
**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 23, 2017

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 23, 2017, TherapeuticsMD, Inc. issued a press release announcing its financial results for its fourth quarter and full year ended December 31, 2016. 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 23, 2017, entitled “TherapeuticsMD Announces Fourth Quarter and Full-Year 2016 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 23, 2017

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	<u>Press Release from TherapeuticsMD, Inc., dated February 23, 2017, entitled "TherapeuticsMD Announces Fourth Quarter and Full-Year 2016 Financial Results."</u>

**FOR IMMEDIATE RELEASE****TherapeuticsMD Announces Fourth Quarter and Full-Year 2016 Financial Results**

– Pipeline of two late-stage product candidates advancing towards commercialization, with launch of TX-004HR expected in fourth quarter 2017 pending regulatory approval –

– Management to host conference call today at 8:00 a.m. EST –

BOCA RATON, Fla. – February 23, 2017 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its fourth quarter and full-year financial results for 2016.

2016 and Recent Developments

- Net revenue for the company’s prescription prenatal vitamin business was approximately \$19.4 million in 2016 compared with approximately \$20.1 million for the prior year.
- Net loss was approximately \$89.9 million in 2016, compared with approximately \$85.1 million for the prior year, reflecting investment in clinical development for the company’s two phase 3 hormone therapy drug candidates.
- Ended the year with approximately \$131.5 million in cash and no debt.
- Reported positive topline data from the Replenish Trial, a phase 3 clinical trial of TX-001HR, the company’s bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel, for the treatment of moderate-to-severe vasomotor symptoms due to menopause. Topline results from the trial in 1,835 post-menopausal women demonstrated that multiple doses of TX-001HR resulted in a statistically significant reduction from baseline in both the frequency and severity of hot flashes compared to placebo. In addition, endometrial safety was established with an incidence rate of endometrial hyperplasia or malignancy of 0% across all doses. The company plans to submit a New Drug Application (NDA) for TX-001HR to the U.S. Food and Drug Administration (FDA) in the third quarter of 2017.
- Submitted an NDA for TX-004HR, the company’s applicator-free estradiol vaginal softgel capsule 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 NDA is supported by the complete TX-004HR clinical program, including positive results from all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the phase 3 Rejoice Trial. The FDA’s Prescription Drug User Fee Act (PDUFA) target action date for the NDA is May 7, 2017.
- Published three manuscripts with detailed results of the TX-004HR phase 3 Rejoice Trial in the peer-reviewed journal *Menopause*. The manuscripts review the positive results of TX-004HR across pre-specified co-primary and secondary endpoints in the Rejoice Trial, data from a pharmacokinetic (PK) substudy demonstrating the low systemic absorption of TX-004HR, as well as data from a patient acceptability and satisfaction survey demonstrating a high level of product acceptability, ease of use, and patient satisfaction with TX-004HR.
- The company’s intellectual property portfolio grew to a current total of 144 patent filings, including 74 international filings, with one allowed and 17 issued U.S. patents.
- Strengthened relationships with key medical, pharmacy, patient and industry organizations worldwide. This includes the recent launch of the company’s BIO-IGNITE™ program, an outreach program to quantify the number of compounded bio-identical estradiol and progesterone prescriptions currently dispensed by the 3,000-3,500 high-volume compounding pharmacies and qualify their interests in distributing the company’s bio-identical hormone product candidates, if approved.

“During 2016, we made significant advancements with our two late-stage pipeline candidates while we pursued our goal to bring new healthcare solutions to women to help manage their menopause symptoms,” said TherapeuticsMD CEO Robert G. Finizio. “As we look forward to 2017, we are planning the launch of TX-004HR, pending regulatory approval, as a highly differentiated new treatment for moderate-to-severe dyspareunia, a symptom of VVA due to menopause. We also intend to file an NDA for TX-001HR, which, if approved, would be the first and only FDA-approved bio-identical combination of estradiol and progesterone for the treatment of moderate-to-severe vasomotor symptoms due to menopause.”

Summary of 2016 Financial Results

For the year ended December 31, 2016, net revenue was approximately \$19.4 million compared with approximately \$20.1 million for the prior year. Net revenue for the fourth quarter of 2016 was approximately \$4.5 million compared with net revenue of approximately \$5.6 million for the prior year's quarter. These changes were primarily due to a decrease in the average net sales price of our products, partially offset by an increase in the number of units sold.

Total operating expenses for the fourth quarter and full-year 2016 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses for the full-year 2016 were approximately \$53.9 million compared with approximately \$72.0 million for the prior year. R&D expenses for the fourth quarter of 2016 were approximately \$10.3 million compared to approximately \$13.3 million during the prior year's quarter. The decreases in R&D were primarily due to lower clinical trial costs as the company completed its phase 3 clinical trials for TX-001HR and TX-004HR. SG&A expenses for the full-year 2016 were approximately \$51.3 million compared with approximately \$28.7 million for the prior year. SG&A expenses for the fourth quarter of 2016 were approximately \$16.3 million compared with approximately \$8.6 million for the prior year's quarter. The increases in SG&A were primarily due to higher sales, marketing, regulatory expenditures, and personnel costs to support future commercialization.

Net loss for the full-year 2016 was approximately \$89.9 million, or \$0.46 per basic and diluted share, compared with approximately \$85.1 million, or \$0.49 per basic and diluted share, for the full-year 2015. Net loss in the fourth quarter of 2016 was approximately \$22.8 million, or \$0.12 per basic and diluted share, compared with approximately \$17.5 million, or \$0.10 per basic and diluted share, for the fourth quarter of 2015.

At December 31, 2016, cash on hand was approximately \$131.5 million, compared with approximately \$64.7 million at December 31, 2015.

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 23, 2017
Time:	8:00 a.m. EST
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	68412683

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: 68412683.

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 late stage clinical pipeline includes two phase 3 product candidates: TX-001HR for treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause and TX-004HR for treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

Forward-Looking Statements

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; whether the company will be able to prepare a new drug application for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the application; whether the FDA will approve the company's new drug application for its TX-004HR product candidate and whether any such approval will occur by the PDUFA date; 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.

###

Investor Contact

David DeLucia
Director, Investor Relations
561-961-1900
David.DeLucia@TherapeuticsMD.com

Media Contact

Ami Knoefler
SparkBioComm
650-739-9952
Ami@SparkBioComm.com

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2016	2015
ASSETS		
Current Assets:		
Cash	\$ 131,534,101	\$ 64,706,355
Accounts receivable, net of allowance for doubtful accounts of \$376,374 and \$81,910, respectively	4,500,699	3,049,715
Inventory	1,076,321	690,153
Other current assets	2,299,052	2,233,897
Total current assets	139,410,173	70,680,120
Fixed assets, net	516,839	198,592
Other Assets:		
Intangible assets, net	2,405,972	1,615,251
Security deposit	139,036	125,000
Prepaid expense	—	1,109,883
Total other assets	2,545,008	2,850,134
Total assets	\$ 142,472,020	\$ 73,728,846
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 7,358,514	\$ 3,126,174
Other current liabilities	7,624,085	7,539,526
Total current liabilities	14,982,599	10,665,700
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 shares authorized: 196,688,222 and 177,928,041 issued and outstanding, respectively	196,688	177,928
Additional paid-in capital	436,995,052	282,712,078
Accumulated deficit	(309,702,319)	(219,826,860)
Total stockholders' equity	127,489,421	63,063,146
Total liabilities and stockholders' equity	\$ 142,472,020	\$ 73,728,846

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,		
	2016	2015	2016	2015	2014
Revenues, net	\$ 4,487,427	\$ 5,629,740	\$ 19,356,450	\$ 20,142,898	\$ 15,026,219
Cost of goods sold	709,711	1,235,978	4,185,708	4,506,673	3,671,803
Gross profit	3,777,716	4,393,762	15,170,742	15,636,225	11,354,416
Operating expenses:					
Sales, general, and administrative	16,329,146	8,631,238	51,348,414	28,721,236	22,124,072
Research and development	10,341,144	13,253,472	53,943,477	72,042,774	43,218,938
Depreciation and amortization	48,132	18,000	132,451	62,400	52,467
Total operating expenses	26,718,422	21,902,710	105,424,342	100,826,410	65,395,477
Operating loss	(22,940,706)	(17,508,948)	(90,253,600)	(85,190,185)	(54,041,061)
Other income and (expense)					
Miscellaneous income	101,438	23,991	367,317	95,719	46,569
Accreted interest	2,974	2,280	10,824	17,442	37,309
Financing costs	—	—	—	—	(260,027)
Total other income (expense)	104,412	26,271	378,141	113,161	(176,149)
Loss before income taxes	(22,836,294)	(17,482,677)	(89,875,459)	(85,077,024)	(54,217,210)
Provision for income taxes	—	—	—	—	—
Net loss	\$ (22,836,294)	\$ (17,482,677)	\$ (89,875,459)	\$ (85,077,024)	\$ (54,217,210)
Loss per share, basic and diluted:					
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.10)	\$ (0.46)	\$ (0.49)	\$ (0.36)
Weighted average number of common shares outstanding, basic and diluted	196,613,297	177,876,462	196,088,196	173,174,229	149,727,228

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2016	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (89,875,459)	\$ (85,077,024)	\$ (54,217,210)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	77,906	29,959	28,987
Amortization of intangible assets	54,545	32,441	23,480
Provision for (recovery of) doubtful accounts	2,524,909	22,157	(5,436)
Share-based compensation	17,411,021	7,189,699	4,970,312
Amortization of deferred financing costs	—	—	260,027
Changes in operating assets and liabilities:			
Accounts receivable	(3,975,893)	(917,656)	(458,028)
Inventory	(386,168)	491,960	(138,495)
Other current assets	709,907	(773,532)	680,281
Other assets	—	(17,442)	(37,309)
Accounts payable	4,232,340	(3,200,955)	4,212,912
Deferred revenue	—	(522,613)	(1,079,967)
Other current liabilities	84,559	3,698,887	239,450
Net cash used in operating activities	<u>(69,142,333)</u>	<u>(79,044,119)</u>	<u>(45,520,996)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs	(845,266)	(419,104)	(586,480)
Purchase of fixed assets	(396,154)	(165,257)	(30,962)
(Payment) refund of security deposit	<u>(14,036)</u>	<u>—</u>	<u>10,686</u>
Net cash used in investing activities	<u>(1,255,456)</u>	<u>(584,361)</u>	<u>(606,756)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	134,863,475	91,374,649	42,771,353
Proceeds from exercise of options	989,060	1,232,579	345,746
Proceeds from exercise of warrants	<u>1,373,000</u>	<u>366,000</u>	<u>181,000</u>
Net cash provided by financing activities	<u>137,225,535</u>	<u>92,973,228</u>	<u>43,298,099</u>
Increase (decrease) in cash	66,827,746	13,344,748	(2,829,653)
Cash, beginning of period	64,706,355	51,361,607	54,191,260
Cash, end of period	<u>\$ 131,534,101</u>	<u>\$ 64,706,355</u>	<u>\$ 51,361,607</u>