
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): May 3, 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))
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Item 2.02. Results of Operations and Financial Condition.

On May 3, 2016, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its first fiscal quarter ended March 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.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release from TherapeuticsMD, Inc., dated May 3, 2016, entitled “TherapeuticsMD announces first quarter 2016 financial results.”

EXHIBIT INDEX

Exhibit
Number

Description

99.1

[Press Release from TherapeuticsMD, Inc., dated May 3, 2016, entitled "TherapeuticsMD announces first quarter 2016 financial results."](#)



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces First Quarter 2016 Financial Results

- NDA filing for TX-004HR planned by end of June 2016 -

- Strong cash position of approximately \$182 million to advance pipeline products -

BOCA RATON, Fla. – May 3, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its first quarter financial results for the quarter ended March 31, 2016.

First Quarter and Recent Developments

- Net revenue from the company’s prescription prenatal vitamin business increased 10 percent to approximately \$4.9 million for the first quarter of 2016, compared with approximately \$4.5 million for the first quarter of 2015.
- Net loss was approximately \$21.0 million for the first quarter of 2016, compared with approximately \$20.9 million for the first quarter of 2015.
- Ended the quarter with approximately \$182.1 million in cash and no debt.
- Presented posters at ENDO 2016 and the International Society for the Study of Women’s Sexual Health (ISSWSH) Annual Meeting 2016 detailing results of the phase 3 Rejoice Trial for Yuvvexy, the conditionally approved trade name for 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 findings showed patients treated with Yuvvexy achieved a statistically significant improvement over placebo across all four co-primary endpoints at all three doses evaluated. A New Drug Application filing is planned for Yuvvexy by end of June 2016.
- Exited approximately 1,500 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.
- Launched VitaTrue™, the first certified vegan and kosher prescription prenatal multivitamin, which expands the company’s line of prescription prenatal vitamin products and further strengthens its women’s health capabilities.
- Grew the company’s intellectual property portfolio to a current total of 134 patent filings, including 72 international filings, with 17 issued U.S. patents.
- Strengthened relationships with key medical, pharmacy, patient and industry organizations worldwide.

“During the first quarter, we successfully executed on our goals across the company,” said TherapeuticsMD CEO Robert G. Finizio. “We presented detailed phase 3 data from the Rejoice Trial at multiple conferences, and we are preparing to file our NDA for TX-004HR, the first of our two novel pipeline candidates in development to treat symptoms of menopause. We also expect topline data late in the fourth quarter of 2016 from our Replenish Trial for TX-001HR. We remain optimistic about the potential of our pipeline products and intend to leverage them, along with our current commercial infrastructure, to establish a leadership position in women’s health.”

Summary of First Quarter 2016 Financial Results

For the quarter ended March 31, 2016, net revenue from the company's prescription prenatal vitamins was approximately \$4.9 million compared with net revenue of approximately \$4.5 million for the prior year's quarter. Revenue growth during the quarter 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, partially offset by the impact of annual changes in insurance plans.

Cost of goods sold was approximately \$1.1 million for the three months ended March 31, 2016, compared with approximately \$1.0 million in the prior year's quarter.

Total operating expenses for the first quarter of 2016 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses during the first quarter of 2016 were approximately \$15.1 million compared to approximately \$18.2 million during the prior year's quarter, reflecting a 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 first quarter of 2016 were approximately \$9.7 million compared with approximately \$6.2 million for the prior year's quarter, primarily due to an increase in share-based compensation expense.

Non-operating income was insignificant for the first quarter of both 2016 and 2015 and included primarily interest income for both periods.

Net loss for the first quarter of 2016 was approximately \$21.0 million, or \$0.11 per basic and diluted share, compared with approximately \$20.9 million, or \$0.13 per basic and diluted share, for the first quarter of 2015.

At March 31, 2016, cash on hand was approximately \$182.1 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:	Tuesday, May 3, 2016
Time:	4:30 p.m. EDT
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	88600937

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.

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Contacts

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash	\$ 182,097,345	\$ 64,706,355
Accounts receivable, net of allowance for doubtful accounts of \$318,061 and \$81,910, respectively	5,063,773	3,049,715
Inventory	957,434	690,153
Other current assets	1,718,069	2,233,897
Total current assets	189,836,621	70,680,120
Fixed assets, net	264,706	198,592
Other Assets:		
Intangible assets, net	1,694,546	1,615,251
Prepaid expense	1,047,970	1,109,883
Security deposit	125,000	125,000
Total other assets	2,867,516	2,850,134
Total assets	\$ 192,968,843	\$ 73,728,846
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,430,649	\$ 3,126,174
Other current liabilities	6,165,764	7,539,526
Total current liabilities	9,596,413	10,665,700
Total liabilities	9,596,413	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; 196,253,700 and 177,928,041 issued and outstanding, respectively	196,254	177,928
Additional paid-in capital	423,932,401	282,712,078
Accumulated deficit	(240,756,225)	(219,826,860)
Total stockholders' equity	183,372,430	63,063,146
Total liabilities and stockholders' equity	\$ 192,968,843	\$ 73,728,846

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended	
	March 31, 2016	March 31, 2015
Revenues, net	\$ 4,930,091	\$ 4,475,049
Cost of goods sold	<u>1,108,443</u>	<u>1,043,641</u>
Gross profit	<u>3,821,648</u>	<u>3,431,408</u>
Operating expenses:		
Sales, general, and administrative	9,678,552	6,163,612
Research and development	15,097,017	18,176,835
Depreciation and amortization	19,597	13,572
Total operating expense	<u>24,795,166</u>	<u>24,354,019</u>
Operating loss	<u>(20,973,518)</u>	<u>(20,922,611)</u>
Other income		
Interest income	41,617	18,513
Accreted interest	2,536	9,842
Total other income	<u>44,153</u>	<u>28,355</u>
Loss before income taxes	(20,929,365)	(20,894,256)
Provision for income taxes	<u>—</u>	<u>—</u>
Net loss	<u>\$ (20,929,365)</u>	<u>\$ (20,894,256)</u>
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>
Weighted average number of common shares outstanding-basic and diluted	<u>194,901,560</u>	<u>163,448,130</u>

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended	
	March 31, 2016	March 31, 2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (20,929,365)	\$ (20,894,256)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	8,363	6,881
Amortization of intangible assets	11,234	6,691
Provision for doubtful accounts	236,151	13,004
Share-based compensation	4,381,690	840,464
Changes in operating assets and liabilities:		
Accounts receivable	(2,250,209)	(502,836)
Inventory	(267,281)	222,925
Other current assets	477,312	91,412
Other assets	(2,536)	(9,842)
Accounts payable	304,475	(91,946)
Deferred revenue	—	(522,613)
Other current liabilities	(1,373,762)	1,038,813
Other long-term liabilities	—	651,567
Net cash used in operating activities	<u>(19,403,928)</u>	<u>(19,149,736)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(90,529)	(36,853)
Purchase of fixed assets	(74,478)	—
Net cash used in investing activities	<u>(165,007)</u>	<u>(36,853)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	134,863,475	59,117,827
Proceeds from exercise of options	786,450	7,208
Proceeds from exercise of warrants	1,310,000	358,400
Net cash provided by financing activities	<u>136,959,925</u>	<u>59,483,435</u>
Increase in cash	117,390,990	40,296,846
Cash, beginning of period	64,706,355	51,361,607
Cash, end of period	<u>\$ 182,097,345</u>	<u>\$ 91,658,453</u>