

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): February 20, 2018

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 February 20, 2018, TherapeuticsMD, Inc. issued a press release announcing its financial results for its fourth quarter and full year ended December 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.*

Exhibit

Number

Description

99.1

[Press Release from TherapeuticsMD, Inc., dated February 20, 2018, entitled “TherapeuticsMD Announces Fourth Quarter and Full-Year 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: February 20, 2018

THERAPEUTICSMD, INC.

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



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Fourth Quarter and Full Year 2017 Financial Results

- PDUFA target action date of May 29, 2018 for TX-004HR -

- Acceptance of New Drug Application for TX-001HR expected in March 2018 -

BOCA RATON, Fla. – February 20, 2018 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced its fourth quarter and full-year financial results for 2017.

2017 and Recent Developments

- Resubmitted 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 29, 2017. The Food and Drug Administration (FDA) has acknowledged that the resubmission is a complete, class 2 response to the Complete Response Letter (CRL) received on May 5, 2017 for TX-004HR. The PDUFA target action date for the completion of the FDA's review of the NDA is May 29, 2018.
- 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 submitted the NDA for TX-001HR on December 28, 2017.
- Net revenue for the company's prescription prenatal vitamin business was approximately \$16.8 million for 2017 compared with approximately \$19.4 million for 2016.
- Net loss was approximately \$76.9 million for 2017, compared with approximately \$89.9 million for 2016.
- Ended the year with approximately \$127.1 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 211 patent filings, including 123 international filings, with one allowed and 18 issued U.S. patents.

"Our company has tremendous opportunity in 2018," said TherapeuticsMD CEO Robert G. Finizio. "We have the potential for approvals of both of our late-stage product candidates in 2018, representing a major inflection point for our company."

Summary of 2017 Financial Results

For the year ended December 31, 2017, net revenue was approximately \$16.8 million compared with approximately \$19.4 million for the prior year. Net revenue for the fourth quarter of 2017 was approximately \$4.1 million compared with net revenue of approximately \$4.5 million for the prior year's quarter. These changes were primarily due to a decrease in the average net revenue per unit of the company's products, primarily related to higher coupons in 2017, partially offset by a slight increase in the number of units sold.

Total operating expenses for the fourth quarter and full-year 2017 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses for the full-year 2017 were approximately \$33.9 million compared with approximately \$53.9 million for the prior year. R&D expenses for the fourth quarter of 2017 were approximately \$11.0 million compared to approximately \$10.3 million during the prior year's quarter. The decreases in R&D for full-year 2017 were primarily due to lower clinical trial costs as the company completed its phase 3 clinical trials for TX-001HR and TX-004HR. SG&A expenses for the full-year 2017 were approximately \$57.7 million compared with approximately \$51.3 million for the prior year. SG&A expenses for the fourth quarter of 2017 were approximately \$14.2 million compared with approximately \$16.3 million for the prior year's quarter. The increases in SG&A for full-year 2017 were primarily due to higher sales, marketing, regulatory expenditures, and personnel costs to support future commercialization.

Net loss for the full-year 2017 was approximately \$76.9 million, or \$0.37 per basic and diluted share, compared with approximately \$89.9 million, or \$0.46 per basic and diluted share, for the full-year 2016. Net loss in the fourth quarter of 2017 was approximately \$21.4 million, or \$0.10 per basic and diluted share, compared with approximately \$22.8 million, or \$0.12 per basic and diluted share, for the fourth quarter of 2016.

At December 31, 2017, cash on hand was approximately \$127.1 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.

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, February 20, 2018
Time:	4:30 p.m. EST
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	3789163

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: 3789163.

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 FDA will approve the amended NDA for the company's TX-004HR product candidate and whether such approval will occur by the PDUFA target action 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 FDA will accept and approve the NDA for the company's TX-001HR product candidate; 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

	December 31,	
	2017	2016
ASSETS		
Current Assets:		
Cash	\$ 127,135,628	\$ 131,534,101
Accounts receivable, net of allowance for doubtful accounts of \$380,580 and \$376,374, respectively	4,328,802	4,500,699
Inventory	1,485,358	1,076,321
Other current assets	6,604,284	2,299,052
Total current assets	<u>139,554,072</u>	<u>139,410,173</u>
Fixed assets, net	<u>437,055</u>	<u>516,839</u>
Other Assets:		
Intangible assets, net	3,099,747	2,405,972
Security deposit	139,036	139,036
Total other assets	3,238,783	2,545,008
Total assets	<u>\$ 143,229,910</u>	<u>\$ 142,472,020</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,097,600	\$ 7,358,514
Other current liabilities	9,223,595	7,624,085
Total current liabilities	<u>13,321,195</u>	<u>14,982,599</u>
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	516,351,405	436,995,052
Accumulated deficit	(386,659,120)	(309,702,319)
Total stockholders' equity	<u>129,908,715</u>	<u>127,489,421</u>
Total liabilities and stockholders' equity	<u>\$ 143,229,910</u>	<u>\$ 142,472,020</u>

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,		
	2017	2016	2017	2016	2015
Revenues, net	\$ 4,124,218	\$ 4,487,427	\$ 16,777,713	\$ 19,356,450	\$ 20,142,898
Cost of goods sold	594,769	709,711	2,636,943	4,185,708	4,506,673
Gross profit	3,529,449	3,777,716	14,140,770	15,170,742	15,636,225
Operating expenses:					
Sales, general, and administrative	14,178,958	16,329,146	57,703,370	51,348,414	28,721,236
Research and development	10,974,956	10,341,144	33,852,993	53,943,477	72,042,774
Depreciation and amortization	56,174	48,132	213,117	132,451	62,400
Total operating expenses	25,210,088	26,718,422	91,769,480	105,424,342	100,826,410
Operating loss	(21,680,639)	(22,940,706)	(77,628,710)	(90,253,600)	(85,190,185)
Other income					
Miscellaneous income	253,309	101,438	695,631	367,317	95,719
Accreted interest	—	2,974	7,699	10,824	17,442
Total other income	253,309	104,412	703,330	378,141	113,161
Loss before income taxes	(21,427,330)	(22,836,294)	(76,925,380)	(89,875,459)	(85,077,024)
Provision for income taxes	—	—	—	—	—
Net loss	\$ (21,427,330)	\$ (22,836,294)	\$ (76,925,380)	\$ (89,875,459)	\$ (85,077,024)
Loss per share, basic and diluted:					
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.12)	\$ (0.37)	\$ (0.46)	\$ (0.49)
Weighted average number of common shares outstanding, basic and diluted	216,429,642	196,613,297	205,523,288	196,088,196	173,174,229

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2017	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (76,925,380)	\$ (89,875,459)	\$ (85,077,024)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	141,601	77,906	29,959
Amortization of intangible assets	71,516	54,545	32,441
Provision for doubtful accounts	4,206	2,524,909	22,157
Share-based compensation	6,889,323	17,411,021	7,189,699
Changes in operating assets and liabilities:			
Accounts receivable	167,691	(3,975,893)	(917,656)
Inventory	(409,037)	(386,168)	491,960
Other current assets	(4,434,130)	709,907	(773,532)
Other assets	—	—	(17,442)
Accounts payable	(3,260,914)	4,232,340	(3,200,955)
Deferred revenue	—	—	(522,613)
Other current liabilities	1,599,510	84,559	3,698,887
Net cash used in operating activities	(76,155,614)	(69,142,333)	(79,044,119)
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs	(765,291)	(845,266)	(419,104)
Purchase of fixed assets	(61,817)	(396,154)	(165,257)
Payment of security deposit	—	(14,036)	—
Net cash used in investing activities	(827,108)	(1,255,456)	(584,361)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	68,572,635	134,863,475	91,374,649
Proceeds from exercise of options	212,615	989,060	1,232,579
Proceeds from exercise of warrants	3,798,999	1,373,000	366,000
Net cash provided by financing activities	72,584,249	137,225,535	92,973,228
(Decrease) increase in cash	(4,398,473)	66,827,746	13,344,748
Cash, beginning of period	131,534,101	64,706,355	51,361,607
Cash, end of period	<u>\$ 127,135,628</u>	<u>\$ 131,534,101</u>	<u>\$ 64,706,355</u>