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): March 8, 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 (*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 7.01 Regulation FD Disclosure.

On March 8, 2018, TherapeuticsMD, Inc., a Nevada corporation ("TherapeuticsMD" or the "Company"), issued a press release announcing the acceptance of the New Drug Application (NDA) for TX-001HR by the U.S. Food and Drug Administration (FDA). TX-001HR is 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. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated in this Item 7.01 by reference.

The information in Items 7.01 and 9.01 of this Current Report on Form 8-K (including the exhibit) 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 Items 7.01 and 9.01 of 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.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated March 8, 2018, entitled "TherapeuticsMD Announces FDA Acceptance of New Drug Application and Prescription Drug User Fee Act (PDUFA) Date for TX-001HR."

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: March 8, 2018

THERAPEUTICSMD, INC.

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces FDA Acceptance of New Drug Application (NDA) and Prescription Drug User Fee Act (PDUFA) Date for TX-001HR

- No Filing Review Issues Identified -
- PDUFA target action date of October 28, 2018 -

BOCA RATON, Florida, March 8, 2018 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced the acceptance of the NDA for TX-001HR by the U.S. Food and Drug Administration (FDA). TX-001HR is 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 FDA in its 74-day letter stated that the application is sufficiently complete to permit a substantive review and that, at this time, the FDA has not identified any potential review issues. The FDA noted that the filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during the FDA's review. The PDUFA target action date for the completion of the FDA's review is October 28, 2018.

"The acceptance of the NDA for TX-001HR is another important milestone for TherapeuticsMD and reaffirms the strength and commitment of our organization," said TherapeuticsMD CEO Robert G. Finizio. "If approved, TX-001HR has the potential to be the first and only combination of bio-identical estradiol and bio-identical progesterone in a single, oral softgel to meet the needs of patients, physicians, and pharmacies as an FDA-approved, third-party reimbursed treatment option for women suffering from moderate-to-severe vasomotor symptoms due to menopause."

The 505(b)(2) NDA submission for TX-001HR is supported by the complete TX-001HR clinical program, including positive results of the phase 3 Replenish Trial, which evaluated the safety and efficacy of four doses of TX-001HR (1 mg estradiol/100 mg progesterone, 0.5 mg estradiol/100 mg progesterone, 0.5 mg estradiol/50 mg progesterone, 0.25 mg estradiol/50 mg progesterone) compared to placebo. The co-primary efficacy endpoints in the Replenish Trial were the change from baseline in the number and severity of hot flashes at weeks 4 and 12 as compared to placebo. The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. General safety was also evaluated. Both the 1 mg estradiol/100 mg progesterone and the 0.5 mg estradiol/100 mg progesterone doses achieved statistically significant and clinically meaningful results across the four co-primary efficacy endpoints. In addition, the incidence rate of endometrial hyperplasia was 0% across all doses with up to 12 months of treatment, meeting the primary safety endpoint of less than 1% incidence of endometrial hyperplasia.

About TX-001HR

TX-001HR is 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.

About Menopause and Vasomotor Symptoms (VMS)

Menopause is a natural life-stage transition for women with an average onset of 51 years. According to the United States Census Bureau, approximately 43 million women in the U.S. are of menopausal age (45-64 years).

As the ovaries stop producing hormones, levels of circulating estrogen decrease, often causing vasomotor symptoms (VMS) such as night sweats, hot flashes, and sleep disturbances. VMS affect as many as 60-80 percent of all menopausal women.

Menopausal women can benefit from hormone therapy (HT), also known as hormone replacement therapy (HRT), which is recognized by key medical societies as the most effective treatment for relief of symptoms related to menopause.

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 product candidates that have completed phase 3 trials and are awaiting approval by the FDA: 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; 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; 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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