

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 23, 2015

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))

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 June 23, 2015 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 Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. presentation dated June 2015.

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 23, 2015

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. presentation dated June 2015.

TherapeuticsMD®

A Woman's Health Company

TXMD Overview

June 2015

www.TherapeuticsMD.com

TXMD-000001 6/15



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 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 therefor; 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.

PDF copies of press releases and financial tables can be viewed and downloaded at our website:
<http://www.therapeuticsmd.com/pressreleases.aspx>.

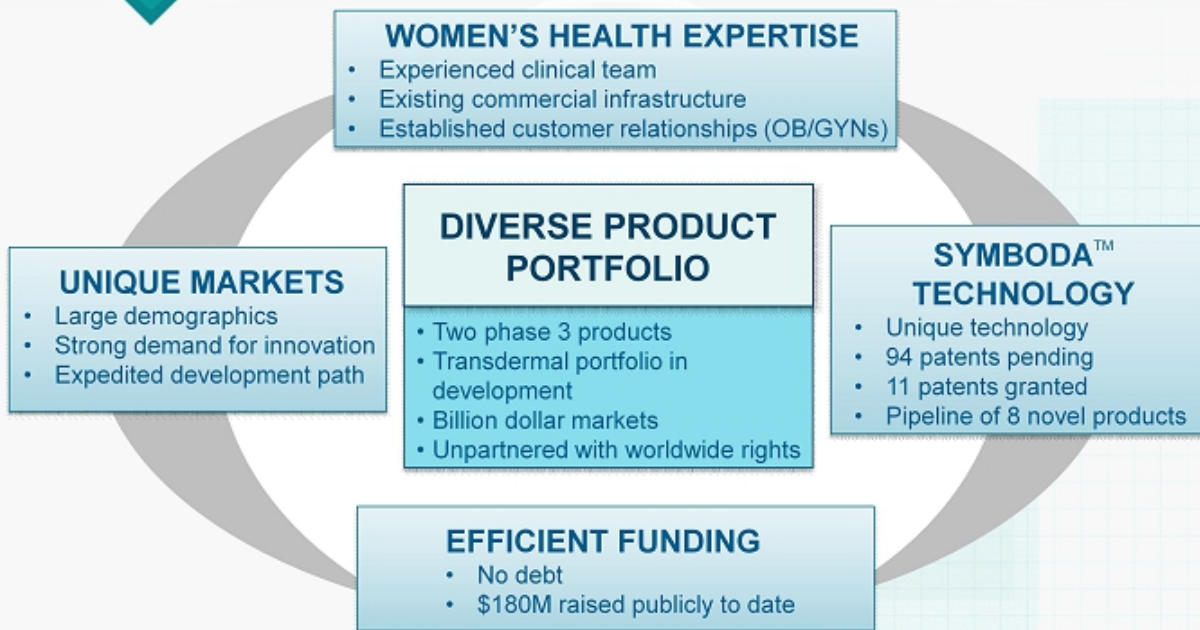
TherapeuticsMD (TXMD)

Innovative women's health company exclusively focused on developing and commercializing products for women throughout their life cycles

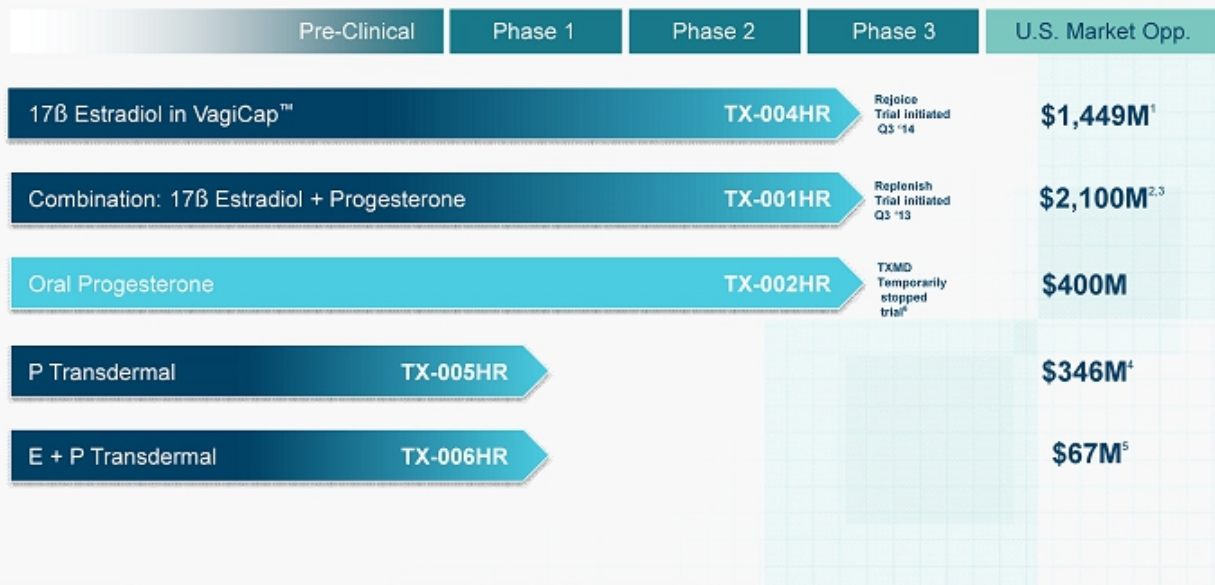


Drug candidate portfolio is built on patented SYMBODA™ technology, developed to enable new bio-identical hormone combinations, forms and administration routes

TXMD: Long-Term Growth Opportunity



Pipeline Targets Large Markets



1) PHAST Prescription Monthly by Source Healthcare Analytics as of 5/15

2) PHAST by Symphony Health Solutions, full year 2014

3) Pinkerton, J.V. 2015. Menopause. Vol 22, No 8, pp 9-11

4) Estimated U.S. sales, based on half estradiol patch sales

5) PHAST by Symphony Health Solutions as of 10/14

6) In July 2014 we temporarily suspended enrollment in the Sory Trial and, in October we temporarily stopped it. In order to update the Phase 3 protocol based on discussions with the FDA. We intend to update the Phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial.

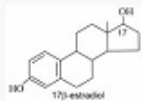
TXMD SYMBODA™ Technology Resolves Current Market Chemistry and Formulation Challenges

Current Market Challenge

Chemistry

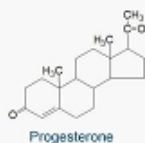
Estrace® 17β-estradiol

- Hydrophobic
- Crystalline
- Small amounts
- Low doses 0.5-1 mg
- Low oral bioavailability

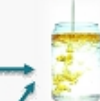


Prometrium® progesterone

- Large molecule
- High doses 100-200 mg
- Micronized
- Suspended in peanut oil
- 100% inter-/intra-subject variability
- Hydrophobic
- ~7% oral bioavailability



Formulation



- One capsule
- 100x more progesterone than estradiol
- Bioequivalence to both RLDs
- Content uniformity
- Stability
- Improved bioavailability
- Consistent product characterization
- Prevent recrystallization in presence of moisture

TXMD Solution



- Lipid solubilized mixture of the two APIs
- Medium chain fatty acids
- C6 – C12
- Continuous estradiol solubilization
- Safety & efficacy in Phase 3

TX-004HR
VVA Program

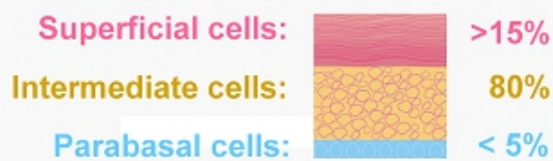


TherapeuticsMD®

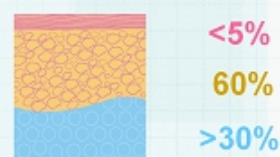
Overview – Vulvar and Vaginal Atrophy (VVA)

- Diagnosed in approximately 50% of postmenopausal women¹
- Most bothersome symptoms include: dyspareunia, dryness, itching, irritation, dysuria, bleeding with sexual activity¹
- FDA guidance for efficacy requirements:
 - Statistical increase in superficial cells
 - Statistical decrease in parabasal cells
 - Changes in vaginal pH
 - Statistical reduction in most bothersome symptom

Healthy Vaginal Tissue



Atrophic Vaginal Tissue



VVA Market – Established and Growing

- U.S. sales more than doubled since 2008
- Global market expected to be \$2.1 billion in 2022⁴
- Currently no generic competition

Product ²	Compound	TRx ¹ 12 Month Rolling	U.S. Sales (\$M) ¹ 12 Month Rolling	WAC Price ³
Premarin [®] Cream	Equine vaginal estrogen	1,780,516	\$489	\$263.52
Vagifem [®] Tablets	Vaginal estradiol	1,894,045	\$428	\$306.00*
Estrace [®] Cream	Vaginal estradiol	1,756,494	\$376	\$240.05
Osphena [®] Tablets	Oral SERM	261,251	\$61	\$158.00
Estring [®]	Vaginal estradiol ring	337,277	\$95	\$283.66
Total¹		6,029,583	\$1,449	

1) PHAST Prescription Monthly by Symphony Health Solutions as of 5/15

2) Femring data was excluded due to WAC indication

3) West-Span Price For Basic as of 6/10/15 * For 10 tablets (\$135.00 WAC for 8 tablets)

4) GlobalData July 2013 report GDHP54P/DR

VVA Market Dynamics – Untapped Market

32 million U.S. women currently experiencing VVA symptoms

40% of women with VVA symptoms are currently utilizing treatment (12.8 million):

- OTC only: (non-estrogenic) 29% (9.3 Million)
- Rx only: 7% (2.2 Million)
- Both Rx and OTC: 4% (1.3 Million)

Perceived Challenges in Dyspareunia Treatment

Consumer Perspective

- Exposure to estrogen/estradiol
- Reluctance to discuss symptoms with provider
- Lack of knowledge regarding treatment options
- Messiness of creams, re-washable applicator
- Drug placement issues
- Interferes with daily routine, can't apply in the morning
- Affects sex life
- Residue and/or vaginal discharge
- Questions about effectiveness

Provider Perspective

- Cream's messiness creates callbacks and repeat visits
- Lack of patient compliance due to messiness
- Lack of time to counsel
- Dissatisfaction with currently available treatments
- Desire for variety of doses

One-year treatment persistence with local estrogen in women diagnosed as having vaginal atrophy¹

- Vaginal tablets (Vagifem®) were associated with greater persistence of use in the treatment of VVA compared to estrogen creams
- During 12-month period, 86.2% to 89.4% of cream users discontinued after the first prescription compared with 57.8% of tablet users ($P<0.0001$)
- Treatment duration was 103.4 days for tablet users compared to 44.6-48.1 days for cream users ($P<0.0001$)
- Tablet users had a lower risk for discontinuation compared to cream users ($P<0.0001$)
- Tablets attributed to less messiness, fixed dosing and convenience

TX-004HR – Target Product Profile



Target Goals

Preliminary Supportive Data

Lower systemic exposure

Phase 1 data with 10 mcg and 25 mcg suggest lower systemic absorption

Faster onset of action

Phase 2 demonstrated efficacy in 14 days

New lower effective dose

Phase 3 evaluating broad range of doses, including 4, 10 and 25 mcg

Improved user experience

Phase 2 showed patient satisfaction; 97% said “easy to use”

Target Product Profile being evaluated in ongoing Phase 3 Rejoice Trial

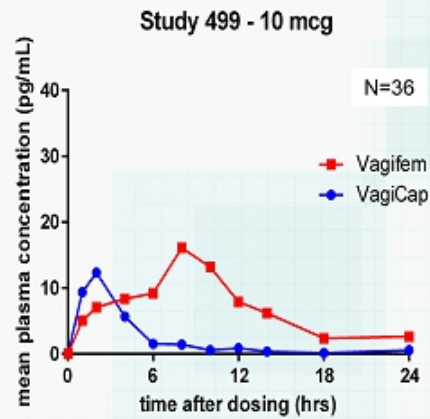
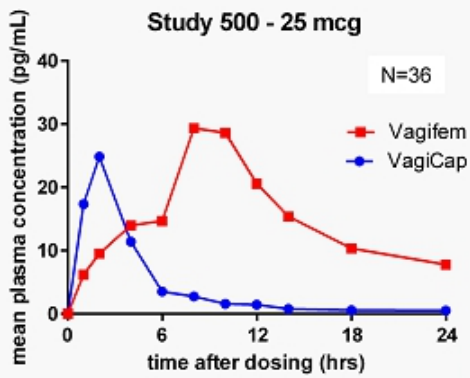
TherapeuticsMD®

TX-004HR vs. Vagifem®

Phase 1 Single Dose PK Studies

Key Findings

- T_{max} ~2 hours with TX-004HR and ~8 hours with Vagifem
- Systemic absorption AUC (0-24 hours) is 2- to 3-fold lower with TX-004HR relative to Vagifem



TX-004HR Phase 2 Study

Double-blind and Controlled

Study Design

- 48 postmenopausal women with VVA (24 active, 24 placebo)
- Randomized 1:1 to 10 mcg; 1x daily for 2-week period
- Endpoints measured at 2 weeks; same endpoints to be measured in Phase 3 at 12 weeks

Co-primary Endpoint Results

- Increase in superficial cells 35% treatment vs. 4% placebo (p=0.0002)¹
- Decrease in parabasal cells 54% treatment vs. 4% placebo (p<0.0001)¹
- Decrease in vaginal pH -0.97 units for treatment vs. -0.34 units for placebo (p=0.0002)¹
- Numerical reduction of most bothersome symptoms¹

Secondary Endpoint Results

- Improved patient satisfaction, 97% said easy to use²
- Reduction in atrophic effects on epithelial integrity and vaginal secretions³

TX-004HR Phase 2 Study: Patient Experience Secondary Endpoint

Patient Experience Survey Results Summary^{1,2}

- 97% reported “easy to use”
- 96% reported the TX-004HR softgel (VagiCap™) was “easy to insert”
- 94% reported “convenient to use”
- 0% experienced expulsion of capsule
- 8% were “dissatisfied”; >60% “very satisfied”
- 63% reported quality of life was “somewhat better” to “much better” after only 14 days of use

The satisfaction and quality of life questions were not defined and therefore open to patient interpretation.

TX-004HR Phase 3 Trial Timelines & Milestones



Last Patient Out Details*

- Last subject last visit scheduled for Sept 2015
- Endometrial biopsy (EB) – 3 independent pathologists must read
- If insufficient tissue, repeat EB
- If no tissue on repeat biopsy – ultrasound assessment
- If endometrium >4 mm, then D&C hysteroscopy with specimens sent to all three pathologists



TherapeuticsMD®

Rejoice Trial Co-primary Endpoints

- FDA required co-primary endpoints for proposed indication (from baseline to week 12 versus placebo)¹
"Treatment of moderate to severe dyspareunia as a symptom of VVA due to menopause"
 - Statistically significant increase in the percentage of vaginal superficial cells
 - Statistically significant decrease in the percentage of vaginal parabasal cells
 - Statistically significant change in vaginal pH from basic to acidic
 - Statistically significant reduction in the severity of dyspareunia
- Each arm (4 mcg, 10 mcg, and 25 mcg) tested against each co-primary endpoint

Phase 3 – TX-004HR Vaginal Estradiol

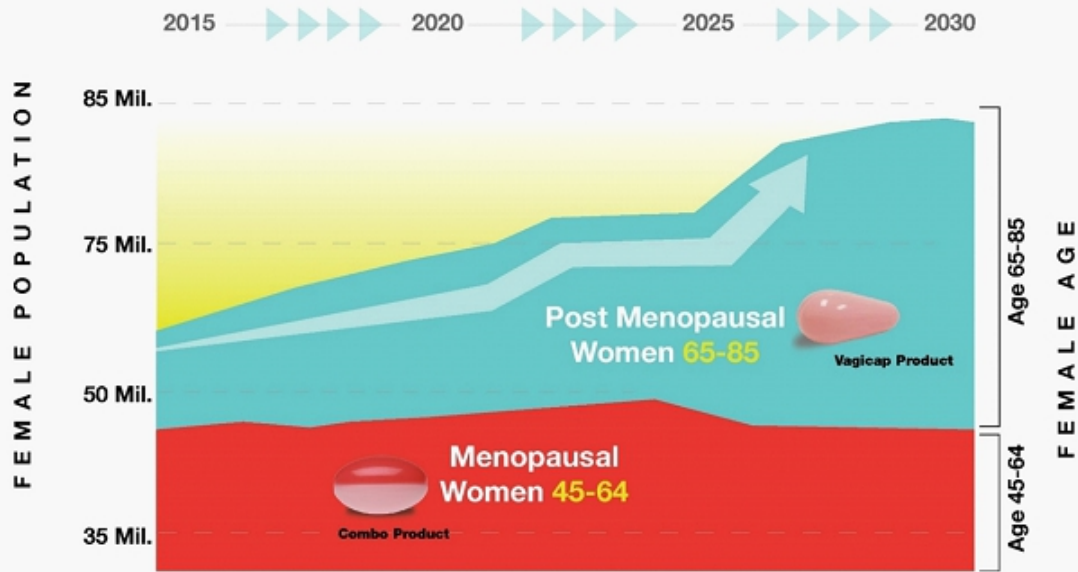


	Q1 '15	Q2 '15	Q3 '15	Q4 '15	Q1 '16	Q2 '16	Q3 '16	Q4 '16	Q1 '17
TX-004HR Estradiol VVA VagiCap		Enroll Cmpltd		Data Read					
	Phase 3								
NDA Prep/ Filing/PDUFA									



- **Trial: 12 weeks, Sites: ~100**
- **Subjects: ~700 fully enrolled as of June 2015**
 - 3 active arms: 4 mcg, 10 mcg, 25 mcg (~175 per arm)
 - 175 placebo
- **Co-Primary Endpoints¹**
 - Statistically significant increase in the % of vaginal superficial cells
 - Statistically significant decrease in the percentage of vaginal parabasal cells
 - Statistically significant change in vaginal pH from basic to acidic
 - Statistically significant reduction in the severity of dyspareunia
- **Additional Endpoints**
 - PK measures Days 1,14, 84
 - FSFI (Female Sexual Function Index), acceptability survey

Growing Opportunity for Hormone Therapy



TX-001HR Combination Program





TherapeuticsMD®

Menopause Overview

Menopause is defined as the final menstrual period and is typically confirmed after an otherwise healthy woman has not had a period for 12 consecutive months.

- Hot flashes are due to lower estrogen levels
- Estrogen is given to reduce hot flashes
- Estrogen causes the uterus to thicken (hyperplasia)
- Progesterone is given to non-hysterectomized women to prevent thickening of the uterus

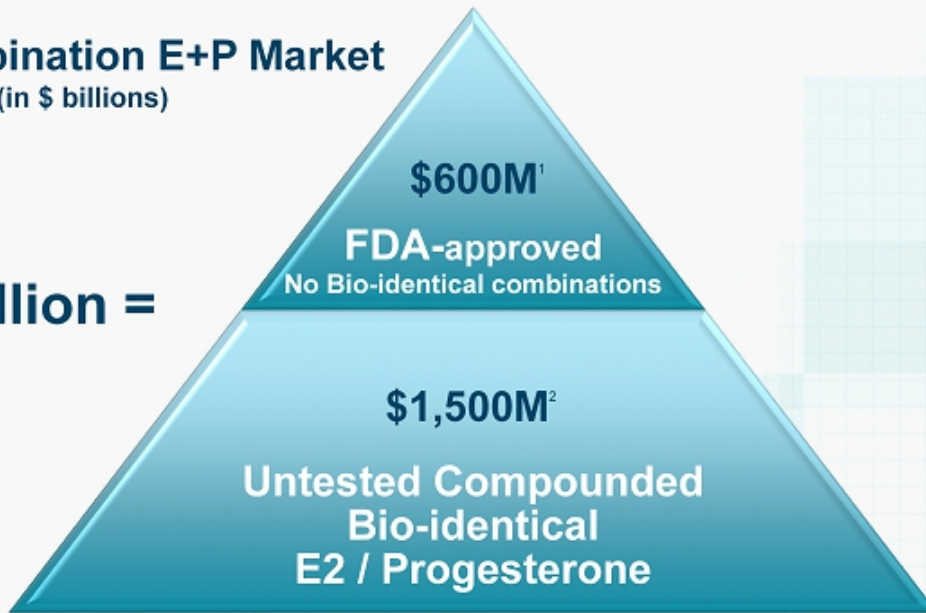
FDA Approved Hormone Therapy Market Size

FDA-Approved Product		U.S. Sales (est.)	Company
17β Estradiol + NETA / DSP Activella® / FemHRT® / Angeliq®	Non bio-identical progestins	\$ 42M ¹	 Bayer  novo nordisk®  Warner Chilcott
Generic 17β + Progestins	Non bio-identical progestins	\$ 216M ¹	 TEVA
Premarin + MPA Prempro® / Premphase®	Non bio-identical CEE + progestin	\$ 336M ¹	 Pfizer
Premarin + SERM Duavee®	Non bio-identical CEE + SERM	\$ 6M ¹	 Pfizer
Paroxetine Brisdelle®	SSRI non-hormonal	\$ 20M	 NOVA
Total FDA-Approved Oral Combination Sales		\$ 600M	

Hormone Therapy Market = Two Markets

Total Combination E+P Market
(in \$ billions)

\$2.1 billion =



Number of U.S. Women Using Non-FDA-Approved Compounded HT



Pinkerton, J.V. Compounded bio-identical hormone therapy: identifying use trends and knowledge gaps among U.S. women. *Menopause* Vol.22, No.9, 2015.



Pinkerton, J.V. Menopause Hormone Therapy (MHT) Usage: FDA-Approved MHT has decreased while Compounded non-FDA-approved MHT has increased, ENDO, 2015.



Archer, D.F., et al. Prevalence of Use and Cost of Compounded Menopausal Hormone Therapy (CMHT) 2015 ACOG, presentation, May, 2015.

1-2.5M

U.S. women using custom-compounded menopausal hormone therapy

26-33M

Annual custom-compounded prescriptions

\$49

Average monthly cash cost



\$1-2B

TherapeuticsMD®

TX-001HR – Target Product Profile

Target Goals

Preliminary Supportive Data

Meet patient demand for bio-identical hormones

Potential for FDA-approved first natural estradiol plus natural progesterone combination pill

New lower effective dose

Broad range of doses being evaluated in Phase 3

Labeling differentiation

Bio-identical terminology as both hormones similar to those produced by the ovary

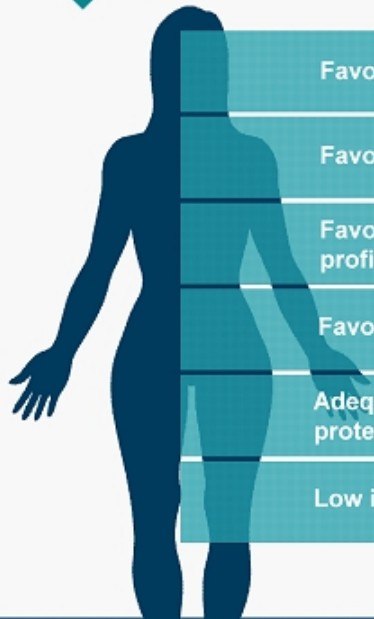
Leverage data on natural progesterone and 17β estradiol







Inclusion of Progesterone/E2 differences data via label negotiation

Target Product Profile being evaluated in ongoing Phase 3 Replenish Trial

Evidence Supports Bio-identical Progesterone

Favorable Clinical Profile Compared to Synthetic Progestins



Favorable CNS profile		Freeman E, et al
Favorable breast profile		E3N-EPIC
Favorable cardiovascular profile		PEPI, ELITE
Favorable lipid profile		PEPI
Adequate endometrial protection		PEPI
Low incidence of bleeding		Lorrain, et al.

Freeman E, Roberts K, Sandheimer S, et al. A double-blind trial of oral progesterone, abiraterone and placebo in treatment of severe premenstrual syndrome. *JAMA*. 1999;274:51-57.

Fourvier A, Berrino F, Clavel-Chapelon F. Unequal risks for breast cancer associated with different hormone replacement therapies: results from the E3N cohort study. *Breast Cancer Res Treat*. 2008;107:103-111.

Lorrain J, Lalumière L, G, Caron P. The effects of oral micronized progesterone on bleeding patterns, endometrial histology and bone density in postmenopausal women on hormone replacement therapy. *Int J Gynaecol Obstet*. 1994;46:77-79.

The Writing Group for the PEPI Trial. Effects of hormone replacement therapy on endometrial histology in postmenopausal women. The postmenopausal estrogen/progestin interventions (PEPI) trial. *JAMA*. 1996;275:370-376.

Writing Group for the PEPI Trial. Effects of estrogen or estrogen/progestin regimens on heart disease. Risks factors in postmenopausal women. *JAMA*. 1996;273:199-206.

Hoad H, et al. Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol. *AHA*. 2014. Abstract: 13283.

TherapeuticsMD®

Potential Advantages of Natural Estradiol

“CEE (Premarin) were associated with a higher incidence of venous thrombosis and myocardial infarction than estradiol.”¹

— *Journal of the American Medical Association*, September 2013

“Oral estradiol may be associated with a lower risk of stroke ... compared with conventional-dose oral CEE.”²

— *Menopause*, September 2014

The ELITE trial demonstrated that estradiol is cardioprotective when given during the early postmenopausal years.³

— *Circulation*, November 2014

Cochrane meta analysis demonstrated that estradiol is cardioprotective and reduced overall mortality when given 10 years before the onset of menopause.⁴

— Cochrane Collaboration, 2015

Drug Quality and Security Act (DQSA)

- Spurred by public health scares, DQSA establishes clear FDA oversight of compounding pharmacies
- Prohibits compounding of essential copies of an FDA-approved and marketed drug except in limited circumstances such as drug shortages
- Recent FDA enforcement actions related to essential copies
- DQSA anticipated to have significant impact on market post-approval of first combination drug
- TXMD would look to distribute through compounding pharmacies once approved



TherapeuticsMD®

Phase 3 – TX-001HR (Estradiol + Progesterone)

2015E				2016E				2017E				
Q1 '15	Q2 '15	Q3 '15	Q4 '15	Q1 '16	Q2 '16	Q3 '16	Q4 '16	Q1 '17	Q2 '17	Q3 '17	Q4 '17	Q1 '18



TX-001HR
Combination 17β
Estradiol +
Progesterone

NDA Prep/Filing/ PDUFA

Phase 3 Vasomotor & Endometrial Safety



- Designed to enroll 1,750 subjects at ~100 U.S. sites
 - Four active arms (N=400/arm)
 - Estradiol 1 mg/Progesterone 100 mg
 - Estradiol 0.5 mg/Progesterone 100 mg
 - Estradiol 0.5 mg/Progesterone 50 mg
 - Estradiol 0.25 mg/Progesterone 50 mg
 - Placebo arm (N=150)
- 12-month study with 12-week VMS substudy endpoints:
 - Vasomotor substudy: number and severity of hot flashes (4 weeks and 12 weeks)
 - Endometrial safety: incidence of endometrial hyperplasia (12 months)

Transdermal Programs

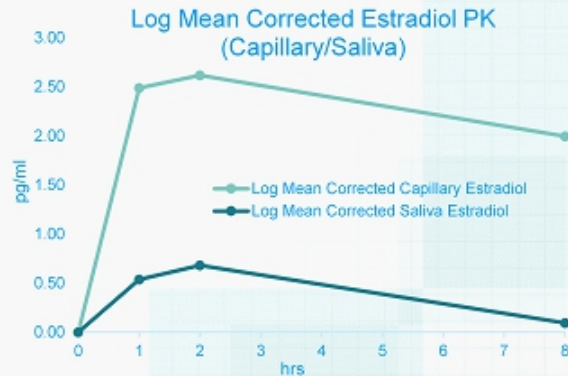
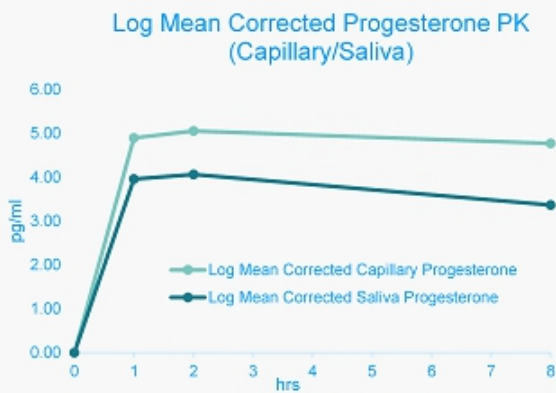


Why Transdermal?

- Transdermal delivery perceived safer due to a lower first-pass effect
- No FDA-approved transdermal progesterone
- New TXMD PK data suggest leveraging solubilized progesterone, show elevated and sustained transdermal levels
- Leveraging this technology creates an opportunity for new progesterone IP, products and novel dosage forms

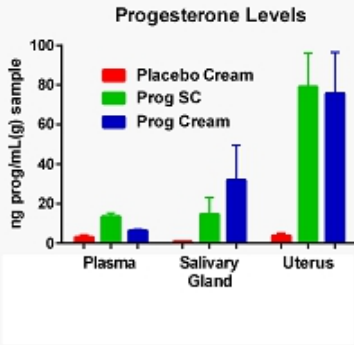
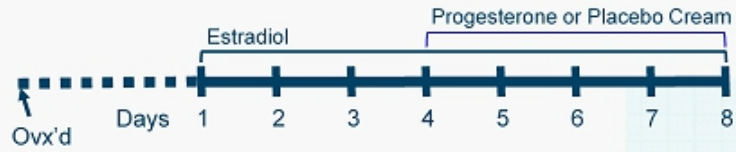
E+P Topical PK Results

New Formulation PK Data Suggest Sustained 8-hour Duration

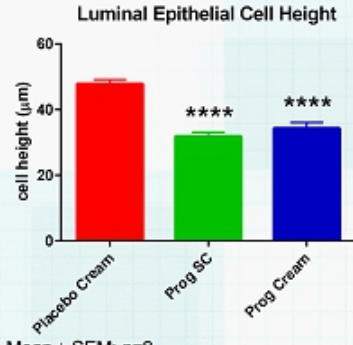


- Levels in the saliva and capillary samples are higher than in the serum, where it was not detectable
- Consistent with published article from Du and Stanczyk 2013¹

Proof Of Concept Efficacy Study











Mean \pm SEM; n=8
 * p=0.02 vs. Placebo Cream



Mean \pm SEM; n=8
 **** p<0.0001 vs. Placebo Cream

Transdermal Market Opportunity

Product (Combination E+P)	TRx ⁽¹⁾⁽²⁾	U.S. Sales (est.) ⁽¹⁾⁽²⁾	Company
Estradiol/Levonorgestrel (Climara Pro®)	129,755	\$ 22.5M	 Bayer
Estradiol/Norethindrone Acet (CombiPatch®)	408,598	\$ 44.0M	 NOVEN PHARMACEUTICALS, INC.
Total Combination Transdermal Sales	538,353	\$ 66.5M	
Product (Estradiol Only)	TRx ⁽¹⁾⁽²⁾	U.S. Sales (est.) ⁽¹⁾⁽²⁾	Company
Estradiol (Patch, Gel, Spray) (Alora®, Climara®, Estraderm®, Menostar®, Vivelle®, Vivelle-Dot®, Minivelle®; Divigel®, Elestrin®, Estrogel®; Evamist®)	5,762,725	\$ 692M	 Bayer   NOVARTIS   MEDA  IMPERVA
Total Estradiol Transdermal Sales	5,762,725	\$ 692M	

Intellectual Property Update



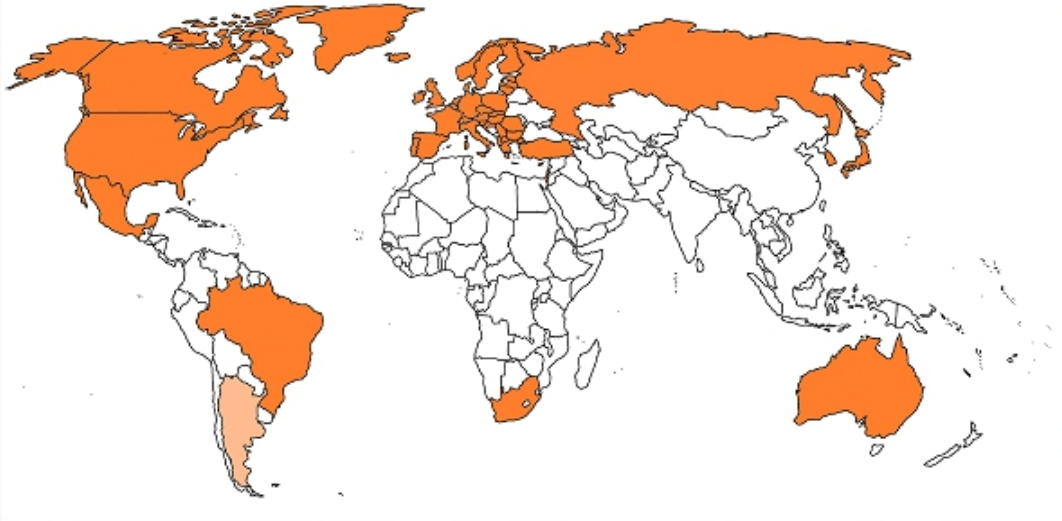
Growing Patent Portfolio

	Filed	Provisional	Non-Provisional	Issued
U.S.	46	14	21	11
Ex-U.S.	59			

- Seven new patents issued in 2015 strengthening competitive barriers to entry and building on layered coverage strategies
- Others issued:
 - Field spanning estradiol and progesterone pharmaceutical compositions and methods
 - OPERA reporting and analysis software patent
- Layered patent strategies
 - Field spanning pharmaceutical compositions and methods by family of estradiol and progesterone alone and in combination
 - Siloed strategy for each product

Worldwide Patent Filings*

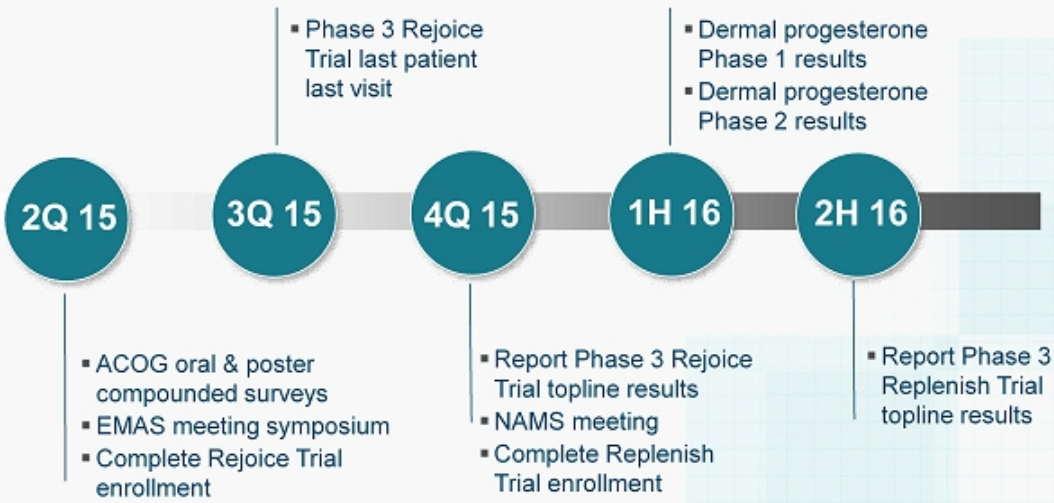
Strong IP Portfolio with 59 Patents Pending in 12 Jurisdictions Outside the United States



Investment Rationale

- **Worldwide commercial rights for multiple hormone therapy products in Phase 3** and earlier stages:
 - Well-known chemical entities with established safety and efficacy thresholds; 505(b)(2)
 - Unique, large, and growing markets with favorable competitive dynamics (DQSA)
 - Additional early stage pipeline candidates
 - Strong IP portfolio with 59 patents pending in 12 foreign jurisdictions
- **Growing U.S. commercial business** marketing prescription and OTC prenatal vitamins
 - Customer base of OB/GYNs and other women's health specialists
 - Recognized by Deloitte Technology Fast 500 as 41st in North America
- **Experienced management team** with proven development and commercial success in women's health

Key Milestones



TXMD: Financial Snapshot

Listing Exchange	NYSE MKT
Shares outstanding	173 million (as of May 4, 2015)
Cash	\$91.7 million (as of March 31, 2015)
Debt	\$ 0 million

TherapeuticsMD®

A Women's Health Company

Thank You

www.TherapeuticsMD.com

