which option was exercised in full. The net proceeds from the offering were approximately $59.1 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on February 17, 2015 and we issued 15,617,282 shares of our Common Stock.

On July 29, 2014, we entered into an underwriting agreement with Goldman Sachs & Co, or Goldman Sachs, as the representative of the underwriters named therein, or the Goldman Sachs Underwriters, relating to an underwritten public offering of 8,565,310 shares of Common Stock. The price to the public in the offering was $4.67 per share. Under the terms of the underwriting agreement, we granted the Goldman Sachs Underwriters a 30-day option to purchase up to an additional 1,284,796 shares of Common Stock. On July 30, 2014, the Goldman Sachs Underwriters exercised their option to purchase the additional 1,284,796 shares of Common Stock. Net proceeds from this offering were approximately $42.8 million, after deducting underwriting discounts and commissions and other offering expenses. The offering closed on August 4, 2014 and we issued 9,850,106 shares of our Common Stock.

Exercises During 2015

During the three months ended September 30, 2015, certain individuals exercised stock options to purchase 95,000 shares of Common Stock for $98,478 in cash. During the nine months ended September 30, 2015, certain individuals exercised stock options to purchase 472,867 shares of Common Stock for $589,829 in cash.

Exercises During 2014

During the nine months ended September 30, 2014, certain individuals exercised stock options to purchase 793,800 shares of Common Stock. Stock options to purchase shares of Common Stock were exercised as follows: (i) 674,193 options for $315,546 in cash and (ii) 119,607 options, pursuant to the stock options' cashless provision, wherein 113,837 shares of Common Stock were issued. Also during the nine months ended September 30, 2014, we issued 50,000 shares of Common Stock to an employee upon the vesting of restricted stock units that were granted in December 2013.

Warrants to Purchase Common Stock

As of September 30, 2015, we had warrants outstanding to purchase an aggregate of 12,772,431 shares of Common Stock with a weighted-average contractual remaining life of 1.92 years, and exercise prices ranging from $0.24 to $6.35 per share, resulting in a weighted average exercise price of $1.93 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes-Merton valuation model, or the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the warrant.

In January 2013, we granted warrants to purchase 1,250,000 shares of Common Stock in connection with the issuance of a Revolving Credit Note to Plato and Associates, LLC, or the Plato Warrant. The Plato Warrant has an exercise price of $3.20 per share. The Plato Warrant vested on October 31, 2013 and may be exercised prior to its expiration on January 31, 2019. The Plato Warrant, with a fair value of $1,711,956, was valued on the date of the grant using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. For the nine months ended September 30, 2015 and 2014, $0 and $260,027, respectively, was recorded as financing costs in connection with the issuance of the Plato Warrant on the accompanying consolidated financial statements.

In May 2013, we entered into a consulting agreement with Sancilio & Company, Inc., or SCI, to develop drug technology to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain U.S. Food and Drug Administration, or the FDA, approval for our drug candidates, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of 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 grant 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 five 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 the vesting using a term of five years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. As of September 30, 2015, we recorded $115,543 in other current assets in the accompanying consolidated financial statements with respect to such shares. During the three and nine month periods ended September 30, 2015 and 2014, we recorded $38,517 and $115,551, respectively, as non-cash compensation in the accompanying consolidated financial statements with respect to such shares; and

3. 283,334 shares will vest upon the receipt by us of any final FDA approval of a drug candidate that SCI helped us design. It is anticipated that this event will not occur before December 2016.

As of September 30, 2015, unamortized costs associated with the SCI warrants issued in 2013 and 2012 totaled approximately $567,000 and will be recognized over a period of 1.75 years.

During the nine months ended September 30, 2015, we granted warrants to purchase 50,000 shares of Common Stock to an outside consultant at an exercise price of $6.35 and the expiration date of April 6, 2020. The total non-cash compensation expense related to this warrant was $42,266 and $86,008, respectively, for the three and nine months ended September 30, 2015.

Warrant exercises

During the three months ended September 30, 2015, certain individuals and an entity exercised warrants to purchase 310,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 232,197 shares of Common Stock were issued. During the nine months ended September 30, 2015, certain individuals and an entity exercised warrants to purchase 1,255,485 shares of Common Stock as follows: (i) 945,485 shares of Common Stock were issued for $366,000 in cash and (ii) warrants to purchase 310,000 shares of Common Stock were exercised pursuant to the warrants' cashless exercise provisions, wherein 232,197 shares of Common Stock were issued.

During the nine months ended September 30, 2014, certain individuals exercised warrants to purchase 365,583 shares of Common Stock for $181,000 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. During the nine months ended September 30, 2015, we granted 1,231,000 non-qualified stock options under the 2009 Plan. As of September 30, 2015, there were non-qualified stock options to purchase 15,445,768 shares of Common Stock outstanding 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. There are 10,000,000 shares of Common Stock authorized for issuance thereunder. As of September 30, 2015, there were non-qualified stock options to purchase 1,968,474 shares of Common Stock outstanding 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 estimated 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 during the nine months ended September 30, 2015 and 2014 are set forth in the table below.

	Nine Months Ended September 30,	
	2015	2014
Risk-free interest rate	1.47-1.54%	1.68-1.77%
Volatility	58.77-62.94%	69.15-70.93%
Term (in years)	5.27-6.25	5-6.25
Dividend yield	0.00%	0.00%

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 expected term. Estimated volatility is a measure of the amount by which the price of our Common Stock is expected to fluctuate each year during the term of an award. Our estimated volatility is an average of the historical volatility of the stock prices of our peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the historical volatility of our peer entities due to the lack of sufficient historical data on our stock price. The average expected life is based on the contractual terms of the stock option using the simplified method.

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, 2014	16,792,443	$ 1.88	6.92	$ 43,996,311
Granted	1,231,000	$ 6.38		
Exercised	(472,867)	$ 1.25		
Expired/Forfeited	(136,334)	$ 3.01		
Balance at September 30, 2015	17,414,242	$ 2.21	6.09	$ 64,265,785
Vested and Exercisable at September 30, 2015	13,848,923	$ 1.59	5.49	$ 59,095,453

At September 30, 2015, our outstanding stock options had exercise prices ranging from $0.10 to $7.72 per share.

Share-based compensation expense for options recognized in our results of operations (based on vested awards) for the three and nine months ended September 30, 2015 were $1,626,862 and $4,328,964, respectively, and $1,047,493 and $3,341,604, respectively, for the same periods in 2014. ASC 718-10 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates. At September 30, 2015, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $5,593,000 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.3 years. No tax benefit was realized due to a continued pattern of operating losses.

NOTE 12 – INCOME TAXES

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We do not expect to pay any significant federal or state income tax for 2015 as a result of (i) the losses recorded during the nine months ended September 30, 2015, (ii) additional losses expected for the remainder of 2015, and/or (iii) net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is "more likely than not" that some component or all of the benefits of deferred tax assets will not be realized. As of September 30, 2015, we maintain a full valuation allowance for all deferred tax assets. Based on these requirements, no provision or benefit for income taxes has been recorded. There were no recorded unrecognized tax benefits at the end of the reporting period.

NOTE 13 – RELATED PARTIES

On February 29, 2012, Cooper C. Collins, who was then president and largest shareholder of Pernix Therapeutics, LLC, or Pernix, was elected to serve on our board of directors. From time to time, we have entered into agreements with Pernix in the normal course of business. All such agreements are reviewed by independent directors of our company or a committee consisting of independent directors of our company.

During the nine months ended September 30, 2015 and 2014, we did not engage in any transactions with Pernix. At September 30, 2015 and December 31, 2014, there were amounts due Pernix of approximately $46,000.

Additionally, there were amounts due to us from Pernix for legal fee reimbursement relating to a litigation matter stemming from a license and supply agreement in the amounts of approximately $250,000 at both September 30, 2015 and December 31, 2014.

NOTE 14 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 54% and 77% of our purchases supplied from one vendor for the nine months ended September 30, 2015 and 2014, 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. Revenue generated from four major customers accounted for approximately 90% and 95% of our recognized revenue for the nine months ended September 30, 2015 and 2014, respectively.

Customers that generated more than 10% of our sales are designated as customers “A”, “B”, “C” and “D”. During the nine months ended September 30, 2015, two customers generated more than 10% of revenues and during the nine months ended September 30, 2014, four customers generated more than 10% of revenues. During the nine months ended September 30, 2015, customer A generated approximately $6,930,000 in revenues and customer B generated approximately $3,005,000 in revenues. During the nine months ended September 30, 2014, customers A, B, C and D generated approximately $3,930,000, $1,846,000, $1,590,000 and $1,555,000 in sales, respectively.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

We lease administrative office space in Boca Raton, Florida pursuant to a 63 month non-cancelable operating lease that commenced on July 1, 2013 and expires on September 30, 2018. On February 18, 2015, we entered into an agreement to lease additional administrative office space in Boca Raton, Florida, pursuant to an addendum to such lease. This addendum was effective beginning April 1, 2015 and will expire with the original lease term on September 30, 2018.

The straight line rental expense related to our current lease totaled approximately $119,000 and $90,000 for the three months ended September 30, 2015 and 2014, respectively, and approximately $328,000 and $271,000 for the nine months ended September 30, 2015 and 2014, respectively. The 2014 amounts were partially offset by the rent income of approximately $6,000 and $42,000, respectively, for sublet space. We did not sublet any space during the nine months ended September 30, 2015.

As of September 30, 2015, future minimum rental payments are as follows:

Years Ending December 31,		
2015 (3 months)	$	121,698
2016		493,790
2017		507,087
2018		388,976
Minimum lease payments	$	1,511,551

NOTE 16 – SUBSEQUENT EVENTS

In October 2015, we completed enrollment in the REPLENISH trial, a phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The trial was designed to enroll approximately 1,750 patients at approximately 100 sites.

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 consolidated 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, 2014 filed with the Securities and Exchange Commission, or the Commission or the SEC, on March 12, 2015, 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 maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of our clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

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

On June 30, 2015, we exceeded the $750 million public float threshold to trigger “large accelerated filer” reporting status with the SEC beginning in fiscal year 2016. Consequently, as of January 1, 2016, we will no longer be an “accelerated filed” as such term is defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and we will need to comply with the large accelerated filer reporting deadlines for our Annual Report on Form 10-K for the fiscal year ending December 31, 2015, and our Quaterly Reports on Form 10-Q beginning with the quarter ending March 31, 2016.

Overview

We are a women’s health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products. The current drug candidates used in our 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 equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins.

Our common stock, par value $0.001 per share, or Common Stock, is traded on the NYSE MKT under the symbol “TXMD”. We maintain the following 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

Overview

We have obtained the U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our hormone therapy drug candidates: 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 vaginal estradiol softgel with estradiol alone.

We are currently conducting phase 3 clinical trials for TX-001HR and TX-004HR. In July 2014, we temporarily suspended enrollment in the phase 3 clinical trial for TX-002HR, and in October 2014 we temporarily stopped the trial in order to update the phase 3 protocol based on discussions with the FDA. We have no current plans to conduct clinical trials for TX-003HR.

TX-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal discomfort for post-menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to 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 of the REPLENISH Trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is 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 vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include 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 is designed to enroll approximately 1,750 patients at approximately 100 sites. We completed enrollment in the REPLENISH Trial in October 2015 and we currently anticipate that results of the trial will be reported in the fourth quarter of 2016 or the first quarter of 2017. Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-001HR during the fourth quarter of 2016 or the first quarter of 2017 and assuming 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 during the fourth quarter of 2017 or the first quarter of 2018.

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 chemically identical to 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 temporarily suspended enrollment and in October 2014 we temporarily stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. We intend to update 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 approved by the FDA, will 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 that we intend to propose.

TX-004HR is a vaginal estradiol softgel drug candidate for the treatment of vulvar and vaginal atrophy, or 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. We initiated the REJOICE Trial, a multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. We are conducting a single 12 week study, evaluating three different doses of estradiol: 4 mcg, 10 mcg and 25 mcg versus placebo. The FDA has noted that a single, large, well-controlled clinical trial to support safety and efficacy should be sufficient to submit an NDA for TX-004HR for the proposed indication and that to support the indication in a single trial, evidence of efficacy for a given dose would need to show statistical significance of at a 0.01 level. The study has been designed to include four primary endpoints: the reduction of vaginal pH levels to less than 5.0, an increase in superficial cells, a decrease in parabasal cells and the improvement of dyspareunia. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The trial is designed to enroll approximately 700 patients across approximately 100 sites. The last patient was enrolled in the REJOICE Trial in June 2015, and we have completed the last patient visit in the trial. We currently anticipate that the topline results of the trial will be reported during the fourth quarter of 2015. Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-004HR as soon as the first half of 2016 and that such NDA could be approved by the FDA as soon as the first quarter of 2017, assuming an FDA review period of ten months from the receipt date to the PDUFA date for a non-new molecular entity.

As of September 30, 2015, we had 13 issued patents, which included 11 utility patents that relate to our combination progesterone and estradiol formulations, one utility patent that relates to TX-004HR, which establishes an important intellectual property foundation for TX-004HR, and one method 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 products. 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.

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 were $948,499 at September 30, 2015, of which $755,152 was included in Other current assets and $193,347 was included in long term Prepaid expense on the accompanying consolidated balance sheets. Advance payments to be expensed in future research and development activities were $1,175,082 at December 31, 2014, of which $711,362 was included in Other current assets and $463,720 was included in long term Prepaid expense on the accompanying consolidated balance sheets.

The following table indicates our research and development expense by project/category for the periods indicated (in 000s):

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
TX-001HR	$ 8,175	$ 11,518	$ 27,504	$ 20,320
TX-002HR	6	85	18	1,381
TX-004HR	4,581	567	18,242	931
Other research and development[(1)]	3,660	2,739	13,025	6,420
	$ 16,422	$ 14,909	$ 58,789	$ 29,052

[(1)] Product costs are classified as other research and development expenses until one of our drug products receives IND approval from the FDA.

Research and development expenditures will continue to be significant as we continue development of our pipeline of novel drug candidates. We expect to incur significant research and development costs as we develop our drug pipeline, complete the ongoing clinical trials of our drug candidates, conduct our ongoing phase 3 clinical trials, manufacturing, scale-up, and prepare regulatory submissions.

The costs of clinical trials may vary significantly over the life of a project due 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 estimated expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties.

Results of Operations

Three months ended September 30, 2015 compared with three months ended September 30, 2014

	Three Months Ended September 30,		
	2015	2014	Change
		(000s)	
Revenues, net	$ 5,190	$ 4,186	$ 1,004
Cost of goods sold	1,194	1,069	125
Operating expenses	23,499	20,965	2,534
Operating loss	(19,503)	(17,848)	(1,655)
Total other income	31	16	15
Net loss	$ (19,472)	$ (17,832)	$ (1,640)

Revenues and Cost of Goods Sold

Revenues for the three months ended September 30, 2015 increased approximately $1,004,000, or 24%, to approximately $5,190,000, compared with approximately $4,186,000 for the three months ended September 30, 2014. Of this $1,004,000 increase, approximately $825,000, or 82%, was attributable to an increase in the number of units sold and approximately $179,000, or 18%, was attributable to product mix and an increase in the average net sales price of our products. Cost of goods sold increased approximately $125,000 or 12%, to approximately $1,194,000 for the three months ended September 30, 2015, compared with approximately $1,069,000 for the three months ended September 30, 2014. Cost of goods sold as a percentage of revenue was approximately 23% and 26% for the three months ended September 30, 2015 and 2014, respectively, which was primarily attributable to a favorable change in product mix.

Operating Expenses

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

	Three Months Ended September 30,	
	2015	2014*
Research and development costs	69.9%	71.1%
Human resource costs, including salaries, benefits and taxes	14.7%	12.8%
Sales and marketing costs, excluding human resource costs	6.2%	8.0%
Professional fees for legal, accounting and consulting	4.8%	3.5%
Other operating expenses	4.4%	4.6%

*Prior year numbers have been reclassified to conform to current year's presentation

Operating expenses increased by approximately $2,534,000 or 12%, to approximately $23,499,000 for the three months ended September 30, 2015, from approximately $20,965,000 for the three months ended September 30, 2014 as a result of the following items:

	(000s)
Increase in research and development costs	$ 1,513
Increase in human resource costs, including salaries, benefits and taxes	764
Increase in professional fees for legal, accounting and consulting	396
Increase in other operating expenses	82
Decrease in sales and marketing, excluding human resource costs	(221)
	$ 2,534

Research and development costs for the three months ended September 30, 2015 increased by approximately $1,513,000, or 10%, to approximately $16,422,000, compared with $14,909,000 for the three months ended September 30, 2014. 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. The increase in research and development costs was primarily due to an increase in scale-up and manufacturing activities for our phase 3 hormone therapy drug candidates, partially offset by lower clinical trial costs. Research and developments costs during the three months ended September 30, 2015 included the following research and development projects.

During the three months ending September 30, 2015 and the period from February 2013 (project inception) through September 30, 2015, we have incurred approximately $8,175,000 and $58,436,000, 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, 2015 and the period April 2013 (project inception) through September 30, 2015, we have incurred approximately $6,000 and $2,520,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the three months ended September 30, 2015 and the period from August 2014 (project inception) through September 30, 2015, we have incurred approximately $4,581,000 and $22,225,000, respectively, in research and development costs with respect to TX-004HR, our vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Research and Development” in our Annual Report. 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.” 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,” “Item 1. Business — Products in Development” and “Item 1. Business — Pharmaceutical Regulation” in our Annual Report. Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Human resource costs, including salaries, benefits and taxes, for the three months ended September 30, 2015 increased by approximately $764,000, or 28%, to approximately $3,465,000, compared with $2,701,000 for the three months ended September 30, 2014, primarily as a result of increases of approximately $520,000 in non-cash compensation related to stock option awards and approximately $244,000 in personnel costs.

Professional fees for the three months ended September 30, 2015 increased by approximately $396,000, or 54%, to approximately $1,129,000, compared with $733,000 for the three months ended September 30, 2014, primarily as a result of higher consulting fees.

Other operating expense for the three months ended September 30, 2015 increased by approximately $82,000, or 9%, to approximately $1,034,000, compared with $952,000 for the three months ended September 30, 2014, primarily as a result of increased travel and rent expense.

Sales and marketing costs for the three months ended September 30, 2015 decreased by approximately $221,000, or 13%, to approximately $1,448,000, compared with $1,669,000 for the three months ended September 30, 2014, as a result of decreased costs related to advertising programs.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $1,655,000, or 9%, to approximately $19,503,000 for the three months ended September 30, 2015, compared with approximately $17,848,000 for the three months ended September 30, 2014, primarily as a result of increased research and development costs associated with our continued development of our hormone therapy drug candidates, partially offset by increased revenue from sales of our prenatal vitamin products.

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.

Total other income

Other income increased by approximately $15,000, or 94%, to approximately $31,000 for the three months ended September 30, 2015 compared with $16,000 for the comparable period in 2014.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $1,640,000, or 9%, to approximately $19,472,000 for the three months ended September 30, 2015, compared with approximately $17,832,000 for the three months ended September 30, 2014. Net loss per share of Common Stock, basic and diluted, was $0.11 for the three months ended September 30, 2015, compared with $0.12 per share of Common Stock for the three months ended September 30, 2014.

Nine months ended September 30, 2015 compared with nine months ended September 30, 2014

	Nine Months Ended September 30,		
	2015	2014	Change
		(000s)	
Revenues, net	$ 14,513	$ 10,769	$ 3,744
Cost of goods sold	3,271	2,792	479
Operating expenses	78,923	45,703	33,220
Operating loss	(67,681)	(37,726)	(29,955)
Other income (expense)	87	(189)	276
Net loss	$ (67,594)	$ (37,915)	$ (29,679)

Revenues and Cost of Goods Sold

Revenues for the nine months ended September 30, 2015 increased approximately $3,744,000, or 35%, to approximately $14,513,000, compared with approximately $10,769,000 for the nine months ended September 30, 2014. Of this $3,744,000 increase, approximately $2,818,000, or 75 %, was attributable to an increase in the number of units sold and approximately $926,000, or 25%, was attributable to product mix and an increase in the average net sales price of our products. Cost of goods sold increased approximately $479,000, or 17%, to approximately $3,271,000 for the nine months ended September 30, 2015, compared with approximately $2,792,000 for the nine months ended September 30, 2014. Cost of goods sold as a percentage of revenue was approximately 23% and 26% for the nine months ended September 30, 2015 and 2014, respectively, which was primarily attributable to a favorable change in product mix.

Operating Expenses

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

	Nine Months Ended September 30,	
	2015	2014*
Research and development costs	74.5%	63.6%
Human resource costs, including salaries, benefits and taxes	12.2%	17.4%
Sales and marketing costs, excluding human resource costs	5.6%	9.9%
Professional fees for legal, accounting and consulting	3.9%	3.7%
Other operating expenses	3.8%	5.4%

*Prior year numbers have been reclassified to conform to current year's presentation

Operating expenses increased by approximately $33,220,000 or 73%, to approximately $78,923,000 for the nine months ended September 30, 2015, from approximately $45,703,000 for the nine months ended September 30, 2014 as a result of the following items:

	(000s)
Increase in research and development costs	$ 29,737
Increase in professional fees for legal, accounting and consulting	1,360
Increase in human resource costs, including salaries, benefits and taxes	1,674
Increase in other operating expenses	582
Decrease in sales and marketing, excluding human resource costs	(133)
	$ 33,220

Research and development costs for the nine months ended September 30, 2015 increased by approximately $29,737,000, or 102%, to approximately $58,789,000, compared with $29,052,000 for the nine months ended September 30, 2014. 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 increased as a direct result of the development of our hormone therapy candidates, related clinical trials and manufacturing, and scale-up. Research and developments costs during the nine months ended September 30, 2015 included the following research and development projects.

During the nine months ending September 30, 2015 and the period from February 2013 (project inception) through September 30, 2015, we have incurred approximately $27,504,000 and $58,436,000, 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, 2015 and the period April 2013 (project inception) through September 30, 2015, we have incurred approximately $18,000 and $2,520,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the nine months ended September 30, 2015 and the period from August 2014 (project inception) through September 30, 2015, we have incurred approximately $18,242,000 and $22,225,000, respectively, in research and development costs with respect to TX-004HR, our vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Research and Development” in our Annual Report. 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.” 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,” “Item 1. Business — Products in Development” and “Item 1. Business — Pharmaceutical Regulation” in our Annual Report. Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Professional fees for the nine months ended September 30, 2015 increased by approximately $1,360,000, or 79%, to approximately $3,072,000, compared with $1,712,000 for the nine months ended September 30, 2014, as a result of higher legal, consulting, accounting and Board of Director expenses.

Human resource costs, including salaries, benefits and taxes, for the nine months ended September 30, 2015 increased by approximately $1,674,000, or 21%, to approximately $9,644,000, compared with $7,970,000 for the nine months ended September 30, 2014, primarily as a result of an increase of approximately $978,000 in personnel costs, and an increase of approximately $696,000 in non-cash compensation related to stock option awards.

Other operating expense for the nine months ended September 30, 2015 increased by approximately $582,000, or 24%, to approximately $3,035,000, compared with approximately $2,453,000 for the nine months ended September 30, 2014, primarily as a result of increases in data services and insurance expenses.

Sales and marketing costs for the nine months ended September 30, 2015 decreased by approximately $133,000, or 3%, to approximately $4,383,000, compared with $4,516,000 for the nine months ended September 30, 2014, as a result of decreased marketing expense following the launch of our VitaPearl and Prena1 Pearl products during the first quarter of 2014, partially offset by increased costs related to sales force incentive programs during the nine months ended September 30, 2015.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $29,955,000, or 79%, to approximately $67,681,000 for the nine months ended September 30, 2015, compared with approximately $37,726,000 for the nine months ended September 30, 2014, primarily as a result of increased research and development costs associated with our continued development of our hormone therapy drug candidates, partially offset by increased revenue from sales of our prenatal vitamin products.

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.

Total other income (expense)

Total other income (expense) changed by approximately $276,000, or 146%, to non-operating income of approximately $87,000 for the nine months ended September 30, 2015 compared with an expense of approximately $189,000 for the comparable period in 2014. This change was primarily a result of the elimination of financing costs for the nine months ended September 30, 2015.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $29,679,000, or 78%, to approximately $67,594,000 for the nine months ended September 30, 2015, compared with approximately $37,915,000 for the nine months ended September 30, 2014. Net loss per share of Common Stock, basic and diluted, was $0.39 for the nine months ended September 30, 2015, compared with $0.26 per share of Common Stock for the nine months ended September 30, 2014.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our Common Stock and the private placement of equity and debt securities. For the years ending December 31, 2014 and 2013, we received approximately $43 million and $79 million in net proceeds, respectively, from the issuance of shares of our Common Stock. During the nine months ended September 30, 2015, we received approximately $91 million in net proceeds from the issuance of shares of our Common Stock. As of September 30, 2015, we had cash and cash equivalents totaling approximately $81 million, 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 July 9, 2015, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC, as the representatives of the several underwriters, or the Stifel Underwriters, relating to an underwritten public offering of 3,846,154 shares of Common Stock at a public offering price of $7.80 per share. Under the terms of the underwriting agreement, we granted the Stifel Underwriters a 30-day option to purchase up to an aggregate of 576,923 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $32.2 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on July 15, 2015 and we issued 4,423,077 shares of our Common Stock.

On February 10, 2015, we entered into an underwriting agreement, or the Cowen Agreement, with Cowen and Company, LLC, as the representative of the several underwriters, or the Cowen Underwriters, relating to an underwritten public offering of 13,580,246 shares of Common Stock, at a public offering price of $4.05 per share. Under the terms of the Cowen Agreement, we granted the Cowen Underwriters a 30-day option to purchase up to an aggregate of 2,037,036 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $59.1 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on February 17, 2015 and we issued 15,617,282 shares of our Common Stock.

We believe that our existing cash will allow us to fund our operating plan through at least the next 12 months. If our available cash is insufficient to satisfy our liquidity requirements, 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 interest 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 stockholders. 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 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,	
	2015	2014
	(000)	
Net cash used in operating activities	$ (62,434)	$ (30,236)
Net cash used in investing activities	$ (134)	$ (224)
Net cash provided by financing activities	$ 92,330	$ 43,268

Operating Activities

The use of cash in both periods resulted primarily from our net loss adjusted for non-cash charges and changes in components of working capital. The increase of approximately $32,198,000 in cash used in operating activities for the nine months ended September 30, 2015 compared with the comparable period in the prior year was due primarily to increased research and development, and sales, general, and administrative costs. These were partially offset by an increase of approximately $3,744,000 in revenue over the same periods.

Investing Activities

A reduction in spending on patent and trademarks and property and equipment resulted in a minor decrease in cash used in investing activities for the nine months ended September 30, 2015 compared with the same period in 2014.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the nine months ended September 30, 2015 consisted of the proceeds from the February 2015 and July 2015 underwritten public offering of our Common Stock and stock option and warrant exercises.

Contractual Obligations

On February 18, 2015, we entered into an agreement to lease additional administrative office space in Boca Raton, Florida, pursuant to an addendum to our existing 63 month non-cancelable operating lease that commenced on July 1, 2013 and expires on September 30, 2018. This addendum became effective April 1, 2015 and will expire with the original lease term on September 30, 2018. The lease addendum stipulates, among other things, average base monthly rents of $9,367 (inclusive of estimated operating expenses) and sales tax, for total minimum payments over the life of the lease of $393,429.

New Accounting Pronouncements

Recently Issued Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board, or FASB, issued final guidance that requires entities to measure inventory at the lower of cost or net realizable value rather than at the lower of cost or market (LOCOM). The guidance applies only to inventories for which cost is determined by methods other than last-in first-out (LIFO) or the retail inventory method (RIM). Entities that use LIFO or RIM will continue to use existing impairment models. The new guidance does not change the calculation of Entities already calculate net realizable value that entities are required to calculate when applying today's existing LOCOM guidance, and the new guidance doesn't change that calculation. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Under the new guidance, however, entities will no longer need to calculate other measures of "market." The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In June 2015 the FASB issued Accounting Standards Update, or ASU, Technical Corrections and Improvements, No. 2015-10, to correct differences between original guidance and the Accounting Standards Codification, or ASC, clarify the guidance, correct references and make minor improvements affecting a variety of topics. Amendments that the FASB deemed more substantive are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The other amendments are effective immediately. We do not expect the adoption of ASU 2015-10 to have a material effect on our consolidated financial statements and disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of ASU 2014-15 to have a material effect on our consolidated financial statements and disclosures.

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. We are currently evaluating the impact of ASU 2014-09 on our consolidated financial statements and disclosures.

We do not believe there would have been a material effect on the accompanying consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Critical Accounting Policies

The accompanying unaudited interim consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States. As such, we are required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We routinely evaluate our estimates based on historical experience and on various other assumptions that management believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended September 30, 2015, we did not experience any significant changes in estimates or judgments inherent in the preparation of our consolidated financial statements. A summary of our significant accounting policies is contained in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014 and Note 3 of our unaudited interim consolidated financial statements included in this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015.

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, 2015, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

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

On August 7, 2015, we issued 80,635 shares of Common Stock, pursuant to the warrant cashless exercise provision, upon the exercise of warrants previously issued to an outside service provider. On July 29, 2015, we issued 151,562 shares of Common Stock, pursuant to the warrant cashless exercise provision, upon the exercise of warrants previously issued to an outside party. The shares of Common Stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit	Date	Description
1.1	July 9, 2015	Underwriting Agreement, dated July 9, 2015, between the Company and Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC, as the representatives of the several underwriters named in Schedule A thereto (previously filed as Exhibit 1.1 to the Current Report on Form 8-K filed by the Company with the SEC on July 15, 2015 and incorporated herein by reference).
31.1*	November 5, 2015	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	November 5, 2015	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	November 5, 2015	Section 1350 Certification of Chief Executive Officer
32.2*	November 5, 2015	Section 1350 Certification of Chief Financial Officer
101.INS*	n/a	XBRL Instance Document
101.SCH*	n/a	XBRL Taxonomy Extension Schema Document
101.CAL*	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB*	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE*	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

* Filed herewith.

SIGNATURES

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

DATE: November 5, 2015

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 5, 2015

/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 5, 2015

/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, 2015 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 5, 2015

/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, 2015 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 5, 2015

/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.