# 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>TM</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
<b>Telephone access (International):</b>	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.vitamedmdrx.com</u> and <u>www.bocagreenmd.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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## THERAPEUTICSMD, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2014 (Unaudited)		Dece	mber 31, 2013
ASSETS				
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
LIABILITIES AND STOCKHOLDER	S' EQU	ITY		
Current Liabilities:				
Accounts payable	\$	5,648,679	\$	2,114,217
Deferred revenue		848,149		1,602,580
Other current liabilities		4,511,079		3,601,189
Total current liabilities		11,007,907		7,317,986
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; 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
Total liabilities and stockholders' equity	\$	74,608,473	\$	62,016,393

#### 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	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					
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,		
		2014 Septem		2013
	(	(Unaudited)	(	Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	\$	(37,914,629)	\$	(20,040,174)
Adjustments to reconcile net loss to net cash flows used in				<i>、</i> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
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
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Net cash flows used in operating activities		(30,235,734)		(15,999,083)
CASH FLOWS FROM INVESTING ACTIVITIES				
Patent and trademark costs, net of abandoned costs		(193,349)		(257,633)
Purchase of property and equipment		(30,962)		(23,755)
Net cash flows used in investing activities		(224,311)		(281,388)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from sale of common stock, net		42,771,353		78,984,960
Proceeds from exercise of options		315,546		6,231
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		-		(4,691,847)
Net cash flows provided by financing activities		43,267,899		74,299,344
Increase in cash		12,807,854		58,018,873
Cash, beginning of period	_	54,191,260		1,553,474
Cash, end of period		66,999,114		59,572,347
SUPPLEMENTAL DISCLOSURES OF CAS	H FLOW	/ INFORMATIO	N:	
Cash paid for interest	\$	_	\$	212,853
Cash paid for income taxes	\$	-	\$	

Warrants issued for financing\$-\$1,711,956Warrants issued for services\$-\$462,196