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): April 7, 2017

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 8.01. Other Events.

On July 7, 2016, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), submitted to the U.S. Food and Drug Administration (the "FDA") a New Drug Application (the "NDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for three doses of TX-004HR, the Company's applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (VVA), in post-menopausal women. The submission was accepted by the FDA and the FDA set a target action date under the Prescription Drug User Fee Act ("PDUFA") of May 7, 2017 to complete the FDA's review of the NDA. In a letter dated September 19, 2016, the FDA notified the Company of the FDA's target date of April 9, 2017 for communicating to the Company proposed labeling and/or postmarketing requirements/commitments in accordance with FDA's PDUFA Reauthorization Performance Goals And Procedures – Fiscal Years 2013 Through 2017.

On April 7, 2017, the Company received a letter from the FDA (the "Letter") stating that, as part of its ongoing review of the NDA, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The Letter states that it does not reflect a final decision on the information under review. The Letter does not specify the deficiencies identified by the FDA and at this time the Company is not aware of the nature of the deficiencies. The Company intends to work with the FDA to understand the nature of the deficiencies and resolve them as quickly as possible.

On April 10, the Company issued a press release (the "Press Release") announcing its receipt of the Letter. Copies of the Press Release and the Letter are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

By filing this Current Report on Form 8-K, the Company makes no admission as to the materiality of any information contained herein. The information contained in this report is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission (the "Commission") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, except as required by law, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

This report contains forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to the Company'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 the Company's 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 Commission, including its most recent Annual Report on Form 10-K for the year ended December 31, 2016, and include the following: the Company's ability to resolve the deficiencies identified by the FDA in the Company's NDA for its TX-004HR product candidate; 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 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 will be able to prepare an NDA for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; 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.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release of TherapeuticsMD, Inc., dated April 10, 2017.
99.2	FDA Letter received April 7, 2017.

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: April 10, 2017

THERAPEUTICSMD, INC.

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

Exhibit Index

Exhibit Number	Description
99.1	Press Release of TherapeuticsMD, Inc., dated April 10, 2017.
99.2	FDA Letter Received April 7, 2017.

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Provides TX-004HR Regulatory Update

BOCA RATON, Fla., April 10, 2017 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced that, on April 7, 2017, the Company received a letter from the U.S. Food and Drug Administration (FDA) stating that, as part of the FDA's ongoing review of the Company's new drug application (NDA) for TX-004HR, the Company's applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (VVA), in post-menopausal women, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The letter states that the notification does not reflect a final decision on the information under review.

The letter does not specify the deficiencies identified by the FDA and at this time the Company is not aware of the nature of the deficiencies. The Company intends to work with the FDA to understand the nature of the deficiencies and resolve them as quickly as possible.

The FDA previously set a target action date under the Prescription Drug User Fee Act (PDUFA) of May 7, 2017 to complete the FDA's review of the NDA and had communicated to the Company the FDA's target date of April 9, 2017 for communicating to the Company proposed labeling and/or postmarketing requirements/commitments in accordance with FDA's PDUFA Reauthorization Performance Goals And Procedures – Fiscal Years 2013 Through 2017.

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 NDA for its TX-004HR product candidate; 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 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 will be able to prepare an NDA for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; 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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Investor Contact

David DeLucia
Director, Investor Relations
561-961-1900
David.DeLucia@TherapeuticsMD.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208564

DEFICIENCIES PRECLUDE DISCUSSION

TherapeuticsMD, Inc.
Attention: Valerie Ahmuty
Sr. Director, Regulatory Affairs
6800 Broken Sound Parkway NW
3rd Floor
Boca Raton, FL 33487

Dear Ms. Ahmuty:

Please refer to your New Drug Application (NDA) dated July 7, 2016, received July 7, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for estradiol vaginal insert, 4, 10 and 25 mcg.

We also refer to our September 19, 2016 letter in which we notified you of our target date of April 9, 2017 for communicating labeling changes and/or postmarketing requirements/commitments in accordance with the "PDUFA Reauthorization Performance Goals And Procedures – Fiscal Years 2013 Through 2017."

As part of our ongoing review of your application, we have identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time.

This notification does not reflect a final decision on the information under review.

If you have any questions, call Kim Shiley, R.N., B.S.N., Regulatory Project Manager, at [redacted]

Sincerely,

{See appended electronic signature page}

Shelley R. Slaughter, M.D., Ph.D.
Clinical Team Leader
Division of Bone, Reproductive, and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHELLEY R SLAUGHTER
04/06/2017