

TherapeuticsMD, Inc.
Form 8-K
September 27, 2018

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 (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:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

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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