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): May 4, 2016

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 May 4, 2016 and at subsequent meetings with investors or analysts.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated May 2016.

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: May 4, 2016

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 May 2016.

Exhibit 99.1


TherapeuticsMD®
TXMD Overview
May 2016
TherapeuticsMD.com
THER-0086 5/16

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.

YUVVEXY™ (TX-004HR) is an investigational drug and is 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

Why TXMD? Why Now?

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

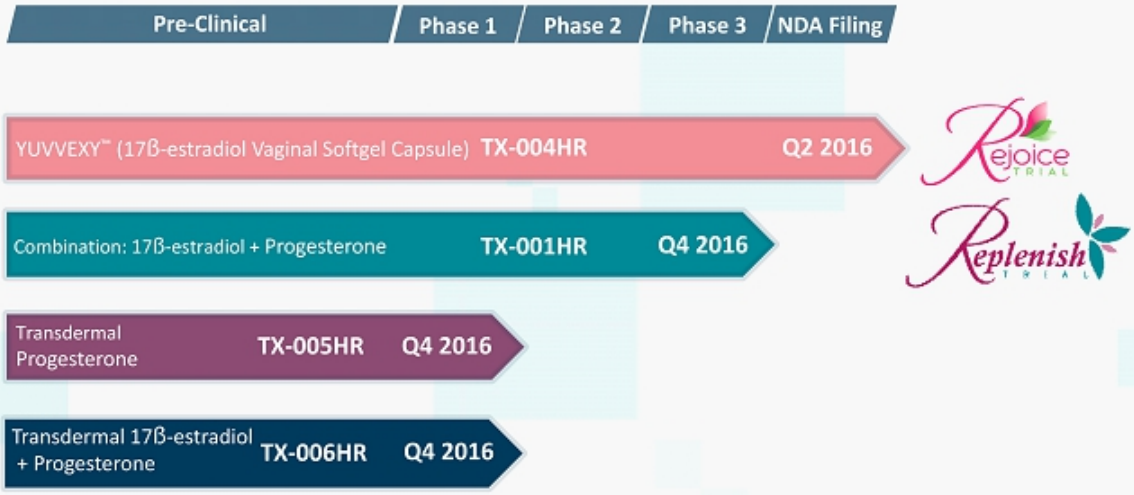
- Well-known chemical entities with established safety and efficacy thresholds
- Large U.S. markets with favorable competitive and regulatory dynamics
- Additional early stage pipeline candidates
- Strong global IP portfolio with 134 patent applications and 17 issued U.S. patents

2 Growing U.S. commercial business marketing prescription and OTC prenatal vitamins to established OB/GYN customer base

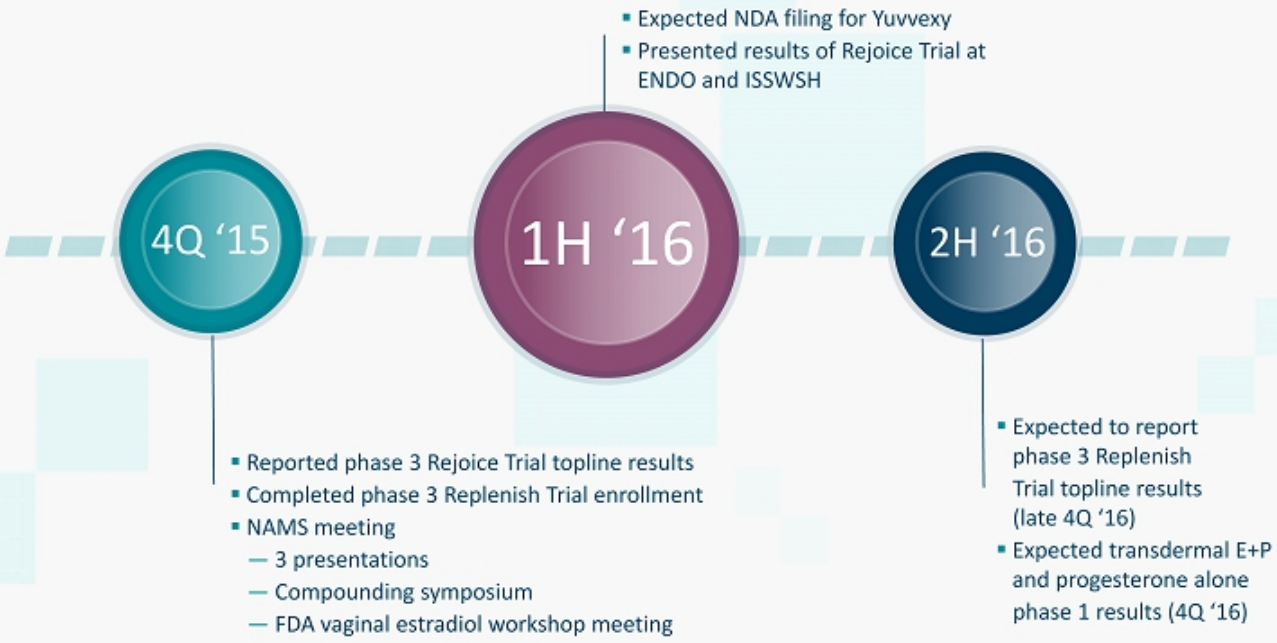
- Over $20M in annual revenue in 2015 with continued runway for growth
- Recognized in 2014 and 2015 by Deloitte Technology Fast 500 as 41st and 140th in North America

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

Investigational Pipeline



Key Milestones and Anticipated Milestones



YUVVEXY™

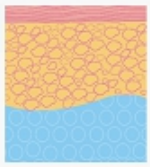
TX-004HR | Vulvar and Vaginal Atrophy (VVA) Program

TherapeuticsMD®

Overview – Vulvar and Vaginal Atrophy (VVA)

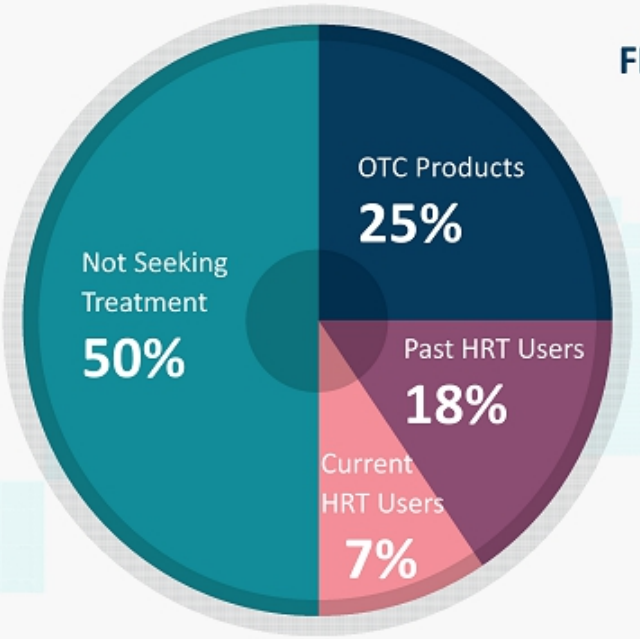
- Chronic and progressive condition characterized by thinning of vaginal tissue from decreased estrogen levels
- Diagnosed in approximately 50% of postmenopausal women[1]
- Primary symptom = dyspareunia
- Secondary symptoms include: dryness, itching, irritation, dysuria, bleeding with sexual activity
- 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 ChangE) Survey." International Society for Sexual Medicine 2013, no. 10, 1790-1799.

32MM Women with VVA Symptoms[1,2]



FDA-Approved HRT Market Overview

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

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

~$11B Branded Market Opportunity in Women Already Seeking Treatment

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
** 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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FDA-Approved Competitive Landscape

Product[2]	Company	Compound	2015 TRx (000) [1]	2015 U.S. Sales ($MM)[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*
Estrace® Cream	Allergan	Vaginal estradiol	1,548	$420	$263.81
Osphena® Tablets	Shionogi	Oral SERM	263	$66	$530.07
Estring® Ring	Pfizer	Vaginal estradiol ring	284	$91	$310.44
Total			**5,330**	**$1,535**	

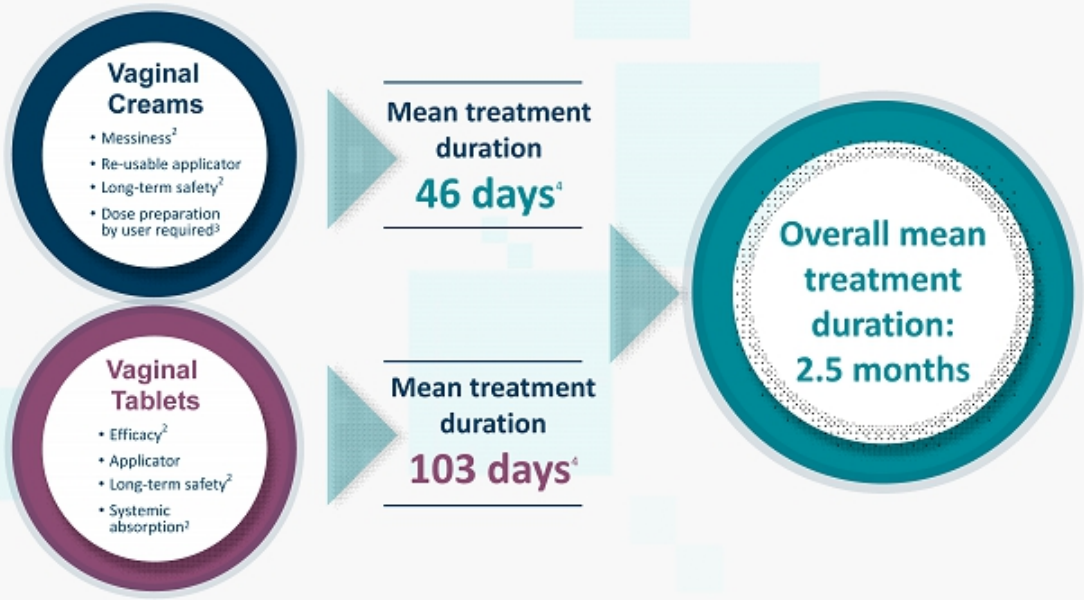
1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Femring data is excluded due to VMS indication
3) Medi-Span Price Rx Basic as of 4/01/16. * for 18 tablets ($170.16 WAC for 8 tablets)
4) Global Data July 2013 report GDHCS4PRDR.
5) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20(9):888–902.
6) 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):

FDA-Approved Competitive Landscape

Products	Premarin®	Vagifem®	Estrace® Cream	Osphena®	Estring®
					
Method of Admin	Vaginal Cream	Vaginal Tablet	Vaginal Cream	Oral Tablet	Vaginal Ring
Application	Reusable Vaginal Applicator	Vaginal Applicator	Reusable Vaginal Applicator	Oral Daily SERM	Vaginal Ring
Active Ingredient	625 mcg/g CEEs	10 mcg estradiol	100 mcg/g estradiol	60,000 mcg ospemifene	2,000 mcg estradiol
Avg Maintenance Dose	312.5 mcg 2x/week	10 mcg 2x/week	100 mcg 2x/week	60,000 mcg daily	7.5 mcg daily

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?4007706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

Current VVA Market Product Use Falls Short

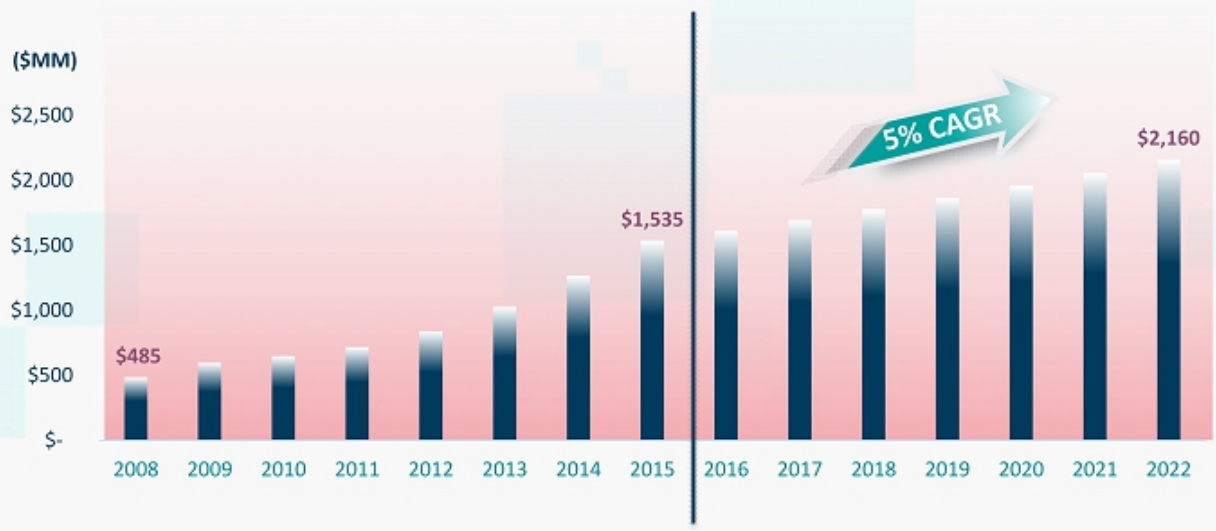


- Chronic and progressive condition that reverses when untreated
- Continued use of product alleviates most bothersome symptoms

1) IMS Health Plan Claims (April 2008-Mar 2013).
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.S14498.
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.

Established Estrogen VVA Market

- U.S. sales more than doubled since 2008[1]
- Global market expected to be $2.1 billion in 2022[4]
- Currently no generic competition – Vagifem AG expected October 2016
- 7% current market penetration and 2.5 months average length of use



1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Femring data is excluded due to VMS indication
3) Medi-Span Price Rx Basic as of 2/25/16 * for 18 tablets ($156.24 WAC for 8 tablets)
4) Global Data July 2013 report GDHC54PRDR.
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) 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):

TherapeuticsMD®

YUVVEXY™ (TX-004HR)

- Small, digitally inserted rapidly dissolving softgel capsule
- No applicator
- Proposed dose packaging to optimize compliance and convenience

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

TherapeuticsMD®

Co-Primary and Key Secondary Endpoints LS Mean Change from Baseline to Week 12 Compared to Placebo

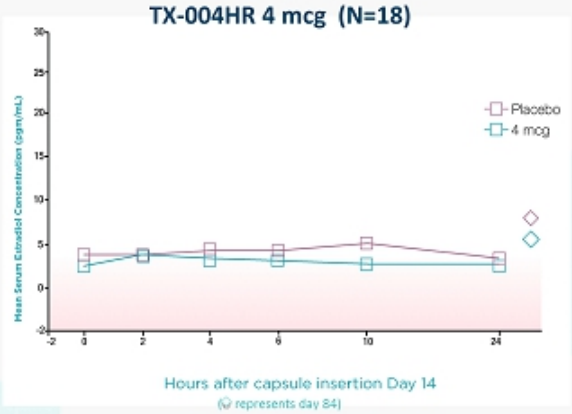
	4 mcg	10 mcg	25 mcg
Superficial Cells	<0.0001	<0.0001	<0.0001
Parabasal Cells	<0.0001	<0.0001	<0.0001
Vaginal pH	<0.0001	<0.0001	<0.0001
Severity of Dyspareunia	0.0149	<0.0001	<0.0001
Severity of Vaginal Dryness	0.0014	<0.0001	<0.0001

MMRM P-value vs placebo

LS = Least Squares

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

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



	$AUC_{0\text{-}24}$ (pg.h/mL)	$C_{avg(0\text{-}24)}$ (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

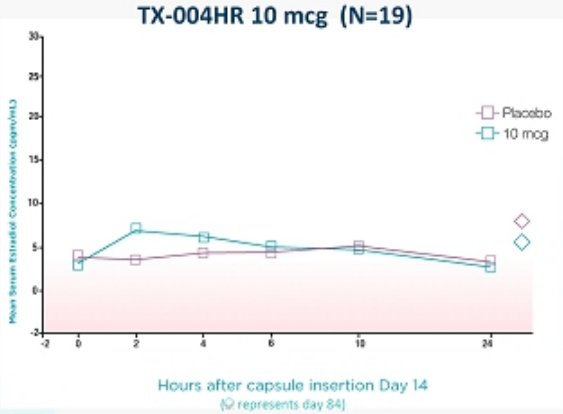
4 mcg	LS Mean Change from Baseline to Week 12		P-value
	4 mcg	Placebo	
Superficial Cells	17%	6%	<0.0001
Parabasal Cells	-41%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.5	-1.3	0.0149
Severity of Vaginal Dryness	-1.27	-0.97	0.0014

MMRM P-value vs placebo

LS = Least Squares

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

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



	$AUC_{0\text{-}24}$ (pg.h/mL)	$C_{avg(0\text{-}24)}$ (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

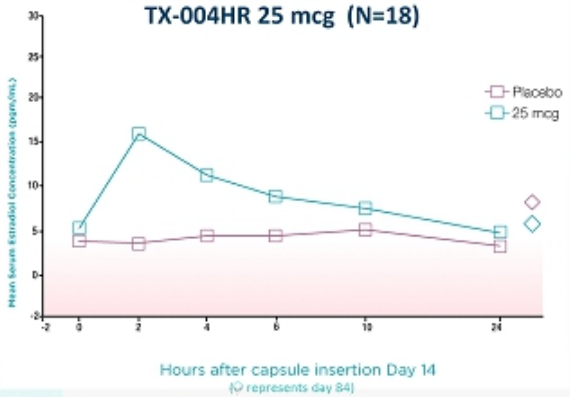
MMRM P-value vs placebo

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

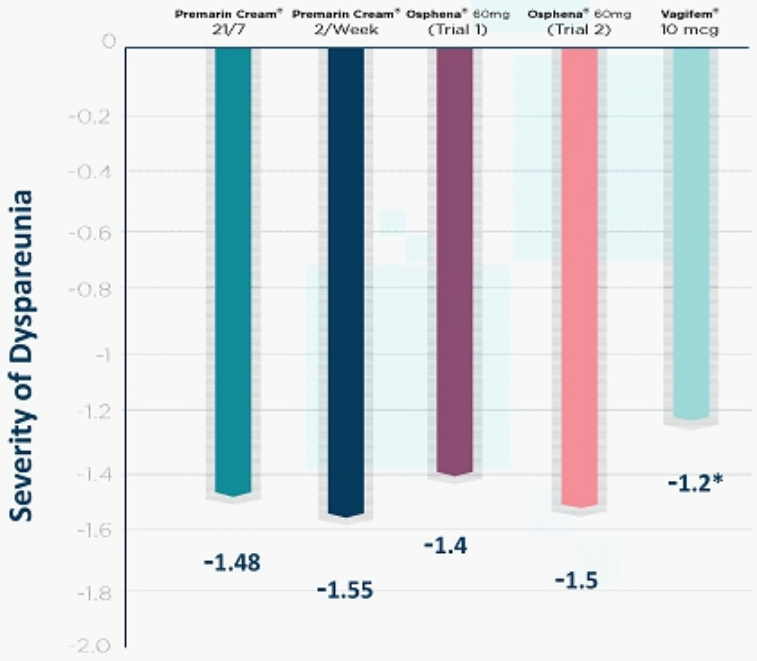
25mcg	LS Mean Change from Baseline to Week 12		P-value
	25 mcg	Placebo	
Superficial Cells	23%	6%	<0.0001
Parabasal Cells	-46%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.7	-1.3	<0.0001
Severity of Vaginal Dryness	-1.47	-0.97	<0.0001

MMRM P-value vs placebo

LS = Least Squares

Unadjusted Change From Baseline Severity Score Dyspareunia

Based on Pivotal Clinical Data - Not Head-to-Head Comparative Studies



*Composite score of most bothersome symptoms, including dyspareunia

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?400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

TherapeuticsMD®

Dyspareunia and Vaginal Dryness By Study Visit

Statistical Significance of Severity of Dyspareunia
LS Mean Change from Baseline (by Study Visit)

	4 mcg	10 mcg	25 mcg
Week 2	0.026	0.0019	0.0105
Week 6	0.0069	0.0009	< 0.0001
Week 8	0.0003	< 0.0001	< 0.0001
Week 12	0.0149	< 0.0001	< 0.0001

Statistical Significance of Severity of Vaginal Dryness
LS Mean Change from Baseline (by Study Visit)

	4 mcg	10 mcg	25 mcg
Week 2	0.1269	0.0019	0.0082
Week 6	0.0094	0.0001	0.0005
Week 8	0.0128	< 0.0001	0.0008
Week 12	0.0014	< 0.0001	< 0.0001

LS = Least Squares
REJOICE Trial Results

Efficacy and Onset of Action
Not Head-to-Head Comparative Studies

	Premarin®	Vagifem®	Estrace®	Osphena®	Estring®
Onset of Action Dyspareunia	Week 4+	Week 8 (composite score)	Approval without dyspareunia and dryness data	Week 12	Approval without dyspareunia and dryness data
Onset of Action Dryness	Not demonstrated			Not demonstrated	

Onset of Action = First efficacy observation

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?400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

Yuvvexy Qualitative Attributes

Ease of Use

	4 mcg (N=181)	10 mcg (N=181)	25 mcg (N=184)	Placebo (N=185)
Easy to Use	171 (94.5%)	172 (95.0%)	175 (95.1%)	164 (88.9%)

Overall p-value = 0.035

Patient Satisfaction

	4 mcg (N=181)	10 mcg (N=181)	25 mcg (N=184)	Placebo (N=185)
Very Satisfied	74 (40.1%)	84 (46.4%)	83 (45.1%)	41 (22.2%)
Satisfied	57 (31.5%)	55 (30.4%)	62 (33.7%)	68 (36.8%)
Unsure	23 (12.7%)	28 (15.5%)	21 (11.4%)	39 (21.1%)
Dissatisfied	19 (10.5%)	9 (5.0%)	12 (6.5%)	20 (10.8%)
Very Dissatisfied	8 (4.4%)	5 (2.8%)	6 (3.3%)	17 (9.2%)

Overall p-value <0.0001

Preferred vs Competition

	4 mcg (N=119)	10 mcg (N=113)	25 mcg (N=128)
TX-004HR over previously used VVA therapies	73.9%	67.3%	74.2%
P-value vs. Placebo	0.0010	0.0212	0.0003

LS = Least Squares
REJOICE Trial Results

Black Box Warning Citizen Petition

FDA Scientific Workshop on Labeling "Lower" Dose Estrogen-Alone Products for Symptoms of VVA - November 10, 2015[1]

* This workshop was to provide an opportunity for FDA to obtain input from experts on several topics related to the prescribing information of lower dose estrogen-alone products approved solely for the treatment of moderate to severe symptoms of VVA due to menopause.

Lower-dose estrogen means products that contain less than the 625 mcg of conjugated estrogens used in the WHI study and estradiol products containing 37.5 mcg and below[3]

A Citizen Petition organized by the North American Menopause Society (NAMS) to be submitted to FDA and supported by[2]:

NAMS The North American Menopause Society
ACOG The American College of Obstetricians and Gynecologists
ENDOCRINE SOCIETY
ISSWSH
TRANSFORMING SCIENCE SWHR
AMWA
ACADEMY OF WOMEN'S HEALTH
NPWH Nurse Practitioners in Women's Health
The American Society for Reproductive Medicine

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy

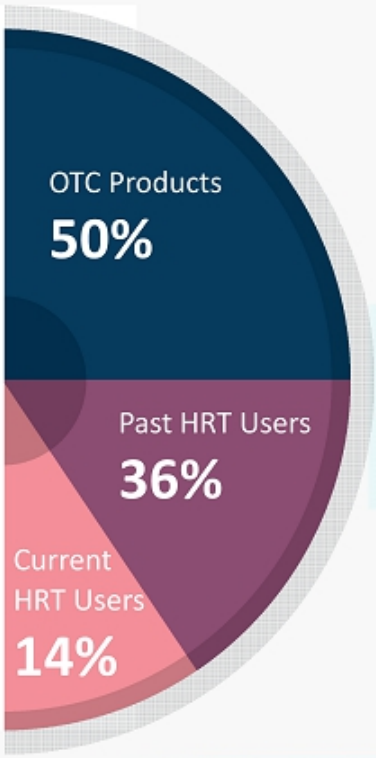
- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens (5.3)
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia (5.2, 5.4)
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) (5.2)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older (5.4)

Estrogen Plus Progestin Therapy

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia (5.2, 5.4)
- The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE), and myocardial infarction (MI) (5.2)
- The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer (5.3)
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older (5.4)

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. Form Letter Comment from North American Menopause Society. http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-3275-0060
3. FDA Notice https://www.federalregister.gov/articles/2015/03/20/2015-24509/labeling-lower-dose-estrogen-alone-products-for-symptoms-of-vulvar-and-vaginal-atrophy

16MM Women Seeking Treatment Need New Options



YUVVEXY™
Market Opportunity

**Assuming 0% penetration of women not seeking treatment*

- ~16M total women[2]
- $11B branded market opportunity
- 5.7M past users that have sought out HRT treatment but were unsatisfied/unsuccessful[2]
- Currently only 14% penetrated[1]

15% increase in penetration = 2.4M incremental women

Market size increase of >100% by 2022

1) IMS Health Plan Claims (April 2008-Mar 2011).
2) TherapeuticsMD "EMPOWER" Survey, 2016

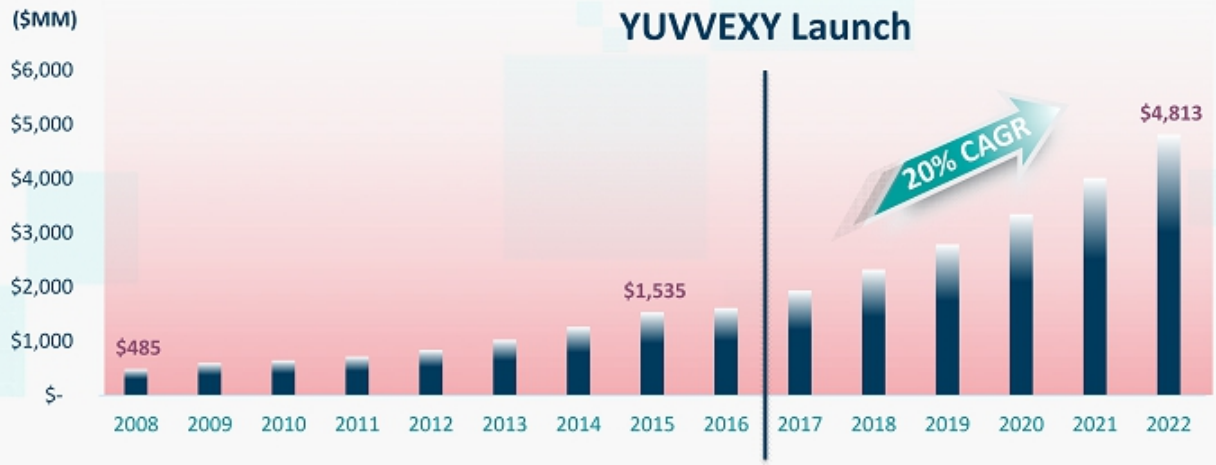
** Not treated with an FDA approved Rx product. OTC products do not effectively treat the underlying pathological causes of VVA and therefore do not halt or reverse the progression of this condition.

TherapeuticsMD®

Estrogen VVA Market of the Future

TherapeuticsMD VVA Market Goals

- Potential launch of Yuvvexy
- Increase market awareness for VVA and the symptoms associated
- Convert unsatisfied past users of HRT therapy to satisfied patients on drug
- Increase market penetration among OTC product users



1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Global Data July 2013 report GDHCS4PIDR.

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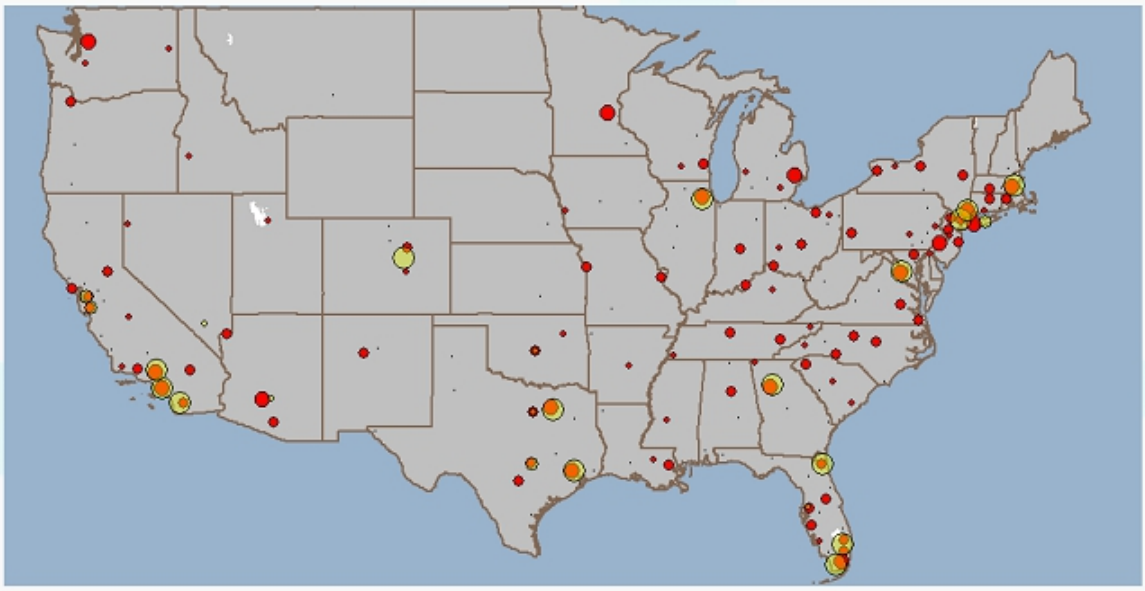
Foundation Built for a Strong Launch

Operational leverage of OB/GYN relationships in key markets



Map Legend:

- Current TXMD Sales Presence
- Highest Prescribing Physicians for VVA

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

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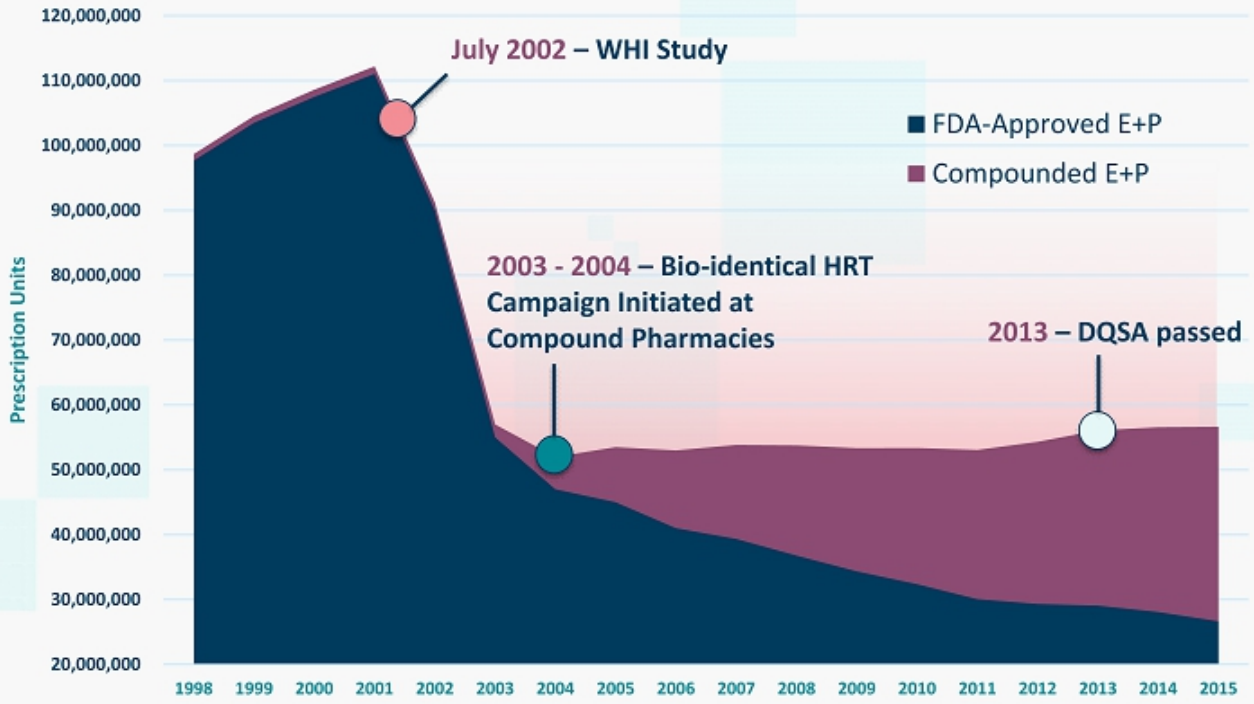
Menopause Overview

- Menopause represents the natural life-stage transition when women stop having periods
- May result in physical and emotional symptoms[1]
  - Average age of menopause 51 years
  - Hot flashes due to lower estrogen levels
  - Estrogen given to reduce hot flashes
  - Estrogen causes uterus to thicken (hyperplasia)
  - Progesterone given to prevent thickening of the uterus in non-hysterectomized women
- Market Opportunity
  - No FDA-approved bio-identical combination product of estrogen and progesterone

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

Evolution of U.S. HRT Market Post WHI Study



1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. *Menopause*, Vol 22, No 9, pp 0-11.
WHI = Women's Health Initiative, DQSA = Drug Quality and Security Act, BHRT = Bio-identical Hormone Replacement Therapy

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Compounded Bio-identical HRT: Why Has It Been So Successful?

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	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 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" 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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Compounded Bio-identical HRT: Why Has It Been So Successful?

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 13283: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol;HN Hodis, et al. *Circulation*. 2014; 130:A13283.
4) Cochrane Collaboration; HT for preventing cardiovascular disease in postmenopausal women; Boardmen HMP, et al., 2015.

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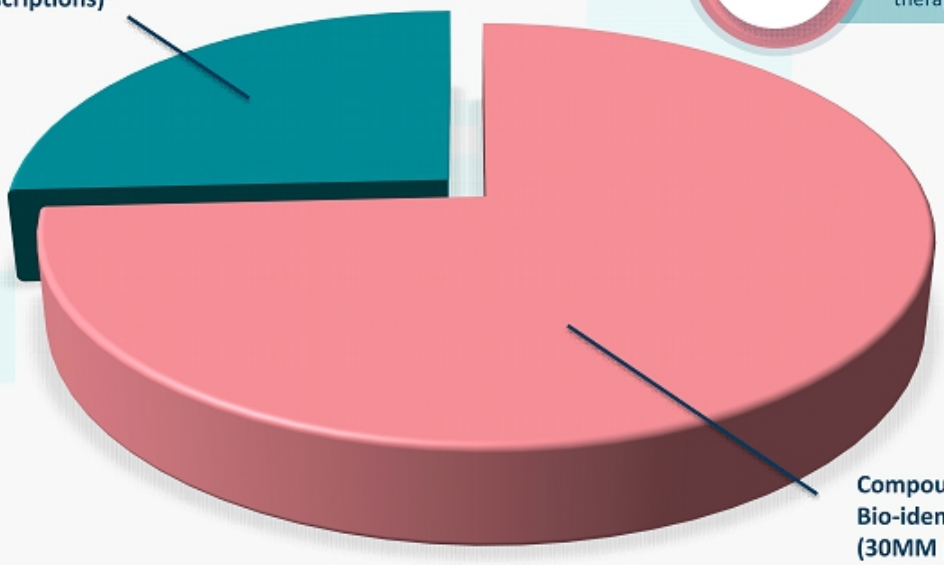
Total Addressable Market = 38MM Prescriptions

FDA-approved Combinations of Estradiol, Estrogens, Progesterones & Progestins (8.1MM prescriptions)[1]



Compounded Bio-identical Hormones (30MM prescriptions)[2,3]

1-2.5MM[3] U.S. women using custom-compounded menopausal hormone therapy

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
Includes Single Pill Combination of E+P and Estradiol, Estrogen, Progesterone and Progestins taken in combination (oral and transdermal)
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. *Menopause*, Vol.22, No.9, pp 0-11.

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Non-FDA-Approved BHRT Market Represents Significant Opportunity for First FDA-Approved Product

Potential First Ever FDA-Approved Bio-identical Therapy Could Transform Existing Market

1. Pinkerton, J.V. Compounded bio-identical hormone therapy: identifying use trends and knowledge gaps among U.S. women. Menopause, Vol.22, No.9, 2015
2. Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA Approved MHT Has Increased http://press.endocrine.org/doi/abs/10.1210/endo-meetings.2015.RF.5.FRI-124#sthash.PySEhZ9P.dpuf
3. *Obstetrics & Gynecology* 2015;Vol 125, No. 5, p. 98S (Supplement), May 2015
4. Symphony Health Solutions PHAST Data powered by IDV

Regulatory Tailwinds for FDA-Approved Products

Drug Quality and Security Act (DQSA)[1]

- Prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortages
- Anticipate significant impact on compounding upon FDA approval of first bio-identical 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/m7808.pdf
3) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%2020150%20FINAL.pdf

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Medical Societies Have Expressed Concerns 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) Villiers, T.J. et al. Global Consensus Statement on Menopausal Hormone Therapy, *Climacteric*, June 2013, Vol. 16, No. 3 : Pages 316-337.

FDA-Approved HRT Script Market Share Underwhelming

FDA-Approved Product	Non-Bioidentical	2015 TRx[1] (000)	2015 U.S. Sales[1] ($MM)	Company
17β-estradiol + NETA / DSP Activella®/ FemHRT®/ Angeliq®	Non bio-identical containing progestins	138	$28	BAYER, novo nordisk®, Allergan
Generic 17β + Progestins	Non bio-identical containing progestins	1,218	$218	TEVA Pharmaceuticals
Premarin + MPA Prempro® / Premphase®	Non bio-identical CEE + progestin	1,431	$302	Pfizer
Premarin + SERM Duavee®	Non bio-identical CEE + SERM	163	$30	Pfizer
Paroxetine Brisdelle®	SSRI non-hormonal	181	$38	noven THERAPEUTICS, LLC
Total FDA-Approved Oral Combination Sales		3,131	$616	
% Market Share of Total Addressable Market		8.2%		

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.

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

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

Phase 3 Vasomotor & Endometrial Safety

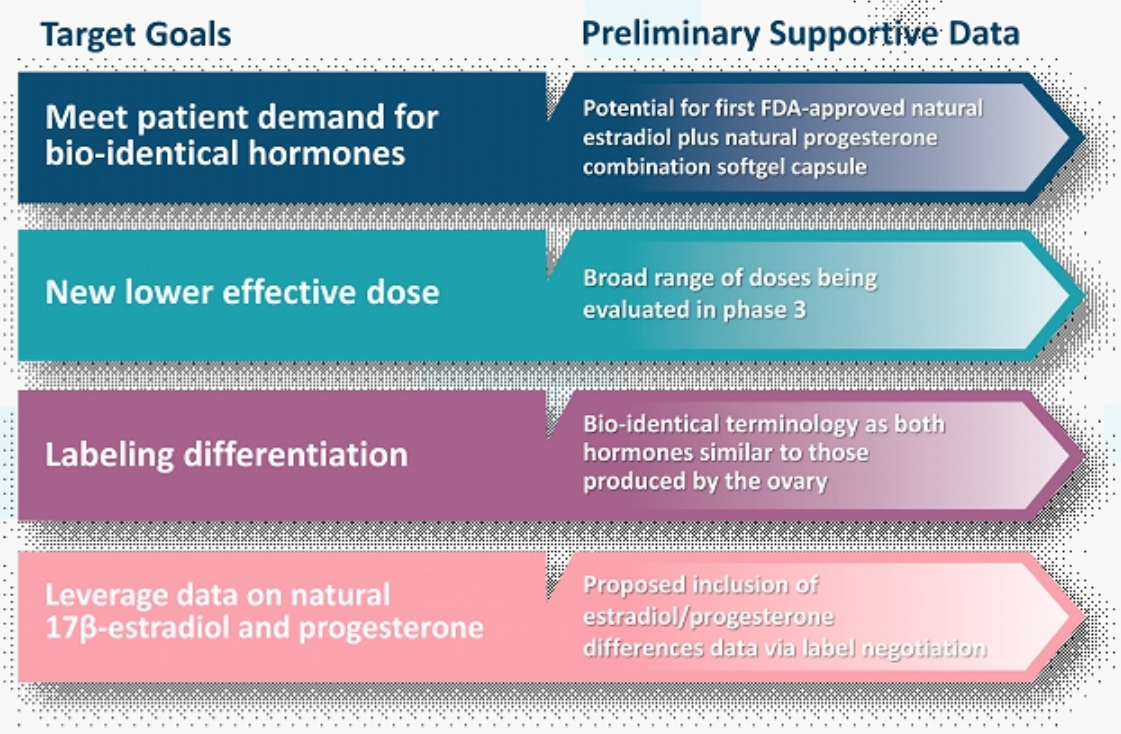
NDA Prep/Filing/PDUFA

- **Phase 3 Trial[1]: ~100 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
  - Control arm: Placebo (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)
- **As of May 3, 2016, over 1,500 subjects have exited the trial and the incidence of endometrial hyperplasia is less than 1%**

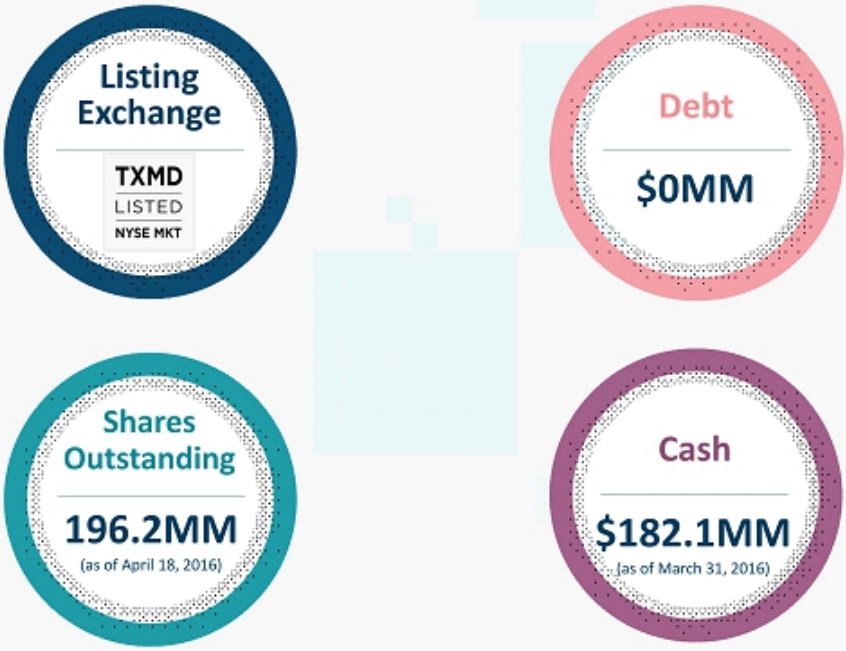
Replenish TRIAL

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

TX-001HR – Target Product Profile

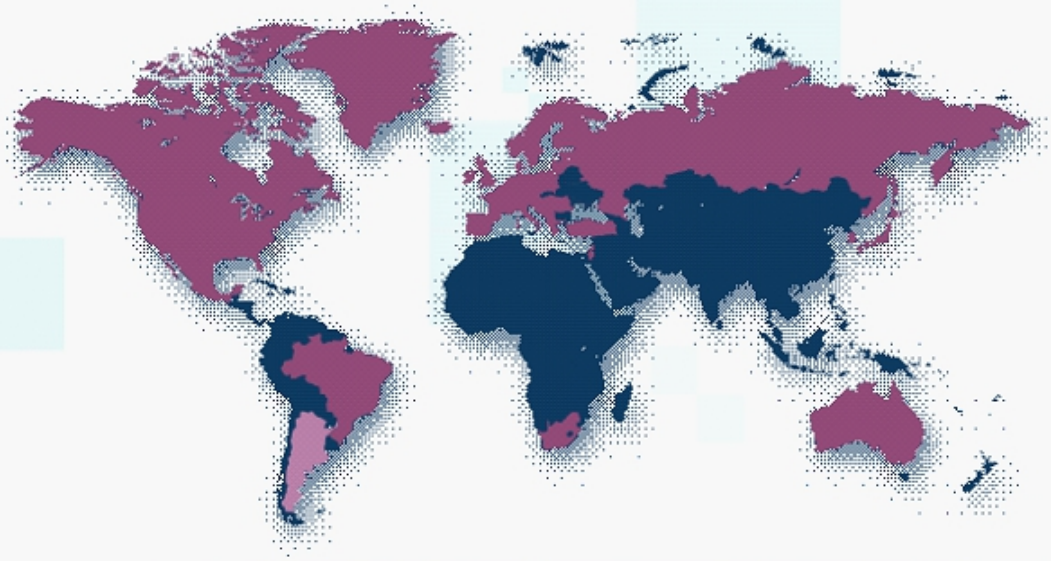


TXMD: Financial Snapshot



Worldwide Patent Filings*

Strong IP Portfolio with 134 Patent Applications, including 72 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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Management with Deep Experience in Women's Health

- 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

- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2006)
- 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

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

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

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

- 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

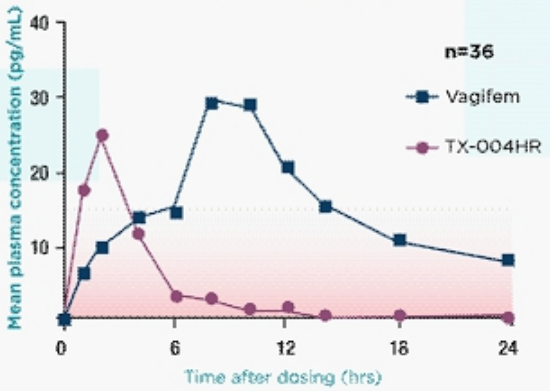
Supported by a team of regulatory consultants with decades of FDA experience

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

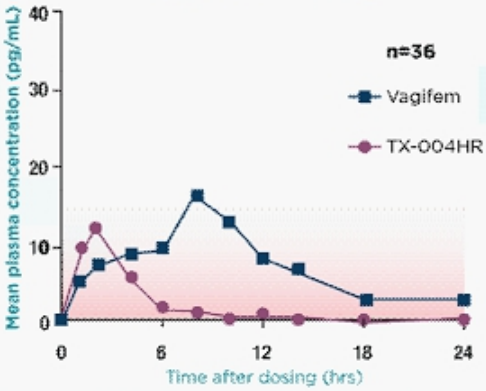
Key Findings

- Tmax ~2 hours with TX-004HR and ~8 hours with Vagifem
- Systemic absorption of estradiol AUC (0-24 hours) is 2- to 3-fold lower with TX-004HR relative to Vagifem

Study 500 - 25 mcg



Study 499 - 10 mcg



Vagifem is a registered trademark of Novo Nordisk A/S Corp.
Pickar, et al. Climacteric 2016

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