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): December 5, 2016

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.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K a press release on December 5, 2016.

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	Press Release from TherapeuticsMD, Inc. dated December 5, 2016, entitled "TherapeuticsMD Announces Positive Top-Line Results from Pivotal Phase 3 Replenish Trial in Postmenopausal Women with Moderate to Severe Vasomotor Systems (VMS) Treated with TX-001HR."

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: December 5, 2016

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

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Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Positive Top-Line Results from Pivotal Phase 3 Replenish Trial in Postmenopausal Women with Moderate to Severe Vasomotor Symptoms (VMS) Treated with TX-001HR

- TX-001HR, the first bio-identical combination therapy of estradiol and progesterone evaluated in a randomized, controlled clinical trial met all co-primary efficacy and safety endpoints at multiple doses -

- TX-001HR, if approved, offers a potential new alternative for millions of post-menopausal women currently using unapproved compounded hormone therapy for the treatment of VMS -

- Conference call today at 4:30 p.m. ET to discuss results -

BOCA RATON, Florida, December 5, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced positive top-line results from its pivotal phase 3 Replenish Trial of TX-001HR, an investigational bio-identical hormone therapy combination of 17ß-estradiol and progesterone in a single, oral softgel, for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause in post-menopausal women with an intact uterus.

The Replenish Trial evaluated four doses of TX-001HR and placebo in 1,835 post-menopausal women between 40 and 65 years old. The doses studied were:

- 17ß-estradiol 1 mg/progesterone 100 mg (n = 416)
- 17ß-estradiol 0.5 mg/progesterone 100 mg (n = 423)
- 17ß-estradiol 0.5 mg/progesterone 50 mg (n = 421)
- 17ß-estradiol 0.25 mg/progesterone 50 mg (n = 424)
- Placebo (n = 151)

The Replenish Trial results demonstrated:

- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both achieved all four of the co-primary efficacy endpoints and the primary safety endpoint.
- TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg both demonstrated a statistically significant and clinically meaningful reduction from baseline in both the frequency and severity of hot flashes compared to placebo.
- TX-001HR estradiol 0.5 mg/progesterone 50 mg and TX-001HR estradiol 0.25 mg/progesterone 50 mg were not statistically significant at all of the co-primary efficacy endpoints. The estradiol 0.25 mg/progesterone 50 mg dose was included in the clinical trial as a non-effective dose to meet the recommendation of the FDA guidance to identify the lowest effective dose.
- The incidence of consensus endometrial hyperplasia or malignancy was 0 percent across all four TX-001HR doses, meeting the recommendations established by the U.S. Food and Drug Agency's (FDA) draft guidance.[1]

As outlined in the FDA guidance, the co-primary efficacy endpoints in the Replenish Trial were the change from baseline in the number and severity of hot flashes at weeks 4 and 12 as compared to placebo.[1] The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. General safety was also evaluated.

The results of the Replenish Trial are summarized in the table below (p-values of < 0.05 meet FDA guidance and support evidence of efficacy):

Replenish Trial Co-Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-MITT Population					
Estradiol/Progesterone	**1 mg/100 mg (n = 141)**	**0.5 mg/100 mg (n = 149)**	**0.5 mg/50 mg (n = 147)**	**0.25 mg/50 mg (n = 154)**	**Placebo (n = 135)**
Frequency					
Week 4 P-value versus placebo	**<0.001**	**0.013**	**0.141**	**0.001**	**-**
Week 12 P-value versus placebo	**<0.001**	**<0.001**	**0.002**	**<0.001**	**-**
Severity					
Week 4 P-value versus placebo	**0.031**	**0.005**	**0.401**	**0.100**	**-**
Week 12 P-value versus placebo	**<0.001**	**<0.001**	**0.018**	**0.096**	**-**
Replenish Trial Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population[†]					
Endometrial Hyperplasia	**0% (0/280)**	**0% (0/303)**	**0% (0/306)**	**0% (0/274)**	**0% (0/92)**

MITT = Modified intent to treat

[†]Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis[1]

P-value < 0.05 meets FDA guidance and supports evidence of efficacy

Figure 1. Mean Change from Baseline in Weekly Frequency of Moderate to Severe Hot Flashes for Weeks 1 to 12

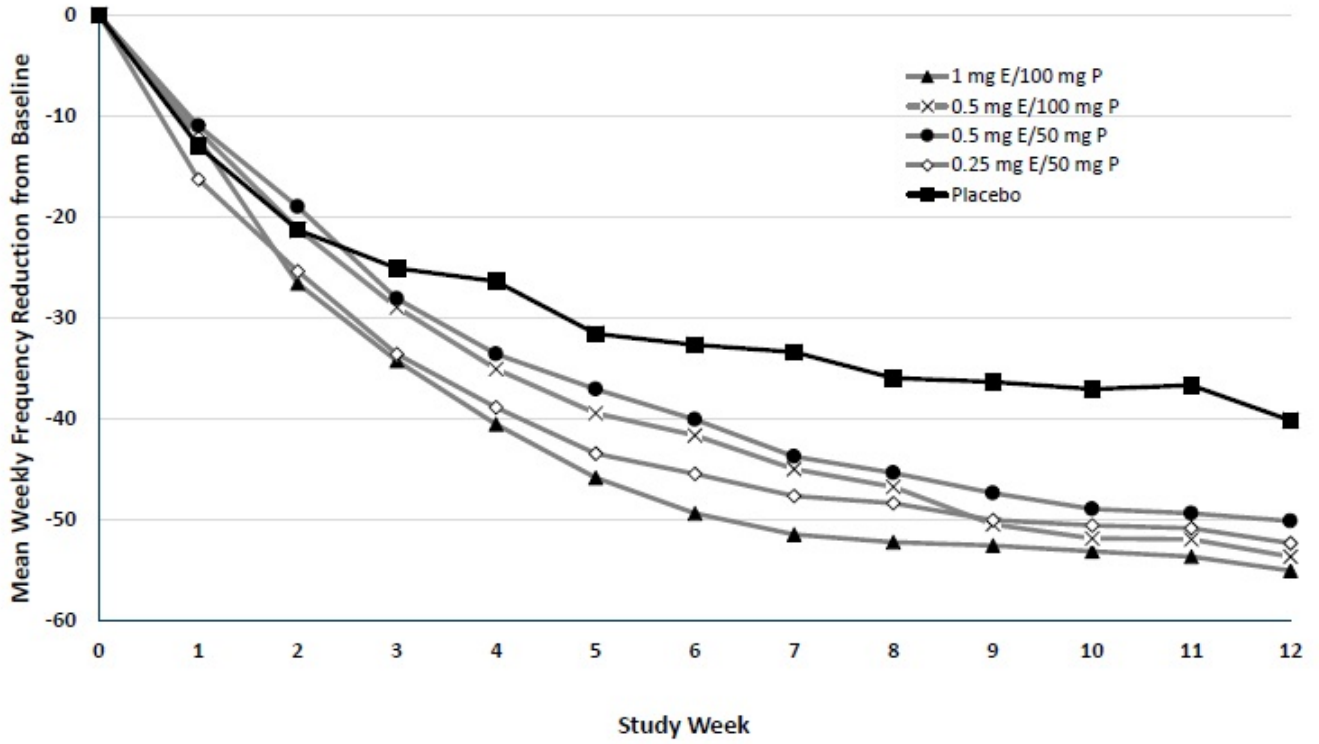
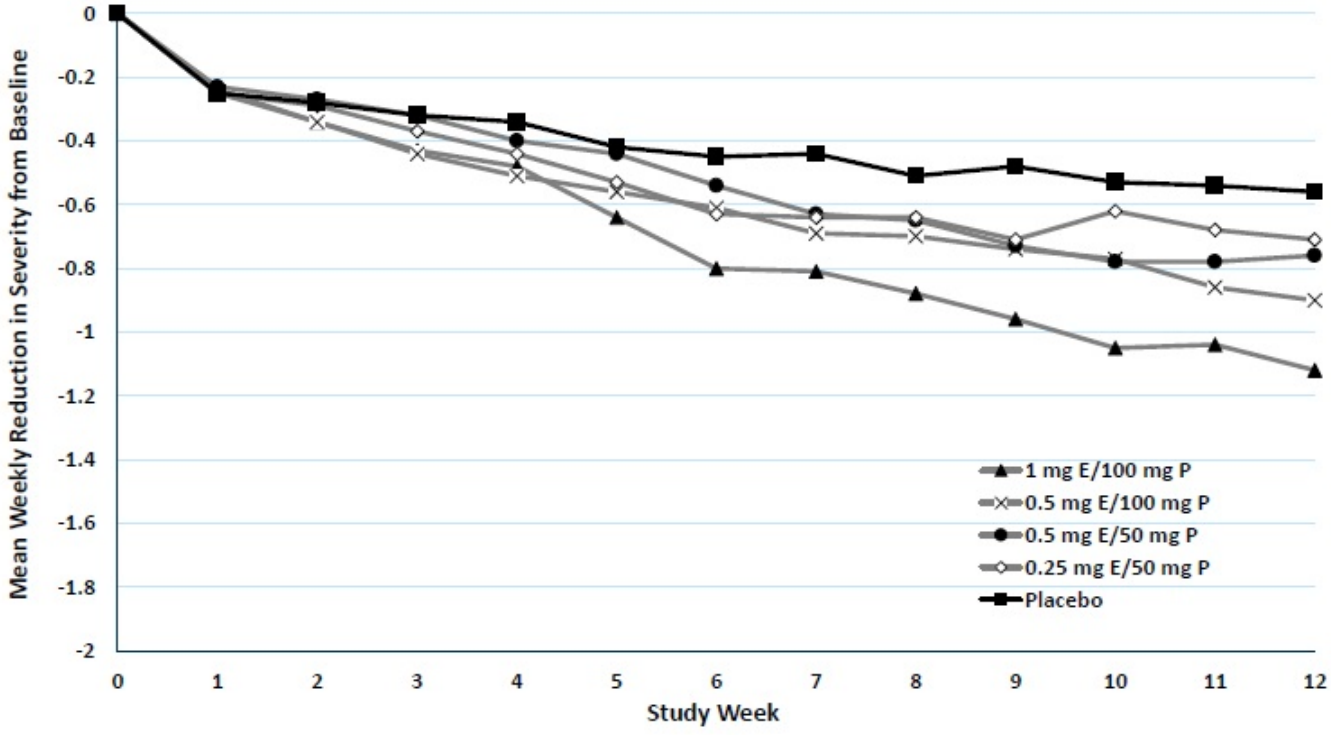


Figure 2. Mean Change from Baseline in Weekly Severity of Moderate to Severe Hot Flashes for Weeks 1 to 12



“We are very pleased that multiple doses of TX-001HR studied in the Replenish Trial demonstrated these positive results, suggesting that, if approved, this drug product candidate is poised to address the significant demand for bio-identical hormone therapy,” said Chief Executive Officer Robert G. Finizio. “We have successfully advanced the science for post-menopausal women’s health by finding a way to effectively combine bio-identical estradiol and bio-identical progesterone. The need for a bio-identical FDA-approved combination therapy has been unanswered for decades, driving women to use unapproved drugs mixed together by independent and community pharmacies that compound these products. We believe that TX-001HR, if approved, will provide women, healthcare providers and pharmacists with a proven safe, effective and insurance reimbursed bio-identical combination product, finally answering that need. We will continue to evaluate these promising data, and look forward to submitting a New Drug Application for TX-001HR to the Food and Drug Administration as early as the third quarter of 2017.”

The trial also demonstrated a dose response favoring the higher doses of estradiol in combination with progesterone. The availability of multiple doses of TX-001HR would allow for individualized therapy to meet the needs of a diverse population of women.

The most common adverse events (>5 percent) reported on average in all the active treatment groups were headache, nasopharyngitis, breast tenderness, and upper respiratory infection. There was a very low reported incidence of adverse events of somnolence with TX-001HR, in contrast to commercially available oral progesterone where somnolence has been reported as a significant side effect. There were no unexpected safety signals.

The Replenish Trial evaluated various secondary endpoints using well-validated patient reported outcome tools, including the Menopause-Specific Quality of Life (MENQOL), the Clinical Global Impression scale (CGI), and the responder analysis rate. Both TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg demonstrated clinically meaningful and statistically significant improvements in the secondary endpoints using these tools.

Additional efficacy and safety analyses of the Replenish Trial data are ongoing and TherapeuticsMD plans to submit the full Replenish Trial results for presentation at future scientific meetings and for publication in peer-reviewed journals.

“TX-001HR is the first bio-identical combination hormone therapy of estradiol in combination with progesterone to be evaluated in a large, well-controlled, randomized clinical trial,” said TherapeuticsMD Chief Medical Officer Sebastian Mirkin, M.D. “The Replenish Trial demonstrated for the first-time safety and robust efficacy for the treatment of hot flashes at multiple doses of TX-001HR. If approved, TX-001HR estradiol 1 mg/progesterone 100 mg and TX-001HR estradiol 0.5 mg/progesterone 100 mg would provide TherapeuticsMD with a complete portfolio to meet the demands of women currently taking unapproved compounded hormones for the treatment of VMS, along with the healthcare providers and pharmacies that prescribe and compound these products.”

About TX-001HR

TX-001HR is a novel combination of 17ß-estradiol and natural progesterone under investigation for treating vasomotor symptoms related to menopause. If approved by the FDA, TX-001HR would represent the first bio-identical estradiol and progesterone approved for use in a single, combined product for postmenopausal women with an intact uterus offering women an important alternative to both the available FDA-approved synthetic (non-bio-identical) hormones and the unapproved compounded bio-identical hormone products. Bio-identical refers to estradiol and progesterone that are molecularly identical to the hormones circulating naturally in the woman's body. An estimated one to two-and-a-half million women in the U.S. are using unapproved, compounded bio-identical hormone therapies to treat vasomotor symptoms.[2] Leading medical societies and the FDA advise that compounded hormone therapies may pose significant risk to women given lack of efficacy and safety data and lack of uniform manufacturing processes.

TX-001HR was developed using TherapeuticsMD's unique SYMBODA™ technology (meaning "similar to the body"), which enables partial and complete solubilization of estradiol and progesterone into medium-chain fatty acid oils often derived from coconut oil.

About Menopause and Vasomotor Symptoms (VMS)

Menopause is a natural life-stage transition for women with an average onset of 51 years. According to the United States Census Bureau, approximately 43 million women in the U.S. are of menopausal age (45-64 years).[3]

As the ovaries stop producing hormones, levels of circulating estrogen decrease, often causing vasomotor symptoms (VMS) such as night sweats, hot flashes, and sleep disturbances. VMS affect as many as 60-80 percent of all menopausal women.

Menopausal women can benefit from hormone therapy (HT), also known as hormone replacement therapy (HRT), which is recognized by key medical societies as the most effective treatment for relief of symptoms related to menopause.

Conference Call and Webcast

TherapeuticsMD will host a conference call today, during which management will discuss the top-line results of the pivotal phase 3 Replenish Trial. Details for the call are:

Date: December 5, 2016
Time: 4:30 p.m. ET
Telephone Access (US): (866) 665-9531
Telephone Access (International): (724) 987-6977
Access Code for All Callers: 30215405

Additionally, a live webcast of the conference call can be accessed on the company's website, www.therapeuticsmd.com, under the "Investors & Media" section.

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 under the vitaMedMD® and BocaGreenMD® brands. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com and www.bocagreenmd.com.

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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References

[1] 2003 FDA Draft Guidance for Industry Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Recommendations for Clinical Evaluation http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071643.pdf

[2] Pinkerton JV, Santoro N. 2015. *Menopause*, Vol.22, No.9, pp 0-11

[3] United States Census Bureau