

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): August 3, 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 12v-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 August 3, 2017, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its second fiscal quarter ended June 30, 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 August 3, 2017, entitled “TherapeuticsMD Announces Second 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: August 3, 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 August 3, 2017, entitled "TherapeuticsMD Announces Second Quarter 2017 Financial Results."



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Second Quarter 2017 Financial Results

BOCA RATON, Fla. – August 3, 2017 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its financial results for the quarter ended June 30, 2017.

Second Quarter and Recent Developments

- Net revenue for the company’s prescription prenatal vitamin business was approximately \$4.3 million for the second quarter of 2017 compared with approximately \$4.4 million for the second quarter of 2016.
- Net loss was approximately \$19.7 million for the second quarter of 2017, compared with approximately \$21.1 million for the second quarter of 2016.
- Ended the quarter with approximately \$96.5 million in cash and no debt.
- Participated in a Type A Post-Action Meeting on June 14, 2017 with the Division of Bone, Reproductive, and Urologic Products (DBRUP) of the FDA to discuss the Complete Response Letter (CRL) regarding the New Drug Application (NDA) for TX-004HR, 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 Company has formally submitted additional information for consideration related to the NDA for TX-004HR and has been informed by the FDA that it will be receiving an Advice Letter within the next week outlining the FDA’s timing of its review of the submitted additional data.
- Pre-NDA meeting for 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, scheduled with the FDA at the end of August 2017. The company anticipates that it will submit the NDA for TX-001HR in the fourth quarter of 2017.
- Dismissal without prejudice of the primary federal securities class action lawsuit recently filed against the company.
- 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 continue to focus 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 Second Quarter 2017 Financial Results

Net revenue from the company's prescription prenatal vitamin business was approximately \$4.3 million for the second quarter of 2017 compared with net revenue of approximately \$4.4 million for the prior year's quarter. These changes were primarily due to a decrease in the number of units sold.

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

Total operating expenses for the second quarter of 2017 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses for the second quarter of 2017 were approximately \$8.7 million compared with approximately \$13.8 million for the prior year's quarter. The decrease in R&D expenses was a direct result of the completion of the REPLENISH Trial for TX-001HR. SG&A expenses for the second quarter of 2017 were approximately \$14.6 million compared with approximately \$10.6 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 second quarter of 2017 was approximately \$19.7 million, or \$0.10 per basic and diluted share, compared with approximately \$21.1 million, or \$0.11 per basic and diluted share, for the second quarter of 2016.

At June 30, 2017, cash on hand was approximately \$96.5 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 new drug application for its TX-004HR product candidate and the time frame associated with such resolution; whether the company will be able to prepare an amended NDA for its TX-004HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; 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, including any additional clinical trials that the FDA may require in connection with TX-004HR; 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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Investor Contact

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash	\$ 96,476,483	\$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of \$358,268 and \$376,374, respectively	3,396,419	4,500,699
Inventory	1,414,015	1,076,321
Other current assets	2,228,755	2,299,052
Total current assets	103,515,672	139,410,173
Fixed assets, net	483,688	516,839
Other Assets:		
Intangible assets, net	2,739,686	2,405,972
Security deposit	139,036	139,036
Total other assets	2,878,722	2,545,008
Total assets	\$ 106,878,082	\$ 142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 8,108,034	\$ 7,358,514
Other current liabilities	5,180,218	7,624,085
Total current liabilities	13,288,252	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; 204,027,142 and 196,688,222 issued and outstanding, respectively	204,027	196,688
Additional paid in capital	443,952,952	436,995,052
Accumulated deficit	(350,567,149)	(309,702,319)
Total stockholders' equity	93,589,830	127,489,421
Total liabilities and stockholders' equity	\$ 106,878,082	\$ 142,472,020

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenues, net	\$ 4,250,433	\$ 4,403,247	\$ 8,235,897	\$ 9,333,338
Cost of goods sold	681,725	1,130,108	1,341,360	2,238,551
Gross profit	<u>3,568,708</u>	<u>3,273,139</u>	<u>6,894,537</u>	<u>7,094,787</u>
Operating expenses:				
Sales, general, and administration	14,628,927	10,619,006	31,466,544	20,297,558
Research and development	8,716,395	13,841,193	16,441,235	28,938,210
Depreciation and amortization	53,189	24,262	102,888	43,859
Total operating expense	<u>23,398,511</u>	<u>24,484,461</u>	<u>48,010,667</u>	<u>49,279,627</u>
Operating loss	<u>(19,829,803)</u>	<u>(21,211,322)</u>	<u>(41,116,130)</u>	<u>(42,184,840)</u>
Other income:				
Miscellaneous income	149,054	114,320	275,022	155,937
Accreted interest	3,832	2,863	7,699	5,399
Total other income	<u>152,886</u>	<u>117,183</u>	<u>282,721</u>	<u>161,336</u>
Loss before taxes	<u>(19,676,917)</u>	<u>(21,094,139)</u>	<u>(40,833,409)</u>	<u>(42,023,504)</u>
Provision for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$ (19,676,917)</u>	<u>\$ (21,094,139)</u>	<u>\$ (40,833,409)</u>	<u>\$ (42,023,504)</u>
Net loss per share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.11)</u>	<u>\$ (0.20)</u>	<u>\$ (0.21)</u>
Weighted average number of common shares outstanding	<u>203,384,610</u>	<u>196,325,715</u>	<u>200,602,778</u>	<u>195,613,639</u>

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

	Six Months Ended	
	June 30, 2017	June 30, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (40,833,409)	\$ (42,023,504)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	69,000	19,216
Amortization of intangible assets	33,888	24,643
(Recovery of) provision for doubtful accounts	(18,106)	447,388
Share-based compensation	3,051,357	9,200,844
Changes in operating assets and liabilities:		
Accounts receivable	1,122,386	(1,874,980)
Inventory	(337,694)	(193,503)
Other current assets	(58,601)	1,001,120
Accounts payable	749,520	(86,786)
Other current liabilities	(2,443,867)	(1,239,743)
Net cash used in operating activities	<u>(38,665,526)</u>	<u>(34,725,305)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(367,602)	(393,221)
Purchase of fixed assets	(35,849)	(265,036)
Payment of security deposit	—	(4,864)
Net cash used in investing activities	<u>(403,451)</u>	<u>(663,121)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	—	134,863,475
Proceeds from exercise of warrants	3,798,999	1,373,000
Proceeds from exercise of options	212,360	978,042
Net cash provided by financing activities	<u>4,011,359</u>	<u>137,214,517</u>
(Decrease) increase in cash	(35,057,618)	101,826,091
Cash, beginning of period	131,534,101	64,706,355
Cash, end of period	<u>\$ 96,476,483</u>	<u>\$ 166,532,446</u>