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): November 17, 2015

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-00100**	**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 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 November 17, 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.*

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated November 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: November 17, 2015

THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated November 2015.

Exhibit 99.1


TherapeuticsMD
TXMD Overview
November 2015
TherapeuticsMD.com
THER-0063 11/15

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 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 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.

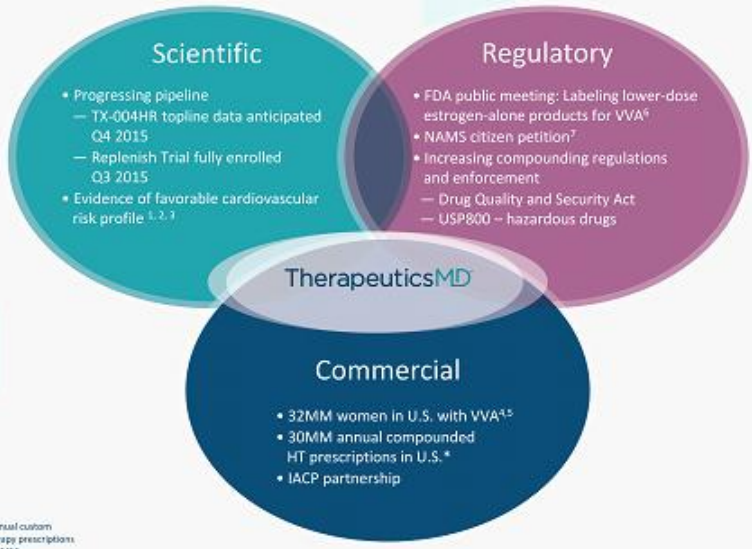
PDF copies of press releases and financial tables can be viewed and downloaded at our website: www.therapeuticsmd.com/pressreleases.aspx.

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 SYMBODA™ technology to enable solubilization of new bio-identical hormone combinations, forms, and administration routes

Unique Confluence of Factors



* The reported number of annual custom compounded hormone therapy prescriptions is estimated at 26MM to 33MM.

1) Writing Group for the PEPI Trial. Effects of estrogen or estrogen/progestin regimens on heart disease. Risk factors in postmenopausal women. JAMA. 1995;273:199–208.
2) Hodis HN, et al. "Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol" JAMA 2014; Abstract 13181.
3) Abstract 13181: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol.HN Hodis, et al. Circulation. 2016; 133:A13181.
4) 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.
5) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. Menopause. 2011;18(11):1160–1171.
6) https://federalregister.gov/a/2015-24569, last accessed November 10, 2015
7) www.menopause.org/home/nams-citizen-petition, Last accessed November 10, 2015

Pipeline Targets Large Markets

1] Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.
2] Pinkerton, J.V. 2015. Menopause; Vol.22, No.9, pp.0-11.
3] Estimated U.S. sales, based on half estradiol patch sales.

TherapeuticsMD®

Management with Deep Experience in Women's Health

- Former U.S. Secretary of Health and Human Services (2001-2005)
- Governor of Wisconsin (1987-2001)
- Holds multiple board memberships, including Centene and United Therapeutics
- 40-year public health career

- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2009)
- 16 years of experience in early stage healthcare company development

- Co-founded CareFusion
- Held executive, sales, and operation management positions at McKesson, Cardinal, and Omnicell
- 20+ years of operations experience

- Co-founded vitaMedMD in 2008
- Board member of VitalMD, largest physician-owned managed medical group
- Former Boca Raton Regional Hospital OBGYN Department Chair
- Practicing OBGYN from UChicago

- Former Clinical Lead of Women's Health at Pfizer and developer of Premarin®
- 15+ years of experience developing women's health products
- Global Endometrial Expert

- Former CFO of American Wireless, Telegeography, and WEB Corp
- Participated in American Wireless/Arush Entertainment merger
- Former KPMG and PricewaterhouseCoopers accountant

- 25+ years of women's health pharmaceutical experience
- Product development leader for J&J, Wyeth, Aventis, and others
- Worked on development of Prempro®, Premphase®, and Estalis®

- 25+ years of pharmaceutical marketing, sales, and operations experience
- Led commercialization of anti-estrogens/estradiol, breast cancer, and ovarian cancer drugs

- Global lead for Osphena®, late stage development through approval
- 13 years of experience in women's health
- Established relationships with key women's health opinion leaders and organizations

Supported by a team of regulatory consultants with decades of FDA experience


TX-004HR | VVA Program
TherapeuticsMD
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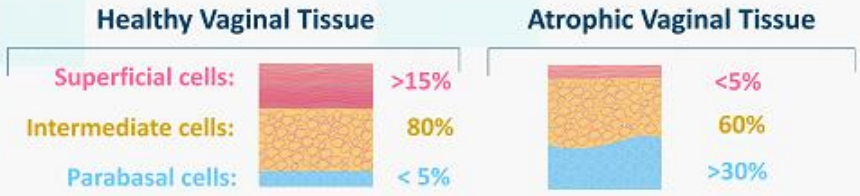
Overview – Vulvar and Vaginal Atrophy (VVA)

- Diagnosed in approximately 50% of postmenopausal women[1]
- Most bothersome symptom commonly reported is dyspareunia[1]
- FDA guidance for efficacy requirements:
  - Statistically significant increase in superficial cells
  - Statistically significant decrease in parabasal cells
  - Statistically significant change in vaginal pH
  - Statistically significant reduction in severity of dyspareunia



1) Kingsberg, Sheryl A., et al. "Vulvar and Vaginal Atrophy in Postmenopausal Women: Findings from the REVIVE (REal Women's Views of Treatment Options for Menopausal Vaginal ChangEs) Survey." International Society for Sexual Medicine 2013, no. 10, 1790-1799.

VVA Market – Established and Growing

- U.S. sales more than doubled since 2008
- Global market expected to be $2.1 billion in 2022[4]
- Currently no generic competition
- 32 million U.S. women currently experiencing VVA symptoms[5,6]

Product[2]	Compound	TRx[1] 12 Month Rolling (000)	U.S. Sales ($MM)[1] 12 Month Rolling	WAC Price[3]
Premarin® Cream	Equine vaginal estrogen	1,774	$511	$263.52
Vagifem® Tablets	Vaginal estradiol	1,851	$463	$351.54*
Estrace® Cream	Vaginal estradiol	1,751	$406	$240.05
Osphena® Tablets	Oral SERM	280	$67	$158.00
Estring®	Vaginal estradiol ring	336	$99	$283.66
Total		**5,992**	**$1,546**	

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.
2) Femring data is excluded due to VMS indication.
3) Medi-Span Price Rx Basic as of 11/6/15. * for 18 tablets ($158.54 WAC for 8 tablets)
4) GlobalData July 2013 report GDHCS439DR.
5) 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.
6) Goss ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. Menopause. 2011;18(11)

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VVA Market Dynamics Ready for New Product

Why?

Only 2.3MM U.S. women treated with Rx product[1]

Vaginal Creams
- Messiness[2]
- Long-term safety[2]
- Dose preparation by user required[2]

Mean treatment duration **46 days**[4]

Vaginal Tablets
- Long-term safety[2]
- Systemic absorption[2]

Mean treatment duration **103 days**[4]

Women primed for conversion to new product

1] IMS Health Plan Claims (April 2008-Mar 2011).
2] Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23-30 doi:10.4137/CMRH.S14488.
3] 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.
4] Portman, D, et al. One-Year Treatment Persistence with Local Estrogen Therapy in Postmenopausal Women Diagnosed as Having Vaginal Atrophy. Menopause. 2015; 22 (11) 1197-203.

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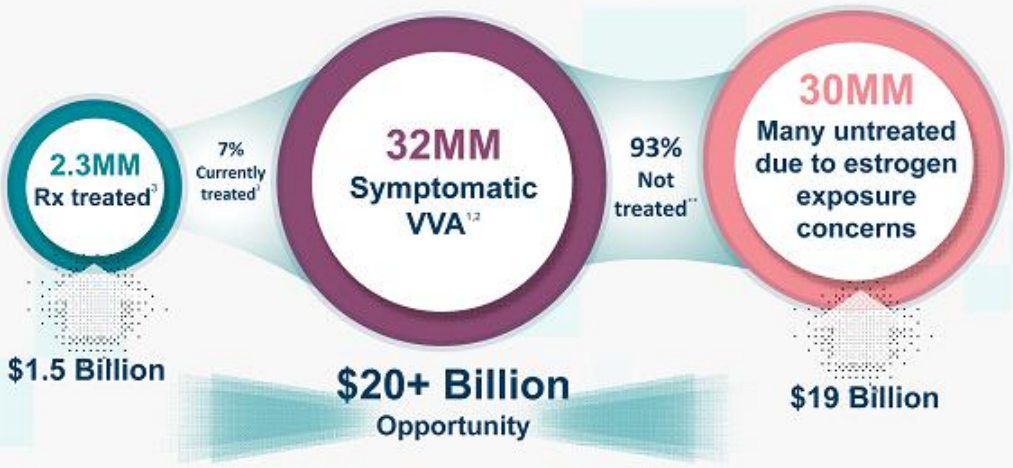
30MM Women with VVA Untreated**



1] 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.
2] Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. Menopause. 2011;18(11):1160–1171.
3] IMS Health Plan Claims (April 2008-Mar 2011).
** Not treated with an FDA approved Rx product. OTC products do not effectively treat the underlying pathological causes of VVA and therefore do not halt or reverse the progression of this condition.

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Vagifem® 25 mcg to 10 mcg Market Share

	Vagifem	
Year	2009	2014
Dosage Strength	25 mcg*	10 mcg*
Market Share[1] (%)	40%	32%

- VVA market TRx increased 15% 2009-2014[1]
- Vagifem had an 18% decrease of its own market share moving to 10 mcg only

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, Annual Data 2009-2014.
*Vagifem 25 mcg was discontinued on July 30, 2010. †Vagifem 10 mcg was approved by the FDA November 25, 2009 and began shipping to pharmacies in Q1 2010.

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TX-004HR – Target Product Profile

Target Goals	Preliminary Supportive Data
Lower systemic exposure	Phase 1 data with 10 mcg and 25 mcg suggests lower systemic absorption
Fast 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"

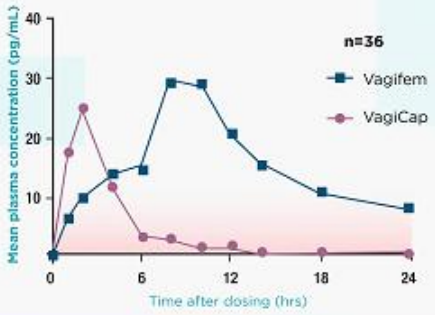
Target Product Profile being evaluated in ongoing phase 3 Rejoice Trial

TX-004HR vs. Vagifem®
Phase 1 Single Dose PK Studies

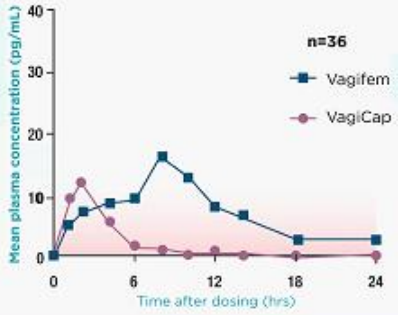
Key Findings

- Tmax ~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

Study 500 - 25 mcg



Study 499 - 10 mcg



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TX-004HR Phase 2 Study
Double-blind and Placebo-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[1]

- Increase in superficial cells 35% treatment vs. 9% placebo (p=0.0002)
- Decrease in parabasal cells 54% treatment vs. 5% placebo (p<0.0001)
- Decrease in vaginal pH -0.97 units for treatment vs. -0.34 units for placebo (p=0.0002)
- Numerical reduction of most bothersome symptom

Secondary Endpoint Results

- Improved patient satisfaction, 97% said easy to use[2]
- Reduction in atrophic effects on epithelial integrity and vaginal secretions[3]

1) Pickar, J.H. et al. Pilot and Pharmacokinetic Studies of Solubilized Estradiol Administered Vaginally in a Softgel Capsule. Menopause. 2014; Vol.21, No.12, 1-8, 1328.
2) Kingsberg, Sheryl."Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap™) presented 2015 Annual Meeting ISSWSH, Feb 20, 2015.
3) Constantine, G.D."Vaginal Physical Examination Correlates with Vaginal Epithelial Cells and pH and Can Be Used to Assess Therapeutic Efficacy," FRI-220, ENDO2015.org. Endocrine Society Meeting and Expo Guide, p. 220.

TX-004HR Vaginal Estradiol U.S. Launch Timeline

- **Phase 3 Trial[1]: 12 weeks, ~100 sites**
- **Subjects: ~700 Fully Enrolled as of June 2015**
  - 3 active arms: 4 mcg, 10 mcg, 25 mcg (~175 per arm)
  - 175 placebo
- **FDA Required Co-Primary Endpoints for Proposed Indication**
  (from baseline to week 12 versus placebo)[2,3]
  - Statistically significant increase in the % of vaginal superficial cells
  - Statistically significant decrease in the % of vaginal parabasal cells
  - Statistically significant change in vaginal pH
  - Statistically significant reduction in the severity of dyspareunia
- **Additional Endpoints**
  - PK measures Days 1, 14, 84
  - FSFI (Female Sexual Function Index), acceptability survey

1) NCT02253173, https://clinicaltrials.gov/ct2/show/NCT02253173?term=rejoice&rank=1, last accessed November 3, 2015.
2) Each arm (4 mcg, 10 mcg, and 25 mcg) tested against each co-primary endpoint.
3) The FDA has noted that a single, large, well-controlled clinical trial to support safety and efficacy should be sufficient to submit an NDA for TX-004HR for the proposed indication and that to support the indication in a single trial, evidence of efficacy for a given dose would need to show statistical significance of at least a .01 level.

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TX-004HR Phase 3 Trial Timelines & Milestones

Last Subject, Last Visit Details

- Endometrial biopsy (EB) – 3 independent pathologists must read
- If insufficient tissue, repeat EB
- If insufficient tissue on repeat biopsy – transvaginal ultrasound (TVU) assessment
- If endometrium >4mm on TVU, then hysteroscopy guided biopsy with specimens sent to all three pathologists


TX-001HR | Combination Program
TherapeuticsMD
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Menopause Overview

- **Menopause represents the natural life-stage transition when women stop having periods**
- **May result in physical and emotional symptoms**
  - Average age of menopause 51 years[1]
  - Hot flashes due to lower estrogen levels
  - Estrogen given to reduce hot flashes
  - Estrogen causes uterus to thicken (hyperplasia)
  - Progesterone given to non-hysterectomized women to prevent thickening of the uterus

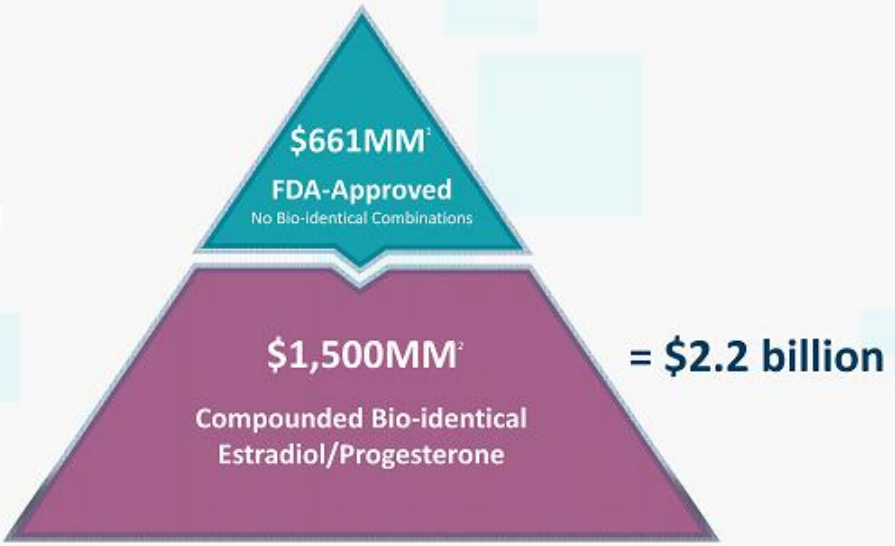
1) National Institutes of Health, National Institute on Aging, https://www.nia.nih.gov/health/publication/menopause, last accessed November 3, 2015.

FDA-Approved Hormone Therapy Market Size

FDA-Approved Product		U.S. Sales ($MM)[1]	Company
17β-estradiol + NETA / DSP Activella® / FemHRT® / Angeliq®	Non bio-identical containing progestins	$37	Allergan, Bayer, novo nordisk®
Generic 17β + Progestins	Non bio-identical containing progestins	$230	Teva Pharmaceuticals
Premarin + MPA Prempro® / Premphase®	Non bio-identical CEE + progestin	$339	Pfizer
Premarin + SERM Duavee®	Non bio-identical CEE + SERM	$19	Pfizer
Paroxetine Brisdelle®	SSRI non-hormonal	$36	noven THERAPEUTICS, LLC
Total FDA-Approved Oral Combination Sales		$661	

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.

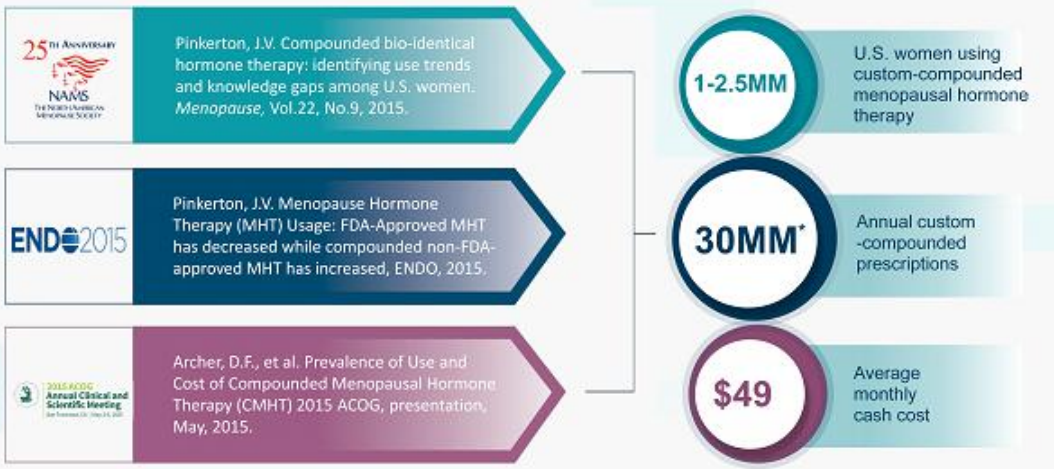
Total Combination E+P = Two Markets



= $2.2 billion

1] Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.
2] Pinkerton, J.V. 2015. Menopause; Vol.22, No.9, pp 0-11.

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



* The reported number of annual custom compounded hormone therapy prescriptions is estimated at 26MM to 33MM.

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Evidence Supports Bio-identical Progesterone

Favorable Clinical Profile Compared to Synthetic Progestins

Bio-identical Progesterone	Synthetic Progestins	References
Favorable CNS profile	No benefit on sleep properties	Freeman E, et al[1]
Favorable breast profile	Increased risk of breast cancer	E3N-EPIC[2]
Favorable cardiovascular profile	Increased risk of MI, stroke, VTE	PEPI[3], ELITE[5]
Favorable lipid profile	Less favorable lipid profile effects (cholesterol, LDL, triglycerides)	PEPI[3]
Adequate endometrial protection	Adequate endometrial protection	PEPI[4]
Low incidence of bleeding	High incidence of bleeding	Lorrain, et al[6]

1) Freeman E., Roberts K., Sondheimer S. J., et al. A double-blind trial of oral progesterone, alprazolam and placebo in treatment of severe premenstrual syndrome. JAMA. 1995;274:51–57.
2) Fournier 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.
3) Writing Group for the PEPI Trial. Effects of estrogen or estrogen/progestin regimens on heart disease. Risk factors in postmenopausal women. JAMA. 1995;273:199–208.
4) 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;275:370–375.
5) Hodis HN, et al. "Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol". ArtS 2014; abstract 11183.
6) Lorrain J., Salvatore S. G., Cano 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. 1995;48:71–79.

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Evidence Supports Bio-identical Estradiol

Favorable Clinical Profile Compared to Conjugated Estrogens

CEEs (Premarin) were associated with a higher incidence of venous thrombosis and myocardial infarction than estradiol.[1]

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

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

— *Circulation*, November 2014

Oral estradiol may be associated with a lower risk of stroke … compared with conventional-dose oral CEE.[2]

— *Menopause*, September 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

1) Smith et al. Lower Risk of Cardiovascular Events in Postmenopausal Women Taking Oral Estradiol Compared with Oral Conjugated Equine Estrogens (CEE).
2) Shufelt et al. Hormone Therapy Dose, Formulation, Route of Delivery, and Risk of Cardiovascular Events in Women: Findings from the Women's Health Initiative Observational Study.
3) Abstract 13203: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol.Hsia, et al. Circulation. 2014; 130:A13283.
4) Cochrane Collaboration; HT for preventing cardiovascular disease in postmenopausal women: Boardman HMP, et al., 2015.

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Medical Societies Express Concern Over Compounded Hormones

- ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products[1]
  - Lack of Good Manufacturing Practices (GMP)
  - Variable purity
  - Variable content uniformity
  - Variable potency (under/over dose)
  - Not approved for efficacy and safety
  - Lack of stability data
- Medical societies' global consensus statement declares that the use of custom-compounded hormone therapy is not recommended[2]

1] Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee, Number 532, August 2012 (Reaffirmed 2014, Replaces No. 387, November 2007 and No. 322, November 2005).
2] Villars, T.J. et al. Global Consensus Statement on Menopausal Hormone Therapy, Climacteric, June 2013, Vol. 16, No. 3 : Pages 316-337.

Compounding Regulations and Enforcement

Drug Quality and Security Act (DQSA)[1]

- Prohibits compounding of essential copies of FDA-approved drug except in limited circumstances such as drug shortages
- Anticipate significant impact on compounding upon FDA approval of first combination hormone therapy product

USP 800 – Hazardous Drugs[2,3]

- New identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs
- Considered "prohibitively expensive" requiring major pharmacy upgrades and renovations to be compliant

1) http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2) http://www.usp.org/sites/default/files/usp_pdf/EN/m7800.pdf
3) https://www.ascp.com/sites/default/files/Join%20USP%20letter%202015%20FINAL.pdf

TherapeuticsMD®

TX-001HR – Target Product Profile

Target Goals	Preliminary Supportive Data
Meet patient demand for bio-identical hormones	Potential for first FDA-approved natural estradiol plus natural progesterone combination softgel capsule
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/estradiol differences data via label negotiation

Target Product Profile being evaluated in ongoing phase 3 Replenish Trial

TX-001HR Estradiol + Progesterone U.S. Launch Timeline

- **Phase 3 Trial[1]: ~110 U.S. sites**
- **Subjects: ~1750 fully enrolled as of October 2015**
  - 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)

Replenish TRIAL

1) https://clinicaltrials.gov/ct2/show/NCT01942668?term=replenish+trial&rank=1, last accessed November 3, 2015.

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Key Milestones

- NDA filing TX-004HR
- Transdermal estradiol and progesterone phase 1 results

- Report phase 3 Rejoice Trial topline results
- Completed phase 3 Replenish Trial enrollment
- NAMS meeting
  - 3 presentations
  - Compounding symposium
  - FDA vaginal estradiol workshop meeting

- Report phase 3 Replenish Trial topline results (4Q '16 – 1Q '17)
- Transdermal estradiol and progesterone phase 2 results


Early Stage Pipeline |
Transdermal Programs
TherapeuticsMD
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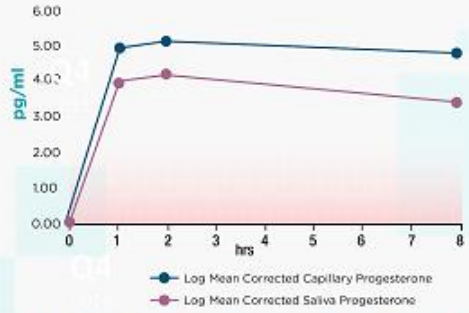
Why Transdermal?

- 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

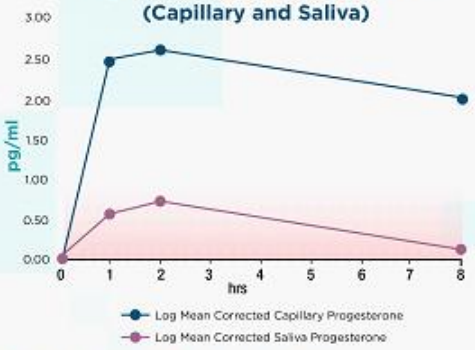
E+P Topical PK Results

New Formulation PK Data Suggest Sustained 8-hour Duration[1]

Log Mean Corrected Progesterone PK (Capillary and Saliva)



Log Mean Corrected Estradiol PK (Capillary and Saliva)

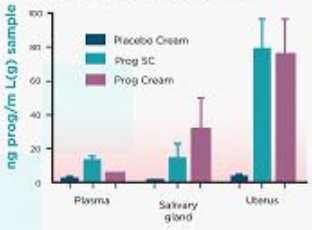


- Levels in the saliva and capillary samples are higher than in the serum, where it was not detectable[1]
- Consistent with published article from Du and Stanczyk 2013[2]

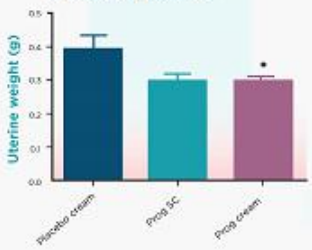
1) Data on file, TherapeuticsMD.
2) Du, Joanna Y. et al. Menopause. 2013, Vol.20, No.11, pp 1-7.

Proof of Concept Efficacy Study[1]

Progesterone Levels

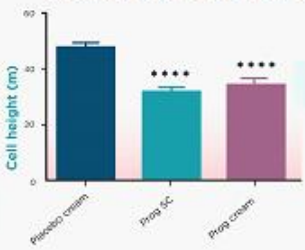


Uterine Weights



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

Luminal Epithelial Cell Height



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

1) Data on File, TherapeuticsMD.

Note: An ovarectomized rat (OVX) is a female rat whose ovaries have been removed.

TherapeuticsMD®

Transdermal Market Opportunity

Product (Combination E+P)	TRx[1] (000)	U.S. Sales ($MM)[1]	Company
Estradiol/Levonorgestrel (Climara Pro®)	111	$23	
Estradiol/Norethindrone Acet (CombiPatch®)	383	$58	
Total Combination Transdermal Sales	494	$81	

Product (Estradiol Only)	TRx[1] (000)	U.S. Sales ($MM)[1]	Company
Estradiol (Patch, Gel, Spray) (Alora®, Climara®, Estraderm®, Menostar®, Vivelle®, Vivelle-Dot®, Minivelle®; Divigel®, Elestrin®, Estrogel®; Evamist®)	5,674	$814	
Total Estradiol Transdermal Sales	5,674	$814	

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.


Intellectual Property |
Update
TherapeuticsMD
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Growing Patent Portfolio

	Filed	Provisional	Non-Provisional	Issued
U.S.	50	15	22	13
Ex-U.S.	61			

- Nine 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 61 Patents Pending
in 12 Jurisdictions Outside the United States

*Not all patent filings filed in all jurisdictions.

TherapeuticsMD®

Investment Rationale

Investment Rationale

1 Worldwide commercial rights for multiple hormone therapy products in phase 3 and earlier stages

- Well-known chemical entities with established safety and efficacy thresholds
- Unique, large, and growing U.S. markets with favorable competitive dynamics
- Additional early stage pipeline candidates
- Strong foreign IP portfolio with 61 patent applications pending in 12 foreign jurisdictions

2 Growing U.S. commercial business marketing prescription and OTC prenatal vitamins

- Strong customer base of OB/GYNs and other women's health specialists
- Recognized in 2014 and 2015 by Deloitte Technology Fast 500 as 41st and 140th in North America

3 Experienced management team with proven development and commercial success in women's health

TXMD: Financial Snapshot


TherapeuticsMD
THANK YOU!
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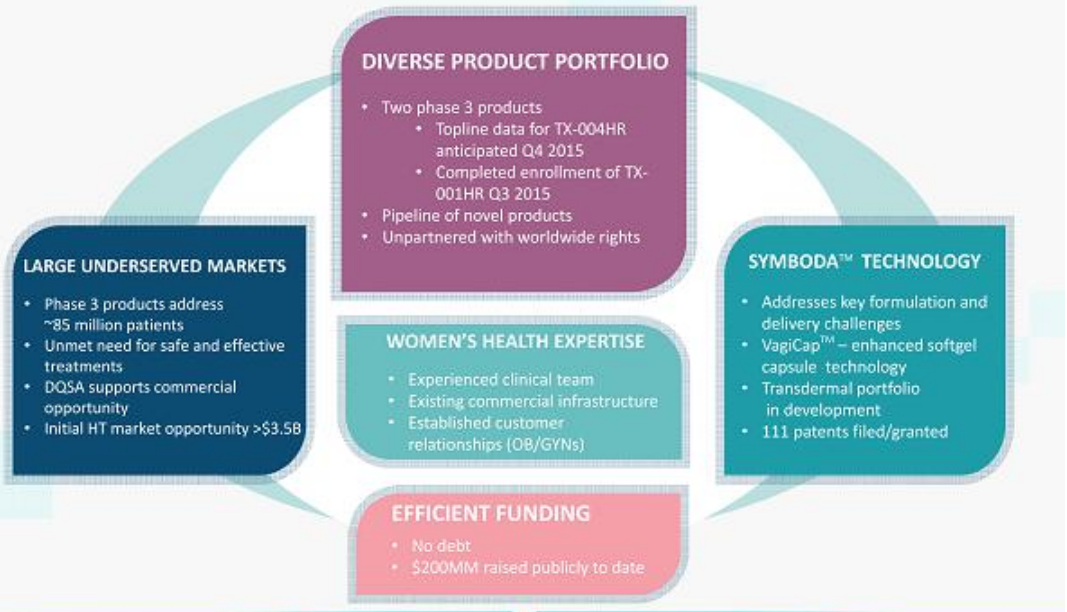
Appendix

Long-Term Growth Opportunity



TX-004HR Phase 2 Study
Patient Experience Secondary Endpoint

n = 49

Patient Experience Survey Results Summary[1]

- 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
- 60% "very satisfied"; 8% were "dissatisfied"
- 63% reported quality of life was "somewhat better" to "much better" after only 14 days of use

1) Kingsberg, Sheryl. "Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap™). Presented at the 2015 ISSWSH Annual Meeting, Feb 20, 2015.