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 7, 2015

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 7, 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	Press Release from TherapeuticsMD, Inc. dated December 7, 2015, entitled "TherapeuticsMD Announces Positive Top-Line Results from its Phase 3 Rejoice Trial in Postmenopausal Women with Vulvar and Vaginal Atrophy (VVA) Treated with 25 mcg, 10 mcg or 4 mcg of TX-004HR."

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 7, 2015

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 its Phase 3 Rejoice Trial in Postmenopausal Women with Vulvar and Vaginal Atrophy (VVA) Treated with 25 mcg, 10 mcg or 4 mcg of TX-004HR

Conference Call Scheduled for Today at 4:45 p.m. ET to Discuss Results

BOCA RATON, Florida, December 7, 2015 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, today announced positive top-line results from its pivotal Phase 3 Rejoice Trial of TX-004HR, an investigational, applicator-free vaginal estradiol softgel, for the treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (VVA) due to menopause. VVA is a chronic condition affecting nearly half of postmenopausal women in the United States that can significantly impair their quality of life.

TX-004HR was evaluated at 25 mcg, 10 mcg, and 4 mcg doses. The pre-specified four co-primary endpoints were the change from baseline to week 12 in the percentage of vaginal superficial cells, percentage of vaginal parabasal cells, vaginal pH, and in participants' self-reported severity of dyspareunia as the most bothersome symptom of VVA.

Statistical Significance of Results for Co-Primary Endpoints
(Based on Mean Change from Baseline to Week 12 Compared to Placebo)

	25 mcg	10 mcg	4 mcg
Superficial Cells	P < 0.0001	P < 0.0001	P < 0.0001
Parabasal Cells	P < 0.0001	P < 0.0001	P < 0.0001
Vaginal pH	P < 0.0001	P < 0.0001	P < 0.0001
Severity of Dyspareunia	P = 0.0001	P = 0.0001	P = 0.0255

The 25 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p \leq 0.0001$ level compared to placebo across all four co-primary endpoints. The 10 mcg dose of TX-004HR demonstrated highly statistically significant results at the $p \leq 0.0001$ level compared to placebo across all four co-primary endpoints. The 4 mcg dose of TX-004HR also demonstrated highly statistically significant results at the $p \leq 0.0001$ level compared to placebo for the endpoints of vaginal superficial cells, vaginal parabasal cells, and vaginal pH; the change from baseline compared to placebo in the severity of dyspareunia was at the $p = 0.0255$ level.

Statistical improvement over placebo was also observed for all three doses at the first assessment at week two and sustained through week 12. The pharmacokinetic data for all three doses demonstrated low systemic absorption, supporting the previous Phase 1 trial data. TX-004HR was well tolerated, and there were no clinically significant differences compared to placebo-treated participants with respect to adverse events. There were no drug-related serious adverse events reported. Additional presentations of this data are included at the end of this press release.

"We are extremely encouraged that all three doses of TX-004HR studied in the Rejoice Trial demonstrated positive results," said TherapeuticsMD CEO Robert G. Finizio. "With efficacy observed as early as two weeks and the convenience of the applicator-free vaginal softgel, we believe that, if approved, TX-004HR has the potential to offer a highly differentiated, new treatment option that meets the needs of the millions of postmenopausal women with VVA who are suffering from pain during sexual intercourse. We look forward to sharing the Rejoice Trial results and to submitting a New Drug Application for TX-004HR to the Food and Drug Administration as soon as the first half of 2016."

TX-004HR features SYMBODA™ technology, which enables partial and complete solubilization of estradiol into medium-chain fatty acid oils often derived from coconut oil. This allows for the production of cohesive, stable formulations and provides content uniformity and accuracy of dosing strengths for TX-004HR.

“Nearly half of all postmenopausal women have VVA, yet few are treated with prescription therapy,” said TherapeuticsMD Chief Medical Officer Sebastian Mirkin, M.D. “The highly statistically significant efficacy results and safety profile from the Rejoice Trial are very promising. We are excited about the potential for TX-004HR to be a new treatment option with low systemic absorption for women with VVA suffering from moderate to severe dyspareunia.”

Safety and efficacy analyses of the Rejoice Trial data are ongoing. TherapeuticsMD plans to submit Rejoice Trial results for presentation at future scientific meetings and for publication in peer reviewed journals.

Rejoice Trial Design

The Rejoice Trial was a randomized, double-blinded, placebo-controlled, multicenter Phase 3 clinical trial designed to evaluate the safety and efficacy of three doses of TX-004HR — 25 mcg, 10 mcg and 4 mcg — compared to placebo for the treatment of moderate to severe dyspareunia in postmenopausal women with VVA. The co-primary efficacy endpoints are change from baseline to week 12 in the percentage of vaginal superficial cells, percentage of vaginal parabasal cells, vaginal pH, and severity of moderate to severe dyspareunia as the most bothersome symptom of VVA. The trial enrolled 764 postmenopausal women (40 to 75 years old) experiencing moderate to severe dyspareunia at approximately 89 sites across the United States and Canada. Trial participants were randomized to receive either TX-004HR at 25 mcg (n=190), 10 mcg (n=191), or 4 mcg (n=191) doses or placebo (n=192) for a total of 12 weeks, all administered once daily for two weeks and then twice weekly (approximately three to four days apart) for ten weeks.

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 Rejoice Trial. Details for the call are:

Date: December 7, 2015
Time: 4:45 p.m. ET
Telephone Access (US): (866) 665-9531
Telephone Access (International): (724) 987-6977
Access Code for All Callers: 98389089

Additionally, a live webcast can be accessed on the company’s website, www.therapeuticsmd.com, under the “Investors & Media” section.

About TX-004HR

TX-004HR is an investigational bio-identical 17β-estradiol vaginal drug product candidate being studied for the treatment of moderate to severe dyspareunia, a symptom of VVA, also known as genitourinary syndrome of menopause (GSM), in postmenopausal women. TX-004HR utilizes a unique applicator-free vaginal estradiol softgel capsule technology.

About Vulvar and Vaginal Atrophy (VVA)

An estimated 32 million women in the United States are currently suffering from symptoms of VVA[1], and only 2.3 million (7%) are currently being treated with prescription therapy.[2,3] The burden of VVA in the United States may increase due to aging of the population.[4] Furthermore, due to increasing longevity,[4] women may now suffer from VVA or other conditions related to decreased reproductive hormone levels for over one-third of their lives.

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 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; 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] Kingsberg SA, Wysocki S, Magnus L, et al. Vulvar and vaginal atrophy in postmenopausal women: Findings from the Revive (REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs) survey. *J Sex Med.* 2013;10:1790-1799.

[2] Mac Bride MB, Rhodes DJ, Shuster LT. Vulvovaginal atrophy. *Mayo Clin Proc.* 2010;85:87-94.

[3] North American Menopause Society. The role of local vaginal estrogen for treatment of vaginal atrophy in postmenopausal women: 2007 position statement of The North American Menopause Society. *Menopause.* 2007; l4(3 Pt 1):355-69.

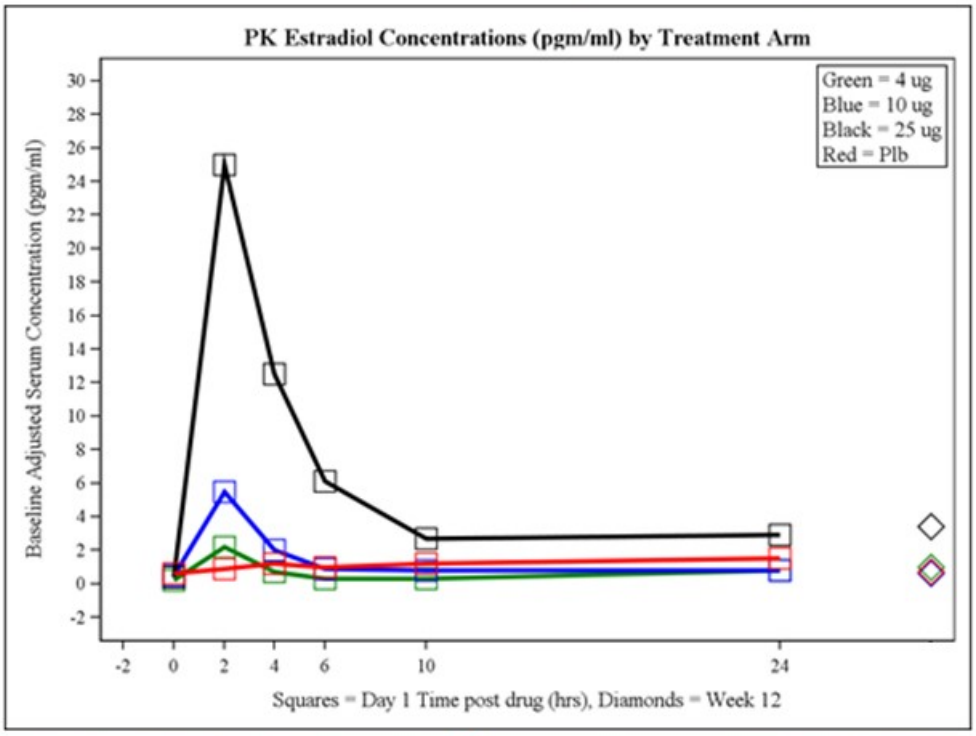
[4] US Census Bureau. Age and Sex Composition: 2010. 2011 May. Report No.: C2010BR-03.

Statistical Significance of Severity of Dyspareunia by Study Visit

(Mean Change from Baseline Dyspareunia Compared to Placebo)

	25 mcg	10 mcg	4 mcg
Week 2	0.0284	0.0026	0.0407
Week 6	0.0001	0.0012	0.0123
Week 8	< 0.0001	< 0.0001	0.0005
Week 12	0.0001	0.0001	0.0255

Baseline Adjusted Mean Estradiol Concentration Day 1



Baseline Adjusted Mean Estradiol Concentration Day 14