

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

FORM 8-K

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

Date of Report (Date of earliest event reported): November 4, 2015

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW,
Third Floor
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On November 4, 2015, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its third fiscal quarter ended September 30, 2015. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information in this Current Report shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit
Number

Description

99.1	Press Release from TherapeuticsMD, Inc., dated November 4, 2015, entitled “TherapeuticsMD announces third quarter 2015 financial results.”
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SIGNATURES

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

Date: November 4, 2015

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright
Name: Daniel A. Cartwright
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit
Number

Description

99.1

[Press Release from TherapeuticsMD, Inc., dated November 4, 2015, entitled "TherapeuticsMD announces third quarter 2015 financial results."](#)



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2015 Financial Results

- *Topline phase 3 data anticipated in fourth quarter for TX-004HR to treat symptoms of VVA –*
- *Completed enrollment in phase 3 Replenish Trial for first potential FDA-approved bio-identical oral combination hormone therapy –*
- *Management to host conference call today at 4:30 p.m. EST –*

BOCA RATON, Fla. – November 4, 2015 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its third quarter financial results for the period ended September 30, 2015.

Recent and Third Quarter Developments

- Revenues, net for the company’s prescription prenatal vitamin business increased to approximately \$5.2 million for the third quarter of 2015 compared with approximately \$4.2 million for the third quarter of 2014.
- Net loss was approximately \$19.5 million for the third quarter of 2015, compared with approximately \$17.8 million for the third quarter of 2014, reflecting the costs of two phase 3 clinical trials for the company’s novel hormone therapy drug candidates.
- Completed last patient visit in the Rejoice Trial, a phase 3 clinical trial of TX-004HR, an applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause.
- Completed patient enrollment in the Replenish Trial, a phase 3 clinical trial of TX-001HR, a combination estradiol and progesterone drug candidate, for the treatment of moderate to severe vasomotor symptoms due to menopause.
- Ended the quarter with approximately \$81.1 million in cash and no debt.
- Grew the company’s intellectual property portfolio to a current total of 111 patent filings, including 61 international filings, with two allowed and 13 issued U.S. patents.
- Supported scientific abstracts and presentations at the annual meeting of the North American Menopause Society.
- Continued to develop relationships with key medical, pharmacy, patient and industry organizations.

“As we pursue our mission to address women’s health needs, we believe that there is a unique confluence of factors evolving on the scientific, regulatory, legislative and commercial fronts that will help us to make significant progress toward delivering on our vision and strategy,” said TherapeuticsMD CEO Robert G. Finizio. “We continue to execute both commercially and in R&D, including completion of enrollment in our Replenish Trial of TX-001HR, our combination estradiol and progesterone drug candidate for treatment of moderate to severe vasomotor symptoms due to menopause. We also expect topline data from our Rejoice Trial of TX-004HR for dyspareunia associated with VVA by the end of this year. The market need for our products is large and growing, and we are building key alliances with healthcare providers, women’s health advocates and industry organizations.”

Third Quarter Financial Results Summary

Revenues, net for the third quarter of 2015 increased by 24 percent to approximately \$5.2 million compared with revenues, net of approximately \$4.2 million for the prior year's quarter. Revenue growth during the third quarter was primarily driven by increased number of units sold, product mix, and average net sales price of the company's prenatal vitamin products.

Cost of goods sold increased to approximately \$1.2 million for the three months ended September 30, 2015, compared with approximately \$1.1 million in the prior year's quarter.

Total operating expenses for the third quarter of 2015 included research and development (R&D) expenses and sales, general and administration (SG&A). R&D expenses for the third quarter of 2015 were approximately \$16.4 million compared with approximately \$14.9 million for the prior year's quarter. The increase in R&D expense was primarily due to an increase in scale-up and manufacturing activities for the company's phase 3 drugs in development, which was partially offset by lower clinical trial costs. SG&A expenses for the third quarter of 2015 were approximately \$7.0 million compared with approximately \$6.0 million for the third quarter of 2014, primarily as a result of increases in human resources costs and professional fees, which were partially offset by a decrease in marketing costs.

Non-operating income remained insignificant for the third quarter of 2015 and 2014 and included miscellaneous and interest income for both periods.

Net loss for the third quarter of 2015 was approximately \$19.5 million, or \$0.11 per basic and diluted share, compared with approximately \$17.8 million, or \$0.12 per basic and diluted share, for the third quarter of 2014.

At September 30, 2015, TherapeuticsMD had cash on hand of approximately \$81.1 million, compared with approximately \$51.4 million at December 31, 2014.

Conference Call Today

As previously announced, TherapeuticsMD will host a conference call today to discuss these financial results and provide a business update. Details for the call are:

Date:	Wednesday, November 4, 2015
Time:	4:30 p.m. EST
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	61714687

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, on the "Home Page" or under the "Investor" section.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. With its SYMBODA™ technology, TherapeuticsMD is developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. The company's clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® brands. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com and www.bocagreenmd.com.

This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates 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 in this press release are made as of the date of this press release, and the company undertakes 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 the company's 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 the company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize its hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of the company's clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of the company's hormone therapy drug candidates; the company's reliance on third parties to conduct its clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the company's common stock and the concentration of power in its stock ownership. PDF copies of the company's historical press releases and financial tables can be viewed and downloaded at its website: www.therapeuticsmd.com/pressreleases.aspx.

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Contacts

Investors:

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Chief Financial Officer

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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		
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

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	<u>3,996,210</u>	<u>3,117,656</u>	<u>11,242,463</u>	<u>7,976,304</u>
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	<u>23,499,245</u>	<u>20,965,531</u>	<u>78,923,700</u>	<u>45,702,073</u>
Operating loss	<u>(19,503,035)</u>	<u>(17,847,875)</u>	<u>(67,681,237)</u>	<u>(37,725,769)</u>
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)	<u>30,390</u>	<u>15,624</u>	<u>86,890</u>	<u>(188,860)</u>
Loss before income taxes	<u>(19,472,645)</u>	<u>(17,832,251)</u>	<u>(67,594,347)</u>	<u>(37,914,629)</u>
Provision for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$ (19,472,645)</u>	<u>\$ (17,832,251)</u>	<u>\$ (67,594,347)</u>	<u>\$ (37,914,629)</u>
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.12)</u>	<u>\$ (0.39)</u>	<u>\$ (0.26)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>177,206,168</u>	<u>152,200,455</u>	<u>171,589,595</u>	<u>147,594,810</u>

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	<u>(62,434,546)</u>	<u>(30,235,734)</u>
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	<u>(133,551)</u>	<u>(224,311)</u>
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	<u>92,330,478</u>	<u>43,267,899</u>
Increase in cash	29,762,381	12,807,854
Cash, beginning of period	51,361,607	54,191,260
Cash, end of period	<u>\$ 81,123,988</u>	<u>\$ 66,999,114</u>