

**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): February 25, 2016

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))

Item 2.02 Results of Operations and Financial Condition.

On February 25, 2016, TherapeuticsMD, Inc. issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 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.

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 February 25, 2016, entitled “TherapeuticsMD Announces Fourth Quarter and Full Year 2015 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: February 25, 2016

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press Release from TherapeuticsMD, Inc., dated February 25, 2016, entitled "TherapeuticsMD Announces Fourth Quarter and Full Year 2015 Financial Results."</u>

**FOR IMMEDIATE RELEASE****TherapeuticsMD Announces Fourth Quarter and Full Year 2015 Financial Results**

– Company to Present additional positive phase 3 data for TX-004HR at the ISSWSH annual meeting –

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

BOCA RATON, Fla. – February 25, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its fourth quarter and full year financial results for 2015.

2015 and Recent Developments

- Net revenue for the company’s prescription prenatal vitamin business increased to approximately \$20.1 million in 2015 compared with approximately \$15.0 million for the prior year.
- Net loss was approximately \$85.1 million in 2015, compared with approximately \$54.2 million for the prior year, reflecting investment in two phase 3 clinical trials for the company’s novel hormone therapy drug candidates.
- Reported positive topline data from 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 vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause. The results showed patients treated with TX-004HR achieved a statistically significant improvement over placebo across all four co-primary endpoints at all three doses evaluated. The validated co-primary endpoint data and additional secondary endpoint results related to vaginal dryness are scheduled to be presented this week at the International Society for the Study of Women’s Sexual Health (ISSWSH) Annual Meeting 2016. A summary of these data is included below in this press release.
- Exited over 1,400 of the 1,750 patients enrolled 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. Topline results are currently anticipated late in the fourth quarter of 2016.
- The company’s intellectual property portfolio grew to a current total of 122 patent filings, including 72 international filings, with one allowed and 14 issued U.S. patents.
- Presented two posters at North American Menopause Society (NAMS) of the company’s transdermal progesterone candidate, TX-005HR, and the company’s transdermal estradiol and progesterone candidate, TX-006HR, demonstrating tissue penetration and target organ activity in a preclinical study.
- Strengthened relationships with key medical, pharmacy, patient and industry organizations worldwide.
- Ended the year with approximately \$64.7 million in cash and no debt, which was further strengthened by an equity offering in January 2016 that generated approximately \$135 million of net proceeds to fund commercialization activities for both of the company’s late stage product candidates and other development activities.

“2015 was a breakthrough year for our company, as we reported positive topline phase 3 data from the Rejoice Trial for TX-004HR, the first of our two novel pipeline candidates in the women’s health arena,” said TherapeuticsMD CEO Robert G. Finizio. “Based on those compelling results, we are preparing to file an NDA before June 30, while we also expect topline data late in the fourth quarter of 2016 from our Replenish Trial for TX-001HR. We believe we are well positioned from a financial, clinical and commercial standpoint to execute on our goals in 2016 and create significant value for shareholders by advancing our pipeline and preparing to launch our first novel hormone product for women, if approved.”

Summary of 2015 Financial Results

For the year ended December 31, 2015, net revenue increased approximately 34 percent to approximately \$20.1 million compared with approximately \$15.0 million for the prior year. Net revenue for the fourth quarter of 2015 was approximately \$5.6 million compared with net revenue of approximately \$4.3 million for the prior year’s quarter. Revenue growth during the fourth quarter was primarily driven by a change in product mix and an increase in the average net sales price of the company’s prenatal vitamin products and revenue growth during the full year was primarily driven by an increase in the number of units sold and an increase in the average sales price of the company’s prenatal vitamin products.

Cost of goods sold increased to approximately \$4.5 million for the full year 2015, compared with approximately \$3.7 million in the prior year.

Total operating expenses for the fourth quarter and full year 2015 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses for the full-year 2015 were approximately \$72.0 million compared with approximately \$43.2 million for the prior year, primarily as a result of an increase in costs related to the company’s phase 3 clinical trials for TX-001HR and TX-004HR and an increase in scale-up and manufacturing activities primarily related to TX-001HR. R&D expenses during the fourth quarter of 2015 were \$13.3 million compared to \$14.2 million during the prior year’s quarter, reflecting a significant decline in the company’s clinical trial costs, partially offset by an increase in scale-up and manufacturing activities to support commercialization. SG&A expenses for the full-year 2015 were approximately \$28.7 million compared with approximately \$22.1 million for the prior year, reflecting an increase in human resources related costs, increased consulting and professional costs, increased insurance cost and increased sales and marketing expenses. SG&A expenses for the fourth quarter of 2015 were approximately \$8.6 million compared with approximately \$5.5 million for the prior year’s quarter, primarily as a result of increased human resource related costs, as well as increased sales and marketing and office expenses.

Non-operating income remained insignificant for the full year 2015 and 2014 and included interest income and other miscellaneous items of income and expense for both periods.

Net loss for the full year 2015 was approximately \$85.1 million, or \$0.49 per basic and diluted share, compared with approximately \$54.2 million, or \$0.36 per basic and diluted share, for the full year 2014. Net loss in the fourth quarter of 2015 was approximately \$17.5 million, or \$0.10 per basic and diluted share, compared with approximately \$16.3 million, or \$0.10 per basic and diluted share, for the fourth quarter of 2014.

At December 31, 2015, cash on hand was approximately \$64.7 million, compared with approximately \$51.4 million at December 31, 2014.

Phase 3 Data Results Presented at ISSWSH Annual Meeting 2016

TherapeuticsMD also announced that data from the phase 3 Rejoice Trial would be presented at the ISSWSH Annual Meeting 2016 taking place February 25-28 in Charleston, South Carolina. The poster to be presented includes validated co-primary endpoint results from the Rejoice Trial and secondary endpoint data that demonstrate the effect of TX-004HR on severity of vaginal dryness as compared with placebo at week 12.

Based on the company's ongoing analyses of the Rejoice Trial data, statistical significance of the results for the co-primary endpoint of severity of participants' self-reported moderate to severe dyspareunia as the most bothersome symptom of VVA has slightly improved for all three doses from the topline results previously reported. The secondary endpoint result for vaginal dryness was also statistically significant for all three doses evaluated in the Rejoice Trial.

Statistical Significance of Results for Co-Primary Endpoints (Based on LS Mean Change from Baseline to Week 12 Compared to Placebo)

	25 mcg	10mcg	4 mcg
Superficial Cells	P < 0.0001	P < 0.0001	P < 0.0001
Parabasal cells	P < 0.0001	P < 0.0001	P < 0.0001
Vaginal pH	P < 0.0001	P < 0.0001	P < 0.0001
Severity of Dyspareunia	P < 0.0001	P < 0.0001	P = 0.0149

Statistical Significance of Results for Secondary Endpoint of Severity of Vaginal Dryness (Based on LS Mean Change from Baseline to Week 12 Compared to Placebo)

Severity of Dryness	P < 0.0001	P < 0.0001	P = 0.0014
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LS= Least Squares

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:	Thursday, February 25, 2016
Time:	4:30 p.m. EST
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	45870409

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, on the Home Page or under the "Investors & Media" section. A digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in 855-859-2056 or international 404-537-3406 and Conference ID: 45870409.

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.

Contacts

Investors:

Dan Cartwright

Chief Financial Officer

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
ASSETS	2015	2014
Current Assets:		
Cash	\$ 64,706,355	\$ 51,361,607
Accounts receivable, net of allowance for doubtful accounts of \$81,910 and \$59,753, respectively	3,049,715	2,154,217
Inventory	690,153	1,182,113
Other current assets	2,233,897	1,537,407
Total current assets	70,680,120	56,235,344
Fixed assets, net	198,592	63,293
Other Assets:		
Intangible assets, net	1,615,251	1,228,588
Prepaid expense	1,109,883	1,427,263
Security deposit	125,000	125,000
Total other assets	2,850,134	2,780,851
Total assets	\$ 73,728,846	\$ 59,079,488
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,126,174	\$ 6,327,129
Other current liabilities	7,539,526	3,840,639
Deferred revenue	—	522,613
Total current liabilities	10,665,700	10,690,381
Commitments and Contingencies - See Note 14		
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; 177,928,041 and 156,097,019 issued and outstanding, respectively	177,928	156,097
Additional paid-in capital	282,712,078	182,982,846
Accumulated deficit	(219,826,860)	(134,749,836)
Total stockholders' equity	63,063,146	48,389,107
Total liabilities and stockholders' equity	\$ 73,728,846	\$ 59,079,488

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,		
	2015	2014	2015	2014	2013
Revenues, net	\$ 5,629,740	\$ 4,257,647	\$ 20,142,898	\$ 15,026,219	\$ 8,775,598
Cost of goods sold	1,235,978	879,535	4,506,673	3,671,803	1,959,597
Gross profit	4,393,762	3,378,112	15,636,225	11,354,416	6,816,001
Operating expenses:					
Sales, general, and administrative	8,631,238	5,514,057	28,721,236	22,124,072	19,014,837
Research and development	13,253,472	14,166,789	72,042,774	43,218,938	13,551,263
Depreciation and amortization	18,000	12,558	62,400	52,467	58,145
Total operating expenses	21,902,710	19,693,404	100,826,410	65,395,477	32,624,245
Operating loss	(17,508,948)	(16,315,292)	(85,190,185)	(54,041,061)	(25,808,244)
Other income and (expenses)					
Miscellaneous income, net	23,991	3,158	95,719	46,569	34,544
Interest income	2,280	9,553	17,442	37,309	27,234
Financing costs	—	—	—	(260,027)	(1,503,922)
Interest expense	—	—	—	—	(1,165,981)
Loan guaranty costs	—	—	—	—	(2,944)
Total other income (expense)	26,271	12,711	113,161	(176,149)	(2,611,069)
Loss before income taxes	(17,482,677)	(16,302,581)	(85,077,024)	(54,217,210)	(28,419,313)
Provision for income taxes	—	—	—	—	—
Net loss	\$ (17,482,677)	\$ (16,302,581)	\$ (85,077,024)	\$ (54,217,210)	\$ (28,419,313)
Loss per share, basic and diluted:					
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.10)	\$ (0.49)	\$ (0.36)	\$ (0.22)
Weighted average number of common shares outstanding, basic and diluted	\$ 177,876,462	\$ 156,054,938	\$ 173,174,229	\$ 149,727,228	\$ 127,569,731

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (85,077,024)	\$ (54,217,210)	\$ (28,419,313)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	29,959	28,987	47,883
Amortization of intangible assets	32,441	23,480	10,262
Provision for (recovery of) doubtful accounts	22,157	(5,436)	(15,493)
Amortization of debt discount	—	—	1,102,680
Share-based compensation	7,189,699	4,970,312	3,844,155
Amortization of deferred financing costs	—	260,027	1,451,934
Loan guaranty costs	—	—	2,944
Changes in operating assets and liabilities:			
Accounts receivable	(917,656)	(458,028)	(1,068,619)
Inventory	491,960	(138,495)	571,592
Other current assets	(773,532)	680,281	(1,386,319)
Other assets	(17,442)	(37,309)	(565,706)
Accounts payable	(3,200,955)	4,212,912	472,851
Deferred revenue	(522,613)	(1,079,967)	457,828
Other current liabilities	3,698,887	239,450	2,875,320
Other liabilities	—	—	(150,068)
Net cash used in operating activities	<u>(79,044,119)</u>	<u>(45,520,996)</u>	<u>(20,768,069)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs	(419,104)	(586,480)	(439,034)
Purchase of fixed assets	(165,257)	(30,962)	(40,790)
Refund (payment) of security deposit	—	10,686	(103,737)
Net cash used in investing activities	<u>(584,361)</u>	<u>(606,756)</u>	<u>(583,561)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	91,374,649	42,771,353	78,650,353
Proceeds from exercise of options	1,232,579	345,746	30,910
Proceeds from exercise of warrants	366,000	181,000	—
Proceeds bank line of credit	—	—	500,000
Repayment of bank line of credit	—	—	(500,000)
Repayment of notes payable	—	—	(4,691,847)
Net cash provided by financing activities	<u>92,973,228</u>	<u>43,298,099</u>	<u>73,989,416</u>
Increase (decrease) in cash	13,344,748	(2,829,653)	52,637,786
Cash, beginning of period	51,361,607	54,191,260	1,553,474
Cash, end of period	<u>\$ 64,706,355</u>	<u>\$ 51,361,607</u>	<u>\$ 54,191,260</u>
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	\$ —	\$ —	\$ 1,711,956
Warrants issued for services	\$ —	\$ —	\$ 462,196