

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): **June 11, 2013**

**THERAPEUTICSMD, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of incorporation)

**000-16731**

(Commission File Number)

**87-0233535**

(IRS Employer Identification No.)

**951 Broken Sound Parkway NW, Suite 320, Boca Raton, FL 33487**

(Address of principal executive offices and Zip Code)

**(561) 961-1900**

(Registrant's telephone number, including area code)

**N/A**

(Former Name and Address of Registrant)

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))
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**SECTION 7 – REGULATION FD**

**Item 7.01. Regulation FD Disclosure**

On June 11, 2013, TherapeuticsMD™, Inc., ("TherapeuticsMD" or the "Company"), received acceptance from the U.S. Food and Drug Administration ("FDA") for its Investigational New Drug ("IND") application for TX12-004HR, a vaginal estradiol suppository. TherapeuticsMD is developing TX12-004HR for vulvar and vaginal atrophy (VVA), a thinning of the vaginal walls that occurs as estrogen levels drop during menopause.

The Company issued a press release announcing the FDA acceptance of the IND for TX12-004HR on June 14, 2013, a copy of which is attached as Exhibit 99.1 hereto.

The information in this Item 7.01 of this Form 8-K, including the exhibit (the "Report"), is furnished pursuant to Item 7.01 and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Act"), or otherwise subject to the liabilities of that section. This Report also shall not be deemed to be incorporated by reference into any filing under the Act except to the extent that the Company specifically incorporates it by reference. This Report will not be deemed an admission as to the materiality of any information in the Report that is required to be disclosed solely by Regulation FD.

The text included with this Report on Form 8-K is available on the Company's website located at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), although the Company reserves the right to discontinue that availability at any time.

**SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS**

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits:

Exh. No.	Date	Document
99.1	June 14, 2012	<a href="#">Press Release from TherapeuticsMD, Inc., dated June 14, 2013, entitled "TherapeuticsMD Investigational New Drug Filing Accepted by FDA"</a>

**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: June 14, 2013

**THERAPEUTICSMD, INC.**

By: /s/ Robert G. Finizio  
Robert G. Finizio, Chief Executive Officer

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**THERAPEUTICSMMD INVESTIGATIONAL NEW DRUG FILING ACCEPTED BY FDA**

**Boca Raton, FL, June 14, 2013** – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women’s healthcare company focused on developing and commercializing products targeted exclusively for women, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company’s Investigational New Drug (IND) application for TX12-004HR, a vaginal estradiol suppository. TherapeuticsMD is developing TX12-004HR for vulvar and vaginal atrophy (VVA), a thinning of the vaginal walls that occurs as estrogen levels drop during menopause. The acceptance of the IND will allow the Company to begin clinical trials.

Julia Amadio, Chief Product Officer stated, “We are very excited to move forward with testing this simple, novel delivery of vaginal estradiol for vulvar and vaginal atrophic symptoms in postmenopausal women. We believe that there is a large and growing unmet need for this product as women will continue to develop vaginal atrophy after menopause without therapy.”

**About Vulvar and Vaginal Atrophy**

For many women going through menopause, the loss of estrogen can result in less vaginal lubrication; thinner, drier vaginal walls and less elastic vaginal tissue. This can cause some very uncomfortable physical symptoms, including: painful intercourse; and drying, burning and itching in and around the vagina.

**About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is a women’s health pharmaceutical company driven to pursue the development and commercialization of advanced hormone replacement therapies. We are currently developing advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies. We are evaluating various other potential indications for our hormone technology, including oral contraception, preterm birth, vulvar and vaginal atrophy, and premature ovarian failure. More information is available at [www.therapeuticsmd.com](http://www.therapeuticsmd.com).

TherapeuticsMD® is a registered trademark.

*Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the Company’s expectation that it will move forward with testing TX12-004HR, and the Company’s beliefs that TX12-004HR represents a simple, novel delivery of vaginal estradiol for vulvar and vaginal atrophic symptoms in postmenopausal women and that there is a large and growing unmet need for this product as women will continue to develop vaginal atrophy after menopause without therapy, are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including but not limited to: the Company’s ability to obtain adequate funding for its clinical trials; timely and successful completion of clinical studies and the results thereof; developments in the women’s healthcare industry; the risks and uncertainties associated with economic and market conditions; risks and uncertainties associated with TherapeuticsMD’s business and finances in general; and other risks detailed in TherapeuticsMD’s filings with the U.S. Securities and Exchange Commission including its annual report on Form 10-K filed on March 12, 2013, reports on Form 10-Q and Form 8-K, and other such filings. These forward-looking statements are based on current information that may change. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and TherapeuticsMD undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.*

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