

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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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 8, 2016

**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 (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))
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**Item 7.01. Regulation FD Disclosure.**

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on December 8, 2016 and at subsequent meetings with investors or analysts.

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.*

| <u>Exhibit<br/>Number</u> | <u>Description</u>                                     |
|---------------------------|--|
| 99.1                      | TherapeuticsMD, Inc. presentation dated December 2016. |

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**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 8, 2016

THERAPEUTICSMD, INC.

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

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EXHIBIT INDEX

| Exhibit<br>Number | Description  |
|-------------------|--|
| 99.1              | <a href="#">TherapeuticsMD, Inc. presentation dated December 2016.</a> |

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# Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as “we” and “our”) may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as “believe,” “hope,” “may,” “anticipate,” “should,” “intend,” “plan,” “will,” “expect,” “estimate,” “project,” “positioned,” “strategy” and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake 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 may be outside of our 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 our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop, protect and defend our intellectual property; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefore; 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 our clinical trials; potential adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership.

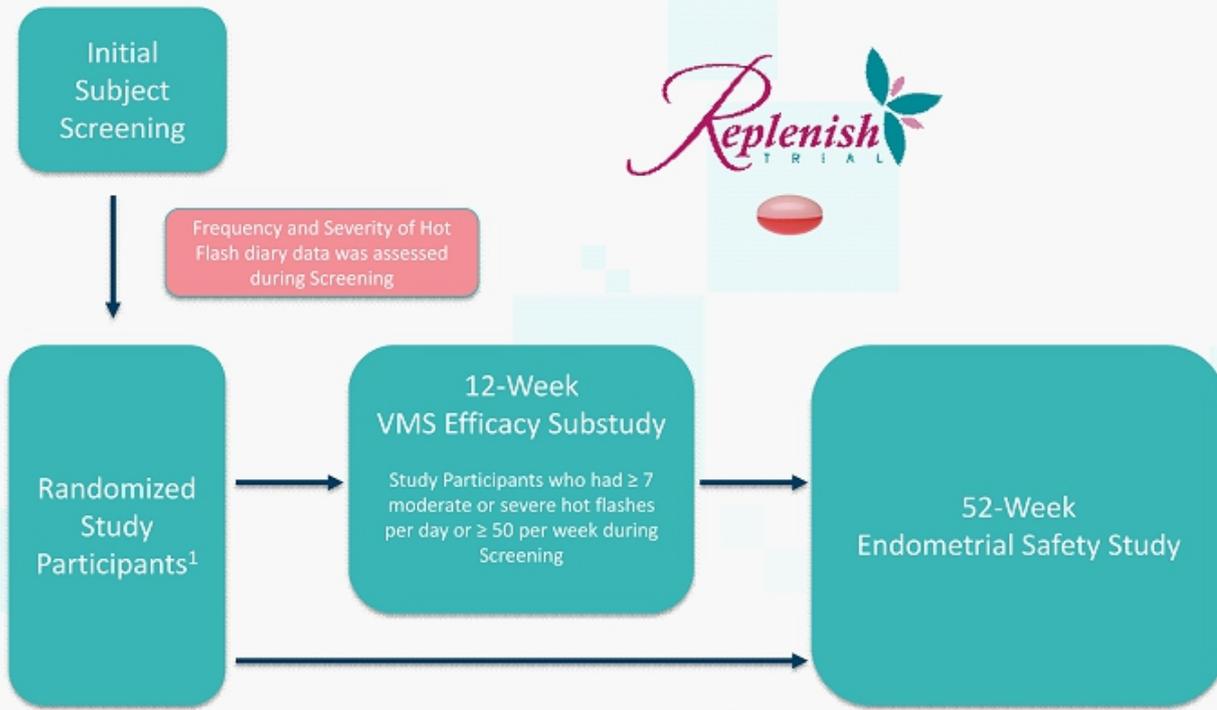
Yuvvexy™ (TX-004HR), TX-001HR, TX-005HR, and TX-006HR are investigational drugs and are not approved by the FDA. This non-promotional presentation is intended for investor audiences only.

*PDF copies of press releases and financial tables can be viewed and downloaded at our website:  
[www.therapeuticsmd.com/pressreleases.aspx](http://www.therapeuticsmd.com/pressreleases.aspx).*

## Replenish Trial Overview

A Phase 3, Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Evaluate the Safety and Efficacy of Estradiol in Combination with Progesterone in Postmenopausal Women with an Intact Uterus

# Replenish Trial Study Design - Flow Chart



1. Healthy postmenopausal women aged 40 to 65 years with an intact uterus who were seeking relief from vasomotor symptoms (VMS) and who met all inclusion/exclusion criteria were eligible for 12 months of study treatment.

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# Replenish Trial Study Design - Populations

- **Safety Population (n = all dosed study subjects)**
  - **52-Week Endometrial Safety Population**
    - A subset of the total safety population group who had a biopsy at week 52
- **VMS Efficacy Population (n = ~150 per active arm & placebo)**
  - **12-Week VMS Efficacy mITT Population**
    - A subset of the total safety population group who had  $\geq 7$  moderate or severe hot flashes per day or  $\geq 50$  per week at baseline, and
    - Took at least one dose of study medication, and
    - Have at least 4 days of evaluable data
  - **All VMS Efficacy mITT Population included in Safety Population**
- **Study Treatment Arms**
  - 17 $\beta$  estradiol 1 mg / progesterone 100 mg
  - 17 $\beta$  estradiol 0.5 mg / progesterone 100 mg
  - 17 $\beta$  estradiol 0.5 mg / progesterone 50 mg
  - 17 $\beta$  estradiol 0.25 mg / progesterone 50 mg
  - Placebo (VMS Substudy only)

# Current FDA Guidance for VMS Drug Products\*

## Primary Endpoints

- **Co-primary efficacy endpoints (12 week VMS Efficacy Population)**
  - Mean Change from Baseline to Weeks 4 and 12 in the frequency and severity of moderate and severe vasomotor symptoms versus placebo
- **Primary safety endpoint (12 month Endometrial Safety Population)**
  - Incidence rate of endometrial hyperplasia at 12 months (to demonstrate a hyperplasia rate that is  $\leq 1\%$  with an upper bound of the one-sided 95% confidence interval for that rate does not exceed 4%)

## Study Analysis

- **Clinically meaningful and statistically significant reduction within 4 weeks of initiation of treatment and maintained throughout 12 weeks of treatment**

## Study Considerations

- **Single, 12-month study to demonstrate endometrial protection**

## Single Pivotal Phase 3 trial required unless:

- **The drug to be studied is considered a new molecular entity**
- **The drug to be studied poses unique safety concerns**

\* 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>

## 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<br>(n = 141) | 0.5 mg/100 mg<br>(n = 149) | 0.5 mg/50 mg<br>(n = 147) | 0.25 mg/50 mg<br>(n = 154) | Placebo<br>(n = 135) |
|---|--------------------------|----------------------------|---------------------------|----------------------------|----------------------|
| <b>Frequency</b>  |                          |                            |                           |                            |                      |
| 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                     | -                    |
| <b>Severity</b>   |                          |                            |                           |                            |                      |
| Week 4 P-value versus placebo   | 0.031                    | 0.005                      | 0.401                     | 0.1                        | -                    |
| Week 12 P-value versus placebo  | <0.001                   | <0.001                     | 0.018                     | 0.096                      | -                    |
| <b>Replenish Trial Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population<sup>f</sup></b> |                          |                            |                           |                            |                      |
| Endometrial Hyperplasia   | 0% (0/280)               | 0% (0/303)                 | 0% (0/306)                | 0% (0/274)                 | 0% (0/92)            |

MITT = Modified intent to treat

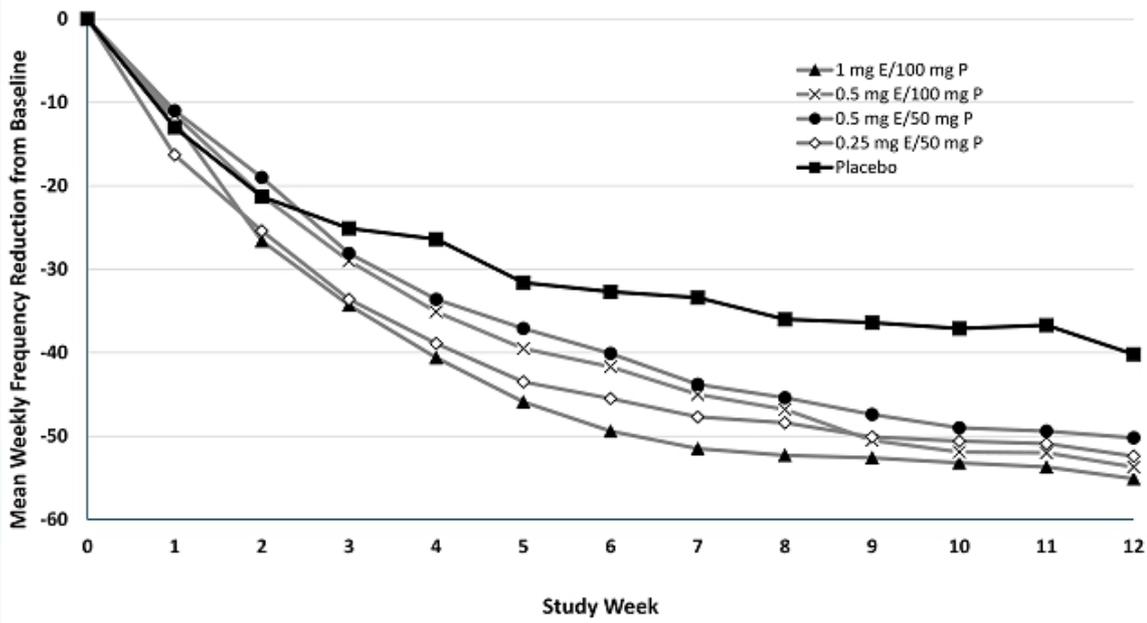
<sup>f</sup>Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis<sup>3</sup>

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

### Primary Efficacy Analysis pre-specified with the FDA in the clinical protocol and Statistical Analysis Plan (SAP)

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

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



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

