
**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): November 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 November 3, 2016, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its third fiscal quarter ended September 30, 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 November 3, 2016, entitled “TherapeuticsMD Announces Third Quarter 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: November 3, 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	Press Release from TherapeuticsMD, Inc., dated November 3, 2016, entitled "TherapeuticsMD Announces Third Quarter 2016 Financial Results."

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2016 Financial Results

- Topline phase 3 data for TX-001HR Replenish Trial on track for fourth quarter of 2016 -

- TX-004HR PDUFA target action date of May 7, 2017 -

BOCA RATON, Fla. – Nov. 3, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its third quarter financial results for the quarter ended September 30, 2016.

Third Quarter and Recent Developments

- Announced acceptance of a New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) for TX-004HR (conditionally-approved trade name Yuvvexy[™]), the company’s investigational applicator-free estradiol vaginal softgel capsule 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 phase 3 results with all three doses of TX-004HR (4 mcg, 10 mcg and 25 mcg) that were evaluated in the Rejoice Trial. The FDA’s Prescription Drug User Fee Act (PDUFA) target action date for the NDA is May 7, 2017.
- Anticipate topline results in the fourth quarter of 2016 for the ongoing Replenish Trial, a phase 3 clinical trial of the company’s TX-001HR product candidate, 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.
- Net revenue from the company’s prescription prenatal vitamin business increased 7 percent to approximately \$5.5 million for the third quarter of 2016, compared with approximately \$5.2 million for the third quarter of 2015.
- Net loss was approximately \$25.0 million for the third quarter of 2016, compared with approximately \$19.5 million for the third quarter of 2015.
- Ended the quarter with approximately \$147.5 million in cash and no debt.
- Supported nine presentations at annual meetings of the International Menopause Society (IMS) and North American Menopause Society (NAMS), including reports on the positive results from the TX-004HR clinical development program and new data that further identify women’s perceptions of VVA and available treatment options.
- Grew the company’s intellectual property portfolio to a current total of 149 patent filings, including 82 international filings, with 17 issued U.S. patents.
- Strengthened relationships with medical, pharmacy, patient and industry organizations internationally.

“We are making excellent progress this year advancing our pipeline and enhancing our commercial capabilities focused on women’s health. During the quarter, we successfully completed the submission of our NDA for TX-004HR as a novel treatment for moderate to severe dyspareunia, a symptom of VVA due to menopause, and we continued ongoing pre-commercialization activities for this important product,” said TherapeuticsMD CEO Robert G. Finizio. “We now eagerly await the topline data from our Replenish Trial for TX-001HR in the fourth quarter of 2016, our second novel hormone therapy program, 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 Third Quarter 2016 Financial Results

Net revenue from the company's prescription prenatal vitamins increased 7 percent to approximately \$5.5 million for the third quarter of 2016 from approximately \$5.2 million for the prior year's quarter.

Cost of goods sold was approximately \$1.2 million for the third quarter of both 2016 and 2015.

Total operating expenses for the third quarter of 2016 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses during the third quarter of 2016 were approximately \$14.7 million compared to approximately \$16.4 million during the prior year's quarter, reflecting a decline in the company's clinical trial costs. SG&A expenses for the third quarter of 2016 were approximately \$14.7 million compared with approximately \$7.1 million for the prior year's quarter. Higher SG&A expenses during the third quarter of 2016 were primarily due to an increase in the company's sales, marketing and regulatory personnel to support future commercialization of the company's pipeline products.

Net loss for the third quarter of 2016 was approximately \$25.0 million, or \$0.13 per basic and diluted share, compared with approximately \$19.5 million, or \$0.11 per basic and diluted share, for the third quarter of 2015.

At September 30, 2016, cash on hand was approximately \$147.5 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, November 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:	99198056

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, in 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: 99198056.

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.

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 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.

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash	\$ 147,534,065	\$ 64,706,355
Accounts receivable, net of allowance for doubtful accounts of \$113,034 and \$81,910, respectively	5,033,298	3,049,715
Inventory	843,398	690,153
Other current assets	2,693,475	2,233,897
Total current assets	156,104,236	70,680,120
Fixed assets, net	460,546	198,592
Other Assets:		
Intangible assets, net	2,118,378	1,615,251
Prepaid expense	—	1,109,883
Security deposit	139,036	125,000
Total other assets	2,257,414	2,850,134
Total assets	\$ 158,822,196	\$ 73,728,846
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,224,419	\$ 3,126,174
Other current liabilities	8,243,421	7,539,526
Total current liabilities	12,467,840	10,665,700
Total liabilities	12,467,840	10,665,700
Commitments and Contingencies - See Note 15		
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; 196,580,212 and 177,928,041 issued and outstanding, respectively	196,580	177,928
Additional paid in capital	433,023,801	282,712,078
Accumulated deficit	(286,866,025)	(219,826,860)
Total stockholders' equity	146,354,356	63,063,146
Total liabilities and stockholders' equity	\$ 158,822,196	\$ 73,728,846

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues, net	\$ 5,535,685	\$ 5,190,175	\$ 14,869,023	\$ 14,513,158
Cost of goods sold	1,237,446	1,193,965	3,475,997	3,270,695
Gross profit	<u>4,298,239</u>	<u>3,996,210</u>	<u>11,393,026</u>	<u>11,242,463</u>
Operating expenses:				
Sales, general, and administration	14,721,710	7,060,944	35,019,268	20,089,998
Research and development	14,664,123	16,421,753	43,602,333	58,789,302
Depreciation and amortization	40,460	16,548	84,319	44,400
Total operating expense	<u>29,426,293</u>	<u>23,499,245</u>	<u>78,705,920</u>	<u>78,923,700</u>
Operating loss	<u>(25,128,054)</u>	<u>(19,503,035)</u>	<u>(67,312,894)</u>	<u>(67,681,237)</u>
Other income:				
Miscellaneous income	109,942	27,630	265,879	71,728
Accreted interest	2,451	2,760	7,850	15,162
Total other income	<u>112,393</u>	<u>30,390</u>	<u>273,729</u>	<u>86,890</u>
Loss before taxes	(25,015,661)	(19,472,645)	(67,039,165)	(67,594,347)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (25,015,661)</u>	<u>\$ (19,472,645)</u>	<u>\$ (67,039,165)</u>	<u>\$ (67,594,347)</u>
Net loss per share, basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>	<u>\$ (0.39)</u>
Weighted average number of common shares outstanding	<u>196,502,327</u>	<u>177,206,168</u>	<u>195,912,173</u>	<u>171,589,595</u>

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

	Nine Months Ended	
	September 30, 2016	September 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (67,039,165)	\$ (67,594,347)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	45,759	22,104
Amortization of intangible assets	38,560	22,296
Provision for doubtful accounts	2,261,568	37,163
Share-based compensation	13,385,215	4,740,906
Changes in operating assets and liabilities:		
Accounts receivable	(4,245,151)	(1,549,532)
Inventory	(153,245)	312,054
Other current assets	379,930	(621,923)
Other assets	—	(15,162)
Accounts payable	1,098,245	(1,025,504)
Deferred revenue	—	(522,613)
Other current liabilities	703,895	2,546,138
Other long-term liabilities	—	1,213,874
Net cash used in operating activities	<u>(53,524,389)</u>	<u>(62,434,546)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(541,686)	(117,992)
Purchase of fixed assets	(307,714)	(15,559)
Payment of security deposit	(14,036)	—
Net cash used in investing activities	<u>(863,436)</u>	<u>(133,551)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	134,863,475	91,374,649
Proceeds from exercise of warrants	1,373,000	366,000
Proceeds from exercise of options	979,060	589,829
Net cash provided by financing activities	<u>137,215,535</u>	<u>92,330,478</u>
Increase in cash	82,827,710	29,762,381
Cash, beginning of period	64,706,355	51,361,607
Cash, end of period	<u>\$ 147,534,065</u>	<u>\$ 81,123,988</u>