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): January 9, 2017

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 January 9, 2017 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 January 2017.

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: January 9, 2017

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 January 2017.

Exhibit 99.1


TherapeuticsMD®
TXMD Overview
January 2017
TherapeuticsMD.com
THER-0086 1/17

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.

TX-004HR (Yuvvexy™), 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.

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 for the solubilization of bio-identical female hormones

Two Late Stage Women's Health Assets With Large Total Addressable Market Opportunities

	TX-004HR (Yuvvexy™)	TX-001HR
		
Proposed Indication	Moderate to Severe Dyspareunia, a Symptom of VVA, due to Menopause	Moderate to Severe Hot Flashes due to Menopause
Condition Description	VVA due to Menopause	Menopause
Active Ingredients	Bio-Identical 17 β-Estradiol	Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone
Form	Vaginal softgel capsule	Oral softgel capsule
Key Value Proposition	Negligible systemic exposure, early onset of action, ease of use	Potential first and only bio-identical FDA-approved combination product
Affected US Population	32 million women[1,2]	36 million women[3]
US TAM Opportunity	>$20B[5]	>$25B[4,5]
Status	NDA submitted July 7, 2016 PDUFA target action date: May 7, 2017	Positive Phase 3 topline data NDA submission expected 3Q17

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) Derived from U.S. Census data
4) Based on pre-WHI annual scripts of FDA-approved HT products
5) Based on market pricing of current FDA-approved HT products

TherapeuticsMD®

Seasoned Management Team with a Proven Track Record of Commercial Execution

Tommy Thompson
Chairman of the Board

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

Angus Russell
Board Member

- Former Chief Executive Officer and Chief Financial Officer of Shire PLC
- Former Vice President of Corporate Finance at AstraZeneca
- Holds multiple board memberships, including Chairman of Revance Therapeutics

J. Martin Carroll
Board Member

- Former President and Chief Executive Officer of Boehringer Ingelheim (U.S.)
- Former EVP of Customer Marketing and Sales of U.S. Human Health at Merck
- Holds multiple board memberships, including Catalent

Robert Finizio
CEO, Co-Founder, and Director

- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2006)
- 22 years of experience in early stage healthcare company development

Brian Bernick, MD
Chief Clinical Officer, Co-Founder

- Co-founded vitaMedMD in 2008
- 25 years of experience in healthcare/women's health
- Past OBGYN Department Chair - Boca Raton Regional Hospital, and
- Past ACOG Committee Member
- OBGYN - trained University of Pennsylvania

Sebastian Mirkin, M.D.
Chief Medical Officer

- Former Clinical Lead of Women's Health at Pfizer
- 15+ years of experience developing women's health products
- Reproductive endocrinologist & infertility specialist

John Milligan
President

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

Dan Cartwright
Chief Financial Officer

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

Julia Amadio
Chief Product Officer

- 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®

Jason Spitz
VP, Marketing

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

Dawn Halkuff
Chief Commercial Officer

- 20+ years of commercial and marketing experience
- SVP of the Pfizer Consumer Healthcare Wellness Organization
- Commercial lead for sales and marketing of the Pfizer Women's Health Division
- Head of Global Innovation at Weight Watchers International

Yulii Bogatyrenko
Executive VP, Corporate Development

- 20+ years of experience in biopharma and consumer businesses
- SVP of BD at Paratek Pharmaceuticals
- VP and GM at Teva Pharmaceuticals
- Senior women's health positions at Bayer and Pfizer


TX-001HR | Combination
Estrogen + Progesterone
(E+P) Program
TherapeuticsMD®
6

Menopause Overview

Menopause represents the natural life-stage transition when women stop having periods as the production of Estrogen (E) and Progesterone (P) decreases

- Average age of menopause 51 years[1]
- Women may spend, on average, more than one-third of their lives in a hypoestrogenic state

May result in physical and emotional symptoms[1]

- Symptoms include hot flashes, night sweats, mood changes and vaginal dryness
- Prolonged lack of estrogen can affect the bones, cardiovascular system, and increases risks for osteoporosis

Long history of Estrogen (E) and Progesterone (P) use

- Estrogen and Progesterone have been used for over 50 years as treatment
- Estrogen to reduce symptoms and other long-term conditions
- Progesterone to prevent thickening of the uterine wall[2]
  - Increased risk for endometrial hyperplasia/endometrial cancer if estrogen unopposed[2]

1] National Institutes of Health, National Institute on Aging, https://www.nia.nih.gov/health/publication/menopause, last accessed November 3, 2015.
2] International Journal on Women's Health, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3897322/

TX-001HR Product Development Rationale

- **July 2002** - Women's Health Initiative (WHI) study showed that ***synthetic*** hormones in combination increased the risk of breast cancer, stroke, heart attack and blood clots
- Since the WHI, both women and healthcare providers have chosen unapproved, bio-identical hormones that are now cash pay over FDA-approved, synthetic hormones that are covered by insurance
- Today, patients have the choice between two second best therapies:
  - Unapproved, **compounded** bio-identical hormones that have not been proven safe and effective, or
  - FDA-approved, **synthetic** hormones

TherapeuticsMD's goal is to deliver a best in class, bio-identical hormone therapy that is FDA-approved based on safety and efficacy and covered by insurance

TX-001HR Specifically Designed to Deliver This Unmet Medical Need

TX-001HR – Potential Best in Class VMS Therapy

	TX-001HR (If Approved)
Bio-Identical	✓
Single Dose Combination	✓
VMS Efficacy Data	✓
Endometrial Cancer Safety Data	✓
FDA-Approved	✓[1]
Third-Party Reimbursement	✓[2]

Potential first and only:

1) **Bio-identical combination**
2) **FDA-approved**

Dosing and Delivery

- Once-a-day Oral Softgel Capsule

Addresses Unmet Medical Need

- First and only bio-identical combination of E2 and P4 product candidate
- Single dose option
- Positive Phase 3 Replenish trial safety and efficacy results
- Potential FDA-approval with insurance coverage

Benefits to women, healthcare providers, and pharmacies

1) NDA to be submitted
2) Reimbursement anticipated if FDA-approved

Medical Societies Discourage Prescribing of Compounded Bio-Identical Hormones

- **ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products[1]**
  - Lack of efficacy and safety data
  - Lack of Good Manufacturing Practices (GMP)
  - Variable purity
  - Variable content uniformity
  - Variable potency (under/over dose)
  - Lack of stability
  - Unopposed E / Ineffective P leads to increased risk of endometrial hyperplasia / cancer


ENDOCRINE SOCIETY 100 YEARS

Compounded Bioidentical Hormones in Endocrinology Practice: An Endocrine Society Scientific Statement

Conclusion:
The widespread availability of FDA-approved bioidentical hormones produced in monitored facilities demonstrates a high quality of safety and efficacy in treating
therefore, there is no rationale for the routine prescribing of unregulated, untested, and potentially harmful custom-compounded bioidentical MTs. Clinicians are encouraged to prescribe FDA-approved hormone products according to labeling indications and to avoid custom-compounded hormones

COMMITTEE OPINION

Compounded Bioidentical Menopausal Hormone Therapy

NAMS Survey

Use of compounded hormone therapy in the United States: report of the North American Menopause Society Survey

ACOG | ENDOCRINE SOCIETY | NAMS THE NORTH AMERICAN MENOPAUSE SOCIETY | AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE 1944 | INTERNATIONAL MENOPAUSE SOCIETY

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).

TX-001HR (if approved) - Healthcare Provider Benefits

- Provide clinically validated dose regimens
- Meet medical standards of care and society guidelines while reducing liability
- Eliminate risks of compounded hormone therapy
- Meet patient demands and reduce patient out-of-pocket costs via insurance coverage

TX-001HR (if approved) - Pharmacy Benefits

- **2014** - Majority of major payors eliminated reimbursement of compounded medications
- **2017** - Average pre-tax profit per script of compounded bio-identical hormones is **$3-$5**

Pharmacy benefits if TX-001HR is approved:

- Improve net margin per script vs compounded bio-identical hormones
- Meet patient and physician demand for bio-identical hormone therapy
- Drive top-line growth due to third-party reimbursement
- Lower legal and regulatory costs and risk

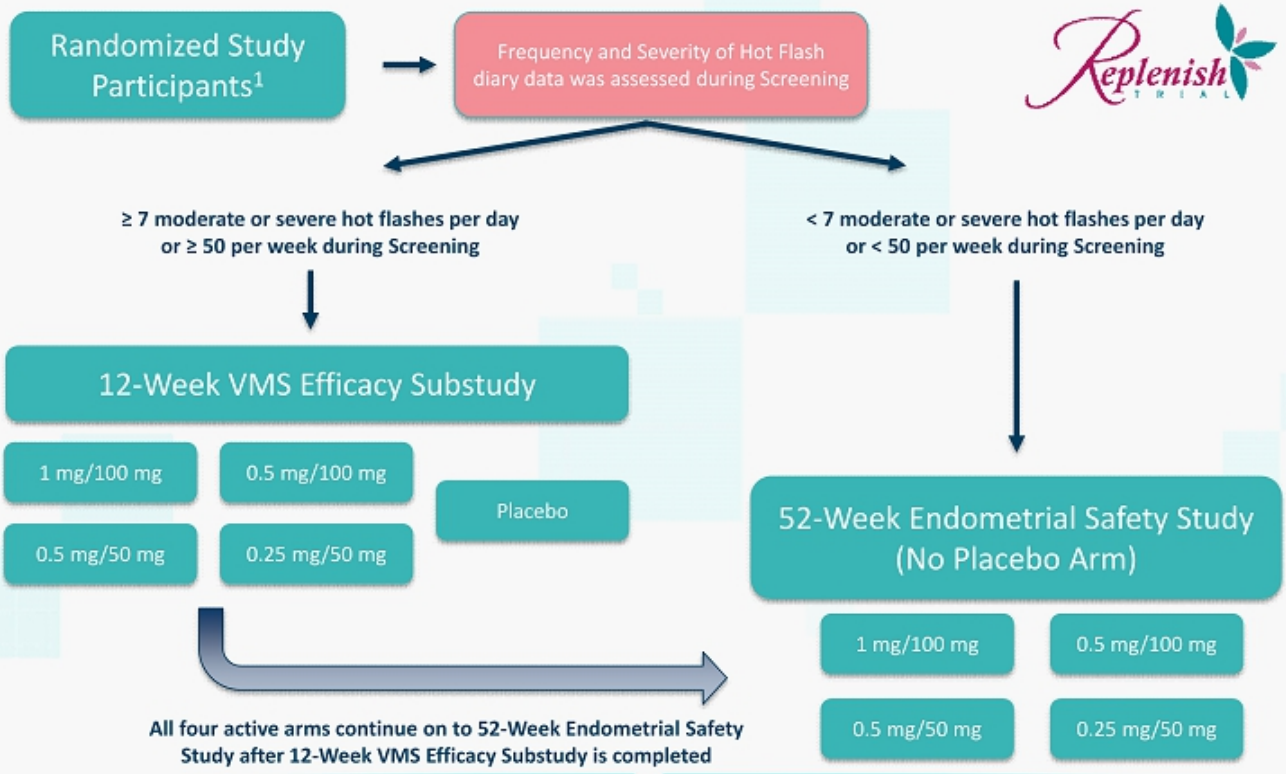
TX-001HR (if approved) - Patient Benefits

- Meet demand for bio-identical hormone therapy that is FDA-approved based on safety and efficacy
- Eliminate risks of compounded hormone therapy
- Reduce out-of-pocket costs via insurance coverage and a single co-pay
- Provide convenience of one combination product
- Be available at most pharmacies

TX-001HR |
Replenish Trial Overview and Results

TherapeuticsMD®

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 Co-Primary Endpoints

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 (n = 141)	0.5 mg/100 mg (n = 149)	0.5 mg/50 mg (n = 147)	0.25 mg/50 mg (n = 154)	Placebo (n = 135)
		Frequency			
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	-
		Severity			
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	-
Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population[ǂ]					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

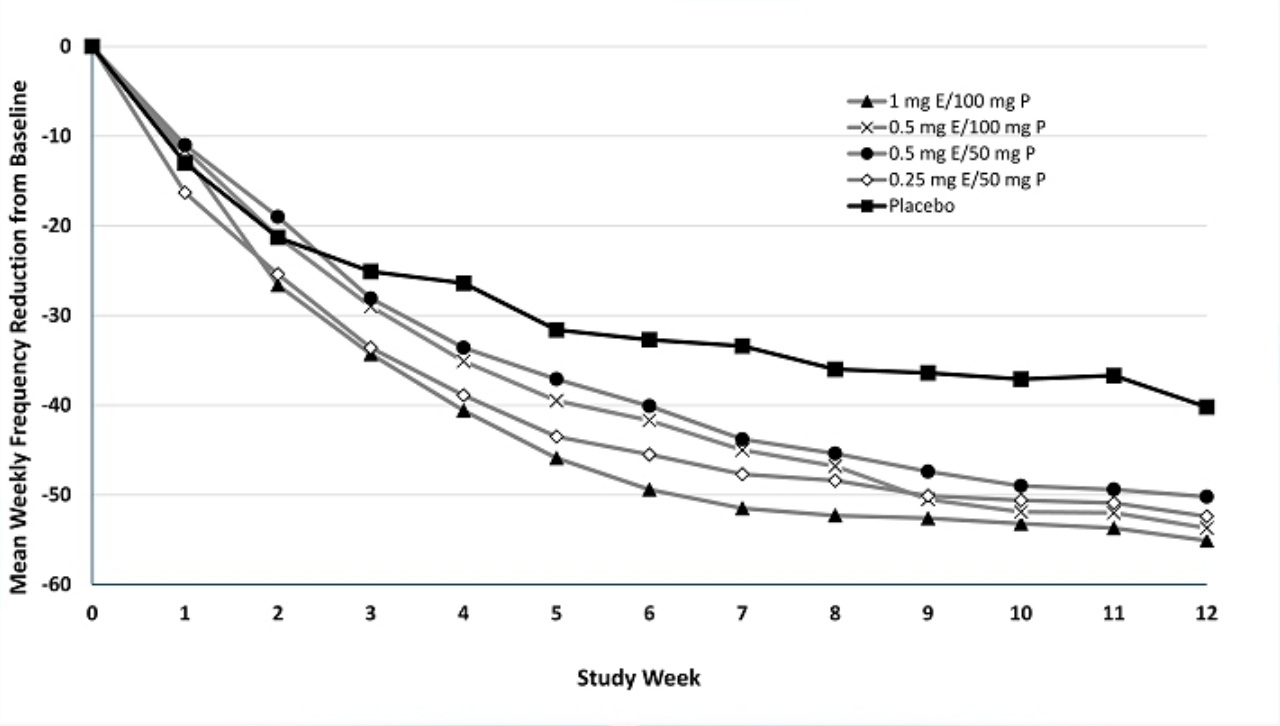
[ǂ]Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

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

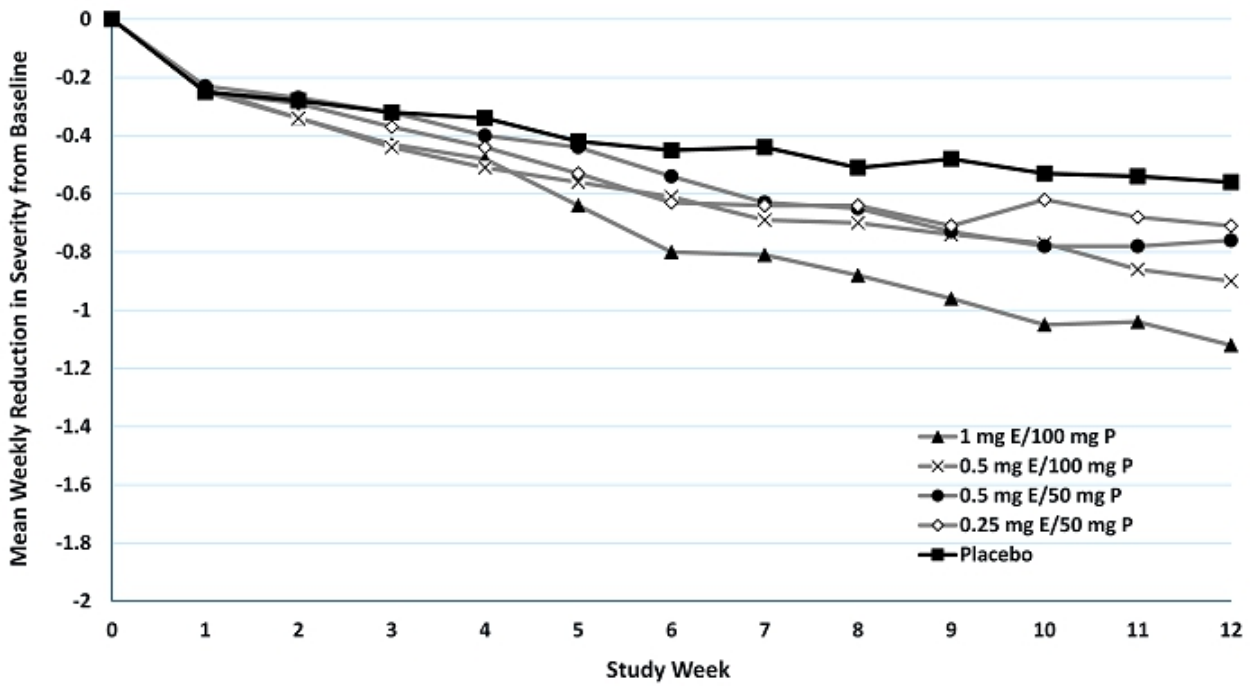
Primary Efficacy Analysis pre-specified with the FDA in the clinical protocol and Statistical Analysis Plan (SAP)

- 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



TX-001HR | Market Opportunity

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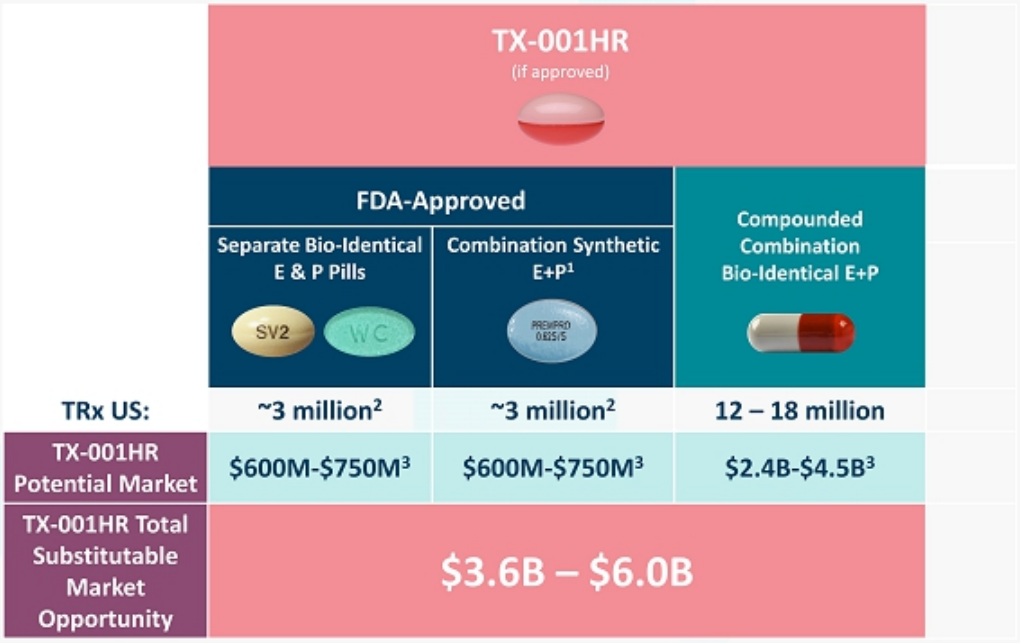
Multi-Billion Dollar Total Substitutable Market Opportunity



	Separate Bio-Identical E & P Pills	Combination Synthetic E+P[1]	Compounded Combination Bio-Identical E+P
TRx US:	~3 million[2]	~3 million[2]	12 – 18 million
TX-001HR Potential Market	$600M-$750M[3]	$600M-$750M[3]	$2.4B-$4.5B[3]
TX-001HR Total Substitutable Market Opportunity	$3.6B – $6.0B		

If approved, TX-001HR can provide a single pill solution for women and physicians who:
1) Demand an FDA-approved bio-identical combination hormone product
2) Do not trust compounded hormones

1) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17β – Progestins, Prempro®, Premphase®, Duavee®, Bridelle®
2) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
3) Assume WAC pricing between $200-250

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Compounded Combination Bio-Identical E+P Substitutable Market Opportunity

Commercialization Strategy: BIO-IGNITE

BIO-IGNITE is an outreach program to quantify and qualify the interests of 3,000 independent and community based pharmacies that compound bio-identical E+P

Goal:

Understand and identify the high volume pharmacies and prescribers that have developed a specialty focus around women's menopausal health

Mission:

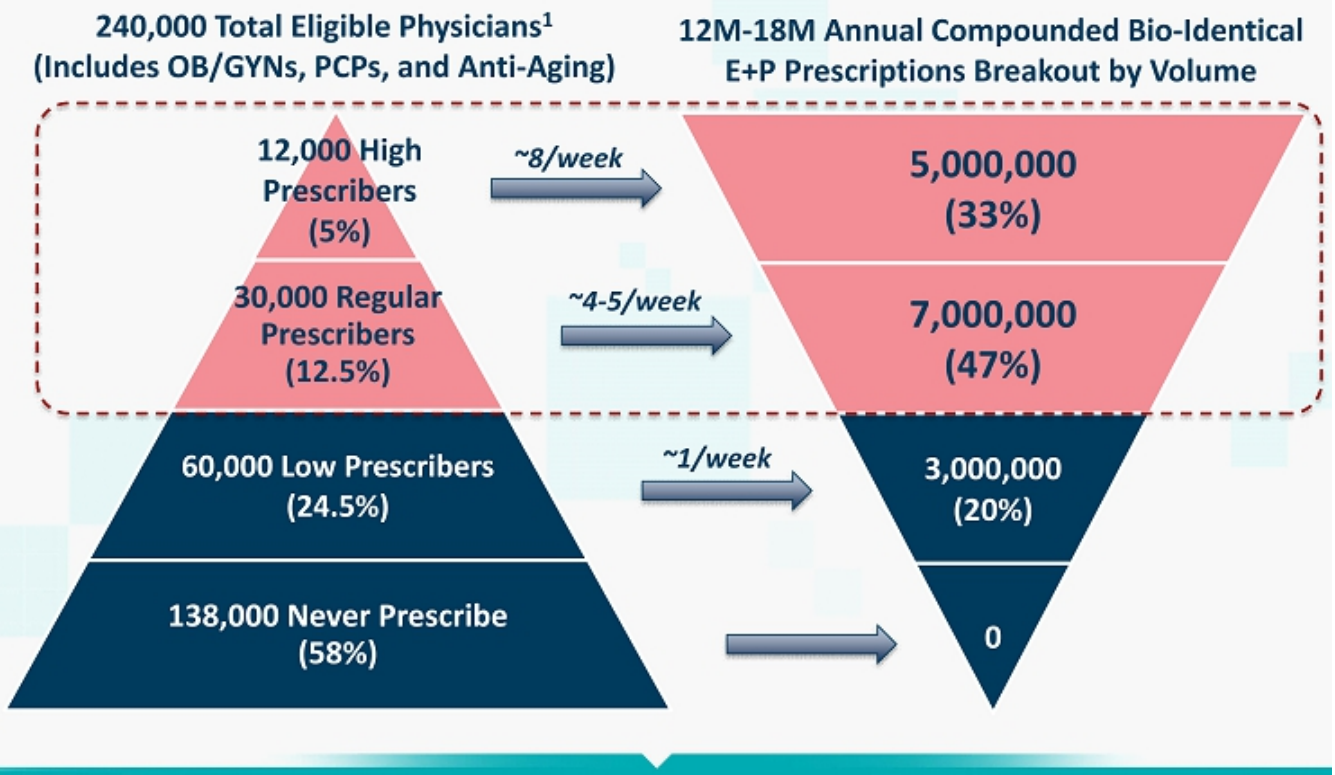
Work with these specialists to transition patients from unapproved compounded therapies to an FDA-approved treatment

BIO-IGNITE Progress and Results

Partnerships with Large Pharmacy Networks

Pharmacy Network Partners	Network Size	Combination Bio-Identical E+P Scripts
Premier Value Pharmacy Compounding Network	225 Pharmacies In Network	~1,000,000 prescriptions annually
TCG The Compounders Group	104 Pharmacies In Network	~500,000 prescriptions annually

Who Writes Compounded Bio-Identical E+P Prescriptions?



1) SK&A Nationwide Physician Specialty Report – June 2015

Adverse Reimbursement and Regulatory Environments Continue to Erode Independent Pharmacy Margins

November 2013: *Congress enacts Drug Quality and Security Act (DQSA), which prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortage*[1]

EXPRESS SCRIPTS®

OPTUM®

June 3, 2014: *ESI launches a "Compound Management Solution," creating a list of excluded ingredients that eliminated almost 95% of all compound claims*[2]

July 2014: *Optum initiates a comprehensive compound management program, including prior authorizations and step therapy for all compounded prescriptions*[3]

July 2018: *USP-800 implementation will set new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs*[4,5]

- Considered "prohibitively expensive" requiring major pharmacy upgrades and renovations to be compliant
- **Large fixed capital expenditure requirements, with some totaling >$150,000 per pharmacy to implement**

1)http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2) http://www.iacprx.org/general/custom.asp?page=CCIns161314
3) http://www.optum.com.br/content/optum/en/optumrx/pharmacy-insights/restoring-trust-compound-medications.html
4) http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
5) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf

Independent Pharmacy Net Income Per Compounded Script

	Insurance Coverage (before 2H14)	Present Day (2017)	Post USP-800 (July 2018)
Revenue			
Patient Co-Pay	50.00	50.00	50.00
Third-Party Reimbursement	115.00	-	-
Total Net Revenue	**$ 165.00**	**$ 50.00**	**$ 50.00**
Costs of Good Sold	7.50	7.50	7.50
Gross Profit	**$ 157.50**	**$ 42.50**	**$ 42.50**
Gross margin	*95.5%*	*85.0%*	*85.0%*
Operating Expenses			
G&A	15.00	15.00	15.00
S&M	7.50	7.50	7.50
Additional Compounding Costs[1]	15.00	15.00	15.00
Cost of USP-800 Requirements[2]	-	-	*10.00*
Total Operating Expenses	**$ 37.50**	**$ 37.50**	**$ 47.50**
Pre-Tax Profit	**$ 120.00**	**$ 5.00**	**$ (5.00)**
Operating margin	*72.7%*	*10.0%*	*-10.0%*

1) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses
2) July 2018 implementation; includes >$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs

TherapeuticsMD®

Economic Incentives Provide Catalyst to Switch to TX-001HR

Independent Pharmacy Net Income Per Script with TX-001HR	Compounded E+P Post USP-800	TX-001HR Launch 2H18
Revenue		
Patient Co-Pay	50.00	50.00
Third-Party Reimbursement	-	200.00
Total Net Revenue	**$ 50.00**	**$ 250.00**[1]
Costs of Good Sold	7.50	200.00[2]
Gross Profit	**$ 42.50**	**$ 50.00**
Gross margin	*85.0%*	*20.0%*
Operating Expenses		
G&A	15.00	15.00
S&M	7.50	5.00
Additional Compounding Costs[3]	15.00	-
Cost of USP-800 Requirements[4]	10.00	-
Total Operating Expenses	**$ 47.50**	**$ 20.00**
Pre-Tax Profit	**$ (5.00)**	**$ 30.00**
Operating margin	*-10.0%*	*12.0%*

1) Assume AWP-18% Third-Party Reimbursement
2) Assume $250 WAC less 20% distribution discount
3) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses
4) July 2018 implementation; includes >$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs

FDA-Approved Separate Bio-Identical E & P Substitutable Market Opportunity

- Healthcare providers not comfortable with compounding will often prescribe two separate FDA-approved bio-identical products to treat menopausal symptoms

Product Use by Age	AGES 41-50	AGES 51-60	AGES 61-70	AGES 71+	TRx Totals
Progesterone*	528,325	1,326,618	1,060,666	678,775	**3,594,384[1]**
Estradiol	2,677,210	5,494,846	2,826,636	1,083,726	**12,082,418[1]**

*Menopausal use of progesterone directly substitutable to TX-001HR

~3M Potential Prescriptions for TX-001HR (if approved)
Market Opportunity = $600M-750M[2]

- This regimen carries **significant risk** of endometrial hyperplasia/cancer if the patient is non-compliant with regular progesterone use
  - Progesterone's side effects of nausea and somnolence can lead to a patient not taking the progesterone
  - Results in two separate co-pays for the patient

1| Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2| Assume WAC pricing between $200-250

FDA-Approved Combination Synthetic E+P Substitutable Market Opportunity

TX-001HR
(If Approved)

FDA-Approved Combination Synthetic E+P Prescriptions by Age

PREMPHASE PREMPRO 0.625/5 Prempro®

AGES 31-40	AGES 41-50	AGES 51-60	AGES 61-70	AGES 71+	Unknown Ages	TRx Totals
52,575	372,968	1,712,852	759,634	151,821	68,672	**3,118,522**[1]

~3M Potential Prescriptions for TX-001HR (if approved)
Market Opportunity = $600M-750M[2]

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
Includes the following drugs: Activella®, FemHRT®, Angeliq®, Generic 17β + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®
2) Assume WAC pricing between $200-$250

TherapeuticsMD®

Expect Robust Insurance Coverage For TX-001HR, If Approved, In-Line with Product Class

4,315 Commercial Plans	% Unrestricted Access of Commercial Plans	Not Covered
Estrace® (Oral)	96%	1%
Prempro®	94%	5%
CombiPatch®	93%	4%
Climara Pro®	92%	4%
FemHRT®	87%	6%
Duavee®	86%	5%
Vivelle-Dot®	84%	5%
Activella®	83%	8%
Prometrium®	83%	6%

Data Source MMIT August 17, 2016 – 4,300 commercial plans

TX-004HR (Yuvvexy™)

Vulvar and Vaginal Atrophy (VVA) Program

TherapeuticsMD®

Overview – Vulvar and Vaginal Atrophy (VVA)

- **Chronic** and **progressive** condition characterized by thinning of vaginal tissue from decreased estrogen levels
- Diagnosed in approximately 50% of postmenopausal women[1]
- Primary symptom = dyspareunia
- Secondary symptoms include: dryness, itching, irritation, dysuria, bleeding with sexual activity
- Current treatments include: prescription creams, lubricants and tablets

	Healthy Vaginal Tissue	Atrophic Vaginal Tissue
Superficial cells:	>15%	<5%
Intermediate cells:	80%	60%
Parabasal cells:	< 5%	>30%
pH:	< 5	> 5

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.

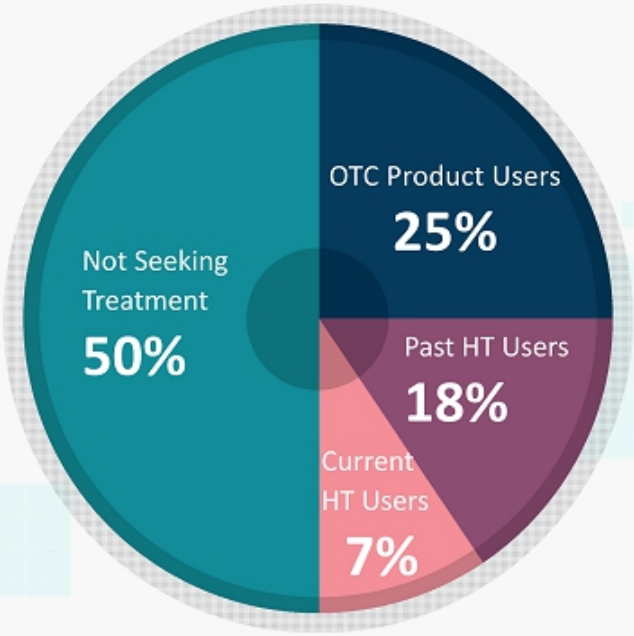
Current FDA-Approved VVA Competitive Landscape

- U.S. sales more than doubled since 2008[1]
- Global market expected to be $2.1 billion in 2022[2]
- **7% current market penetration**

Product	Company	Compound	2015 TRx (000) [1]	2015 U.S. Sales ($M)[1]	WAC Price[3]
Premarin® Cream	Pfizer	Conjugated equine vaginal estrogen	1,615	$502	$288.40
Vagifem® Tablets	Novo Nordisk	Vaginal estradiol	1,620	$456	$382.86*
Yuvafem® Tablets (Vagifem AG)	Amneal	Vaginal estradiol	Launched October 2016		$349.17**
Estrace® Cream	Allergan	Vaginal estradiol	1,548	$420	$263.81
Estring® Ring	Pfizer	Vaginal estradiol ring	284	$91	$310.44
Osphena® Tablets	Shionogi	Oral SERM	263	$66	$530.07
Total			**5,330**	**$1,535**	

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Global Data July 2013 report GDHCS4PDR
3) Medi-Span Price Rx Basic * for 28 tablets ($170.16 WAC for 8 tablets) **for 28 tablets ($155.18 for 8 tablets)

Current VVA Market Overview



32M Women with VVA Symptoms[1,2]

~50% of women seek treatment for VVA[4]

- 7%, or 2.3M women, are currently being treated today with Rx hormone therapy (HT)[3]
- 18%, or 5.7M women, have tried HT and were unsatisfied/unsuccessful[4]
- 25%, or 8M women, use OTC products**, such as lubricants[4]

>$20B Branded Total US Market Opportunity[5]

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).
4) TherapeuticsMD "EMPOWER" Survey, 2016
5) Based on current FDA-approved market pricing
** 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.

Current FDA-Approved VVA Product Use Falls Short

	Market Size	Perceived Product Shortcomings	VVA Market Opportunity
Current HT Users	2.3M Women[2] 7% of VVA Population	▪ Long-term safety concerns[1] ▪ Efficacy[1] ▪ Messiness[1] ▪ Need for applicator[1]	>$1.5B
Past HT Users	5.7M Women[3] 18% of VVA Population	▪ Unsatisfied / unsuccessful with past treatments ▪ Physical and clinical attributes of existing products	>$3B
OTC Product Users	8M Women[3] 25% of VVA Population	▪ Do not effectively treat the underlying pathological causes of VVA ▪ Do not halt or reverse symptoms	>$5B
Not Seeking Treatment	16M Women 50% of VVA Population	▪ Not aware that VVA is a treatable condition ▪ Estrogen exposure concerns	>$10B

1) 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.S14498
2) IMS Health Plan Claims (April 2008-Mar 2013).
3) TherapeuticsMD "EMPOWER" Survey, 2016

TherapeuticsMD®

TX-004HR (Yuvvexy™)

- Small, digitally inserted, rapidly dissolving softgel capsule
- No applicator
- Proposed dose packaging to optimize compliance and convenience
- ***PDUFA target action date of May 7, 2017***

0.69 x 0.3 inch

Prototype Maintenance Pack

YUVVEXY™ is an investigational drug and is not approved for use by the FDA.

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TX-004HR – Potential Best In Class VVA Therapy

Products	Premarin®	Vagifem®	Estrace®	Osphena®	Yuvvexy™ (if approved)
					
	Pfizer	novo nordisk	Allergan	SHIONOGI	TherapeuticsMD
Method of Admin	Vaginal Cream	Vaginal Tablet	Vaginal Cream	Oral Tablet	Vaginal Capsule
Application	Reusable Vaginal Applicator	Vaginal Applicator	Reusable Vaginal Applicator	Oral Daily SERM	Digitally Inserted Softgel
Active Ingredient	625 mcg/g CEEs	10 mcg Estradiol	100 mcg/g Estradiol	60,000 mcg ospemifene	4, 10, 25 mcg 17β-estradiol
Avg Maintenance Dose	312.5 mcg 2x/week	10 mcg 2x/week	100 mcg 2x/week	60,000 mcg daily	4, 10, 25 mcg 2x/week
Onset of Action* Dyspareunia	Week 4+	Week 8	Approval Without Dyspareunia and Dryness Data	Week 12	Week 2
Onset of Action* Dryness	Not Demonstrated			Not Demonstrated	Week 2
					Easy to Use
					Easy to Prescribe
					Negligible Systemic Exposure

*Onset of Action = First efficacy observation

Based on Product Prescribing Information
Not Head-to-Head Comparative Studies

Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?600706572

TX-004HR - Designed for Long Term Compliance

Current Market

Vaginal Creams:

Mean Duration of Use: 1.5 Months[2]

- Reasons Women Stop
- Messiness[1]
- Reusable Applicator[1]
- Long-term Safety[1]
- Dose Preparation by User Required[3]

Vaginal Tablets:

Mean Duration of Use: 3.5 Months[2]

- Reasons Women Stop
- Efficacy[1]
- Applicator[1]
- Long-term Safety[1]
- Systemic Absorption[1]

Yuvvexy™

- Muco-adhesive, Dissolves Quickly and Completely
- No Applicator and No Dose Preparation
- Onset-of-Action (Efficacy observed at 2 weeks)
- Negligible Systemic Exposure
- >75% Patient Satisfaction in a Market with Historically Low Compliance Rate

Potential Long Term Usage

0.69 x 0.3 inch

1) 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.S14498
2) 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
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.

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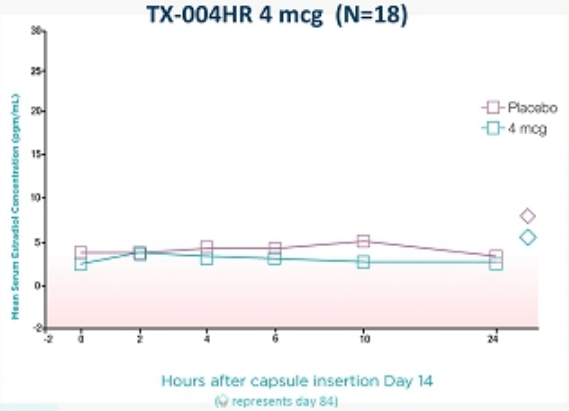
Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 4 mcg

Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
TX-004HR 4 mcg (N=18)



	AUC_{0-24} (pg.h/mL)	$C_{avg[0-24]}$ (pg/mL)
4 mcg	87.22 (42.77)	3.634 (1.78)
Placebo	104.16 (66.38)	4.34 (2.76)
P-value vs Placebo	0.3829	0.3829

LS Mean Change from Baseline to Week 12

4 mcg	LS Mean Change from Baseline to Week 12		P-value
	4 mcg	Placebo	
Superficial Cells	17%	6%	<0.0001
Parabasal Cells	-41%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.5	-1.3	0.0149
Severity of Vaginal Dryness	-1.27	-0.97	0.0014

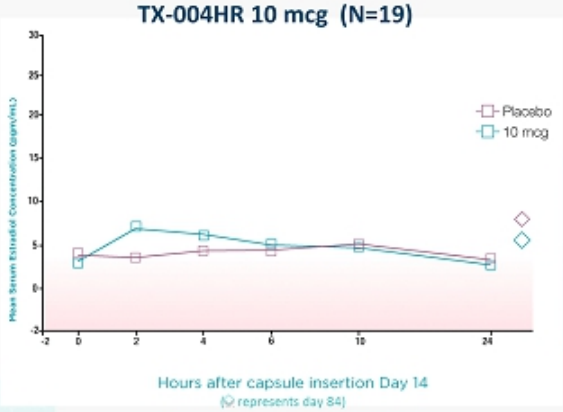
MMRM P-value vs placebo

LS = Least Squares

REJOICE Trial Results

Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 10 mcg

Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
TX-004HR 10 mcg (N=19)



	AUC_{0-24} (pg.h/mL)	$C_{avg(0-24)}$ (pg/mL)
10 mcg	110.14 (54.57)	4.58 (2.27)
Placebo	104.16 (66.38)	4.34 (2.76)
P-value vs Placebo	0.7724	0.7724

LS Mean Change from Baseline to Week 12

10 mcg	LS Mean Change from Baseline to Week 12		P-value
	10 mcg	Placebo	
Superficial Cells	17%	6%	<0.0001
Parabasal Cells	-44%	-7%	<0.0001
Vaginal pH	-1.4	-0.3	<0.0001
Severity of Dyspareunia	-1.7	-1.3	<0.0001
Severity of Vaginal Dryness	-1.47	-0.97	<0.0001

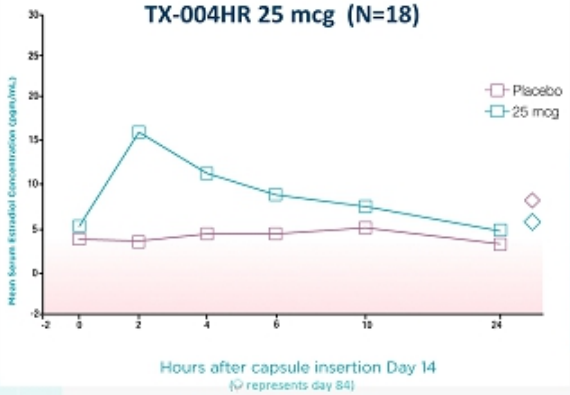
MMRM P-value vs placebo

LS = Least Squares

Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 25 mcg

Arithmetic Mean Estradiol Serum Concentrations - Unadjusted

TX-004HR 25 mcg (N=18)



	AUC_{0-24} (pg.h/mL)	$C_{avg(0-24)}$ (pg/mL)
25 mcg	171.56 (80.13)	7.14 (3.33)
Placebo	104.16 (66.38)	4.34 (2.76)
P-value vs Placebo	0.0108	0.0108

LS Mean Change from Baseline to Week 12

25mcg	LS Mean Change from Baseline to Week 12		P-value
	25 mcg	Placebo	
Superficial Cells	23%	6%	<0.0001
Parabasal Cells	-46%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.7	-1.3	<0.0001
Severity of Vaginal Dryness	-1.47	-0.97	<0.0001

MMRM P-value vs placebo

LS = Least Squares

REJOICE Trial Results

Favorable Regulatory Dynamics Driven by Change in Treatment Paradigm

Removal of Black Box Warning

- Citizen's Petition, spearheaded by NAMS, for modification of black box warnings
- Nov. 2015 – FDA "boxed warnings" workshop provided an opportunity for FDA to obtain input related to prescribing information of lower-dose estrogen alone products[1]

Citizen's Petition Supporters:

Estrogen Use in Breast Cancer Survivors

- ACOG released opinion stating it is safe for breast cancer survivors to use vaginal estrogen as data showed no increased risk[2]
- Healthcare practitioners may now consider topical estrogen therapy for patients with a history of estrogen-dependent breast cancer

Changing Perception on Use of Estrogen

- Women's Health Initiative's Hormone Trials follow up concluded that the risk/benefit profile for estrogen use is positive[3]:
  - 63% lower risk of dying of breast cancer
  - 16% reduced risk of illness and death
  - Preventative for heart disease, diabetes, and other illnesses if started early

1) Scientific Workshop on Labeling "Lower" Dose Estrogen-Alone Products for Symptoms of Vulvar and Vaginal Atrophy (VVA) http://www.fda.gov/Drugs/NewsEvents/ucm459690.htm
2) ACOG Supports the Use of Estrogen for Breast Cancer Survivors http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/ACOG-Supports-the-Use-of-Estrogen-for-BreastCancer-Survivors
3) Manson JE, Chlebowski RT, Stefanick ML, et al. "Menopausal Hormone Therapy and Health Outcomes During the Intervention and Extended Poststopping Phases of the Women's Health Initiative Randomized Trials." JAMA. 2013;310(13):1353-1368.

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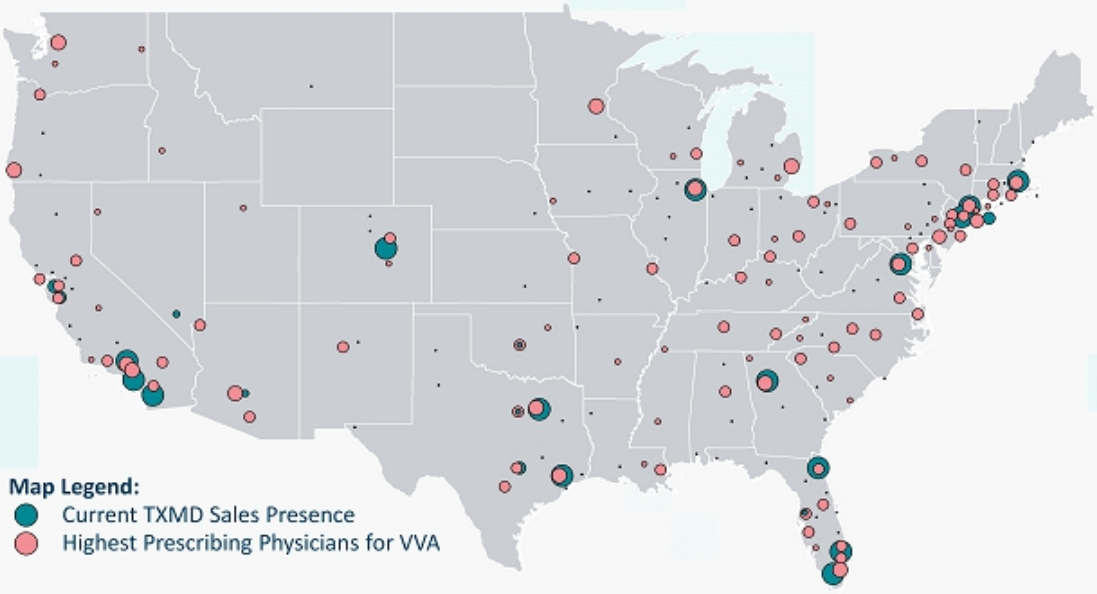
Foundation Built for a Strong Launch

Operational leverage of OB/GYN relationships in key markets



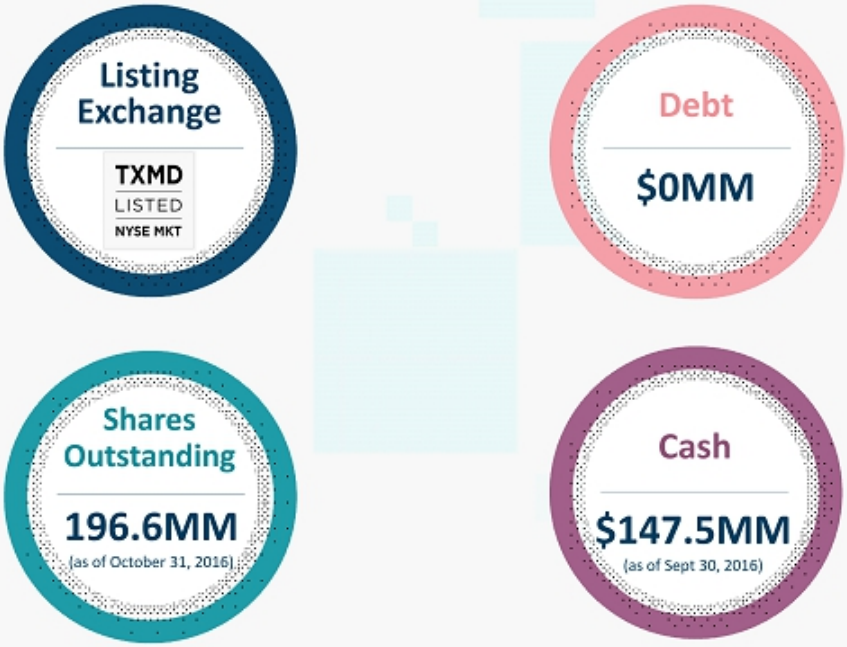
50 Sales Representatives; Planned Increase to 100-120 With Launch of Yuvvexy™

Expect Robust Insurance Coverage For TX-004HR, If Approved, In-Line with Product Class

4,312 Commercial Plans	% Unrestricted Access of Commercial Plans	Not Covered
Premarin Cream®	94%	2%
Estrace Cream®	96%	2%
Vagifem®	90%	2%
Estring®	93%	1%

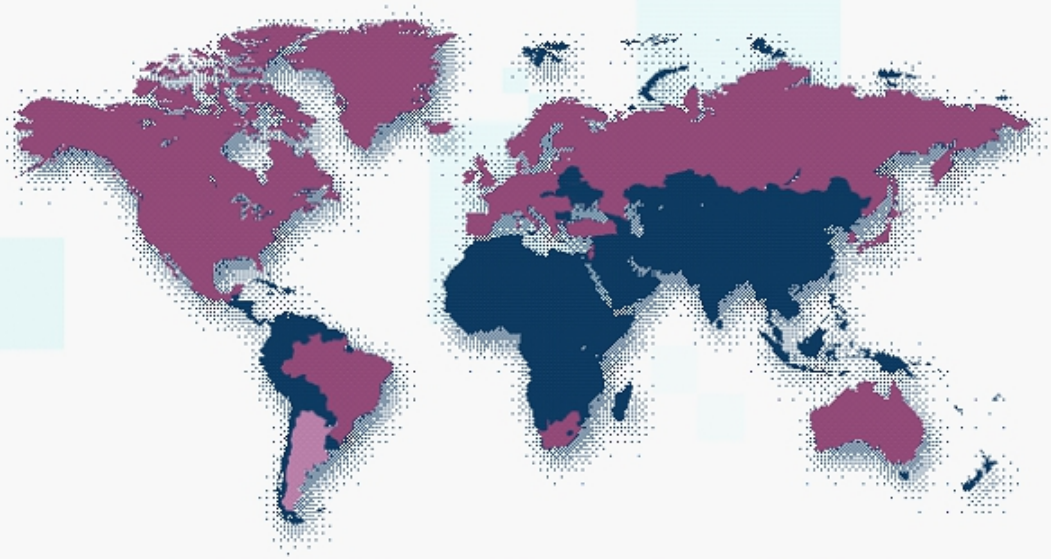
Data Source MMIT August 17, 2016 – 4,300 commercial plans

TXMD: Financial Snapshot



Worldwide Patent Filings*

Strong IP Portfolio with 149 Patent Applications, including 82 international filings, and 17 issued U.S. patents



*Not all patent filings filed in all jurisdictions.

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THANK YOU!

Appendix

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Compounded Combination Bio-Identical E+P: Why Has It Been So Successful?

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

1) Freeman E, Rickels 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 regimes on heart disease. Risks 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 woman. 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" AHA 2014; Abstract 13283.
6) Regidor, P-A, et al. Progesterone in Peri- and Postmenopausal: A Review. Geburtshilfe Frauenheilkd. 2014 Nov; 74 (11): 995-1002.

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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 ≤ 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

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