# 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 6, 2014

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

001-00100

Nevada (State or Other

Jurisdiction of Incorporation)

(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))

## Item 2.02. Results of Operations and Financial Condition.

On November 6, 2014, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its third fiscal quarter ended September 30, 2014. 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.	
<u>Exhibit</u> <u>Number</u>	Description
99.1	Press Release from TherapeuticsMD, Inc., dated November 6, 2014, entitled "TherapeuticsMD announces third quarter financial results."

# 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 6, 2014

# THERAPEUTICSMD, INC.

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

# EXHIBIT INDEX

Exhibit <u>Number</u>	Description
99.1	Press Release from TherapeuticsMD, Inc., dated November 6, 2014, entitled "TherapeuticsMD announces third quarter financial results."

Exhibit 99.1

# Therapeutics MD<sup>®</sup>

## FOR IMMEDIATE RELEASE

#### TherapeuticsMD announces third quarter financial results

- Company advances two phase 3 programs for novel hormone therapy product candidates -

- Sales increased by 82 percent over prior year period -

- Management to host conference call today at 4:30 p.m. EST -

**BOCA RATON, Fla., Nov. 6, 2014** – TherapeuticsMD Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced its third quarter financial results for the period ending Sept. 30, 2014.

#### Third quarter and recent developments

- Net revenue increased to approximately \$4.2 million compared with approximately \$2.3 million in the prior year, reflecting an 82 percent increase in product sales
- Net loss was approximately \$17.8 million compared with approximately \$7.7 million in the prior year, reflecting continued investment in two phase 3 pipeline products
- The company initiated its phase 3 REJOICE Trial for TX-004HR (VagiCap<sup>™</sup>), the investigational softgel vaginal suppository for treatment of painful intercourse, a symptom of vulvar and vaginal atrophy (VVA) due to menopause
- The company continues to enroll patients in its phase 3 REPLENISH Trial for TX-001HR, a novel investigational bio-identical estradiol-progesterone combination product candidate
- · Cash totaled approximately \$67.0 million as of the end of the quarter with no outstanding debt

"The third quarter was an important time of progress at TherapeuticsMD, with our late-stage clinical programs advancing and our current women's health business continuing to perform well," said TherapeuticsMD CEO Robert G. Finizio. "Additionally, market dynamics continue to evolve in favor of our novel hormone therapy development programs, and we are progressing toward study results for our phase 3 VVA program next year."

## Summary of financial results

For the third quarter ended Sept. 30, 2014, net revenue totaled approximately \$4.2 million compared with approximately \$2.3 million for the prior year's quarter, reflecting an 82 percent increase in sales of the company's current women's health products. Revenue growth during the quarter was primarily driven by recently launched prenatal vitamin products and continued growth of product sales in this highly competitive market.

Cost of goods sold increased to approximately \$1.1 million for the third quarter of 2014, compared with approximately \$0.6 million for the prior year's third quarter.

Total operating expenses for the third quarter of 2014 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses for the quarter were approximately \$14.9 million, reflecting a one-time investment of approximately \$4.1 million in clinical recruitment costs for the company's ongoing phase 3 REPLENISH Trial. Third quarter 2013 R&D totaled approximately \$4.1 million. SG&A expenses for the third quarter of 2014 were approximately \$6.0 million and included marketing and sales expenses to support the launch of new prenatal products. SG&A totaled approximately \$4.8 million for the third quarter of 2013.

Non-operating income for the third quarter of 2014 included miscellaneous and interest income of approximately \$16,000, compared with expenses of approximately \$436,000 primarily from financing costs in the prior year's third quarter.

Net loss was approximately \$17.8 million for the third quarter of 2014 or \$0.12 per basic and diluted share, compared with approximately \$7.7 million or \$0.06 per basic and diluted share for the third quarter of 2013.

At Sept. 30, 2014, TherapeuticsMD had cash of approximately \$67.0 million, compared with approximately \$54.2 million at Dec. 31, 2013. At Nov. 4, 2014, TherapeuticsMD common stock outstanding totaled 156,030,476 shares.

## **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 conference call include:

Date:	Nov. 6, 2014
Time:	4:30 p.m. EST
Telephone access (U.S. & Canada):	866-665-9531
Telephone access (International):	724-987-6977
Access code for all callers:	20658896

Additionally, a live webcast may be accessed on the company's website, <u>www.therapeuticsmd.com</u>, under the "Investor" section.

### About TherapeuticsMD

TherapeuticsMD Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. With its patented SYMBODA<sup>TM</sup> technology platform, 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 three phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins and cosmetics under the vitaMedMD<sup>®</sup> and BocaGreenMD<sup>®</sup> brands. More information is available at the following websites: <u>www.therapeuticsmd.com</u>, <u>www.vitamedmd.com</u>, <u>www.vitamedmd.com</u>.

This press release by TherapeuticsMD Inc. may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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**

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Media: Julia Amadio Chief Product Officer 561-961-1900 Julia.Amadio@TherapeuticsMD.com

# THERAPEUTICSMD, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS	September 30, 2014 (Unaudited)			December 31, 2013		
Current Assets:						
Cash	\$	66,999,114	\$	54,191,260		
Accounts receivable, net of allowance for doubtful accounts		, ,		, ,		
of \$29,149 and \$26,555, respectively		2,148,724		1,690,753		
Inventory		1,011,945		1,043,618		
Other current assets		2,020,118		2,477,715		
Total current assets		72,179,901		59,403,346		
		, -,				
Fixed assets, net		69,567		61,318		
Other Assets:						
Prepaid expense		1,392,264		1,750,455		
Intangible assets		841,741		665,588		
Security deposit		125,000		135,686		
Total other assets		2,359,005		2,551,729		
		,		,, -		
Total assets	\$	74,608,473	\$	62,016,393		
	Ψ	74,000,475	Ψ	02,010,000		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current Liabilities:						
Accounts payable	\$	5,648,679	\$	2,114,217		
Deferred revenue	Ψ	848,149	Ψ	1,602,580		
Other current liabilities		4,511,079		3,601,189		
Total current liabilities		11,007,907		7,317,986		
		11,007,507		7,517,500		
Commitments and Contingencies						
Communents 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; 250,000,000 shares authorized;						
156,030,476 and 144,976,757 issued and outstanding, respectively		156,030		144,977		
Additional paid-in capital		181,891,791		135,086,056		
Accumulated deficit		(118,447,255)		(80,532,626)		
Total stockholder' equity		63,600,566		54,698,407		
		,,,000		2 .,200,107		
Total liabilities and stockholders' equity	\$	74,608,473	\$	62,016,393		
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## THERAPEUTICSMD, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,					
		2014		2013		2014		2013
		(Unaudited)	(	(Unaudited)		(Unaudited)		(Unaudited)
Revenues, net	\$	4,186,261	\$	2,294,720	\$	10,768,572	\$	5,912,800
Cost of goods sold		1,068,605		648,403		2,792,268	<u> </u>	1,492,355
Gross profit		3,117,656		1,646,317		7,976,304		4,420,445
Operating expenses:								
Sales, general, and administration		6,043,354		4,752,062		16,610,015		14,455,839
Research and development		14,909,430		4,098,903		29,052,149		7,710,546
Depreciation and amortization		12,747		32,356		39,909		50,949
Total operating expense		20,965,531		8,883,321		45,702,073		22,217,334
Operating loss		(17,847,875)		(7,237,004)		(37,725,769)		(17,796,889)
Other income (expense):								
Miscellaneous income		6,260		11,965		43,411		15,444
Interest income		9,364		—		27,756		18,133
Interest expense		_		_		_		(1,165,981)
Financing costs		—		(447,969)		(260,027)		(1,107,937)
Loan guaranty costs						—		(2,944)
Total other income (expense)		15,624		(436,004)		(188,860)		(2,243,285)
Loss before taxes		(17,832,251)		(7,673,008)		(37,914,629)		(20,040,174)
Provision for income taxes					<u> </u>		<u>.</u>	
Net loss	\$	(17,832,251)	\$	(7,673,008)	\$	(37,914,629)	\$	(20,040,174)
Loss per share, basic and diluted:								
Net loss per share, basic and diluted	\$	(0.12)	\$	(0.06)	\$	(0.26)	\$	(0.16)
Weighted average number of common								
shares outstanding	_	152,200,455		131,212,706		147,594,810		121,701,292

## THERAPEUTICSMD, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,				
		2013			
	(	2014 Unaudited)		(Unaudited)	
	· · · · ·	,		. ,	
ASH FLOWS FROM OPERATING ACTIVITIES Net loss	\$	(37,914,629)	\$	(20,040,174	
Adjustments to reconcile net loss to net cash flows used in	¢	(37,914,029)	Φ	(20,040,172	
operating activities:					
Depreciation		22,713		41,186	
Amortization of intangible assets		17,196		9,764	
Provision for doubtful accounts		2,594		48,355	
Stock based compensation		3,226,241		1,926,992	
Stock based expense for services		708,595		804,878	
Amortization of deferred financing costs		260,027		1,055,948	
Amortization of debt discount				1,102,680	
Loan guaranty costs		_		2,944	
Changes in operating assets and liabilities:				_,	
Accounts receivable		(460,565)		(1,235,433	
Inventory		31,673		467,624	
Other current assets		197,569		(1,927,156	
Other assets		(17,069)		(984,974	
Accounts payable		3,534,462		830,585	
Deferred revenue		(754,431)		707,520	
Accrued expenses and other current liabilities		909,890		1,190,178	
		303,030		1,150,170	
Net cash flows used in operating activities		(30,235,734)		(15,999,083	
ASH FLOWS FROM INVESTING ACTIVITIES					
Patent and trademark costs, net of abandoned costs		(193,349)		(257,633	
Purchase of property and equipment		(30,962)	. <u></u>	(23,755	
Net cash flows used in investing activities		(224,311)		(281,388	
ASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from sale of common stock, net		42,771,353		78,984,960	
Proceeds from exercise of options		315,546		6,23	
Proceeds from exercise of warrants		181,000			
Proceeds from line of credit		—		500,000	
Repayment of line of credit		_		(500,000	
Repayment of notes payable		—		(4,691,842	
Net cash flows provided by financing activities		43,267,899		74,299,344	
Increase in cash		12,807,854			
Cash, beginning of period				58,018,873	
		54,191,260		1,553,474	
Cash, end of period		66,999,114		59,572,342	
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:					
Cash paid for interest	\$		\$	212,853	
Cash paid for income taxes	\$	—	\$	_	
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:					
	*		*		
Warrants issued for financing	\$	<u> </u>	\$	1,711,956	