TherapeuticsMD, Inc.
Form 10-Q
November 05, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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

For the transition period from_____ to _____

Commission File No. **001-00100**

THERAPEUTICSMD, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL 33487 **(561) 961-1900**
(Address of Principal Executive Offices) (Issuer's Telephone Number)

N/A

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of November 2, 2015 was 177,848,041.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

THERAPEUTICSMD, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash	$81,123,988	$51,361,607
Accounts receivable, net of allowance for doubtful accounts of $96,916 and $59,753, respectively	3,666,586	2,154,217
Inventory	870,059	1,182,113
Other current assets	2,120,805	1,537,407
Total current assets	87,781,438	56,235,344
Fixed assets, net	56,748	63,293
Other Assets:		
Prepaid expense	1,172,051	1,427,263
Intangible assets, net	1,324,284	1,228,588
Security deposit	125,000	125,000
Total other assets	2,621,335	2,780,851
Total assets	$90,459,521	$59,079,488
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$5,301,625	$6,327,129
Other current liabilities	6,386,777	3,840,639
Deferred revenue	—	522,613
Total current liabilities	11,688,402	10,690,381
Long-Term Liabilities:		
Accrued expenses	1,213,874	—
Total liabilities	12,902,276	10,690,381
Commitments and Contingencies - See Note 15		
Stockholders' Equity:		

Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 350,000,000 and 250,000,000 shares authorized; 177,787,927 and 156,097,019 issued and outstanding, respectively	177,788	156,097
Additional paid-in capital	279,723,640	182,982,846
Accumulated deficit	(202,344,183)	(134,749,836)
Total stockholders' equity	77,557,245	48,389,107
Total liabilities and stockholders' equity	$90,459,521	$59,079,488

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

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

Cash, end of period	$81,123,988	$66,999,114

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

NOTE 1 – THE COMPANY

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

Nature of Business

We are a women’s health care product company focused on creating and commercializing products targeted exclusively for women. As of the date of these unaudited consolidated financial statements, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of our advanced hormone therapy pharmaceutical products. The drug candidates used in our clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal discomfort. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins.

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements of TherapeuticsMD, Inc., which include our wholly owned subsidiaries, should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the

Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2014. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited interim consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year, or any other interim period.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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

Recently Issued Accounting Pronouncements

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

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

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

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

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Impairment of Long-Lived Assets

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

Fair Value of Financial Instruments

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

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

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

At September 30, 2015 and December 31, 2014, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets or long-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with any required impairment test.

Revenue Recognition

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

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques.

Over-the-Counter Products

We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound shipping and handling fees in revenues, net, and bill them upon shipment. We include shipping expenses in cost of goods sold. A majority of our customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce customers. We recognize our revenue from OTC sales, net of estimated returns, sales discounts, and eCommerce fees.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

Prescription Products

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

We accept returns of unsalable product from customers within a return period of six months prior to and up to 12 months following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture. As of January 1, 2015, we started estimating returns based on historical return rates and recorded actual product returns against this reserve as received. Prior to January 1, 2015, we deferred the recognition of revenue on certain arrangements until the right of return no longer existed.

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

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future research and development activities were $948,499 at September 30, 2015, of which $755,152 was included in Other current assets and $193,347 was included in long term Prepaid expense on the accompanying consolidated balance sheets. Advance payments to be expensed in future research and development activities were $1,175,082 at December 31, 2014, of which $711,362 was included in Other current assets and $463,720 was included in long term Prepaid expense on the accompanying consolidated balance sheets. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal fees and costs. The activities undertaken by our regulatory consultants that were classified as research and development expenses include assisting, consulting with, and advising

our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as research and development expenses related to designing experiments to generate data for patents and to further the formulation development process for our pipeline technologies. Outside legal counsel also provided professional research and advice regarding research and development, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. As of September 30, 2015, we classified $1,213,874 of the accrued clinical study costs as long term Accrued Expenses related to the costs that will be paid at the completion of one of our clinical trials. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

Segment Reporting

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

NOTE 4 – INVENTORY

Inventory consists of the following:

	September 30, 2015	December 31, 2014
Finished product	$787,232	$874,294
Raw material	82,827	155,341
Deferred costs	—	152,478
TOTAL INVENTORY	$870,059	$1,182,113

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2015	December 31, 2014
Prepaid insurance	$870,949	$394,878

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

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

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

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

NOTE 7 – PREPAID EXPENSE

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

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