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 24, 2013

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

Nevada	**000-16731**	**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 8.01. Other Events.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately $10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in vulvar and vaginal atrophy, or VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be approximately $25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately $650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately $490 million (as converted from the Euro at an exchange rate of €1.0=US$1.2875) in international sales.

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12 002HR to be approximately $6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately $340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately $780 million (as converted from the Euro at an exchange rate of €1.0=US$1.2875) in international sales.

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately $16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately $1 billion in U.S. sales.

We intend to leverage and grow our current marketing and sales organization to commercialize our proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved menopause-related estrogen market was approximately $2.5 billion in U.S. sales.

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 24, 2013

THERAPEUTICSMD, INC.

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