**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): October 13, 2015

**TherapeuticsMD, Inc.**
(Exact Name of Registrant as Specified in its Charter)

| **Nevada** | **001-001000** | **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.**

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K a press release on October 13, 2015.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) *Exhibits.*

| Exhibit Number | Description |
|---|---|
| 99.1 | TherapeuticsMD, Inc. press release dated October 13, 2015. |

**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: October 13, 2015

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 October 13, 2015, entitled "TherapeuticsMD Completes Enrollment in Phase 3 Clinical Trial of Bio-identical Oral Combination of Estradiol and Progesterone Product Candidate" |

**Exhibit 99.1**

FOR IMMEDIATE RELEASE

## TherapeuticsMD Completes Enrollment in Phase 3 Clinical Trial of Bio-identical Oral Combination of Estradiol and Progesterone Product Candidate

*– Study evaluates TX-001HR, first bio-identical combination product candidate to treat vasomotor symptoms of menopause –*

**BOCA RATON, Fla., October 13, 2015** – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced that the company has completed patient enrollment in the Replenish Trial, a phase 3 clinical trial evaluating multiple doses of the investigational once-daily oral softgel capsule, TX-001HR (estradiol and progesterone), to reduce the frequency and severity of moderate to severe vasomotor symptoms (VMS), including hot flashes and night sweats, in postmenopausal women.

TherapeuticsMD believes TX-001HR, if approved by the FDA, would represent the first time estradiol and progesterone (bio-identical to the estradiol and progesterone produced by a woman's ovaries), would be approved for use in a single, combined product. Patented TX-001HR was developed with SYMBODA™, an advanced technology for solubilizing the bio-identical hormones 17β-estradiol and progesterone.

"There are currently no FDA-approved oral bio-identical estradiol and progesterone combination products for women experiencing hot flashes and night sweats. Approximately 1 million to 2.5 million women are currently estimated to use non FDA-approved compounded menopausal hormone therapy in the U.S. TherapeuticsMD seeks to address the unmet needs of post-menopausal women as we develop potentially the first FDA-approved 17β-estradiol plus progesterone combination softgel capsule in the United States," stated Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. "Completion of patient recruitment in the Replenish Trial marks an important milestone in our development efforts and illustrates continued progress towards our goal of bringing novel hormone therapy options to women."

**Trial Design**
A pivotal safety and efficacy study, the Replenish Trial is a prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter study evaluating four doses of TX-001HR: combined estradiol 1 mg/progesterone 100 mg; combined estradiol 0.5 mg/progesterone 100 mg; combined estradiol 0.5 mg/progesterone 50 mg; and combined estradiol 0.25 mg/progesterone 50 mg. If approved, each of these combinations of estradiol and progesterone doses would represent a lower daily dose of estradiol and/or progesterone than those in currently approved products. The 12-month trial enrolled more than 1,750 healthy postmenopausal women (age 40 to 65 years old) in approximately 110 sites across the United States. The primary efficacy objective is to determine whether TX-001HR given daily is effective at reducing the frequency and severity of moderate to severe vasomotor symptoms associated with menopause when compared to placebo treatment at weeks 4 and 12. The Replenish Trial will also evaluate whether ongoing treatment with TX-001HR given daily is effective at achieving a ≤1% incidence rate of endometrial hyperplasia following 12 months of therapy (primary safety objective).

**About SYMBODA Technology**
SYMBODA, meaning "similar to the body," is a technology for formulation of solubilized hormones identical in chemical structure (bio-identical) to the estradiol and progesterone women naturally produce. TherapeuticsMD is leveraging this leading-edge technology to create new bio-identical drug forms and combinations that are designed to meet FDA uniformity and stability requirements.

**About Hormone Therapy (also referred to as Hormone Replacement Therapy or Menopausal Hormone Therapy)**
Hormone Therapy (HT) is the administration of hormones to treat menopausal symptoms that arise from a reduction of naturally occurring hormones. Current HT options include FDA-approved combination products using non-bio-identical hormones, FDA-approved estrogen-only and progestogen-only products and non-FDA approved compounded bioidentical products. According to Symphony Health Solutions, the current market for FDA-approved combination HT products is approximately $661 million annually, while various sources estimate that pharmacy-compounded, bioidentical HT product sales are approximately $1.5 billion annually.

**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 clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® brands. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com and www.bocagreenmd.com.

*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; 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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Contact:
Dan Cartwright
Chief Financial Officer
561-961-1900
Dan.Cartwright@TherapeuticsMD.com