

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): March 3, 2014

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

000-16731

(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 March 3, 2014, TherapeuticsMD, Inc. issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2013. 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.

We do not have, and expressly disclaim, any obligation to release publicly any updates or any changes in our expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

The text included with this Current Report on Form 8-K is available on our website located at www.therapeuticsmd.com, although we reserve the right to discontinue that availability at any time.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit

Number Description

99.1 Press Release from TherapeuticsMD, Inc., dated March 3, 2014, entitled “TherapeuticsMD Reports Fourth Quarter and Full-Year 2013 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: March 3, 2014

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release from TherapeuticsMD, Inc., dated March 3, 2014, entitled "TherapeuticsMD Reports Fourth Quarter and Full-Year 2013 Results."</u>

TherapeuticsMD[®]

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FOR IMMEDIATE RELEASE

THERAPEUTICSMD REPORTS FOURTH QUARTER AND FULL-YEAR 2013 RESULTS

Management to Host Conference Call at 4:30 EST Today

Boca Raton, FL, March 3, 2014 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company, ("TherapeuticsMD" or the "Company") today announced results for the three-month period and full-year ended December 31, 2013.

Fourth Quarter 2013 Highlights:

- Net revenue increased to \$2.9 million compared with \$1.2 million for the fourth quarter of 2012;
- Net loss increased to \$8.4 million compared with a net loss of \$5.7 million for the fourth quarter of 2012;
- Received approval ahead of schedule to screen and enroll subjects at the 50th site in the REPLENISH Trial, a phase 3 clinical trial designed to measure the safety and efficacy of TX-12-001HR, our combination 17 β -estradiol and natural progesterone drug candidate for the treatment of vasomotor symptoms in post-menopausal women;
- Initiated the SPRY Trial, a phase 3 clinical trial designed to evaluate safety and efficacy of TX-12-002HR, our oral progesterone drug candidate for the treatment of secondary amenorrhea;
- Announced positive results from two PK studies of TX-12-004HR, our estradiol VagiCap drug candidate, data from which suggests that VagiCap may be a similar but more effective product with less systemic exposure than Vagifem[®];
- Received patents for our platform technology (Symboda) and lead drug candidate, TX-12-001HR;
- Filed 11 additional patent applications, covering various aspects of our technology and drug candidates, to ensure patent exclusivity through 2032;
- Strengthened senior management team with appointments of Sebastian Mirkin, M.D., as Chief Medical Officer; Joel S. Krasnow, M.D., M.B.A., as Chief Scientific Officer and head of our regulatory department; and Randall S. Stanicky, CFA, to our Board of Directors; and,
- Closed out 2013 with \$54.2 million in cash and cash equivalents, and no debt.

Robert G. Finizio, Co-Founder and Chief Executive Officer, stated, "This has been an exciting year for the Company, highlighted by advancements in clinical trials for our three principal hormone therapy drug candidates. The Drug Quality and Security Act was passed into law in November 2013, and the quick action of the FDA to implement and enforce the new law means that compounding pharmacies are now clearly governed by it. This law is a catalyst, and presents an opportunity to move the market from compounded bio-identical hormone replacement therapies, or BHRT, to an FDA-approved bioidentical drug market. We believe that we with our phase 3 REPLENISH Trial to evaluate our combination product well underway, we are well-positioned to capitalize on this new opportunity.

“We have strengthened our Board and management team, which will support and guide us as we continue our evolution as a publicly traded company. Our robust pipeline and strong cash position also contribute to a positive outlook for the Company, and we look forward to our ongoing progress,” Finizio concluded.

Fourth Quarter Results

Net revenue for the fourth quarter of 2013 totaled \$2.9 million compared with net revenue of \$1.2 million for the year ago quarter. The increase of approximately \$1.7 million, or approximately 130%, was directly attributable to an increase in the number of physicians writing prescriptions for our prenatal products, the increased productivity of our sales force, an increase in the average net sales price of our product, and new prescription products introduced in March, April, May, and November 2012. Cost of goods sold increased by \$134,000, or 40.4%, for the three months ended December 31, 2013 compared with the prior year quarter. Research and development expenses increased to \$5.8 million for the fourth quarter of 2013 compared with \$1.4 million for the fourth quarter of 2012, because of costs incurred in the development of our new hormone replacement therapy and prescription prenatal products. Sales, general, and administrative expenses decreased to \$4.6 million for the fourth quarter of 2013 compared with \$4.9 million for the fourth quarter of 2012. As a result, our operating loss was \$8.0 million for the fourth quarter of 2013 compared with \$5.4 million for the fourth quarter of 2012.

Other non-operating expenses increased by approximately \$36,000 for the fourth quarter of 2013 compared with the comparable quarter in 2012. This increase was primarily a result of non-cash financing costs incurred during the current period totaling approximately \$396,000, partially offset by a decrease in interest expense of approximately \$520,000 and loss on extinguishment of debt of approximately \$197,000.

As a result, net loss for the fourth quarter of 2013 was \$8.4 million, or \$0.06 per basic and diluted share, compared with a net loss of \$5.7 million, or \$0.06 per basic and diluted share, for the fourth quarter of 2012.

Full Year Results

Net revenue for the year ended December 31, 2013 totaled \$8.8 million compared with net revenue of approximately \$3.8 million for the year ended December 31, 2012. The increase of approximately \$5.0 million, or approximately 130%, was directly attributable to an increase in the number of physicians writing prescriptions for our prenatal products, the increased productivity of our sales force, an increase in the average net sales price of our product, and new prescription products introduced in March, April, May and November 2012. Cost of goods sold increased by approximately \$611,000, or 45%, for the full year ended December 31, 2013 compared with the prior year period. Research and development expenses increased to \$13.5 million for 2013, compared with \$4.5 million for 2012 because of costs incurred in the development of our new hormone therapy drug candidates. Sales, general, and administrative expenses increased to \$19.0 million for 2013 compared with \$14.1 million for the prior year. As a result, our operating loss was \$25.8 million for the year ended December 31, 2013 compared with \$16.1 million for the year ended December 31, 2012.

Other non-operating expenses decreased by \$16.4 million for the year ended December 31, 2013 compared with the prior year. This decrease resulted primarily from a reduction in financing related costs.

As a result, net loss for the full year ended December 31, 2013 was \$28.4 million, or \$0.22 per basic and diluted share, compared with a net loss of \$35.1 million, or \$0.38 per basic and diluted share, for the year ended December 31, 2012.

Cash and cash equivalents were \$54.2 million at December 31, 2013.

Conference Call

As previously announced, today Robert G. Finizio, Co-Founder and Chief Executive Officer, and Dan Cartwright, Chief Financial Officer, will host a conference call, which may include forward-looking statements, to review the financial results as follows:

Date	March 3, 2014
Time	4:30 p.m. (Eastern Standard Time)
Telephone access	800-709-0218 (U.S. and Canada) 212-231-2900 (International)
Access code	21708486
Live webcast	www.therapeuticsmd.com , under the Investor tab

An audio replay will be available on-demand shortly after the completion of the call until March 24, 2014 at 11:59 p.m. EST at www.therapeuticsmd.com, and will also be available by dialing 800-633-8284 in the U.S. and Canada, or 402-977-9140 for international callers. The access code for all callers is 21708486.

About Hormone Therapy

Hormone therapy (HT) is the administration of hormones to supplement a lack of naturally occurring hormones. HT options include natural, bioidentical, and non-bioidentical (conjugated) hormones. HT is projected to be the largest growth segment in the overall women's health market. The potential market for pharmacy-compounded, bioidentical HT products is estimated to be approximately \$1.5 billion per year.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is a women's healthcare company focused on developing and commercializing products targeted exclusively for women. We manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under our vitaMedMD[®] and BocaGreenMD[®] brands. We are currently developing advanced hormone therapy pharmaceutical drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies. We are also evaluating various other potential indications for our hormone therapy technology, including oral contraception, preterm birth, vulvar and vaginal atrophy, and premature ovarian failure. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com.

vitaMedMD[®], TherapeuticsMD[®], and BocaGreenMD[®] are registered trademarks of TherapeuticsMD, Inc.

Except for the historical information contained herein, the matters set forth in this press release, including statements relating to future events or performance, including statements regarding the Company's performance; the progress of the phase 3 clinical trials for TX 12-001HR and 12-002HR; the results of the PK studies of TX 12-004HR and the Company's belief that such results suggest that TX 12-004HR will be a similar but more effective product with less systemic exposure than Vagifem; the Company's belief in the impact on the Company of the recent appointments of Drs. Mirkin and Krasnow to the Company's senior management team and the appointment of Mr. Stanicky to the Company's Board of Directors; the Company's belief that the potential of its three principal drug candidates has been validated by external parties, namely the size of the market to which these products would be introduced and the passage of the Drug Quality and Security Act; the effect of the Drug Quality and Security Act on compounding pharmacies; the Company's belief that its robust pipeline and strong cash position contribute to a positive outlook for the Company; the impact of the number of physicians writing prescriptions for the Company's prenatal products, the increased productivity of the Company's sales force, an increase in the average net sales price of the Company's products, and new prescription products introduced in 2012; projected growth and the size of the potential market for pharmacy-compounded, bioidentical HT products; and the Company's current product pipeline and hormone technology that the Company is evaluating are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including but not limited to: timely and successful completion of clinical studies and the results thereof; challenges and costs inherent in product marketing; the risks and uncertainties associated with economic and market conditions; risks and uncertainties associated with the Company's business and finances in general; and other risks detailed in the Company's filings with the U.S. Securities and Exchange Commission including its annual report on Form 10-K filed on March 12, 2013, reports on Form 10-Q and Form 8-K, and other such filings. These forward-looking statements are based on current information that may change. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

(tables follow)

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31,	
	2013	2012
ASSETS		
Current Assets:		
Cash	\$ 54,191,260	\$ 1,553,474
Accounts receivable, net of allowance for doubtful accounts of \$26,555 and \$42,048, respectively	1,690,753	714,425
Inventory	1,043,618	1,615,210
Other current assets	2,477,715	751,938
Total current assets	59,403,346	4,635,047
Fixed assets, net	61,318	65,673
Other Assets:		
Prepaid expense	1,750,455	953,655
Intangible assets	665,588	239,555
Security deposit	135,686	31,949
Total other assets	2,551,729	1,225,159
Total assets	\$ 62,016,393	\$ 5,925,879
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,114,217	\$ 1,641,366
Deferred revenue	1,602,580	1,144,752
Other current liabilities	3,601,189	833,654
Total current liabilities	7,317,986	3,619,772
Long-Term Liabilities:		
Notes payable, net of debt discount of \$0 and \$1,102,680, respectively	—	3,589,167
Accrued interest	—	150,068
Total long-term liabilities	—	3,739,235
Total liabilities	7,317,986	7,359,007
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; 144,976,757 and 99,784,982 issued and outstanding, respectively	144,977	99,785
Additional paid in capital	135,086,056	50,580,400
Accumulated deficit	(80,532,626)	(52,113,313)
Total stockholder' equity	54,698,407	(1,433,128)
Total liabilities and stockholders' equity	\$ 62,016,393	\$ 5,925,879

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

THERAPEUTICSMD, INC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,		
	2013	2012	2013	2012	2011
Revenues, net	\$ 2,862,798	\$ 1,240,715	\$ 8,775,598	\$ 3,818,013	\$ 2,088,177
Cost of goods sold	467,242	332,776	1,959,597	1,348,113	947,112
Gross profit	2,395,556	907,939	6,816,001	2,469,900	1,141,065
Operating expenses:					
Sales, general, and administration	4,558,998	4,929,807	19,014,837	14,069,701	6,406,197
Research and development	5,840,717	1,361,056	13,551,263	4,492,362	107,241
Depreciation and amortization	7,196	12,308	58,145	56,260	54,845
Total operating expense	10,406,911	6,303,171	32,624,245	18,618,323	6,568,283
Operating loss	(8,011,355)	(5,395,232)	(25,808,244)	(16,148,423)	(5,427,218)
Other income and (expense)					
Miscellaneous income	19,100	515	34,544	3,001	6,392
Interest income	9,101	—	27,234	—	—
Financing costs	(395,985)	—	(1,503,922)	—	—
Interest expense	—	(520,200)	(1,165,981)	(1,905,409)	(64,380)
Loan guaranty costs	—	(9,801)	(2,944)	(45,036)	(38,159)
Loss on extinguishment of debt	—	197,383	—	(10,307,864)	(7,390,000)
Beneficial conversion feature	—	—	—	(6,716,504)	—
Total other income (expense)	(367,784)	(332,103)	(2,611,069)	(18,971,812)	(7,486,147)
Loss before taxes	(8,379,139)	(5,727,335)	(28,419,313)	(35,120,235)	(12,913,365)
Provision for income taxes	—	—	—	—	—
Net loss	\$ (8,379,139)	\$ (5,727,335)	\$ (28,419,313)	\$ (35,120,235)	\$ (12,913,365)
Net loss per share, basic and diluted	\$ (0.06)	\$ (0.06)	\$ (0.22)	\$ (0.38)	\$ (0.21)
Weighted average number of common shares outstanding	144,983,681	99,784,982	127,569,731	91,630,693	62,516,461

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

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

	Year Ended December 31,		
	2013	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (28,419,313)	\$ (35,120,235)	\$ (12,913,365)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	—	—	(255,753)
Depreciation	47,883	27,484	25,686
Amortization of intangible assets	10,262	28,776	29,159
Provision for doubtful accounts	(15,493)	40,548	1,500
Loss on extinguishment of debt	—	10,307,864	7,390,000
Beneficial conversion feature	—	6,716,504	—
Amortization of debt discount	1,102,680	1,604,240	28,719
Stock based compensation	3,207,238	1,868,345	190,513
Amortization of deferred financing costs	1,451,934	—	25,980
Stock based expense for services	636,917	338,457	22,630
Loan guaranty costs	2,944	45,036	38,159
Changes in operating assets and liabilities:			
Accounts receivable	(1,068,619)	(728,253)	(16,409)
Inventory	571,592	(1,027,137)	29,996
Other current assets	(1,386,319)	42,281	(346,822)
Other assets	(565,706)	—	—
Accounts payable	472,851	1,334,855	188,876
Deferred revenue	457,828	1,144,752	—
Accrued expenses and other current liabilities	2,875,320	639,157	594,535
Other liabilities	(150,068)	—	—
Net cash flows used in operating activities	(20,768,069)	(12,737,326)	(4,966,596)
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs, net of abandoned costs	(439,034)	(206,101)	(8,870)
Payment of security deposit	(103,737)	—	—
Purchase of property and equipment	(40,790)	(66,405)	(28,766)
Net cash flows used in investing activities	(583,561)	(272,506)	(37,636)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	78,650,353	7,895,485	1,000,000
Proceeds bank line of credit	500,000	—	300,000
Proceeds from exercise of options	30,910	191,000	17,250
Proceeds from notes and loans payable	—	8,700,000	2,684,160
Proceeds from sale of warrants	—	400	—
Proceeds from notes and loans payable-related parties	—	—	300,000
Proceeds from sale of membership units, net of expenses	—	—	707,000
Repayment of bank line of credit	(500,000)	(300,000)	—
Repayment of notes payable-related party	—	(200,000)	(100,696)
Repayment of notes payable	(4,691,847)	(1,850,000)	(200,000)
Net cash flows provided by financing activities	73,989,416	14,436,885	4,707,714
Increase in cash	52,637,786	1,427,053	(296,518)
Cash, beginning of period	1,553,474	126,421	422,939
Cash, end of period	\$ 54,191,260	\$ 1,553,474	\$ 126,421

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for interest	\$ 212,853	\$ 17,253	\$ 696
Cash paid for income taxes	\$ —	\$ —	\$ —

SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:

Warrants issued for financing	\$ 1,711,956	\$ 2,509,537	\$ 148,668
Warrants issued for services	\$ 462,196	\$ 1,532,228	\$ 190,280
Warrants exercised in exchange for debt and accrued interest	\$ —	\$ 3,102,000	\$ —
Shares issued in exchange for debt and accrued interest	\$ —	\$ 1,054,658	\$ 849,137

Notes payable issued for accrued interest

\$	—	\$	15,123	\$	—
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The accompanying footnotes are an integral part of these consolidated financial statements.

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