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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

☐ **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. **010-001000**

THERAPEUTICSMD, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL 33487	**(561) 961-1900**
(Address of Principal Executive Offices)	(Issuer's Telephone Number)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ 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 þ 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 þ	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 þ

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of August 1, 2016 was 196,492,195.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash	$ 166,532,446	$ 64,706,355
Accounts receivable, net of allowance for doubtful accounts of $529,298 and $81,910, respectively	4,477,308	3,049,715
Inventory	883,656	690,153
Other current assets	2,136,735	2,233,897
Total current assets	174,030,145	70,680,120
Fixed assets, net	444,412	198,592
Other Assets:		
Intangible assets, net	1,983,829	1,615,251
Prepaid expense	—	1,109,883
Security deposit	129,864	125,000
Total other assets	2,113,693	2,850,134
Total assets	$ 176,588,250	$ 73,728,846
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,039,388	$ 3,126,174
Other current liabilities	6,299,783	7,539,526
Total current liabilities	9,339,171	10,665,700
Total liabilities	9,339,171	10,665,700
Commitments and Contingencies - See Note 15		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 350,000,000 shares authorized; 196,492,195 and 177,928,041 issued and outstanding, respectively	196,492	177,928
Additional paid in capital	428,902,951	282,712,078
Accumulated deficit	(261,850,364)	(219,826,860)
Total stockholders' equity	167,249,079	63,063,146
Total liabilities and stockholders' equity	$ 176,588,250	$ 73,728,846

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues, net	$ 4,403,247	$ 4,847,934	$ 9,333,338	$ 9,322,983
Cost of goods sold	1,130,108	1,033,089	2,238,551	2,076,730
Gross profit	3,273,139	3,814,845	7,094,787	7,246,253
Operating expenses:				
Sales, general, and administration	10,619,006	6,865,442	20,297,558	13,029,054
Research and development	13,841,193	24,190,714	28,938,210	42,367,549
Depreciation and amortization	24,262	14,280	43,859	27,852
Total operating expense	24,484,461	31,070,436	49,279,627	55,424,455
Operating loss	(21,211,322)	(27,255,591)	(42,184,840)	(48,178,202)
Other income:				
Miscellaneous income	114,320	25,585	155,937	44,098
Accreted interest	2,863	2,560	5,399	12,402
Total other income	117,183	28,145	161,336	56,500
Loss before taxes	(21,094,139)	(27,227,446)	(42,023,504)	(48,121,702)
Provision for income taxes	—	—	—	—
Net loss	$ (21,094,139)	$ (27,227,446)	$ (42,023,504)	$ (48,121,702)
Net loss per share, basic and diluted	$ (0.11)	$ (0.16)	$ (0.21)	$ (0.29)
Weighted average number of common shares outstanding	196,325,715	172,782,264	195,613,639	168,734,760

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

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

	Six Months Ended	
	June 30, 2016	June 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (42,023,504)	$ (48,121,702)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	19,216	14,248
Amortization of intangible assets	24,643	13,604
Provision for doubtful accounts	447,388	30,767
Share-based compensation	9,200,844	2,968,811
Changes in operating assets and liabilities:		
Accounts receivable	(1,874,980)	(1,190,068)
Inventory	(193,503)	(66,606)
Other current assets	1,001,120	383,194
Other assets	—	(12,410)
Accounts payable	(86,786)	(508,511)
Deferred revenue	—	(522,613)
Other current liabilities	(1,239,743)	2,047,264
Other long-term liabilities	—	967,286
Net cash used in operating activities	(34,725,305)	(43,996,736)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(393,221)	(78,792)
Purchase of fixed assets	(265,036)	(15,559)
Payment of security deposit	(4,864)	—
Net cash used in investing activities	(663,121)	(94,351)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	134,863,475	59,117,827
Proceeds from exercise of warrants	1,373,000	366,000
Proceeds from exercise of options	978,042	491,351
Net cash provided by financing activities	137,214,517	59,975,178
Increase in cash	101,826,091	15,884,091
Cash, beginning of period	64,706,355	51,361,607
Cash, end of period	$ 166,532,446	$ 67,245,698

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, 2015, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2015. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited interim consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year or any other interim period in the future.

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted in any annual or interim period for which financial statements have not been issued or made available for issuance, but all of the guidance must be adopted in the same period. If an entity early adopts the guidance in an interim period, any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330), simplifying the Measurement of Inventory. This guidance 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, if any, 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. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08) as well as accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10) and narrow-scope improvements and practical expedients (ASU 2016-12) in its new revenue standard. We are currently evaluating the impact of this guidance 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

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, which are considered Level 1 assets under the fair value hierarchy.

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by Accounting Standards Codification, or ASC, 820, *Fair Value Measurements.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1 unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2 quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
Level 3 unobservable inputs for the asset or liability.

At June 30, 2016 and 2015, we had no assets or liabilities that were valued at fair value on a recurring basis. The fair value of indefinite-lived assets or long-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with our impairment test. There was no impairment of intangible assets or long-lived assets during the three and six months ended June 30, 2016 and 2015.

Revenue Recognition

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

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product primarily via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques. The revenue that is generated by us from major customers is all generated from sales of our prescription prenatal vitamin products which is disclosed in Note 14. There are no major customers for our OTC prenatal vitamin or other products.

Over-the-Counter Products

We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound shipping and handling fees in revenues, net, and bill them upon shipment. We include shipping expenses in cost of goods sold. A majority of our OTC customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to OTC sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce OTC customers. We recognize revenue from OTC sales, net of estimated returns, 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 prescription products 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. We estimate returns based on historical return rates and recorded actual product returns against this reserve as received. We offer various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The consumer rebate program is designed to enable the end user to submit a coupon to us. If the coupon qualifies, we send a rebate check to the end user. We estimate the allowance for consumer rebates that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis.

Share-Based Compensation

We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include options, restricted stock, restricted stock units, performance-based awards, share appreciation rights, and employee share purchase plans. As such, compensation cost is measured on the date of grant at fair value. We amortize such compensation amounts, if any, over the requisite service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718 to value options. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including forfeiture rates, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

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

We generally recognize the compensation expense on a straight-line basis over the employee’s requisite service period. We estimate the forfeiture rate based on our historical experience of forfeitures. If our actual forfeiture rate is materially different from our estimate, share-based compensation expense could be significantly different from what we have recorded in the current period.

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 are capitalized, and were $364,959 at June 30, 2016, all of which was included in other current assets on the accompanying consolidated balance sheets. Advance payments to be expensed in future research and development activities were $1,138,073 at December 31, 2015, of which $1,009,175 was included in other current assets and $128,898 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 R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as R&D expenses related to designing experiments to generate data for patents and to further the formulation development process for our pipeline technologies. Outside legal counsel also provided professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

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:

	June 30, 2016	December 31, 2015
Finished product	$ 855,280	$ 661,167
Raw material	28,376	28,986
TOTAL INVENTORY	$ 883,656	$ 690,153

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	June 30, 2016	December 31, 2015
Prepaid insurance	$ 408,411	$ 695,421
Prepaid manufacturing costs	986,384	—
Prepaid consulting	257,796	334,822
Other prepaid costs	267,172	369,812
Prepaid vendor deposits	109,809	159,489
Prepaid research and development costs	107,163	674,353
TOTAL OTHER CURRENT ASSETS	$ 2,136,735	$ 2,233,897

NOTE 6 – FIXED ASSETS, NET

Fixed assets consist of the following:

	June 30, 2016	December 31, 2015
Accounting system in process	$ 310,015	$ 149,699
Equipment	226,165	132,150
Furniture and fixtures	80,158	69,454
	616,338	351,303
Accumulated depreciation	(171,926)	(152,711)
TOTAL FIXED ASSETS, NET	$ 444,412	$ 198,592

Depreciation expense for the three months ended June 30, 2016 and 2015 was $10,853 and $7,367, respectively, and $19,216 and $14,248 for the six months ended June 30, 2016 and 2015, respectively.

NOTE 7 – PREPAID EXPENSE

Prepaid expense consists of the following:

	June 30, 2016	December 31, 2015
Prepaid manufacturing costs	—	$ 980,985
Prepaid research and development costs	—	128,898
TOTAL PREPAID EXPENSE	—	$ 1,109,883

NOTE 8 – INTANGIBLE ASSETS, NET

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of June 30, 2016 and December 31, 2015:

	June 30, 2016			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$ 31,951	$ (5,492)	$ 26,459	13.25
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	954,817	(73,490)	881,327	16.5
Hormone therapy drug candidate patents (pending)	903,694	—	903,694	n/a
Non-amortizing intangible assets:				
Multiple trademarks for vitamins/supplements	172,349	—	172,349	indefinite
TOTAL	$ 2,154,554	$ (170,725)	$ 1,983,829	

	December 31, 2015			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$ 31,951	$ (4,493)	$ 27,458	13.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	705,752	(49,845)	655,907	17
Hormone therapy drug candidate patents (pending)	774,165	—	774,165	n/a
Non-amortizing intangible assets:				
Multiple trademarks for vitamins/supplements	157,721	—	157,721	indefinite
TOTAL	$ 1,761,332	$ (146,081)	$ 1,615,251	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. As of June 30, 2016, the remaining life related to OPERA® patent was approximately 13 years and the remaining life related to the approved hormone therapy drug candidate patents was approximately 16.5 years.

In addition to numerous pending patent applications, as of June 30, 2016, we had 17 issued patents, including:

- 13 utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us and are U.S. jurisdiction patents with expiration dates in 2032. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- two utility patents that relate to TX-004HR, our applicator-free vaginal estradiol softgel product candidate, which establish an important intellectual property foundation for TX-004HR, which are owned by us and are U.S. jurisdiction patents with expiration dates in 2033 and 2032. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- one utility patent that relates to a pipeline transdermal patch technology, which is owned by us and is a U.S. jurisdiction patent with an expiration date in 2032. We have pending patent applications with respect to this technology in Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa; and
- one utility patent that relates to our OPERA® information technology platform, which is owned by us and is a U.S. jurisdiction patent with an expiration date in 2029.

Amortization expense was $13,409 and $6,913 for the three months ended June 30, 2016 and 2015, respectively and $24,643 and $13,604 for the six months ended June 30, 2016 and 2015, respectively. Estimated amortization expense for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2016 (6 months)	$ 26,819
2017	$ 53,638
2018	$ 53,638
2019	$ 53,638
2020	$ 53,638

NOTE 9 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	June 30, 2016	December 31, 2015
Accrued clinical trial costs	$ 3,468,415	$ 3,725,377
Accrued payroll, bonuses and commission costs	1,003,541	2,108,143
Accrued compensated absences	705,326	562,096
Accrued legal and accounting expense	237,265	210,309
Other accrued expenses	511,809	546,264
Allowance for wholesale distributor fees	80,318	32,659
Accrued royalties	36,947	46,851
Allowance for coupons and returns	134,568	224,300
Accrued rent	121,594	83,527
TOTAL OTHER CURRENT LIABILITIES	$ 6,299,783	$ 7,539,526

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 six months ended June 30, 2016 and 2015.

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 potentially dilutive securities that could affect our calculation of diluted net loss per share allocable to common stockholders for the periods presented.

	Three and Six months ended	
	June 30, 2016	June 30, 2015
Stock options	20,668,657	17,525,200
Warrants	12,060,571	13,032,431
TOTAL	32,729,228	30,557,631

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At June 30, 2016, 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 June 30, 2016, we had 350,000,000 shares of Common Stock authorized, of which 196,492,195 shares of Common Stock were issued and outstanding.

On January 6, 2016, we entered into an underwriting agreement with Goldman Sachs & Co. and Cowen and Company, LLC, as the representatives of the several underwriters, or the Underwriters, relating to an underwritten public offering of 15,151,515 shares of our Common Stock at a public offering price of $8.25 per share. Under the terms of the underwriting agreement, we granted the Underwriters a 30-day option to purchase up to an aggregate of 2,272,727 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $134.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on January 12, 2016 and we issued 17,424,242 shares of our Common Stock.

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.

Exercises During 2016

During the three months ended June 30, 2016, certain individuals exercised stock options to purchase 77,123 shares of Common Stock for $191,592 in cash. During the six months ended June 30, 2016, certain individuals exercised stock options to purchase 417,168 shares of Common Stock for $978,042 in cash.

Exercises During 2015

During the three months ended June 30, 2015, certain individuals exercised stock options to purchase 366,617 shares of Common Stock for $484,143 in cash. During the six months ended June 30, 2015, certain individuals exercised stock options to purchase 377,867 shares of Common Stock for $491,351 in cash.

Warrants to Purchase Common Stock

As of June 30, 2016, we had warrants outstanding to purchase an aggregate of 12,060,571 shares of Common Stock with a weighted-average contractual remaining life of 1.5 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.08 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes-Merton valuation model, or the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the warrant. During the three months ended June 30, 2016, we granted warrants to purchase 125,000 shares of Common Stock to outside consultants at an exercise price of $8.20 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 74.10%; risk free rate of 1.04%; and dividend yield of 0%. The grant date fair value of the warrants was approximately $4.95 per share.

These warrants have an expiration date of April 21, 2021 and vest as follows: warrants to purchase 75,000 shares of Common Stock vested on April 21, 2016 and warrants to purchase 50,000 shares of Common Stock vest ratably over a 24-month period.

During the six months ended June 30, 2016, we granted warrants to purchase 245,000 shares of Common Stock to outside consultants at a weighted average exercise price of $7.90 per share. The weighted average grant date fair value of these warrants was $4.78 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 74.10%-74.15%; risk free rate of 1.04%-1.28%; and dividend yield of 0%. These warrants vest and have expiration dates as follows: warrants to purchase 75,000 shares of Common Stock vested on April 21, 2016 and have an expiration date of April 21, 2021, warrants to purchase 50,000 shares of Common Stock vest ratably over a 24-month period and have an expiration date of April 21, 2021, and warrants to purchase 120,000 shares of Common Stock vest ratable over a 12-month period and have an expiration date of January 21, 2021. During the three and six months ended June 30, 2015, we granted warrants to purchase 50,000 shares of Common Stock at an exercise price of $6.35 to an outside consultant. We recorded share-based compensation expense related to these warrants totaling $556,125 and $43,741 for the three months ended June 30, 2016 and 2015, respectively, and $683,590 and $43,741 for the six months ended June 30, 2016 and 2015, respectively, in the accompanying consolidated financial statements.

In May 2013, we entered into a consulting agreement to develop drug platforms to be used in our hormone replacement drug candidates. As consideration under the agreement, we agreed to issue the consultant a warrant to purchase 850,000 shares of our Common Stock at $2.01 per share that has vested or will vest as follows:

1. Warrants to purchase 283,333 shares were earned on May 11, 2013 upon acceptance of an Investigational New Drug application by FDA for an estradiol-based drug candidate in a softgel vaginal capsule for the treatment of VVA; however, pursuant to the terms of the agreement, the shares did not vest until June 30, 2013;
2. Warrants to purchase 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%. During the three months ended June 30, 2016 and 2015, we recorded share-based compensation expense of $38,509 and $38,517, respectively, related to these warrants and during the six months ended June 30, 2016 and 2015, we recorded $77,026 and $77,034, respectively, related to these warrants in the accompanying consolidated financial statements. As of June 30, 2016, the fair value of these warrants has been fully amortized;
3. Warrants to purchase 283,334 shares will vest upon the receipt by us of any final FDA approval of a drug candidate which the warrant holder helped us design. It is anticipated that this event will not occur before March 31, 2017.

In addition, during both the three months ended June 30, 2016 and 2015, we recorded share-based compensation expense of $64,449 and during both the six months ended June 30, 2016 and 2015, we recorded share-based compensation expense of $128,898 related to warrants issued in 2012 for services in support of our drug development efforts. As of June 30, 2016, unamortized costs associated with warrants issued to the same holder in 2012 and 2013 totaled approximately $258,000.

During the three months ended June 30, 2016, certain individuals exercised warrants to purchase 161,372 shares of our Common Stock for $63,000 in cash and during the three months ended June 30, 2015, certain individuals exercised warrants to purchase 20,000 shares of our Common Stock for $7,600 in cash. During the six months ended June 30, 2016, certain individuals exercised warrants to purchase 722,744 shares of our Common Stock for $1,373,000 in cash and during the six months ended June 30, 2015, certain individuals exercised warrants to purchase 945,485 shares of our Common Stock for $366,000 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 six months ended June 30, 2016, we granted 373,000 non-qualified stock options under the 2009 Plan. As of June 30, 2016, there were non-qualified stock options to purchase 17,800,183 shares of Common Stock outstanding and stock options to purchase 3,247,352 shares of Common Stock available to be issued under 2009 Plan.

In 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. There are 10,000,000 shares of Common Stock authorized for issuance thereunder. As of June 30, 2016, there were non-qualified stock options to purchase 2,868,474 shares of Common Stock outstanding and stock options to purchase 7,050,000 shares of Common Stock available to be issued under 2012 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The assumptions used in the Black-Scholes Model for options granted during the six months ended June 30, 2016 and 2015 are set forth in the table below.

	Six Months Ended June 30,	
	2016	2015
Risk-free interest rate	1.26-1.70%	1.47-1.54%
Volatility	70.44-71.22%	58.77-62.94%
Term (in years)	6.25	5.27-6.25
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 expected term 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, 2015	20,725,325	$ 3.28	6.5	$ 146,864,184
Granted	373,000	$ 7.92	9.7	
Exercised	(417,168)	$ 2.34		$ 2,518,090
Expired/Forfeited	(12,500)	$ 6.07		
Balance at June 30, 2016	20,668,657	$ 3.38	6.0	$ 107,122,188
Vested and Exercisable at June 30, 2016	16,782,792	$ 2.45	5.4	$ 102,042,737
Unvested at June 30, 2016	3,885,865	$ 7.42	9.0	$ 5,079,451

At June 30, 2016, our outstanding stock options had exercise prices ranging from $0.10 to $8.92 per share. The weighted average grant date fair value per share of options granted was $5.08 and $3.49 during the six months ended June 30, 2016 and 2015, respectively. Share-based compensation expense for options recognized in our results of operations is based on vested awards. Share-based compensation expense related to options for the three months ended June 30, 2016 and 2015 was $4,160,071 and $1,973,675, respectively, and $8,311,330 and $2,702,102, for the six months ended June 30, 2016 and 2015, respectively. We estimate forfeitures at the time of grant and revise the forfeiture rate in subsequent periods if actual forfeitures differ from the estimates. At June 30, 2016, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $13,321,000 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 1.9 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 six months ended June 30, 2016, (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 June 30, 2016, we maintain a full valuation allowance for all deferred tax assets. Based on these requirements, no provision or benefit for income taxes has been recorded. There were no recorded unrecognized tax benefits at the end of the reporting period.

NOTE 13 – RELATED PARTIES

In July 2015, J. Martin Carroll, a director of our Company, was appointed to the board of directors of Catalent, Inc. From time to time, we have entered into agreements with Catalent, Inc. in the normal course of business. Agreements with Catalent Inc. have been reviewed by independent directors of our Company or a committee consisting of independent directors of our Company since July 2015. During the three and six months ended June 30, 2016, the amounts billed by Catalent, Inc. were $613,919 and $2,078,776, respectively for manufacturing activities related to our clinical trials. As of June 30, 2016, there were amounts due to Catalent, Inc. of $493,721.

NOTE 14 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 96% and 98% of our purchases supplied from one vendor for both the six months ended June 30, 2016 and 2015, 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 major customers accounted for approximately 60% of our recognized revenue for the six months ended June 30, 2016 and revenue generated from major customers accounted for approximately 91% of our recognized revenue for the six months ended June 30, 2015. Customers that generated more than 10% of our sales are designated as customers “A”, “B”, and “C”. During the six months ended June 30, 2016, three customers each generated more than 10% of our total revenues and during the six months ended June 30, 2015, two customers each generated more than 10% of our total revenues. During the six months ended June 30, 2016, customers A, B and C generated approximately $2,237,000, $1,863,000 and $1,540,000, in revenues, respectively. During the six months ended June 30, 2015, customers A and B generated approximately $4,474,000 and $1,832,000, in revenues, respectively.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

We lease administrative office space in Boca Raton, Florida pursuant to a non-cancelable operating lease that commenced on July 1, 2013 and originally provided for a 63-month term. On February 18, 2015, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. In addition, on April 26, 2016, we entered into agreement with the same lessors to lease additional administrative office space in the same location. This agreement was effective beginning May 1, 2016 and extended the original expiration of the lease term to October 31, 2021.

The rental expense related to our lease during the three months ended June 30, 2016 and 2015 was approximately $182,000 and $119,000, respectively. The rental expense related to our lease during the six months ended June 30, 2016 and 2015 was approximately $300,000 and $209,000, respectively.

As of June 30, 2016, future minimum rental payments are as follows:

Years Ending December 31,		
2016 (6 months)	$	304,557
2017		600,236
2018		673,236
2019		810,234
2020		824,268
Thereafter		698,421
Total minimum lease payments	$	3,910,952

NOTE 16 – SUBSEQUENT EVENTS

We submitted the New Drug Application, or NDA, for TX-004HR with the U.S. Food and Drug Administration, or FDA, on July 7, 2016. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the recently completed phase 3 REJOICE Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial. Once submitted, the FDA has a 60-day filing review period to determine whether the NDA is sufficiently complete to permit the FDA to accept the NDA for filing.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

General

The following discussion and analysis provides information that we believe to be relevant to an assessment and understanding of our results of operations and financial condition for the periods described. This discussion should be read together with our consolidated financial statements and the notes to the financial statements, which are included in this Quarterly Report on Form 10-Q. This information should also be read in conjunction with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission, or the Commission or the SEC, on February 26, 2016, 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.

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 clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created using our SYMBODA™ hormone technology, which 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 websites at *www.therapeuticsmd.com*, *www.vitamedmd.com*, *www.vitamedmdrx.com*, and *www.bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites does not constitute part of this Quarterly Report on Form 10-Q.

Research and Development

We have obtained the U.S. Food and Drug Administration, or FDA, acceptance of our 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 applicator-free vaginal estradiol softgel with estradiol alone.

In December 2015, we completed a phase 3 clinical trial of TX-004HR and we are currently conducting a phase 3 clinical trial for TX-001HR. In July 2014, we suspended enrollment in the phase 3 clinical trial for TX-002HR and, in October 2014, we stopped the trial and are considering whether 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 – or having the same chemical and molecular structure as – the estradiol and progesterone produced by the ovaries would be approved for use in a single combined product.

On September 5, 2013, we began enrollment in the REPLENISH Trial, a multicenter, double-blind, placebo-controlled, phase 3 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 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 late in the fourth quarter of 2016. Based on such timeline and assuming a successful trial, we would anticipate a New Drug Application, or NDA, for TX-001HR to be submitted and potentially accepted as soon as the first half 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 as soon as the first quarter of 2018. As of August 2, 2016, approximately 1,642 patients have exited the REPLENISH Trial and the incidence of consensus endometrial hyperplasia among the three pathologists for these patients is less than 1%.

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as – the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. We are considering updating the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if proposed by us and approved by the FDA, would allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol if we propose it.

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. TX-004HR features our SYMBODA™ technology. This allows for the production of cohesive, stable formulations and provides content uniformity and accuracy of dosing strengths for TX-004HR. We initiated the REJOICE Trial, a randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of three doses – 25 mcg, 10 mcg and 4 mcg (compared to placebo) – of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause.

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

We submitted the NDA for TX-004HR with the FDA on July 7, 2016. The NDA submission was supported by the complete TX-004HR clinical program, including positive results of the recently completed phase 3 Rejoice Trial. The NDA submission included all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the REJOICE Trial. Once submitted, the FDA has a 60-day filing review period to determine whether the NDA is sufficiently complete to permit the FDA to accept the NDA for filing. If accepted, the NDA could be approved by the FDA as soon as the first half of 2017, assuming an FDA review period of ten months from the receipt date to the PDUFA date for a non-new molecular entity. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA.

As of June 30, 2016, we had 17 issued patents, which included 13 utility patents that relate to our combination progesterone and estradiol formulations, two utility patents that relate to TX-004HR, which establish an important intellectual property foundation for TX-004HR, one utility patent that relates to a pipeline transdermal patch technology, and one utility patent that relates to our OPERA® information technology platform.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug 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. Other research and development costs listed below consist of costs incurred with respect to drug products that have not received IND approval from the FDA.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future research and development activities are capitalized, and were $364,959 at June 30, 2016, all of which was included in other current assets on the accompanying consolidated balance sheets. Advance payments to be expensed in future research and development activities were $1,138,073 at December 31, 2015, of which $1,009,175 was included in other current assets and $128,898 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 June 30,		Six months ended June 30,	
	2016	2015	2016	2015
TX-001HR	$ 8,324	$ 10,718	$ 17,350	$ 19,329
TX-002HR	—	9	—	12
TX-004HR	2,676	8,614	5,113	13,661
Other research and development	2,841	4,849	6,475	9,365
	$ 13,841	$ 24,190	$ 28,938	$ 42,367

Research and development expenditures will continue to be significant as we continue development of our drug candidates and advance the development of our proprietary 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 planned phase 3 clinical trials, subject to receiving input from regulatory authorities, and prepare regulatory submissions.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include but are not limited to the following: per patient trial costs, the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial, the duration of patient follow-up; and the efficacy and safety profile of the drug candidate. We base our 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 June 30, 2016 compared with three months ended June 30, 2015

	Three Months Ended June 30,		
	2016	2015	Change
	(000s)		
Revenues, net	$ 4,403	$ 4,848	$ (445)
Cost of goods sold	1,130	1,033	97
Operating expenses	24,484	31,070	(6,586)
Operating loss	(21,211)	(27,255)	(6,044)
Other income	117	28	89
Net loss	$ (21,094)	$ (27,227)	$ (6,133)

Revenues and Cost of Goods Sold

Revenues for the three months ended June 30, 2016 decreased approximately $445,000, or 9%, to approximately $4,403,000, compared with approximately $4,848,000 for the three months ended June 30, 2015. This decrease was primarily attributable to a decrease in the average net sales price of our products partially offset by a small increase in the number of units sold. Cost of goods sold increased approximately $97,000 or 9%, to approximately $1,130,000 for the three months ended June 30, 2016, compared with approximately $1,033,000 for the three months ended June 30, 2015. Our gross margins decreased to 74% for the three months ended June 30, 2016 compared to 79% for the three months ended March 31, 2015. The gross margin change was primarily attributable to a decrease in average net sale price of our products.

Operating Expenses

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

	Three Months Ended June 30,	
	2016	2015
Research and development costs	56.5%	77.9%
Human resource costs, including salaries, benefits and taxes	24.8%	10.8%
Sales and marketing costs, excluding human resource costs	8.1%	4.8%
Professional fees for legal, accounting and consulting	3.5%	3.3%
Other operating expenses	7.1%	3.2%

Operating expenses decreased by approximately $6,586,000, or 21%, to approximately $24,484,000 for the three months ended June 30, 2016, from approximately $31,070,000 for the three months ended June 30, 2015 as a result of the following items:

	(000s)
Decrease in research and development costs	$ (10,349)
Increase in human resource costs, including salaries, benefits and taxes	2,717
Increase in other operating expenses	724
Increase in sales and marketing, excluding human resource costs	475
Decrease in professional fees for legal, accounting and consulting	(153)
	$ (6,586)

Research and development costs for the three months ended June 30, 2016 decreased by approximately $10,349,000, or 43%, to approximately $13,841,000, compared with approximately $24,190,000 for the three months ended June 30, 2015. Research and development costs include costs related to clinical trials as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased as a result of the completion of patient enrollment in the REPLENISH Trial for TX-001HR, our combination estradiol and progesterone drug candidate, which were partially offset by an increase in scale up and manufacturing activities to support future commercialization. Research and developments costs during the three months ended June 30, 2016 included the following research and development projects.

During the three months ending June 30, 2016 and the period from February 2013 (project inception) through June 30, 2016, we have incurred approximately $8,324,000 and $81,509,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the three months ended June 30, 2016 and the period from April 2013 (project inception) through June 30, 2016, we have incurred $0 and approximately $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the three months ended June 30, 2016 and the period from August 2014 (project inception) through June 30, 2016, we have incurred approximately $2,676,000 and $28,671,000, respectively, in research and development costs with respect to TX-004HR, our applicator-free vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Research and Development” in our Annual Report and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development” above. For a discussion of the risks and uncertainties associated with completing development of our products, see “Item 1A. Risk Factors — Risks Related to Our Business” in our Annual Report. For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see “Liquidity and Capital Resources” below. For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see “Item 1. Business — Our Hormone Therapy Drug Candidates,” “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 June 30, 2016 increased by approximately $2,717,000, or 81%, to approximately $6,074,000, compared with approximately $3,357,000 for the three months ended June 30, 2015, primarily as a result of an increase of approximately $1,731,000 in non-cash compensation related to stock awards and approximately $986,000 in personnel costs.

Other operating expense for the three months ended June 30, 2016 increased by approximately $724,000, or 72%, to approximately $1,729,000, compared with approximately $1,005,000 for the three months ended June 30, 2015, primarily as a result of software, data services and computer expenses as well as increased reserve for bad debt expense, and higher insurance and investor relations expenses.

Sales and marketing costs for the three months ended June 30, 2016 increased by approximately $475,000, or 32%, to approximately $1,975,000, compared with approximately $1,500,000 for the three months ended June 30, 2015, primarily as a result of increased expenses associated with sales and marketing efforts to support future commercialization, partially offset by a slight decrease in commission expense.

Professional fees for the three months ended June 30, 2016 decreased by approximately $153,000, or 15%, to approximately $864,000, compared with approximately $1,017,000 for the three months ended June 30, 2015, primarily as a result of decreased legal fees, partially offset by increased consulting expenses.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $6,044,000, or 22%, to approximately $21,211,000 for the three months ended June 30, 2016, compared with approximately $27,255,000 for the three months ended June 30, 2015, primarily as a result decreased research and development expenses and professional fees, partially offset by increased stock-based compensation expenses, personnel costs, marketing expenses and other operating expenses and a decrease in our revenue. As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Other Income

Other non-operating income increased by approximately $89,000 or 318%, to approximately $117,000 for the three months ended June 30, 2016 compared with approximately $28,000 for the comparable period in 2015, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss decreased approximately $6,133,000, or 23%, to approximately $21,094,000 for the three months ended June 30, 2016, compared with approximately $27,227,000 for the three months ended June 30, 2015. Net loss per share of Common Stock, basic and diluted, was ($0.11) for the three months ended June 30, 2016, compared with ($0.16) per share of Common Stock for the three months ended June 30, 2015.

Six months ended June 30, 2016 compared with six months ended June 30, 2015

	Six Months Ended June 30,		
	2016	2015	Change
		(000s)	
Revenues, net	$ 9,333	$ 9,323	$ 10
Cost of goods sold	2,239	2,077	162
Operating expenses	49,279	55,424	(6,145)
Operating loss	(42,185)	(48,178)	(5,993)
Other income	161	56	105
Net loss	$ (42,024)	$ (48,122)	$ (6,098)

Revenues and Cost of Goods Sold

Revenues for the six months ended June 30, 2016 increased approximately $10,000, or 0.1%, to approximately $9,333,000, compared with approximately $9,323,000 for the six months ended June 30, 2015. This increase was attributable to an increase in the number of units sold partially offset by a decrease in the average net sales price of our products. Cost of goods sold increased approximately $162,000, or 8%, to approximately $2,239,000 for the six months ended June 30, 2016, compared with approximately $2,077,000 for the six months ended June 30, 2015. Our gross margins decreased to 76% for the six months ended June 30, 2016 compared to 78% for the six months ended March 31, 2015. The gross margin change was primarily attributable to a decrease in average net sale price of our products.

Operating Expenses

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

	Six Months Ended June 30,	
	2016	2015
Research and development costs	58.7%	76.5%
Human resource costs, including salaries, benefits and taxes	23.0%	11.1%
Sales and marketing costs, excluding human resource costs	7.3%	5.3%
Professional fees for legal, accounting and consulting	4.4%	3.5%
Other operating expenses	6.6%	3.6%

Operating expenses decreased by approximately $6,145,000, or 11%, to approximately $49,279,000 for the six months ended June 30, 2016, from approximately $55,424,000 for the six months ended June 30, 2015 as a result of the following items:

	(000s)
Decrease in research and development costs	$ (13,429)
Increase in human resource costs, including salaries, benefits and taxes	5,165
Increase in other operating expenses	1,237
Increase in sales and marketing, excluding human resource costs	660
Increase in professional fees for legal, accounting and consulting	222
	$ 6,145

Research and development costs for the six months ended June 30, 2016 decreased by approximately $13,429,000, or 32%, to approximately $28,938,000, compared with approximately $42,367,000 for the six months ended June 30, 2015. Research and development costs include costs related to clinical trials as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased as a result of the completion of patient enrollment in the REPLENISH Trial for TX-001HR, our combination estradiol and progesterone drug candidate, which were partially offset by an increase in scale up and manufacturing activities to support future commercialization. Research and developments costs during the six months ended June 30, 2016 included the following research and development projects.

During the six months ending June 30, 2016 and the period from February 2013 (project inception) through June 30, 2016, we have incurred approximately $17,350,000 and $81,509,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the six months ended June 30, 2016 and the period April 2013 (project inception) through June 30, 2016, we have incurred $0 and approximately $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the six months ended June 30, 2016 and the period from August 2014 (project inception) through June 30, 2016, we have incurred approximately $5,113,000 and $28,671,000, respectively, in research and development costs with respect to TX-004HR, our applicator-free vaginal estradiol softgel drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Research and Development” in our Annual Report and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development” above. For a discussion of the risks and uncertainties associated with completing development of our products, see “Item 1A. Risk Factors — Risks Related to Our Business” in our Annual Report. For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see “Liquidity and Capital Resources” below. For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see “Item 1. Business — Our Hormone Therapy Drug Candidates,” “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 six months ended June 30, 2016 increased by approximately $5,165,000, or 84%, to approximately $11,344,000, compared with approximately $6,179,000 for the six months ended June 30, 2015, primarily as a result of an increase of approximately $3,919,000 in non-cash compensation related to stock awards and approximately $1,246,000 in personnel costs.

Other operating expense for the six months ended June 30, 2016 increased by approximately $1,237,000, or 62%, to approximately $3,237,000, compared with approximately $2,000,000 for the six months ended June 30, 2015, primarily as a result of increased reserved for bad debt, higher investor relations, insurance and other office expenses.

Sales and marketing costs for the six months ended June 30, 2016 increased by approximately $660,000, or 22%, to approximately $3,594,000, compared with approximately $2,934,000 for the six months ended June 30, 2015, primarily as a result of increased expenses associated with sales, marketing and future commercialization efforts.

Professional fees for the six months ended June 30, 2016 increased by approximately $222,000, or 11%, to approximately $2,165,000, compared with approximately $1,943,000 for the six months ended June 30, 2015, primarily as a result of increased consulting expenses.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $5,993,000, or 12%, to approximately $42,185,000 for the six months ended June 30, 2016, compared with approximately $48,178,000 for the six months ended June 30, 2015, primarily as a result of decreased research and development costs, partially offset by increased stock-based compensation expense, personnel costs, sales and marketing costs and other operating expenses. As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Other Income

Other non-operating income increased by approximately $105,000, or 188%, to approximately $161,000 for the six months ended June 30, 2016 compared with approximately $56,000 for the comparable period in 2015, primarily as a result of increased interest income.

Net Loss

As a result of the net effects of the foregoing, net loss decreased approximately $6,098,000, or 13%, to approximately $42,024,000 for the six months ended June 30, 2016, compared with approximately $48,122,000 for the six months ended June 30, 2015. Net loss per share of Common Stock, basic and diluted, was ($0.21) for the six months ended June 30, 2016, compared with ($0.29) per share of Common Stock for the six months ended June 30, 2015.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our Common Stock and private placements of equity and debt securities. For the six months ended June 30, 2016 and the year ended December 31, 2015, we received approximately $134.9 million and $91.4 million in net proceeds, respectively, from the issuance of shares of our Common Stock. As of June 30, 2016, we had cash and cash equivalents totaling approximately $166.5 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 January 6, 2016, we entered into an underwriting agreement with Goldman Sachs & Co. and Cowen and Company, LLC, as the representatives of the several underwriters, or the Underwriters, relating to an underwritten public offering of 15,151,515 shares of our Common Stock at a public offering price of $8.25 per share. Under the terms of the underwriting agreement, we granted the Underwriters a 30-day option to purchase up to an aggregate of 2,272,727 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $134.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on January 12, 2016 and we issued 17,424,242 shares of our Common Stock.

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 interests of our existing shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products. Additionally, we may have to grant licenses on terms that may not be favorable to us.

We need substantial amounts of cash to complete the clinical development of 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

	Six Months Ended March 31,	
	2016	2015
	(000s)	
Net cash used in operating activities	$ (34,725)	$ (43,997)
Net cash used in investing activities	$ (663)	$ (94)
Net cash provided by financing activities	$ 137,214	$ 59,975

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 decrease of approximately $9,272,000 in cash used in operating activities for the six months ended June 30, 2016 compared with the comparable period in the prior year was due primarily to changes in research and development, and sales, general, and administrative costs.

Investing Activities

An increase in spending on patent and trademarks and fixed assets resulted in an increase in cash used in investing activities for the six months ended June 30, 2016 compared with the same period in 2015.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the both the six months ended June 30, 2016 and 2015 consisted of proceeds from underwritten public offerings of our Common Stock and stock option and warrant exercises.

Contractual Obligations

On April 26, 2016, 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. This addendum was effective beginning May 1, 2016 and extended all operating lease terms to October 31, 2021.

New Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting. This guidance simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted in any annual or interim period for which financial statements have not been issued or made available for issuance, but all of the guidance must be adopted in the same period. If an entity early adopts the guidance in an interim period, any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. We are currently evaluating the impact of this guidance on our consolidated financial statements and disclosures.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330), simplifying the Measurement of Inventory. This guidance 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, if any, 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. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08) as well as accounting for licenses of intellectual property and identifying performance obligations (ASU 2016-10) and narrow-scope improvements and practical expedients (ASU 2016-12) in its new revenue standard. We are currently evaluating the impact of this guidance 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.

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 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

Effective June 30, 2016, we implemented a new general ledger accounting system. We believe we have taken the necessary steps to maintain appropriate levels of internal control over financial reporting during this period of change and we continuously monitor controls through and around the system to provide reasonable assurance that such controls are effective.

During the three months ended June 30, 2016, there were no other 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 May 6, 2016, we issued 61,372 shares of our Common Stock upon the exercise of warrants previously issued to a director of our company and received proceeds of $25,000 in connection with this exercise. On June 30, 2016, we issued 100,000 shares of our Common Stock upon the exercise of warrants previously issued to two consultants and received aggregate proceeds of $38,000 in connection with these exercises. Proceeds from these transactions were used in working capital. The shares of Common Stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit	Date	Description
31.1*	August 5, 2016	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	August 5, 2016	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	August 5, 2016	Section 1350 Certification of Chief Executive Officer
32.2*	August 5, 2016	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: August 5, 2016

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.

August 5, 2016

/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.

August 5, 2016

/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 June 30, 2016 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.

August 5, 2016

/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 June 30, 2016 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.

August 5, 2016

/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.