# 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 27, 2018

## 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:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230-405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

On September 27, 2018, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), issued a press release announcing that the Company has entered into discussions with the U.S. Food and Drug Administration (FDA) regarding the proposed label for TX-001HR, the Company's investigational bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel for the treatment of moderate-to-severe vasomotor symptoms 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 included in this Item 7.01 and in Exhibit 99.1 shall not be deemed "filed" for 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits*

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release from TherapeuticsMD, Inc., dated September 27, 2018. |

**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 27, 2018

THERAPEUTICSMD, INC.

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

Exhibit 99.1

**FOR IMMEDIATE RELEASE**

**TherapeuticsMD Enters Into Label Discussions for TX-001HR**

**BOCA RATON, Fla.—September 27, 2018—** TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced that the Company has entered into discussions with the U.S. Food and Drug Administration (FDA) regarding the proposed label for TX-001HR, the Company's investigational bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel for the treatment of moderate-to-severe vasomotor symptoms due to menopause. As previously announced, the Prescription Drug User Fee Act (PDUFA) target action date for the completion of the FDA's review of the new drug application (NDA) for TX-001HR is October 28, 2018. The Company does not anticipate providing subsequent updates with respect to label discussions prior to the PDUFA target action date. There can be no assurance that the FDA will approve the NDA for TX-001HR, or that such approval will occur by the PDUFA target action date, and the entrance into label discussions does not imply otherwise.

**About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing novel products exclusively for women. Our products are designed to address the unique changes and challenges women experience through the various stages of their lives with a therapeutic focus in family planning, reproductive health, and menopause management. The company is committed to advancing the health of women and championing awareness of their healthcare issues. To learn more about TherapeuticsMD, please visit www.therapeuticsmd.com or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

**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: whether the FDA will approve the NDA for the company's TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize IMVEXXY™, ANNOVERA and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan agreement; 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 or adversely affect the commercialization of the company's current or future approved products; 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**
**Investor Contact**

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