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): May 8, 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 7.01. Regulation FD Disclosure.

On May 8, 2017, TherapeuticsMD, Inc., a Nevada corporation (“TherapeuticsMD” or the "Company"), issued a press release announcing that the Company received a Complete Response Letter (“CRL”) from the U.S. Food and Drug Administration (the “FDA”) regarding the Company’s New Drug Application (the “NDA”) for TX-004HR, the Company’s investigational applicator-free estradiol vaginal softgel capsule for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) 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 8.01. Other Events.

As described above, TherapeuticsMD received a CRL from the FDA regarding the Company’s NDA for TX-004HR, the Company’s investigational applicator-free estradiol vaginal softgel capsule for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

In the CRL, the only approvability concern raised by the FDA was the lack of long-term endometrial safety data for TX-004HR beyond the 12 weeks studied in the pivotal phase 3 Rejoice Trial. No cases of endometrial hyperplasia were observed in the Rejoice Trial at the end of week 12 for all the doses studied and included in the NDA.

The CRL did not identify any issues related to the efficacy of TX-004HR and did not identify any approvability issues related to chemistry, manufacturing, and controls.

The Company intends to meet with the FDA as soon as possible to discuss the concerns raised by the FDA.

This report 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 report are made as of the date of this report, 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 company will be able to prepare an amended NDA for its TX-004HR product candidate and, if prepared, whether the FDA will accept and approve the NDA; 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 from TherapeuticsMD, Inc., dated May 8, 2017, entitled "TherapeuticsMD Receives Complete Response Letter from FDA for TX-004HR New Drug Application".

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: May 8, 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 from TherapeuticsMD, Inc., dated May 8, 2017, entitled TherapeuticsMD Receives Complete Response Letter from FDA for TX-004HR New Drug Application.

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Receives Complete Response Letter from FDA for TX-004HR New Drug Application

– No approvability issues identified by FDA related to efficacy or CMC –

BOCA RATON, Fla. – May 8, 2017 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for TX-004HR, the company's investigational applicator-free estradiol vaginal softgel capsule for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

In the CRL, the only approvability concern raised by the FDA was the lack of long-term endometrial safety data for TX-004HR beyond the 12-weeks studied in the pivotal phase 3 Rejoice Trial. No cases of endometrial hyperplasia were observed in the Rejoice Trial at the end of week 12 for all the doses studied and included in the NDA.

The CRL did not identify any issues related to the efficacy of TX-004HR and did not identify any approvability issues related to chemistry, manufacturing, and controls.

The Company believes that the NDA was approvable as filed and intends to meet with the FDA as soon as possible to address the concerns raised by the FDA.

“While we are disappointed that the NDA for TX-004HR was not approved at this time and respectfully disagree with the FDA's decision, we believe there are multiple paths forward to address the concerns raised by the FDA. The FDA has encouraged us to request a meeting to discuss our path forward and we intend to meet with the FDA as quickly as possible," said TherapeuticsMD CEO Robert G. Finizio. "We are also continuing to prepare the NDA for TX-001HR, our investigational oral bio-identical combination of estradiol and progesterone, and anticipate that we will submit that NDA to the FDA as early as the third quarter of 2017.”

Conference Call Today

As previously announced, TherapeuticsMD will host a conference call today to discuss these financial results and provide a business update. Details for the call are:

Date:	Monday, May 8, 2017
Time:	8:00 a.m. EST
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	6935590

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, on the Home Page or under the “Investors & Media” section. A digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in 855-859-2056 or international 404-537-3406 and Conference ID: 6935590.

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 as well as over-the-counter 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 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 a new drug application for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the application; 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.

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Investor Contact

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