

**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 7, 2016

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))
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Item 7.01 Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K a press release issued on July 7, 2016.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit
Number
99.1

Description

Press Release from TherapeuticsMD, Inc. dated July 7, 2016, entitled “TherapeuticsMD Announces New Drug Application Submission 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: July 7, 2016

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

Exhibit

Number

Description

99.1

[Press Release from TherapeuticsMD, Inc. dated July 7, 2016, entitled "TherapeuticsMD Announces New Drug Application Submission for Yuvvexy™ \(TX-004HR\)."](#)

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces New Drug Application Submission for Yuvvexy™ (TX-004HR)

BOCA RATON, Fla., July 7, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, announced today that it has submitted its New Drug Application (NDA) for Yuvvexy with the U.S. Food and Drug Administration (FDA). The NDA submission is supported by the complete Yuvvexy clinical program, including positive results of the recently completed phase 3 Rejoice Trial. The NDA submission includes all three doses of Yuvvexy (4 mcg, 10 mcg and 25 mcg) that were evaluated in the Rejoice Trial.

Yuvvexy, the conditionally-approved trade name for the company’s TX-004HR drug candidate, is an applicator-free, vaginal, estradiol softgel capsule being proposed 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 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 clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter 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 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 the company’s new drug application for its TX-004HR product candidate; 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.

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Contact:

Investors

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