

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 6, 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 November 6, 2017, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its third fiscal quarter ended September 30, 2017. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 6, 2017, TherapeuticsMD, Inc. issued a press release announcing its plans to resubmit the New Drug Application for its TX-004HR product candidate. A copy of the press release is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including the exhibits) is furnished pursuant to Item 2.02 or Item 7.01, as applicable, 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 6, 2017, entitled “TherapeuticsMD Announces Third Quarter 2017 Financial Results.”
99.2	Press Release from TherapeuticsMD, Inc., dated November 6, 2017, entitled “TherapeuticsMD Announces Plan to Resubmit the New Drug Application for TX-004HR.”

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 6, 2017

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

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99.1	Press Release from TherapeuticsMD, Inc., dated November 6, 2017, entitled “TherapeuticsMD Announces Third Quarter 2017 Financial Results.”
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FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2017 Financial Results

- Resubmission of New Drug Application for TX-004HR expected in the coming weeks -

- Submission of New Drug Application for TX-001HR expected in December 2017 -

BOCA RATON, Fla. – November 6, 2017 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women’s healthcare company, today announced its financial results for the quarter ended September 30, 2017.

Third Quarter and Recent Developments

- On November 3, 2017, the Company participated in an in-person meeting with the Division of Bone, Reproductive, and Urologic Products of the Food and Drug Administration (FDA). At the meeting, the Division agreed to the resubmission of the New Drug Application (NDA) for TX-004HR without the need for an additional pre-approval study. The Company will commit to conduct a post-approval observational study. The Company plans to resubmit the NDA for TX-004HR in the coming weeks.
- Presented five oral abstracts at NAMS 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 in December 2017.
- Net revenue for the company’s prescription prenatal vitamin business was approximately \$4.4 million for the third quarter of 2017 compared with approximately \$5.5 million for the third quarter of 2016.
- Net loss was approximately \$14.7 million for the third quarter of 2017, compared with approximately \$25.0 million for the third quarter of 2016.
- Ended the quarter with approximately \$148.3 million in cash and no debt, which includes approximately \$68.6 million in net proceeds from an equity offering in September 2017.
- Grew the company’s intellectual property portfolio to a current total of 158 patent filings, including 82 international filings, with one allowed and 18 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 Third Quarter 2017 Financial Results

Net revenue from the company’s prescription prenatal vitamin business was approximately \$4.4 million for the third quarter of 2017 compared with net revenue of approximately \$5.5 million for the prior year’s quarter. These changes were primarily due to a decrease in the average net sales price of our products and a slight decrease in the number of units sold.

Cost of goods sold was approximately \$0.7 million for the third quarter of 2017, compared with approximately \$1.2 million for the prior year's quarter.

Total operating expenses for the third quarter of 2017 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses for the third quarter of 2017 were approximately \$6.4 million compared with approximately \$14.7 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 third quarter of 2017 were approximately \$12.1 million compared with approximately \$14.7 million for the prior year's quarter, primarily due to lower sales and marketing expenditures.

Net loss for the third quarter of 2017 was approximately \$14.7 million, or \$0.07 per basic and diluted share, compared with approximately \$25.0 million, or \$0.13 per basic and diluted share, for the third quarter of 2016.

At September 30, 2017, cash on hand was approximately \$148.3 million, which includes approximately \$68.6 million in net proceeds from an equity offering in September 2017, 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

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current Assets:		
Cash	\$ 148,292,654	\$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of \$377,929 and \$376,374, respectively	4,392,635	4,500,699
Inventory	1,293,517	1,076,321
Other current assets	3,001,777	2,299,052
Total current assets	156,980,583	139,410,173
Fixed assets, net	448,066	516,839
Other Assets:		
Intangible assets, net	2,793,421	2,405,972
Security deposit	139,036	139,036
Total other assets	2,932,457	2,545,008
Total assets	\$ 160,361,106	\$ 142,472,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,199,369	\$ 7,358,514
Other current liabilities	6,677,232	7,624,085
Total current liabilities	10,876,601	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; 216,429,642 and 196,688,222 issued and outstanding, respectively	216,430	196,688
Additional paid in capital	514,499,865	436,995,052
Accumulated deficit	(365,231,790)	(309,702,319)
Total stockholders' equity	149,484,505	127,489,421
Total liabilities and stockholders' equity	\$ 160,361,106	\$ 142,472,020

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenues, net	\$ 4,417,598	\$ 5,535,685	\$ 12,653,495	\$ 14,869,023
Cost of goods sold	700,814	1,237,446	2,042,174	3,475,997
Gross profit	<u>3,716,784</u>	<u>4,298,239</u>	<u>10,611,321</u>	<u>11,393,026</u>
Operating expenses:				
Sales, general, and administration	12,057,868	14,721,710	43,524,412	35,019,268
Research and development	6,436,802	14,664,123	22,878,037	43,602,333
Depreciation and amortization	54,055	40,460	156,943	84,319
Total operating expense	<u>18,548,725</u>	<u>29,426,293</u>	<u>66,559,392</u>	<u>78,705,920</u>
Operating loss	<u>(14,831,941)</u>	<u>(25,128,054)</u>	<u>(55,948,071)</u>	<u>(67,312,894)</u>
Other income:				
Miscellaneous income	167,300	109,942	442,322	265,879
Accreted interest	—	2,451	7,699	7,850
Total other income	<u>167,300</u>	<u>112,393</u>	<u>450,021</u>	<u>273,729</u>
Loss before taxes	<u>(14,664,641)</u>	<u>(25,015,661)</u>	<u>(55,498,050)</u>	<u>(67,039,165)</u>
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (14,664,641)</u>	<u>\$ (25,015,661)</u>	<u>\$ (55,498,050)</u>	<u>\$ (67,039,165)</u>
Net loss per share, basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.13)</u>	<u>\$ (0.27)</u>	<u>\$ (0.34)</u>
Weighted average number of common shares outstanding	<u>207,938,338</u>	<u>196,502,327</u>	<u>203,282,335</u>	<u>195,912,173</u>

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

	Nine Months Ended	
	September 30, 2017	September 30, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (55,498,050)	\$ (67,039,165)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	104,622	45,759
Amortization of intangible assets	52,321	38,560
Provision for doubtful accounts	1,555	2,261,568
Share-based compensation	5,037,783	13,385,215
Changes in operating assets and liabilities:		
Accounts receivable	106,509	(4,245,151)
Inventory	(217,196)	(153,245)
Other current assets	(831,623)	379,930
Accounts payable	(3,159,145)	1,098,245
Other current liabilities	(946,853)	703,895
Net cash used in operating activities	<u>(55,350,077)</u>	<u>(53,524,389)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(439,770)	(541,686)
Purchase of fixed assets	(35,849)	(307,714)
Payment of security deposit	—	(14,036)
Net cash used in investing activities	<u>(475,619)</u>	<u>(863,436)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	68,572,635	134,863,475
Proceeds from exercise of warrants	3,798,999	1,373,000
Proceeds from exercise of options	212,615	979,060
Net cash provided by financing activities	<u>72,584,249</u>	<u>137,215,535</u>
Increase in cash	16,758,553	82,827,710
Cash, beginning of period	131,534,101	64,706,355
Cash, end of period	<u>\$ 148,292,654</u>	<u>\$ 147,534,065</u>



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Plan to Resubmit the New Drug Application for TX-004HR

BOCA RATON, Fla. – November 6, 2017 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women’s healthcare company, today announced a regulatory update 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.

On November 3, 2017, the Company participated in an in-person meeting with the Division of Bone, Reproductive, and Urologic Products of the Food and Drug Administration (FDA). At the meeting, the Division agreed to the resubmission of the NDA for TX-004HR without the need for an additional pre-approval study. The Company will commit to conduct a post-approval observational study.

The Company believes it will be in a position to resubmit the NDA for TX-004HR within the coming weeks, with a potential approval of the NDA within two to six months after resubmission, depending on the classification of the review of the NDA.

“We appreciate the hard work and collaborative effort by the FDA in moving TX-004HR one step closer to approval,” said TherapeuticsMD CEO Robert G. Finizio. “We are extremely pleased with the FDA’s position that an additional pre-approval safety study is no longer necessary for the resubmission of the NDA for TX-004HR.”

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