TherapeuticsMD, Inc.
Form 8-K
April 10, 2017

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 expr 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.