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): September 19, 2016

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))

Item 2.02. Results of Operations and Financial Condition.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K a press release on September 19, 2016.

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 September 19, 2016, entitled "TherapeuticsMD Announces FDA Acceptance of New Drug Application (NDA) and Prescription Drug User Fee Act (PDUFA) Date for Yuvvexy™ (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: September 19, 2016

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

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Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces FDA Acceptance of New Drug Application (NDA) and Prescription Drug User Fee Act (PDUFA) Date for Yuvvexy™ (TX-004HR)

- PDUFA target action date of May 7, 2017 -

BOCA RATON, Florida, Sept. 19, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced the acceptance of the NDA for Yuvvexy, the conditionally-approved trade name for TX-004HR, by the U.S. Food and Drug Administration (FDA). Yuvvexy is an investigational bio-identical 17β-estradiol vaginal softgel capsule for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar vaginal atrophy (VVA) in postmenopausal women.

The NDA acceptance by the FDA in its 74-day letter indicates that the application is sufficiently complete to permit a substantive review. The PDUFA target action date for the completion of the FDA's review is May 7, 2017.

"The acceptance of the NDA for Yuvvexy is an important milestone for TherapeuticsMD as we pursue our goal to provide women with novel healthcare solutions that address their needs throughout life," said TherapeuticsMD CEO Robert G. Finizio. "If approved, Yuvvexy has the potential to be a highly differentiated treatment option for the 32 million postmenopausal women in the United States who suffer from symptoms of VVA. Yuvvexy is the first product candidate from our pipeline of novel hormone therapies in development to address women's unmet health needs."

The 505(b)(2) NDA submission for Yuvvexy is supported by the complete Yuvvexy clinical program, including positive results of the phase 3 Rejoice Trial, which evaluated the effect of three doses of Yuvvexy (4 mcg, 10 mcg and 25 mcg) compared to placebo from baseline to week 12. The results demonstrated statistically significant and clinically meaningful improvements in dyspareunia, a co-primary endpoint, and vaginal dryness, a secondary endpoint. Statistically significant results were seen as early as two weeks of treatment. The NDA includes all three doses of Yuvvexy that were evaluated in the Rejoice Trial.

About Yuvvexy

Yuvvexy is an applicator-free vaginal estradiol softgel capsule in development for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

About Vulvar and Vaginal Atrophy (VVA)

An estimated 32 million women in the United States are currently suffering from symptoms of VVA, and only 2.3 million (7 percent) are currently being treated with prescription therapy. VVA symptoms can range from mild to severe and include dyspareunia, vaginal dryness, urinary tract infections, and vaginal bleeding associated with sexual activity. Vaginal dryness and dyspareunia are considered the most bothersome symptoms of VVA. Because of the chronic nature of VVA due to menopause, its symptoms will not likely resolve without intervention.

The burden of VVA in the United States may increase due to aging of the population. Furthermore, due to increasing longevity, women may now suffer from VVA or other conditions related to decreased reproductive hormone levels for over one-third of their lives.

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 hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. The company's clinical development pipeline includes two phase 3 products. The company manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® brands. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com and www.bocagreenmd.com.

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 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 approve the company's new drug application for its TX-004HR product candidate and whether any such approval will occur by the PDUFA date; 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; 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.

Contact:

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