

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 2, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 2, 2017, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its first fiscal quarter ended March 31, 2017. 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 2, 2017, entitled “TherapeuticsMD Announces First Quarter 2017 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: May 2, 2017

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated May 2, 2017, entitled "TherapeuticsMD Announces First Quarter 2017 Financial Results."



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces First Quarter 2017 Financial Results

BOCA RATON, Fla. – May 2, 2017 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its financial results for the quarter ended March 31, 2017.

First Quarter and Recent Developments

- Net revenue for the company’s prescription prenatal vitamin business was approximately \$4.0 million for the first quarter of 2017 compared with approximately \$4.9 million for the first quarter of 2016.
- Net loss was approximately \$21.2 million for the first quarter of 2017, compared with approximately \$20.9 million for the first quarter of 2016.
- Ended the quarter with approximately \$113.5 million in cash and no debt.
- Anticipate FDA action on the New Drug Application (NDA) for TX-004HR on or before the originally scheduled Prescription Drug User Fee Act (PDUFA) target action date of May 7, 2017. TX-004HR is 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.
- Presented two posters at ENDO 2017 reviewing data from the Replenish Trial, a phase 3 clinical trial of TX-001HR, the company’s investigational 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. The results from the trial in 1,835 postmenopausal women demonstrated that multiple doses of TX-001HR resulted in a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo. The company plans to submit the NDA for TX-001HR as early as the third quarter of 2017.
- Launched BIO-IGNITE™, 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. Through the BIO-IGNITE™ program, the company currently has a distribution agreement with Premier Value Pharmacy Compounding Network (PVPCN), representing over 300 pharmacies and 1.5 million annual prescriptions of compounded bio-identical estradiol and progesterone (E+P), to dispense the company’s products in lieu of compounding, if approved. The company has also received prescription data from over 400 additional pharmacies, representing over 500,000 annual prescriptions of compounded bio-identical E+P.
- Grew the company’s intellectual property portfolio to a current total of 158 patent filings, including 82 international filings, with one allowed and 17 issued U.S. patents.

“We are focused on advancing our pipeline of novel hormone therapies and, if approved, bringing new, differentiated treatment options to women suffering from symptoms of menopause,” said TherapeuticsMD CEO Robert G. Finizio.

Summary of First Quarter 2017 Financial Results

Net revenue from the company’s prescription prenatal vitamin business was approximately \$4.0 million for the first quarter of 2017 compared with net revenue of approximately \$4.9 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.

Cost of goods sold was approximately \$0.7 million for the first quarter of 2017, compared with approximately \$1.1 million in the prior year’s quarter.

Total operating expenses for the first quarter of 2017 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses during the first quarter of 2017 were approximately \$7.7 million compared with approximately \$15.1 million for the prior year’s quarter. The decrease in R&D was a direct result of the completion of the Replenish Trial for TX-001HR. SG&A expenses for the first quarter of 2017 were approximately \$16.8 million compared with approximately \$9.7 million for the prior year’s quarter, primarily due to higher sales, marketing, regulatory expenditures, and personnel costs to support future commercialization.

Net loss for the first quarter of 2017 was approximately \$21.2 million, or \$0.11 per basic and diluted share, compared with approximately \$20.9 million, or \$0.11 per basic and diluted share, for the first quarter of 2016.

At March 31, 2017, cash on hand was approximately \$113.5 million, compared with approximately \$131.5 million at December 31, 2016.

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 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 resolve the deficiencies identified by the FDA in the company's NDA for its TX-004HR product candidate; 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 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 an NDA for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; 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

	March 31, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current Assets:		
Cash	\$ 113,525,419	\$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of \$374,771 and \$376,374, respectively	3,921,359	4,500,699
Inventory	1,338,618	1,076,321
Other current assets	2,488,121	2,299,052
Total current assets	121,273,517	139,410,173
Fixed assets, net	511,073	516,839
Other Assets:		
Intangible assets, net	2,497,360	2,405,972
Security deposit	139,036	139,036
Total other assets	2,636,396	2,545,008
Total assets	\$ 124,420,986	\$ 142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 6,146,278	\$ 7,358,514
Other current liabilities	7,940,723	7,624,085
Total current liabilities	14,087,001	14,982,599
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: 198,593,268 and 196,688,222 issued and outstanding, respectively	198,593	196,688
Additional paid-in capital	441,025,624	436,995,052
Accumulated deficit	(330,890,232)	(309,702,319)
Total stockholders' equity	110,333,985	127,489,421
Total liabilities and stockholders' equity	\$ 124,420,986	\$ 142,472,020

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

	Three Months Ended	
	March 31, 2017	March 31, 2016
Revenues, net	\$ 3,985,464	\$ 4,930,091
Cost of goods sold	<u>659,635</u>	<u>1,108,443</u>
Gross profit	<u>3,325,829</u>	<u>3,821,648</u>
Operating expenses:		
Sales, general, and administrative	16,837,617	9,678,552
Research and development	7,724,840	15,097,017
Depreciation and amortization	49,699	19,597
Total operating expenses	<u>24,612,156</u>	<u>24,795,166</u>
Operating loss	<u>(21,286,327)</u>	<u>(20,973,518)</u>
Other income		
Miscellaneous income	125,968	41,617
Accreted interest	3,867	2,536
Total other income	<u>129,835</u>	<u>44,153</u>
Loss before income taxes	(21,156,492)	(20,929,365)
Provision for income taxes	—	—
Net loss	<u>\$ (21,156,492)</u>	<u>\$ (20,929,365)</u>
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.11)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>197,790,040</u>	<u>194,901,560</u>

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

	Three Months Ended	
	March 31, 2017	March 31, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (21,156,492)	\$ (20,929,365)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	33,600	8,363
Amortization of intangible assets	16,099	11,234
(Recovery of) provision for doubtful accounts	(1,603)	236,151
Share-based compensation	1,413,195	4,381,690
Changes in operating assets and liabilities:		
Accounts receivable	580,943	(2,250,209)
Inventory	(262,297)	(267,281)
Other current assets	(253,518)	477,312
Other assets	—	(2,536)
Accounts payable	(1,212,236)	304,475
Other current liabilities	316,638	(1,373,762)
Net cash used in operating activities	<u>(20,525,671)</u>	<u>(19,403,928)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(107,487)	(90,529)
Purchase of fixed assets	(27,834)	(74,478)
Net cash used in investing activities	<u>(135,321)</u>	<u>(165,007)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	—	134,863,475
Proceeds from exercise of options	192,310	786,450
Proceeds from exercise of warrants	2,460,000	1,310,000
Net cash provided by financing activities	<u>2,652,310</u>	<u>136,959,925</u>
(Decrease) increase in cash	(18,008,682)	117,390,990
Cash, beginning of period	131,534,101	64,706,355
Cash, end of period	<u>\$ 113,525,419</u>	<u>\$ 182,097,345</u>