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): July 30, 2018

TherapeuticsMD, Inc.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-00100**	**87-0233535**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

☐ 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 July 30, 2018, the Company issued a press release announcing its financial results for its second quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) is furnished 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 Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in its expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

Item 7.01 Regulation FD Disclosure.

On July 30, 2018, the Company issued a press release announcing the Company's financial results for its second quarter ended June 30, 2018. The press release is furnished as Exhibit 99.1 hereto. The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated June 30, 2018, entitled TherapeuticsMD Announces Second Quarter 2018 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: July 30, 2018

THERAPEUTICSMD, INC.

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Second Quarter 2018 Financial Results

-Imvexxy™ early experience program underway; national launch to commence August 6, 2018-
-PDUFA target action date of October 28, 2018 for TX-001HR-

BOCA RATON, Fla. – **July 30, 2018** – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced its financial results for the quarter ended June 30, 2018.

Second Quarter and Recent Developments

- Received FDA approval of Imvexxy™ (estradiol vaginal inserts) on May 29, 2018 for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.
- Completed the first drawdown of $75 million on June 7, 2018 under its previously announced $200 million term loan facility with MidCap Financial, managed by Apollo Capital Management, L.P, to support the commercial launch of its recently approved product.
- Initiated Imvexxy's limited launch (early experience program) on July 9, 2018 with the 10 mcg dose, which will be followed by the national launch of the 10 mcg dose that is expected to commence on August 6, 2018. In the first three weeks of limited launch (July 9-27, 2018), approximately 1,363 healthcare providers have initiated at least one patient on treatment and sent in the follow-on prescription for continuation of treatment on the maintenance pack. The 4 mcg of Imvexxy is expected to be available in early September 2018.
- Net revenue for the company's prescription prenatal vitamin business was approximately $3.8 million for the second quarter of 2018, compared with approximately $4.3 million for the second quarter of 2017.
- Net loss was approximately $33.2 million for the second quarter of 2018, compared with approximately $19.7 million for the second quarter of 2017.
- Ended the quarter with approximately $154.4 million in cash and approximately $73.1 million in outstanding debt.
- Grew the company's intellectual property portfolio to a current total of 237 global patent applications with 20 issued foreign patents and 19 issued U.S. patents.

"We made important progress during the first half of 2018 that has given us an exciting start to the year," said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. "We are focused on commercial and operational execution with the launch of Imvexxy and an approaching PDUFA date for TX-001HR."

Summary of Second Quarter 2018 Financial Results

Net revenue from the company's prescription prenatal vitamin business was approximately $3.8 million for the second quarter of 2018 compared with net revenue of approximately $4.3 million for the prior year's quarter. This decrease was primarily attributable to a decrease in the average net revenue per unit of the company's products, which was primarily related to higher estimates related to offered discounts in 2018, partially offset by an increase in the number of units sold.

Cost of goods sold was approximately $0.5 million for the second quarter of 2018, compared with approximately $0.7 million for the prior year's quarter.

Total operating expenses for the second quarter of 2018 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses for the second quarter of 2018 were approximately $6.8 million compared with approximately $8.7 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 second quarter of 2018 were approximately $29.5 million compared with approximately $14.6 million for the prior year's quarter, primarily due to higher sales, marketing, and personnel costs to support commercialization of Imvexxy and pre-commercialization expenses for TX-001HR.

Net loss for the second quarter of 2018 was approximately $33.2 million, or $0.15 per basic and diluted share, compared with approximately $19.7 million, or $0.10 per basic and diluted share, for the second quarter of 2017.

Balance Sheet

As of June 30, 2018, the company's cash on hand totaled approximately $154.4 million, compared with approximately $127.1 million at December 31, 2018. Total outstanding debt, net of issuance of costs, was approximately $73.1 million as of June 30, 2018.

Conference Call and Webcast Details

TherapeuticsMD will host a conference call and audio webcast this morning, July 30, 2018, at 8:30 a.m. ET to present second quarter 2018 results and provide a business update.

Date: Monday, July 30, 2018
Time: 8:30 a.m. EST
Telephone Access (US): 866-665-9531
Telephone Access (International): 724-987-6977
Access Code for All Callers: 8884867

A live webcast and audio archive for the event may be accessed on the home page or from the "Investors & Media" section of the TherapeuticsMD website at www.therapeuticsmd.com. Please connect to the website prior to the start of the presentation to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for at least 30 days. In addition, 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: 8884867

About Imvexxy

Imvexxy (estradiol vaginal inserts) is approved in the U.S. for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. Imvexxy is the only product in its therapeutic class to offer a 4 mcg and 10 mcg dose, the 4 mcg representing the lowest approved dose of vaginal estradiol available. The full prescribing information may be viewed by visiting www.Imvexxy.com.

IMPORTANT SAFETY INFORMATION FOR IMVEXXY

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy

- **There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens**
- **Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)**
- **The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older**

Estrogen Plus Progestin Therapy

- **Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)**
- **The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer**
- **The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older**

CONTRAINDICATIONS

- Imvexxy™ is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease or a history of these conditions; known anaphylactic reaction or angioedema to Imvexxy; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS

- Imvexxy is intended only for vaginal administration. Systemic absorption may occur with the use of Imvexxy.
- The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
- Other warnings include: gallbladder disease; severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice.
- Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.
- Women on thyroid replacement therapy should have their thyroid function monitored.

ADVERSE REACTIONS

- The most common adverse reaction with Imvexxy (incidence $\geq$ 3 percent) and greater than placebo was headache.

Please note that this information is not comprehensive. Please visit www.Imvexxy.com for the Full Prescribing Information, including the Boxed Warning.

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 recently received FDA approval for TX-004HR, branded as Imvexxy™ (estradiol vaginal inserts), for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. The company's late stage clinical pipeline includes TX-001HR being evaluated for treatment of moderate-to-severe vasomotor symptoms (VMS) 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: whether the FDA will approve the NDA for the company's TX-001HR 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 company be able to comply with the covenants and conditions under its term loan agreement; 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 or adversely affect the commercialization of the company's current or future approved products; 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

	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash	$ 154,386,930	$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of $418,604 and $380,580, respectively	5,625,987	4,328,802
Inventory	1,880,577	1,485,358
Other current assets	5,203,734	6,604,284
Total current assets	167,097,228	139,554,072
Fixed assets, net	403,574	437,055
Other Assets:		
Intangible assets, net	3,488,401	3,099,747
Prepaid expenses-long term	759,229	—
Security deposit	150,522	139,036
Total other assets	4,398,152	3,238,783
Total assets	$ 171,898,954	$ 143,229,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 11,427,160	$ 4,097,600
Accrued expenses and other current liabilities	9,785,210	9,223,595
Total current liabilities	21,212,370	13,321,195
Long-term Liabilities:		
Long-term debt	73,141,311	—
Total long-term liabilities	73,141,311	—
Total liabilities	94,353,681	13,321,195
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: 216,834,059 and 216,429,642 issued and outstanding, respectively	216,834	216,430
Additional paid-in capital	521,608,436	516,351,405
Accumulated deficit	(444,279,997)	(386,659,120)
Total stockholders' equity	77,545,273	129,908,715
Total liabilities and stockholders' equity	$ 171,898,954	$ 143,229,910

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues, net	$ 3,763,010	$ 4,250,433	$ 7,536,402	$ 8,235,897
Cost of goods sold	454,161	681,725	1,087,784	1,341,360
Gross profit	3,308,849	3,568,708	6,448,618	6,894,537
Operating expenses:				
Sales, general, and administration	29,466,770	14,628,927	50,224,007	31,466,544
Research and development	6,798,380	8,716,395	13,837,677	16,441,235
Depreciation and amortization	65,603	53,189	125,224	102,888
Total operating expense	36,330,753	23,398,511	64,186,908	48,010,667
Operating loss	(33,021,904)	(19,829,803)	(57,738,290)	(41,116,130)
Other income (expense):				
Miscellaneous income	334,238	149,054	648,795	275,022
Accreted interest	—	3,832	—	7,699
Interest expense	(531,382)	—	(531,382)	—
Total other (expense) income	(197,144)	152,886	117,413	282,721
Loss before taxes	(33,219,048)	(19,676,917)	(57,620,877)	(40,833,409)
Provision for income taxes	—	—	—	—
Net loss	$ (33,219,048)	$ (19,676,917)	$ (57,620,877)	$ (40,833,409)
Net loss per share, basic and diluted	$ (0.15)	$ (0.10)	$ (0.27)	$ (0.20)
Weighted average number of common shares outstanding	216,640,186	203,384,610	216,583,067	200,602,778

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

	Six Months Ended	
	June 30, 2018	June 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (57,620,877)	$ (40,833,409)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	79,201	69,000
Amortization of intangible assets	46,023	33,888
Provision for (recovery of) doubtful accounts	38,024	(18,106)
Share-based compensation	4,128,440	3,051,357
Amortization of deferred financing costs	30,155	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,335,209)	1,122,386
Inventory	(395,219)	(337,694)
Other current assets	2,539,394	(58,601)
Accounts payable	7,329,560	749,520
Accrued interest	501,227	—
Accrued expenses and other current liabilities	60,388	(2,443,867)
Net cash used in operating activities	(44,598,893)	(38,665,526)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(434,677)	(367,602)
Purchase of fixed assets	(45,720)	(35,849)
Payment of security deposit	(11,486)	—
Net cash used in investing activities	(491,883)	(403,451)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term loan	75,000,000	—
Payment of deferred financing fees	(3,786,918)	—
Proceeds from exercise of options	1,128,996	212,360
Proceeds from exercise of warrants	—	3,798,999
Net cash provided by financing activities	72,342,078	4,011,359
Increase (decrease) in cash	27,251,302	(35,057,618)
Cash, beginning of period	127,135,628	131,534,101
Cash, end of period	$ 154,386,930	$ 96,476,483