

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): May 30, 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)
- 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 May 30, 2018, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), issued a press release announcing that the Company received approval from the U.S. Food and Drug Administration (FDA) for the Company's New Drug Application (NDA) for TX-004HR: IMVEXXYTM (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), 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 May 30, 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: May 30, 2018

THERAPEUTICSMD, INC.

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



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces FDA Approval of TX-004HR: IMVEXXY™ (estradiol vaginal inserts), the Lowest Dose Vaginal Estrogen Product Approved for the Treatment of Moderate to Severe Dyspareunia, a Symptom of VVA, due to Menopause

-IMVEXXY's applicator-free self-administration was developed with the woman in mind-

-TherapeuticsMD will host a conference call at 8:00 AM EDT today-

BOCA RATON, Fla.--(BUSINESS WIRE)—May 30, 2018—TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced that the United States Food and Drug Administration (FDA) has approved IMVEXXY™ (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. IMVEXXY is the only product in its therapeutic class to offer a 4 mcg and 10 mcg dose, the 4 mcg representing the lowest approved dose of vaginal estradiol available.

"IMVEXXY is a bio-identical vaginal estrogen product that offers a fraction of the estrogen contained in the average doses of many existing products currently on the market," said Brian Bernick, MD, Chief Clinical Officer of TherapeuticsMD. "IMVEXXY is the only product specifically designed to be applicator-free. It dissolves completely without mess or additional clean-up, and can be used anytime of day. It allows women the freedom to immediately return to their normal daily activities. Studies showed that, in patients who used IMVEXXY, systemic absorption of estradiol remained within postmenopausal range."

"We are excited to bring IMVEXXY to market as TherapeuticsMD's first FDA-approved drug as we strive to be the premier Women's Health Company," said Robert Finizio, Chief Executive Officer of TherapeuticsMD. "IMVEXXY reflects our long-standing corporate mission and commitment to health solutions that women want, based on the concepts of medical need, efficacy, safety, simplicity, and affordability. IMVEXXY will be offered at a price in parity with other products that have been on the market for 10 to 30 years. By ensuring patients can access IMVEXXY at an affordable price, TherapeuticsMD is doing the right thing for women."

About Dyspareunia and Vulvar and Vaginal Atrophy (VVA)

VVA is a component of genitourinary syndrome of menopause (GSM), which may include, but is not limited to, genital symptoms of dryness, burning and irritation, sexual symptoms such as decreased lubrication, discomfort, and pain, and urinary symptoms such as urgency, dysuria, and recurrent urinary tract infections.¹ VVA is a chronic, progressive condition that leads to distressing symptoms and can progressively worsen if not treated.²

VVA is a condition that develops when the body makes less estrogen due to menopause. Without sufficient estrogen, the vaginal tissue becomes thin, dry, and less elastic. The vaginal canal can also narrow and shorten. Insufficient estrogen can also decrease vaginal fluids, change the acid balance of the vagina, and weaken pelvic floor muscles. All these factors can lead to dyspareunia.²

VVA affects an estimated 32 million postmenopausal women in the US. Only about seven percent (2.3 million) of these women receive prescription treatment.³ Nearly 1 out of 2 women will experience pain during intercourse due to VVA at some point during their lives.³

“Studies have shown that many women are not seeking treatment for VVA and 81% are unaware that VVA is a treatable medical condition and part of a constellation of symptoms associated with loss of estrogens,” said Dr. Sheryl Kingsberg, President, North American Menopause Society. “I am delighted that our patients will now have a convenient treatment option with IMVEXXY and hope that the excitement generated by this new option will encourage women to talk to their healthcare provider and get relief from their pain and discomfort due to VVA.”

IMVEXXY For the Treatment of Moderate to Severe Dyspareunia Due to Menopause

Imvexxy’s mechanism of action is the re-estrogenization of the tissue in and around the vagina. IMVEXXY’s distinctive formulation ensures that it dissolves completely without mess, so patients can use it any time of day by placing the softgel capsule in the lower part of the vagina to treat the vulva and vagina. IMVEXXY is administered daily for two weeks followed by only twice a week dosing. Nine out of 10 patients who participated in a clinical trial reported that IMVEXXY was “easy to use.”⁴

The FDA approval of IMVEXXY is based on the results of a Phase 3, randomized, double-blind, placebo-controlled study that evaluated the safety and efficacy of IMVEXXY (4 mcg and 10 mcg) compared to placebo from baseline to week 12. The study showed that IMVEXXY provided relief of moderate to severe dyspareunia due to menopause as early as week 2 for both doses.⁵ Statistically significant changes in vaginal cytology and pH were also observed.⁵ A substudy of the REJOICE trial evaluated the pharmacokinetics of IMVEXXY 4 mcg, 10 mcg, and placebo. With both the 4 mcg and 10 mcg doses, the mean concentration of estradiol and estrone remained within average postmenopausal range.⁶ The results were published in the journal *Menopause: The Journal of The North American Menopause Society*.^{5,6}

The most common adverse reaction with IMVEXXY (incidence ≥ 3 percent) and greater than placebo was headache. There were no clinically significant differences in AEs observed between treatment and placebo groups.⁵ Important safety information for IMVEXXY, including the boxed warning for endometrial cancer, cardiovascular disorders, breast cancer, and probable dementia, is provided below. The full prescribing information may be viewed by visiting www.imvexxy.com.

TherapeuticsMD anticipates that IMVEXXY will be available for commercial distribution in July.

As part of the FDA’s approval, TherapeuticsMD has committed to conduct a post-approval observational study.

Conference Call Information

TherapeuticsMD will host a conference call today to discuss the IMVEXXY approval. Details for the call are:

Date:	Wednesday, May 30, 2018
Time:	8:00 AM EDT
Telephone Access (US):	(866) 665-9531
Telephone Access (International):	(724) 987-6977
Access Code for All Callers:	4757309

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, on the Home Page or under the "Investors & Media" section. A digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in (855) 859-2056 or international (404) 537-3406 and Conference ID: 4757309.

IMPORTANT SAFETY INFORMATION

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Estrogen Plus Progestin Therapy

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
- The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)
- The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

CONTRAINDICATIONS

- IMVEXXY™ is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease or a history of these conditions; known anaphylactic reaction or angioedema to IMVEXXY; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.
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WARNINGS AND PRECAUTIONS

- IMVEXXY is intended only for vaginal administration. Systemic absorption may occur with the use of IMVEXXY.
- The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
- Other warnings include: gallbladder disease; severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice.
- Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.
- Women on thyroid replacement therapy should have their thyroid function monitored.

ADVERSE REACTIONS

- The most common adverse reaction with IMVEXXY (incidence \geq 3 percent) and greater than placebo was headache.

Please note that this information is not comprehensive. Please visit www.imvexxy.com for the Full Prescribing Information, including the **Boxed Warning.**

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 has recently received FDA approval for TX-004HR, branded as IMVEXXY™ (estradiol vaginal inserts), for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. The company's late stage clinical pipeline includes TX-001HR for treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

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 its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company 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; 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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2. The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888-902.
3. Wysocki S, Kingsberg S, Krychman M. Management of vaginal atrophy: implications from the REVIVE survey. *Clin Med Insights Reprod Health*. 2014;8:23-30.
4. Kingsberg SA, Kroll R, Goldstein I, et al. Patient acceptability and satisfaction with a low-dose solubilized vaginal estradiol softgel capsule, TX-004HR. *Menopause*. 2017;24:894-899.
5. Constantine GD, Simon JA, Pickar JH, et al. The REJOICE trial: a phase 3 randomized, controlled trial evaluating the safety and efficacy of a novel vaginal estradiol soft-gel capsule for symptomatic vulvar and vaginal atrophy. *Menopause*. 2017;24:409-416.
6. Archer DF, Constantine GD, Simon J, et al. TX-004HR Vaginal Estradiol Has Negligible to Very Low Systemic Absorption of Estradiol. *Menopause* 2017;24:510-516.

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