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): March 1, 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 March 1, 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 March 1, 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: March 1, 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 March 1, 2017.

Exhibit 99.1


Investor Day
March 1, 2017
TherapeuticsMD®
For Her. For Life.
TherapeuticsMD.com
THER-0086 1/17

Introduction

Robert Finizio
Chief Executive Officer

TherapeuticsMD®
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Forward-Looking Statements

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

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop, protect and defend our intellectual property; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefore; whether the company will be able to prepare a new drug application for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the application; whether the FDA will approve the company's new drug application for its TX-004HR product candidate and whether any such approval will occur by the PDUFA date; the length, cost and uncertain results of our clinical trials; potential adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership.

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

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

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Today's Agenda

8:30-8:40 a.m.	**Introduction**
8:40-10:00 a.m.	**TX-004HR**
	▪ Disease & VVA Market Overview - Brian Bernick, M.D.
	▪ Labeling & Regulatory Background - Lisa Rarick, M.D.; Sheryl Kingsberg, Ph.D.
	▪ Payer Overview – Joseph Auci; Tony Lanzone, inVentiv
	▪ Launch Strategy – Dawn Halkuff
9:30-10:00 a.m.	**Q&A Panel**
10:00-10:10 a.m.	**Break**
10:10-11:00 a.m.	**TX-001HR**
	▪ Disease Overview – Brian Bernick, M.D.
	▪ Replenish Trial & Clinical Data – Sebastian Mirkin, M.D.
	▪ Quantifying the Market Opportunity – Robert Finizio
	▪ Launch Strategies & Case Studies – Joseph Auci
	▪ Compounding Regulatory Dynamics – David Miller, R.Ph.
	▪ Compounding Pharmacy Economics – Rich Moon, Principal of PVPCN
11:00-11:30 a.m.	**Q&A Panel**
11:30 a.m.	**Closing Remarks**

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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

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Business Transformation

May 2008
vitaMedMD founded in Boca Raton, Florida

December 2012
Successful Phase 1 PK study of TX-001HR showing bioequivalence to Estrace and Prometrium

April 2013
TherapeuticsMD (TXMD) listed and traded on the NYSE MKT

October 2013
Released positive results from the Phase 1 clinical study for TX-004HR

December 2015
Released positive top-line results from the Phase 3 Rejoice Trial for TX-004HR

September 2016
NDA filing for TX-004HR accepted for review by the FDA

December 2016
Released positive top-line results from the Phase 3 Replenish Trial for TX-001HR

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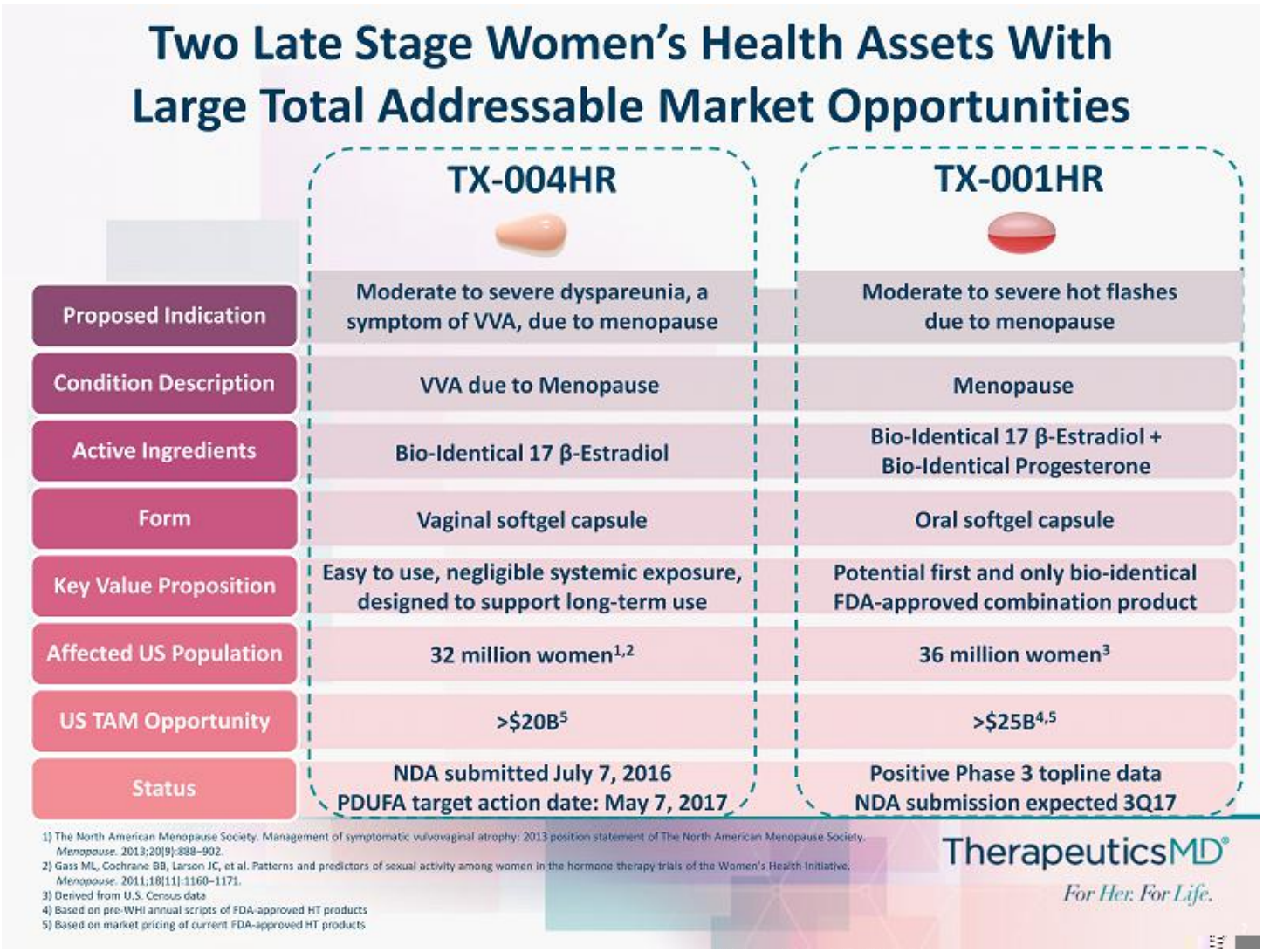
Two Late Stage Women's Health Assets With Large Total Addressable Market Opportunities



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
- 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

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

Brian Bernick, M.D.
Chief Clinical Officer

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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 (painful intercourse)
- Secondary symptoms include: vaginal dryness, itching, irritation, bleeding with sexual activity, dysuria, urgency, frequency, recurrent UTIs, and incontinence
- Current treatments include: prescription creams, tablets, and rings in addition to over-the-counter lubricants

	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.

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Current US VVA Market Overview

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

32M Women with VVA Symptoms[1,2]

~50%, or ~16M seek treatment for VVA[4]

- **Only 7%, or ~2.3M women**, are currently being treated today with Rx hormone therapy (HT)[3]
  - Long-term safety concerns[6]
  - Efficacy[6]
  - Messiness[6]
  - Need for applicator[6]
- **18%, or ~5.7M women**, are **past HT users** and were unsatisfied/unsuccessful with past treatments[4]
- **25%, or ~8M women,** are **users of OTC products*** such as lubricants that do not treat the underlying pathological cause of VVA nor halt or reverse symptoms[4]

~50%, or ~16M women do not seek treatment for VVA[4]

- Lack of awareness that VVA is a treatable condition
- Estrogen exposure concerns

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
6) 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.S1449
* 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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Current FDA-Approved VVA Products

Products	Estrace Cream®	Premarin Cream®	Vagifem®	Estring®	Osphena®	Intrarosa®
						
	Allergan	Pfizer	novo nordisk	Pfizer	SHIONOGI	amag
TRx Dollars 2016[1]	$511,035,880	$505,351,340	$502,715,665[a]	$105,040,703	$72,755,311	Approved 11/2016
Method of Admin	Vaginal Cream	Vaginal Cream	Vaginal Tablet	Ring	Oral Tablet	Vaginal Insert
Application	Reusable Vaginal Applicator	Reusable Vaginal Applicator	Vaginal Applicator	90-day Ring	Oral Daily SERM	Vaginal Applicator
Active Ingredient	100 mcg Estradiol	625 mcg/g Conjugated Equine Estrogens	10 mcg Estradiol	2,000 mcg Estradiol	60,000 mcg Ospemifene	6,500 mcg Prasterone
Average Maintenance Dose	100 mcg 2x/week	312.5 mcg 2x/week	10 mcg 2x/week	7.5 mcg daily	60,000 mcg daily	6,500 mcg daily
Onset of Action* Dyspareunia	Approval Without Dyspareunia and Dryness data	Week 4+	Week 8	Approval Without Dyspareunia and Dryness data	Week 12	Week 6
Onset of Action* Dryness		Not Demonstrated			Not Demonstrated	Week 12

*Onset of Action = First efficacy observation

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

1. Symphony Health Solutions PHAST Data powered by IDV; Annual 2016
   a. 2016 Vagifem and Yuvafem (authorized generic of Vagifem)

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.accessdata.fda.gov/drugsatfda_docs/label/2013/203505s000lbl.pdf
Intrarosa [package label] http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208470s000lbl.pdf

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2016 VVA Market Overview and Metrics

Product	TRx Count[1]	TRx Count % Share[1]	TRx Dollars[1]	TRx Dollars % Share[1]	Patient Count[2]	Patient Count % Share[2]
Estrace®	1,603,209	32%	$511,035,880	30%	868,052	39%
Premarin®	1,363,725	28%	$505,351,340	30%	750,185	34%
Vagifem®	1,280,708	26%	$452,289,452	27%	330,045	15%
Yuvafem® (Vagifem AG)	148,701	3%	$50,426,213	3%	103,142	5%
Estring®	276,151	6%	105,040,703	6%	97,960	4%
Osphena®	271,824	5%	72,755,311	4%	68,868	3%
Grand Total	4,944,318	100%	$1,696,898,899	100%	2,218,252	100%

1] Symphony Health Solutions PHAST Data powered by IDV; Annual 2016
2] IMS SDI's Total Patient Tracker; Annual 2016

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Compliance and Fills Per Year Drives Top-Line Revenue

Current VVA Market

Vaginal Creams:

Average:
1.5 Fills Per Year[2]

Estrace

Premarin

Reasons Women Stop

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

Vaginal Tablets:

Average:
3.5 Fills Per Year[2]

Vagifem

Reasons Women Stop

- Efficacy[1]
- Applicator[1]
- Long-term Safety[1]
- Systemic Absorption[1]

Product	TRx Dollars[1]	Patient Count[2]	Patient Share[2]
Estrace	$511,035,880	868,052	39%
Premarin	$505,351,340	750,185	34%
Vagifem/Yuvafem	$502,715,665	433,187	20%

- Higher average fills per year enable Vagifem/Yuvafem to generate equal revenue as Premarin and Estrace with significantly less patients on therapy

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) Total Rx/Patient Count
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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TX-004HR: Product Candidate Profile

- First vaginal estrogen (4 mcg and 10 mcg) with negligible systemic exposure
- Strong efficacy data on both dyspareunia and vaginal dryness with a 2-week onset of action
- Small, digitally inserted, rapidly dissolving softgel capsule without the need for an applicator
- Fraction of the dose (4 mcg, 10 mcg and 25 mcg) of many existing products (Premarin and Estrace)
- No patient education required for dose preparation or applicators
- Mechanism of action and dosing that is familiar and comfortable
- Proposed dose packaging to optimize compliance and convenience
- Strong patent estate with patent expirations starting 2032
- **FDA PDUFA target action date of May 7, 2017**

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[DRAFT]

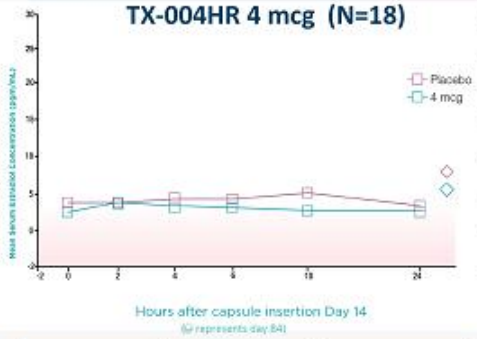
Co-Primary and Key Secondary Efficacy Endpoints

	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

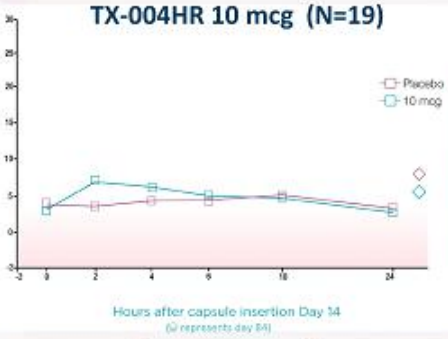
MMRM P-value vs placebo LS = Least Squares

Arithmetic Mean Estradiol Serum Concentrations – Unadjusted

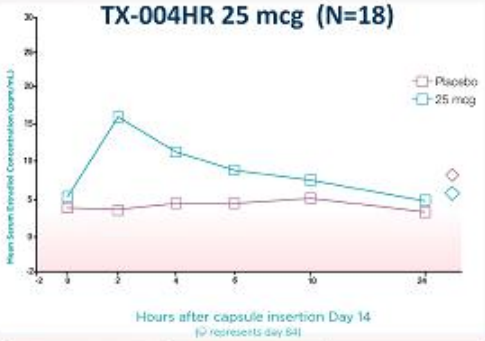
TX-004HR 4 mcg (N=18)



TX-004HR 10 mcg (N=19)



TX-004HR 25 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 (pl)	104.16 (66.38)	4.34 (2.76)
P-value vs Pl	0.3829	0.3829

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

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

TX-004HR 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%)

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%)

Preferred vs Competition

	4 mcg (N=119)	10 mcg (N=113)	25 mcg (N=128)
TX-004HR preferred 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

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Labeling & Regulatory Background

Lisa Rarick, M.D.

Board Certified OB/GYN

FDA Medical Officer 1988-2003

- CDER, Division Director, Division of Reproductive and Urologic Products from its creation (1995-1999)
- Office of the Commissioner, Office of Women's Health (2002-2003)

2003-Present

- Independent consultant to pharmaceutical industry

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TX-004HR Potential Label Discussions

Current Product Labels (based generally on Premarin Vaginal Cream label)	Base Case	Upside case
BOXED WARNINGS Estrogen-Alone Therapy Boxed Warning Estrogen Plus Progestin Therapy Boxed Warning	**BOXED WARNINGS** Class labeling	**BOXED WARNINGS** Removal of Boxed Warning related to Estrogen Alone Therapy – Modified language in the "Warnings and Precautions" Section Removal of Boxed Warning related to Estrogen Plus Progestin Therapy – Removal throughout the label
Section 1 INDICATIONS AND USAGE Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause	**Section 1 INDICATIONS AND USAGE** "TX-004HR is a muco-adhesive vaginal softgel capsule indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause"	**Section 1 INDICATIONS AND USAGE** "TX-004HR is a muco-adhesive vaginal softgel capsule indicated for the treatment of moderate to severe dyspareunia ***and vaginal dryness***, symptoms of vulvar and vaginal atrophy, due to menopause"
Section 2 DOSAGE AND ADMINISTRATION Generally, when estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer Use of estrogen-alone, or in combination with a progestin, should be with the lowest effective dose and for the shortest duration	**Section 2 DOSAGE AND ADMINISTRATION** Class labeling	**Section 2 DOSAGE AND ADMINISTRATION** Removal of progestin use for endometrial protection Removal of shortest duration concept

TX-004HR Potential Label Discussions

Current Product Labels (based generally on Premarin Vaginal Cream label)	Base Case	Upside case
Section 3 DOSAGE FORMS AND STRENGTHS	**Section 3 DOSAGE FORMS AND STRENGTHS** TX-004HR is a small, light pink, tear-shaped, mucoadhesive, softgel capsule containing solubilized estradiol	**Section 3 DOSAGE FORMS AND STRENGTHS** TX-004HR is a small, light pink, tear-shaped, ***rapidly dissolving***, mucoadhesive, softgel capsule containing solubilized estradiol
Section 4 CONTRAINDICATIONS	**Section 4 CONTRAINDICATIONS** Class labeling	**Section 4 CONTRAINDICATIONS** Removal of contraindication of history of breast cancer Removal of contraindication of history of DVT and PE
Section 5 WARNINGS AND PRECAUTIONS **5.1 Risks from Systemic Absorption** Systemic absorption occurs with the use of X	**Section 5 WARNINGS AND PRECAUTIONS** The use of TX-004HR resulted in negligible to very low systemic absorption of estradiol	**Section 5 WARNINGS AND PRECAUTIONS** The use of TX-004HR resulted in ***negligible systemic absorption*** of estradiol
Section 5 WARNINGS AND PRECAUTIONS The warnings, precautions, and adverse reactions associated with the use of systemic estrogen-alone therapy should be taken into account Warnings and precautions of Estrogen alone Warning and precautions of Estrogen Plus Progestins	**Section 5 WARNINGS AND PRECAUTIONS** Class labeling	**Section 5 WARNINGS AND PRECAUTIONS** Although TX-004HR use does not result in the level of systemic exposure associated with (*place holder for individual warning*) increased risk, long-term safety studies with TX-004HR are not available." Modified language in Estrogen Alone "Warnings and Precautions" Elimination of Warnings and Precautions related to Estrogen Plus Progestin Therapy

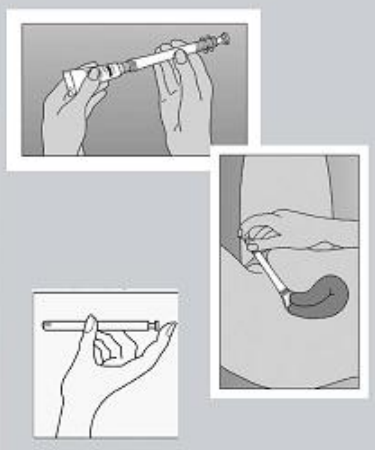
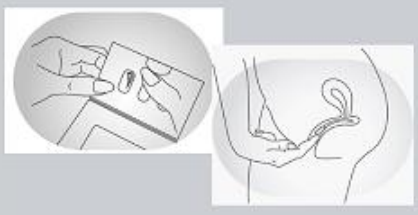
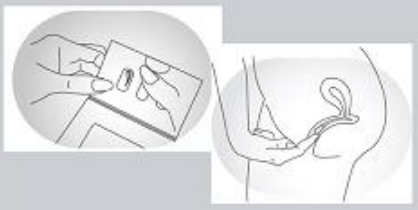
TX-004HR Potential Label Discussions

Current Product Labels (based generally on Premarin Vaginal Cream label)	Base Case	Upside Case
Section 6 ADVERSE REACTIONS - Dysuria - Leukorrhea - Vaginal discharge - UTI - Urinary Frequency - Vasodilatation - Breast pain	**Section 6 ADVERSE REACTIONS** Information from the clinical trials included here	**Section 6 ADVERSE REACTIONS** Specifically state that the active group had fewer reported adverse reactions than placebo in all categories except for headache
Section 8 USE IN SPECIFIC POPULATIONS **8.5 Geriatric Use** WHI Studies information on stroke, breast cancer and dementia in women in greater than 65 years of age	**Section 8 USE IN SPECIFIC POPULATIONS** **8.5 Geriatric Use** Class labeling	**Section 8 USE IN SPECIFIC POPULATIONS** **8.5 Geriatric Use** Removal of information related to stroke, breast cancer and dementia in women greater than 65 years of age
Section 11 DESCRIPTION Each gram of PREMARIN (conjugated estrogens) Vaginal Cream contains 0.625 mg conjugated estrogens, USP in a nonliquefying base containing cetyl esters wax, cetyl alcohol, white wax, glyceryl monostearate, propylene glycol monostearate, methyl stearate, benzyl alcohol, sodium lauryl sulfate, glycerin, and mineral oil	**Section 11 DESCRIPTION** TX-004HR (estradiol vaginal softgel capsules) are **small**, light pink, tear-shaped, softgel capsules containing solubilized **estradiol** TX-004HR softgel capsules are used intravaginally. When the softgel capsule comes in contact with the vaginal mucosa, the softgel capsule dissolves and the estradiol is released into the vagina	**Section 11 DESCRIPTION** TX-004HR (estradiol vaginal softgel capsules) are **small**, light pink, tear-shaped, softgel capsules containing solubilized **estradiol** TX-004HR softgel capsules are used intravaginally. When the softgel capsule comes in contact with the vaginal mucosa, the softgel capsule dissolves ***rapidly*** and the estradiol is released into the vagina

TX-004HR Potential Label Discussions

Current Product Labels (based generally on Premarin Vaginal Cream label)	Base Case	Upside Case
Section 12 CLINICAL PHARMACOLOGY **12.3 Pharmacokinetics Absorption**	**Section 12 CLINICAL PHARMACOLOGY** **12.3 Pharmacokinetics Absorption** In a multicenter, double-blind placebo-controlled study of 764 postmenopausal women randomized to placebo or 4, 10 and 25 mcg of TX-004HR, a subset of 72 subjects participated in a pharmacokinetics substudy. Estradiol, free estrone, and conjugated estrone concentrations were measured in plasma on Day 1 and Day 14, and Day 84 (approximately four days after the last dose). Key pharmacokinetic parameters are presented in Tables 1 to 3. There were no statistical differences between 4 mcg and 10 mcg and placebo at Days 1 and 14. At both Day 1 and Day 14, the 25 mcg dose was statistically significantly higher than placebo. The use of TX-004HR resulted in negligible to very low systemic absorption of estradiol.	**Section 12 CLINICAL PHARMACOLOGY** **12.3 Pharmacokinetics Absorption** In a multicenter, double-blind placebo-controlled study of 764 postmenopausal women randomized to placebo or 4, 10 and 25 mcg of TX-004HR, a subset of 72 subjects participated in a pharmacokinetics substudy. Estradiol, free estrone, and conjugated estrone concentrations were measured in plasma on Day 1 and Day 14, and Day 84 (approximately four days after the last dose). Key pharmacokinetic parameters are presented in Tables 1 to 3. There were no statistical differences between 4 mcg and 10 mcg and placebo at Days 1 and 14. At both Day 1 and Day 14, the 25 mcg dose was statistically significantly higher than placebo. The use of TX-004HR resulted in ***negligible systemic absorption*** of estradiol.
Section 14 CLINICAL STUDIES Co-primary endpoints with p values	**Section 14 CLINICAL STUDIES** Co-primary endpoints with p values	**Section 14 CLINICAL STUDIES** Onset of action at week 2 Vaginal dryness efficacy
Section 14.2 & 14.3 Women's Health Initiative Studies	**Section 14.2 & 14.3 Women's Health Initiative Studies** Class labeling	**Section 14.2 & 14.3 Women's Health Initiative Studies** Modified language for Estrogen Alone studies Removal Estrogen Plus Progestin studies

TX-004HR Potential Label Discussions

Current Product Labels (based generally on Premarin Vaginal Cream label)	Base Case	Upside Case
Section 17 PATIENT COUNSELING 	Section 17 PATIENT COUNSELING 	Section 17 PATIENT COUNSELING 

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Labeling & Regulatory Background

Sheryl Kingsberg, Ph.D

Chief, Behavioral Medicine at University Hospitals Case Medical Center

- Specializes in sexual medicine, female sexual disorders, menopause, pregnancy, postpartum, psychological aspects of infertility
- Principal investigator for clinical trials of sexual dysfunction treatments
- Associate Editor for Sexual Medicine Reviews and editorial board of Menopause
- President-Elect of NAMS

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Continued Activism Against VVA Black Box Warnings

History of Activism

November 2015
FDA "boxed warnings" workshop provided an opportunity for FDA to obtain input related to prescribing information of lower-dose estrogen alone products[1]

March 2016
ACOG Committee Opinion supporting use of vaginal estrogen in women with a history of estrogen-dependent breast cancer as data showed no increased risk[2]

May 2016
Citizen Petition, spearheaded by NAMS, formally filed with the FDA for modification of black box warnings

October 2016
Women's Congressional Caucus writes letter to the FDA addressing concerns of existing black box warnings of VVA products

Citizen's Petition Supporters:

Academy of Women's Health; Endocrine Society; NAMS The North American Menopause Society; NPWH Nurse Practitioners in Women's Health Caring for Women; ISSWSH; The American Society for Reproductive Medicine; AMWA; ACOG

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

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Payer Overview

Joseph Auci
VP, Managed Care,
Distribution, and Policy

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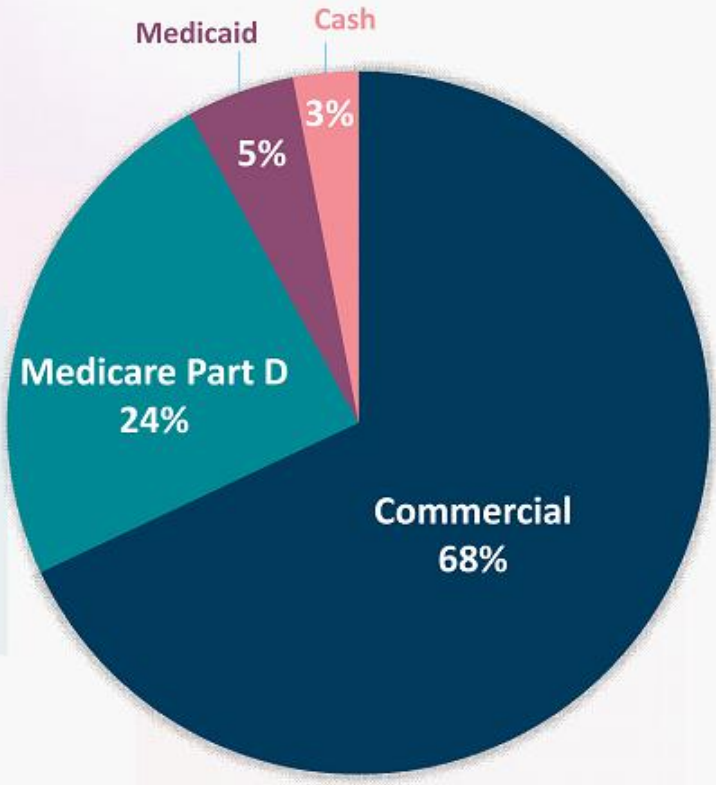
Payer Breakdown of FDA-Approved VVA Products



MMIT Data January 2017

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Payers are Continuing to Provide Choice

80% of Payers Prefer 2+ Products

VVA Category		Estrace Cream	Estring	Osphena	Premarin Cream	Vagifem
Payers	Lives	Univ. Status	Univ. Status	Univ. Status	Univ. Status	Univ. Status
Express Scripts PBM	28,411,137	Preferred	Covered	Covered	Preferred	Preferred
CVS Caremark RX	25,490,409	Preferred	Covered	Preferred	Preferred	Preferred
UnitedHealth Group, Inc.	15,606,808	Covered	Preferred	Covered	Covered	Preferred
Anthem, Inc.	14,307,637	Preferred	Preferred	Covered	Preferred	Covered
OptumRx	9,508,373	Covered	Covered	Covered	Preferred	Covered
Aetna, Inc.	9,265,194	Covered	Covered	Covered	Preferred	Covered
Department of Defense - TRICARE	7,004,961	Preferred	Preferred	Preferred	Preferred	Preferred
Kaiser Foundation Health Plans, Inc.	6,610,331	Preferred	Preferred	Not Covered	Preferred	Not Covered
CIGNA Health Plans, Inc.	6,375,734	Covered	Preferred	Covered	Preferred	Covered
Blue Cross Blue Shield Association Corporatic	5,442,845	Preferred	Covered	Covered	Preferred	Preferred
Health Care Service Corporation	5,135,711	Preferred	Covered	Covered	Covered	Preferred
Department of Veterans Affairs (VHA)	4,803,818	Covered	Covered	Covered	Preferred	Covered
Humana, Inc.	2,325,564	Covered	Covered	Not Covered	Covered	Covered
Blue Cross Blue Shield of Michigan	2,317,410	Covered	Preferred	Covered	Preferred	Preferred
Indian Health Service (IHS)	2,201,809	Covered	Covered	Covered	Preferred	Covered
Blue Shield of California	1,894,377	Preferred	Preferred	Covered	Preferred	Preferred
Prime Therapeutics	1,885,924	Preferred	Covered	Covered	Covered	Preferred
Blue Cross and Blue Shield of Florida, Inc.	1,861,938	Covered	Covered	Covered	Preferred	Preferred
Highmark, Inc.	1,781,021	Covered	Preferred	Covered	Preferred	Covered
CareFirst, Inc.	1,530,652	Preferred	Covered	Preferred	Preferred	Preferred

MMIT Data January 2017

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Why are Payers Providing Open Access?

Several reasons:

- Overall low cost category compared to other therapeutic areas
- Importance of providing choice for women
- Lack of innovation in the VVA category
- Prior authorization to drug cost ratio is not favorable
  - **Cost of a prior authorization runs between $80-$140 per patient per year depending on payer**

Pathway to Obtaining Broad Coverage

- TherapeuticsMD has seasoned managed care professionals on team with significant payer relationships
- Building out managed care team with inVentiv to help staff appropriately for launch
- Performed ad boards and significant payer research pre-launch
- Established relationships and planned meetings with largest plans pre-PDUFA

Reception to TherapeuticsMD and our products has been very favorable

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Payer Overview

Tony Lanzone

Managing Director, inVentiv Health Consulting

- 25 years of consulting in pharmaceutical/life sciences industry; member of Pricing and Market Access Practice
- Former director of Healthcare Informatics at Premier, a hospital GPO; provided consulting and market research
- Formerly in Ernst & Young's healthcare practice
- Commercial roles at Bristol-Myers Squibb

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Primary Research
VVA Management

VVA products are considered to be a very low budget impact category, and as such, the utilization management techniques are minimal, with no PA/SE for most commercial payers.

- Hormone Replacement Therapy (HRT) in general and Vulvar and Vaginal Atrophy (VVA) specifically are not actively managed by payers due to very low budget impact
  - This category is not on payers' radar and can be classified as "top 100" in terms of the financial impact
  - Payers typically don't differentiate deeper than the HRT category – few payers appreciated the nuance of VVA or the specific sub-indications
  - Tiering is the most common utilization management method used by payers, with no Prior Authorization (PA) and Step Edit (SE) techniques for most of the drugs in this category
  - Most of the legacy drugs have been on formulary for a very long time, and payers sometimes don't remember why or when drugs like Premarin or Estrace ended up on Tier 2
- New drugs are usually reviewed through standard P&T committee process, and may not have a coverage decision until 3-6 months post-launch
- There is a perception that in this category very little can be done to show clinical differentiation for a new product

> *"We don't manage this category at all, nothing here, not tight management."*
>
> -Pharmacy Director, National Payer

Research conducted in September-October 2016, sample included 20 national and regional payers, including two PBMs, representing ~157MM lives

Source: inVentiv Health Consulting Primary Research (N=20). September 2016.

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Primary Research
Product X (TX-004HR) Initial Reaction

Reaction to Product X was positive, and respondents are quick to pick up the features of Product X that stand out: elegance, low dose, absence of applicator and local administration.

Unaided mentions of high differentiation features include:

- Absence of applicator
- Route of administration and "elegance" of formulation (locally administered estradiol in dissolving softgel capsule)
- Low dose of estrogen (aligned with guidelines)
- Various doses that may allow to titrate
- Statistically significant safety data
- Absence of BBW is mostly viewed as a "nice to have" feature, with some payers focusing more on real world evidence than just FDA label

Product features that did not resonate with payers include:

- Another form of estradiol, not a new formulation
- No head-to-head comparison with other drugs that would assume clinical differentiation, although many realize that it would not be typical or necessary in this category

"Advantage is that it is the only product with the smallest dose. It does not need applicator. It is soft gel – another difference. Indications are not really that important to us. We don't manage them by indication."

-Pharmacy Director, National Payer

"Good feature – dissolution. Less messy, low dose, simple estrogen. Level of effectiveness is something that is going to come up. Disadvantages – this is still an estrogen, general approach to treating. Nothing new here, we would be interested in cost of the product..."

-Pharmacy Director, National Payer

Research conducted in September-October 2016, sample included 20 national and regional payers, including two PBMs, representing ~157MM lives

Source: inVentiv Health Consulting Primary Research (N=20). September 2016.

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TX-004HR
Launch Strategy*

Dawn Halkuff
Chief Commercial Officer

- Former SVP of the Pfizer Consumer Healthcare Wellness Organization
- Former Marketing and Sales Lead of the Pfizer Women's Health Division
- Former Head of Global Innovation at Weight Watchers International
- 20+ years of commercial experience across pharmaceuticals, consumer packaged goods, and services
- Majority of career spent in Women's Health

*Assuming approval

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Experience Aligns to VVA Market Needs

	Important Touch Point of VVA Market
Kimberly Clark – Marketing Feminine Protection	
▪ Private subject; Innovation through user experience	✓
Weight Watchers - Global Innovation	
▪ Drive urgency to take care of an ongoing and worsening issue	✓
Pfizer Women's Health – Marketing/Sales of Premarin Franchise	
▪ Hormone therapy opportunities and challenges	✓
Pfizer Consumer Products - Head of Wellness	
▪ Drive innovation on both scientific advances and patient desire	✓

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Local Estrogen Therapy Current Standard of Care

Local estrogen therapy currently represents over 95% market share in the VVA market

- Current standard of care per medical society guidelines
- OB/GYNs comfortable with safety and efficacy profile – low education hurdle

However, there has been zero innovation for local estrogen products since 1999

Products	Estrace Cream®	Premarin Cream®	Vagifem®	Estring®	Osphena®	Intrarosa®
						
	Allergan	Pfizer	novo nordisk	Pfizer	SHIONOGI	AMAG
TRx Dollars 2016[1]	$511,035,880	$505,351,340	$502,715,665[a]	$105,040,703	$72,755,311	Approved 11/2016
Active Ingredient	100 mcg Estradiol	625 mcg/g Conjugated Equine Estrogens	10 mcg Estradiol	2,000 mcg Estradiol	60,000 mcg Ospemifene	6,500 mcg Prasterone
Year Approved	1984	1978	1999	1996	2013	2016

1. Symphony Health Solutions PHAST Data powered by IDV; Annual 2016
   a. 2016 Vagifem and Yuvafem (authorized generic of Vagifem)

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.accessdata.fda.gov/drugsatfda_docs/label/2013/203505s000lbl.pdf
Intrarosa [package label] http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208470s000lbl.pdf

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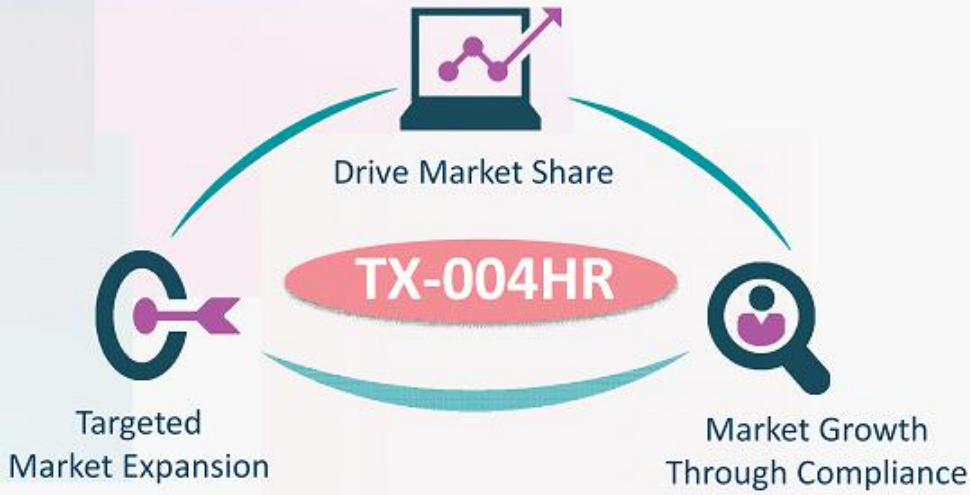
Focus on Three Main Fundamental Levers to Drive TX-004HR Launch



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Aligned Healthcare Providers (HCPs) and Patient Strategies Drive Fundamental Levers of Growth

Drive Market Share

Differentiate TX-004HR as new treatment option that redefines relief

Targeted Market Expansion

Elevate importance of VVA by demonstrating true impact of disease

Market Growth Through Compliance

Build a differentiated national care model for successful diagnosis, treatment, and management of symptoms of VVA caused by menopause

Commercial Execution

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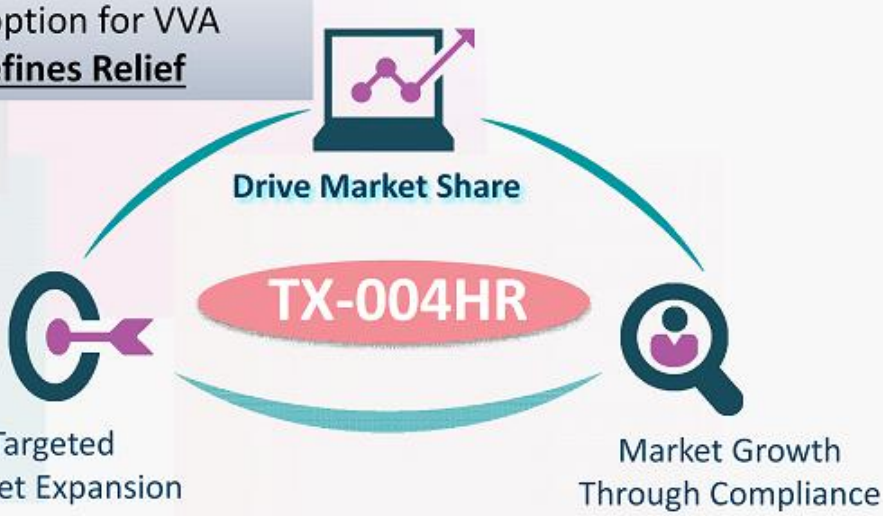
Drive Market Share

Differentiate TX-004HR as new treatment option for VVA that **Redefines Relief**



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Efficacy, Safety, and Positive User Experience Redefines Relief

	Perceived Shortcomings	TX-004HR Solution
Efficacy	▪ 1 in 4 women achieve limited relief[1] ▪ Delayed onset of efficacy[1]	▪ Early efficacy observed at week 2 ▪ Efficacy for vaginal dryness
Safety/ Side Effects	▪ Hormone exposure concerns[1] ▪ Messiness[1]	▪ Negligible systemic exposure ▪ No messiness
Convenience	▪ Products difficult to use[1] ▪ Inadequate instructions on use[1]	▪ No applicator; any time of day use ▪ Simple dose pack; easy instructions

Patients Choose TX-004HR

Rejoice Trial Survey Results	4 mcg (N=119)	10 mcg (N=113)	25 mcg (N=128)
TX-004HR preferred over previously used VVA therapies	73.9%	67.3%	74.2%

1) Wysocki, S et al. Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:6 23-30 doi:10.4137/CMRH.S14498
REJOICE Trial Results

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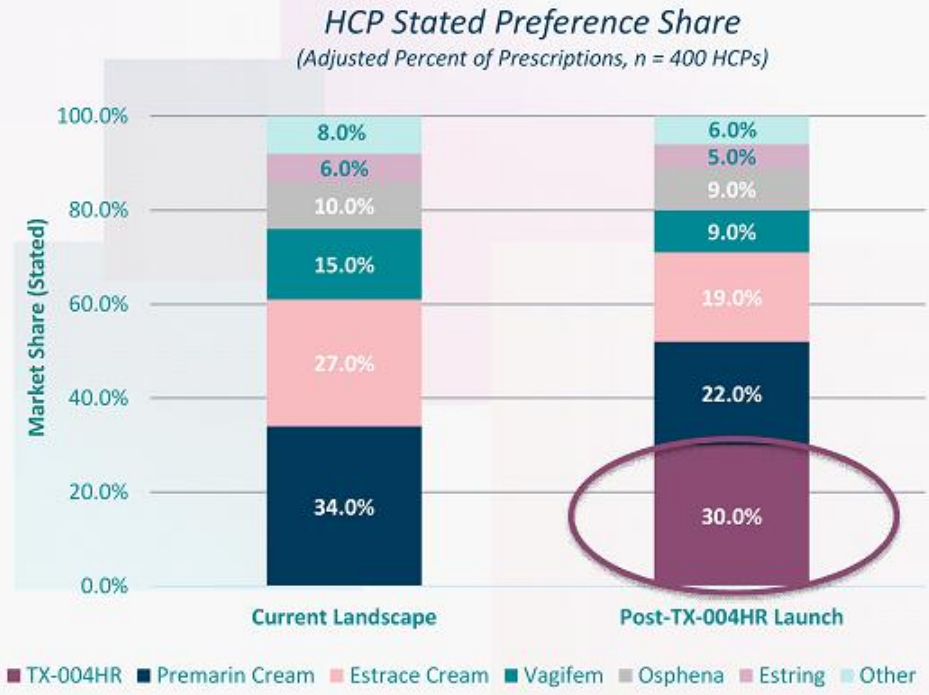
HCPs Estimate Giving TX-004HR 30% Market Share



- Large share gains from 3 largest competitors
- Set attainable 3-5 year company launch goals

TXMD Positioning Study: Preference Share pre and post TX-004HR launch
N=400

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Market Share Comes From High Writing HCPs

Target HCPs Representing 80% of Active Prescribing Volume in Market

- Sales force targets – 8,000 practices = 22,000 HCPs
- Group practice focus vs. individual HCP to maximize impact
  - Efficient launch plan to maximize sales force ROI
- Experienced women's health representatives
- Integrated multi-channel marketing (MCM) campaign to complement sales force and extend reach to lower-decile HCPs

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Our Approach: Detailed HCP Strategy

What needs are we addressing?	What are our core tactics?
Simplify the Prescribing Experience ▪ Simplify the conversation ▪ Simplify the product experience – how to use, product support for patients  	**What We Are Doing Today** ▪ Preparing the sales force: learning from HCPs the main barriers of diagnosing and treating VVA ▪ Unbranded communications of the true impact on their patients **Post Launch** ▪ Branded clinical presentations to pull through "Redefining Relief" (sales force, peer-to-peer programs) ▪ Education, reimbursement and compliance programs via national support model

Foundation Already Built for a Strong Launch

TXMD Sales Force Currently in OB/GYN Offices

- 40% overlap with current prenatal vitamins business
- Currently calling on VVA targets with market condition campaign
- Planned sales force of 100 in place prior to launch
- Partnership with inVentiv, leading contract sales organization
- Operational and analytic systems

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Targeted Market Expansion

Elevate the importance of VVA by demonstrating **true impact** of disease

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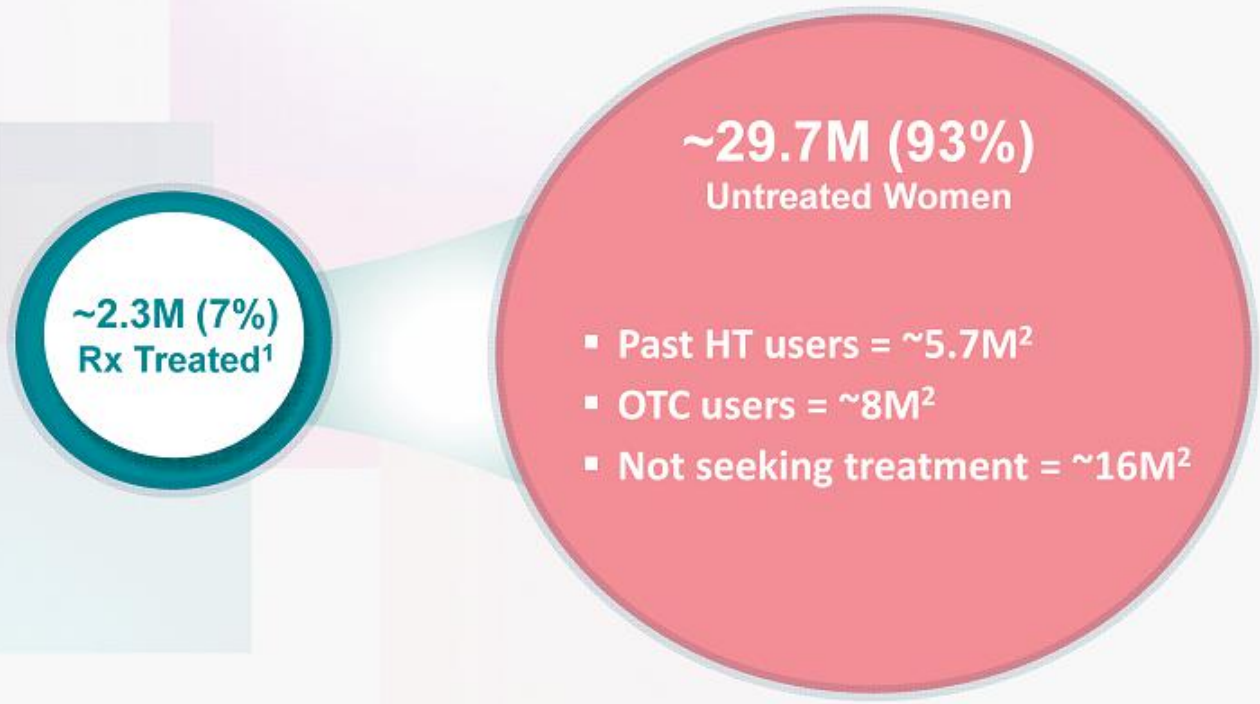
Significant Untapped Opportunity in the VVA Market



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

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Main Barriers to Expansion: Education and Motivation

Women's Reality	Plan to Address
▪ 42% believe VVA is natural part of aging	▪ Help women self-identify
▪ 67% never spoke to doctor about the condition	▪ Prepare women to have a conversation

Educate and Motivate By Helping Women Understand the True Impact of VVA

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Educate and Motivate Women Through True Impact

"I dread going to bed. I'm so guilt-ridden. He doesn't deserve this..."

"He doesn't want to hurt me. He knows it's not the same..."

"We're still young. We want to be young. You just feel so old, dried-up..."

For example purposes only

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Our Approach: Detailed Patient Strategy

What needs are we addressing?	What are our core tactics?
Women's Understanding and Comfort ▪ Educate her on the condition and provide tools to help self-identify ▪ Help her acknowledge the true impact to drive urgency ▪ Make it affordable	**What We Are Doing Pre-Launch** ▪ Unbranded communications to educate on true impact – live, print, and digital **Post Launch** ▪ Branded print, digital, and in office brochures ▪ Education and support programs via national care model

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Other Opportunities To Expand the Market

Relevant Suffering Populations: Oncology

- Currently 3M breast cancer survivors on Aromatase Inhibitors
- Most of these patients suffer from severe VVA due to lack of estrogen production

TX-004HR designed to overcome hurdles oncologists have with HT:

- Potential lowest effective doses
- Negligible systemic exposure

Expanding the Mainstream Market: Primary Care Physicians (PCPs)

- PCPs currently write about 10-15% of the prescriptions for local estrogen therapy
- Menopausal women visit their PCP more frequently than their OB/GYN

TX-004HR designed to overcome hurdles PCPs have with HT:

- Easy to prescribe packaging
- Negligible systemic exposure

Market Growth Through Compliance

Build a differentiated **national care model** for successful diagnosis, treatment, and management of symptoms of VVA caused by menopause

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Current VVA Market Average Compliance and Fills Per Year

Vaginal Creams

Average:
1.5 Fills Per Year[2]

Reasons Women Stop

- Messiness[1]
- Reusable applicator[1]
- Long-term safety[1]
- Dose preparation required by user[3]

Vaginal Tablets

Average:
3.5 Fills Per Year[2]

Reasons Women Stop

- Efficacy[1]
- Applicator[1]
- Long-term safety[1]
- Systemic absorption[1]

Slight, incremental changes have led to increased fills per year for vaginal tablets

- Disposable applicator
- Pre-packaged doses
- Monthly dosing regimen

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.S14898
2) Total Rx/Patient Count
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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Opportunity to Further Increase Compliance with Focus on Patient Journey Drop Off Points

Prescribed Rx → Pick up at Pharmacy → Start Therapy → Continue Therapy

Cost Concerns (32%)

Product Risk Concerns (31%)

Correct Utilization (56%)

National Care Model

Patient Care

• Financial • Condition and product education
• Follow on communications

Proven Results in Prenatal Business

• 70% of patients utilize services

Compliance in Prenatal Business

• 8 months vs category average of 2 months

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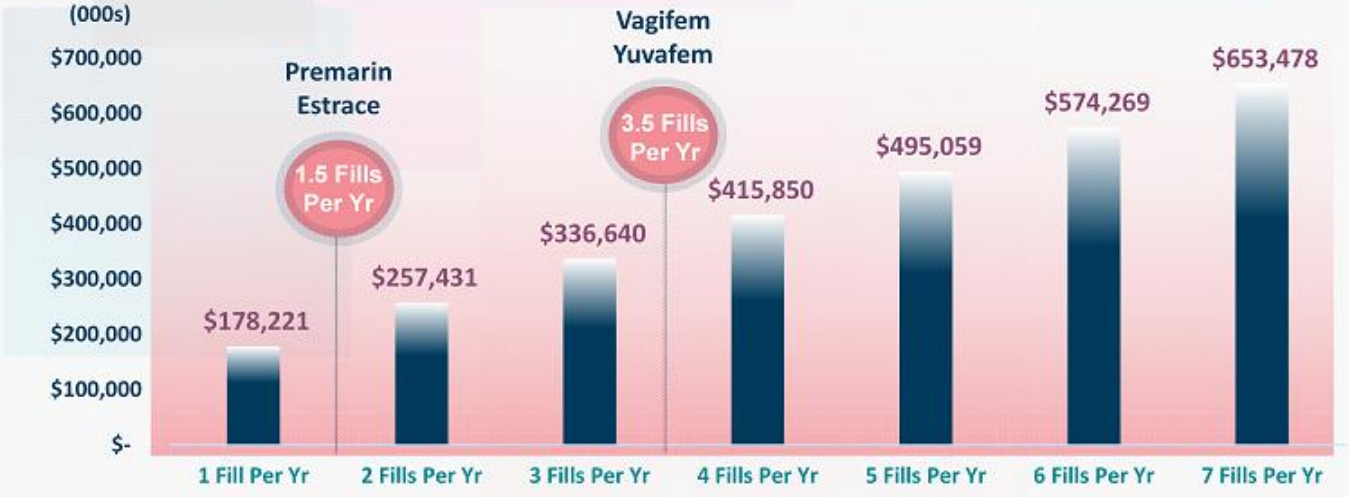
Increased Compliance and Fills Per Year Drives TX-004HR Net Revenue at Year 5 of Launch

Year 5 Assumptions		
Total VVA Patients on HT[1]		2,218,252
TX-004HR Market Share		30%
TX-004HR Patients		665,000
WAC of Loading Dose	$	382.86
WAC of Maintenance Dose	$	170.16
Average Rebate per Rx		30%

→ Zero market growth

→ Parity pricing - Vagifem
Zero price increases



1) IMS SDI's Total Patient Tracker; Annual 2016

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TX-004HR Launch Timeline

- Sales force preparedness
- Payer pipeline discussions
- Launch planning
- Unbranded HCP campaign

- **PDUFA date - May 7th**
- Continued build out of the sales force
- Continued payer outreach to secure broad coverage
- Unbranded patient campaign

- Branded launch
  - Patient
  - HCP campaign
  - Speaker programs
  - MCM/digital
  - Patient and HCP tools
  - Public relations
- Establish national care model
  - Samples
  - Patient programs
  - Reimbursement programs

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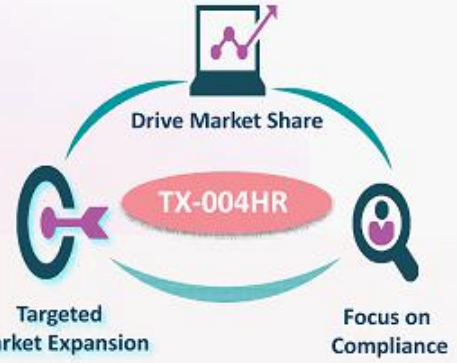
Conclusion



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TX-004HR designed for clinical success and improved user experience

Focus on 3 fundamental levers for continued growth and strong execution

Commitment to women's health drives goodwill and brand loyalty

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Q&A

Panel

Steven Goldstein, M.D.

Robert Gregory, R.Ph.

Dawn Halkuff

Sheryl Kingsberg, Ph.D.

Lisa Rarick, M.D.

Rob Reid

James Simon, M.D.

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TX-001HR
Combination
Estrogen + Progesterone
(E+P) Program
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Menopause & VMS Overview

Brian Bernick, M.D.
Chief Clinical Officer

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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 vasomotor symptoms (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/

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TX-001HR Product Development Rationale

- **2002 Women's Health Initiative (WHI) study showed that *synthetic* hormones increased the risk of breast cancer, stroke, heart attack and blood clots** (all FDA-approved combination hormonal products contain a synthetic Progestin and not a bio-identical Progesterone)
- **Post WHI, women and healthcare providers shifted to Bio-Identical Hormone Therapy (BHRT) containing bio-identical estradiol and bio-identical progesterone as an alternative despite being *unapproved* drugs that are *not covered by insurance***
  - 90M+ scripts of synthetic hormone therapy prescribed annually before 2002, declining to ~10M in 2015[1]
    - Today, patients have the choice between three second best therapies:
      - FDA-approved, **synthetic** combination hormones
      - FDA-approved, **separate** bio-identical hormone products
      - Unapproved, **compounded** bio-identical hormones that have not been proven safe and effective, or covered by insurance
- **Compounding filled the need for BHRT**
  - 30M scripts (3M women) of Compounded Bio-identical Hormone Therapy (CBHRT) prescribed annually in the U.S. currently[2,3]
- **No FDA-approved BHRT combination product of estradiol + bio-identical progesterone**
- **TX-001HR would become the first and only FDA-approved bio-identical combination product to fill this unmet need**

1) Symphony Health Solutions PHAST Data powered by IDV; Annual 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.

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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

ACOG · ENDOCRINE SOCIETY · NAMS The North American Menopause Society · American Society for Reproductive Medicine · 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 2006).

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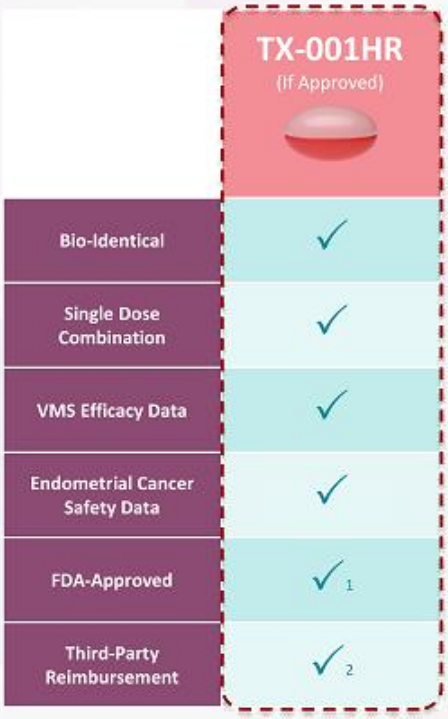
TX-001HR – Potential Best in Class Therapy



Potential first and only:

1) **Bio-identical combination estradiol & progesterone**
2) **FDA-approved**

Dosing and Delivery

- Once-a-day single oral softgel capsule

Addresses Unmet Medical Need

- First and only combination of bio-identical estradiol and bio-identical progesterone product candidate
- Single combination 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

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TX-001HR Could Fulfill Therapeutic Gap For All Participants

Patients

- Meet demand for bio-identical hormone therapy with an FDA approved product that is proven safe and effective
- Reduce of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at all pharmacies and not just compounding pharmacies

Healthcare Providers

- First and only FDA-approved bio-identical combination hormone therapy
- Clinically validated dose regimens
- Eliminate risks of compounded hormone therapy
- Meet patient demands and reduce patient out-of-pocket costs via insurance coverage
- Follow medical standards of care and society guidelines while reducing liability

Pharmacies

- Meet patient and physician demand for bio-identical hormone therapy
- Significantly improve net margin per script with third-party reimbursement
- Lower legal and regulatory costs and risk

FDA/Regulatory Bodies

- Reduce need for compounded hormone products
- Full enforcement of regulations regarding compounded hormones
- Reduce false claims and misleading advertising statements about compounded HT products

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Replenish Trial Results

Sebastian Mirkin, M.D.
Chief Medical Officer

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Replenish Trial Overview

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

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Current FDA Guidance for VMS Drug Products*

- **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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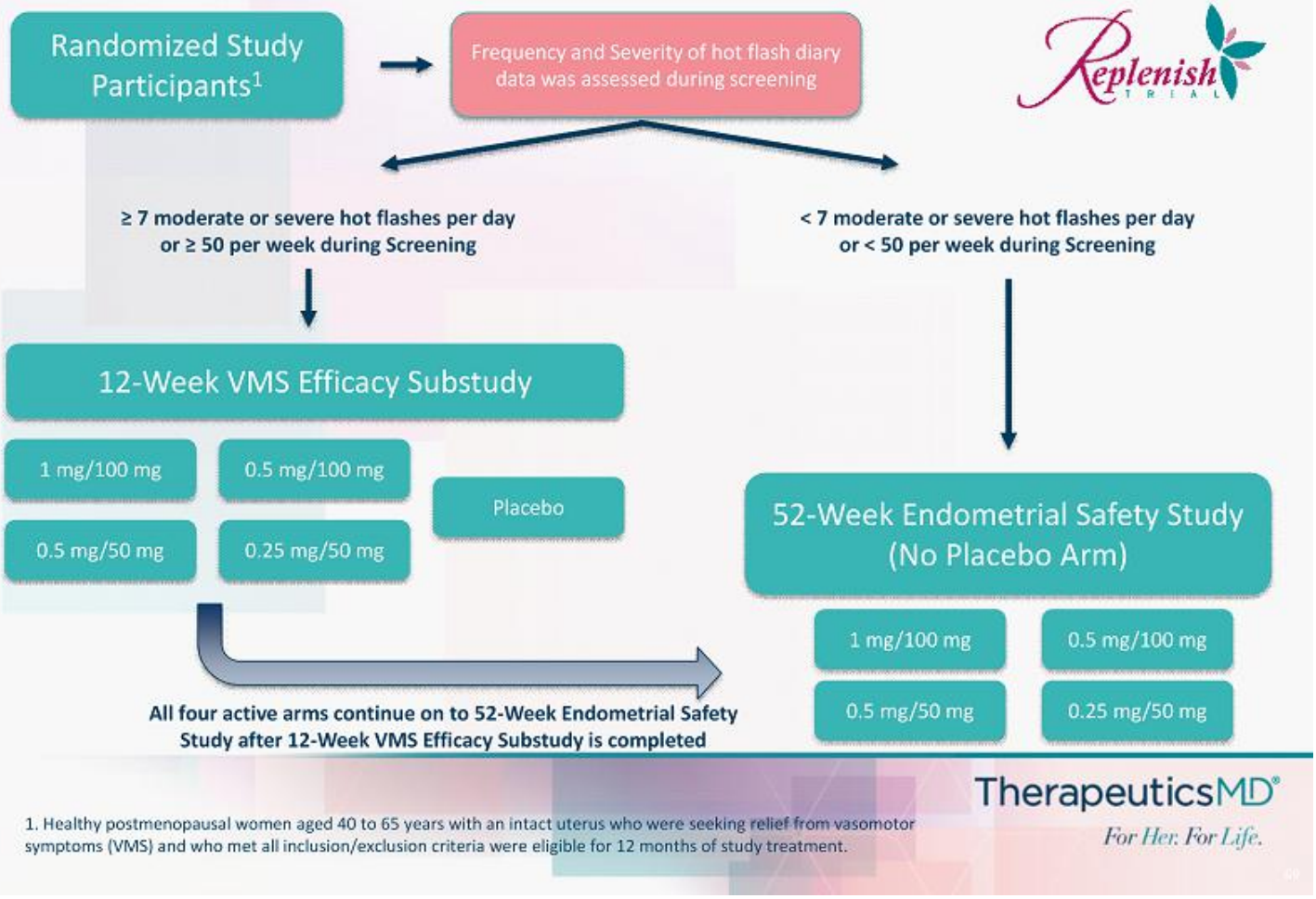
Replenish Trial Study Design - Flow Chart



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[Ŧ]					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

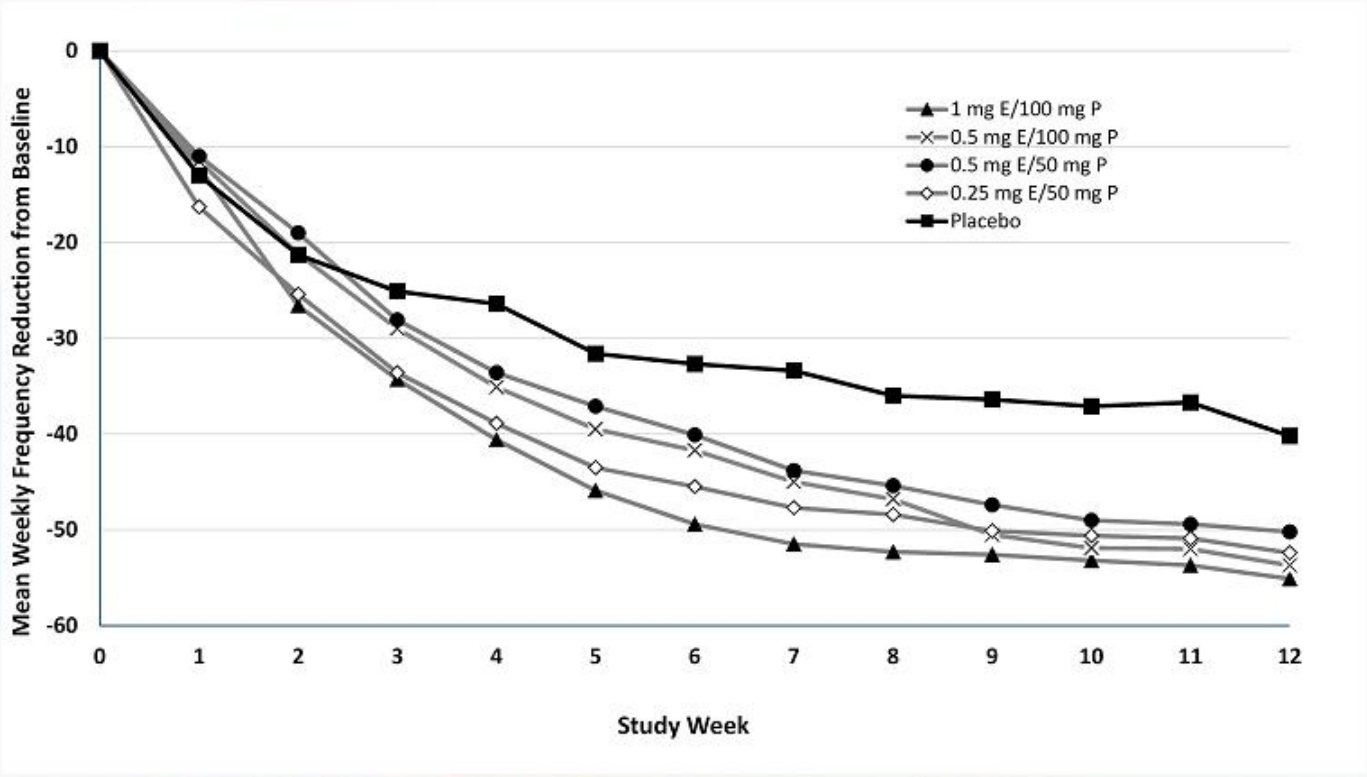
[Ŧ]Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

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

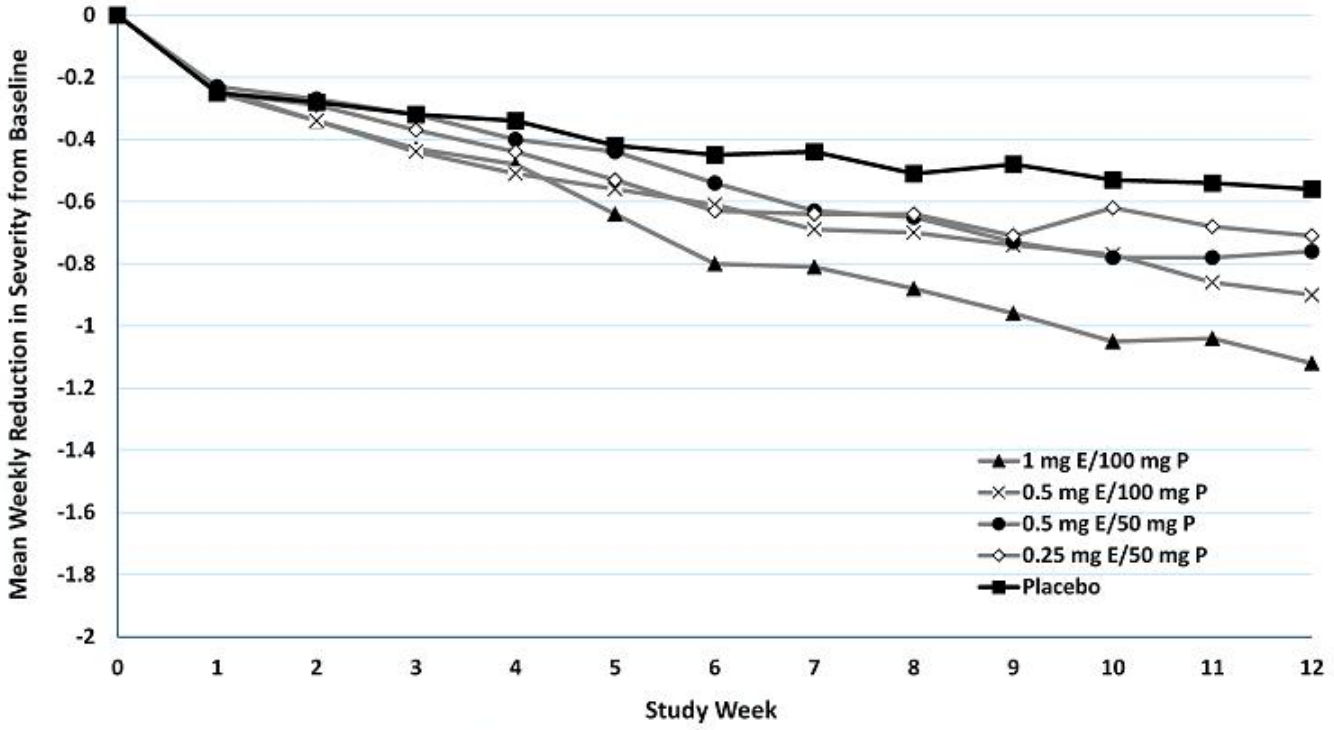
Primary Efficacy Analysis pre-specified with the FDA in the clinical protocol and Statistical Analysis Plan (SAP)

- **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



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Quantifying the Market Opportunity

Robert Finizio
Chief Executive Officer

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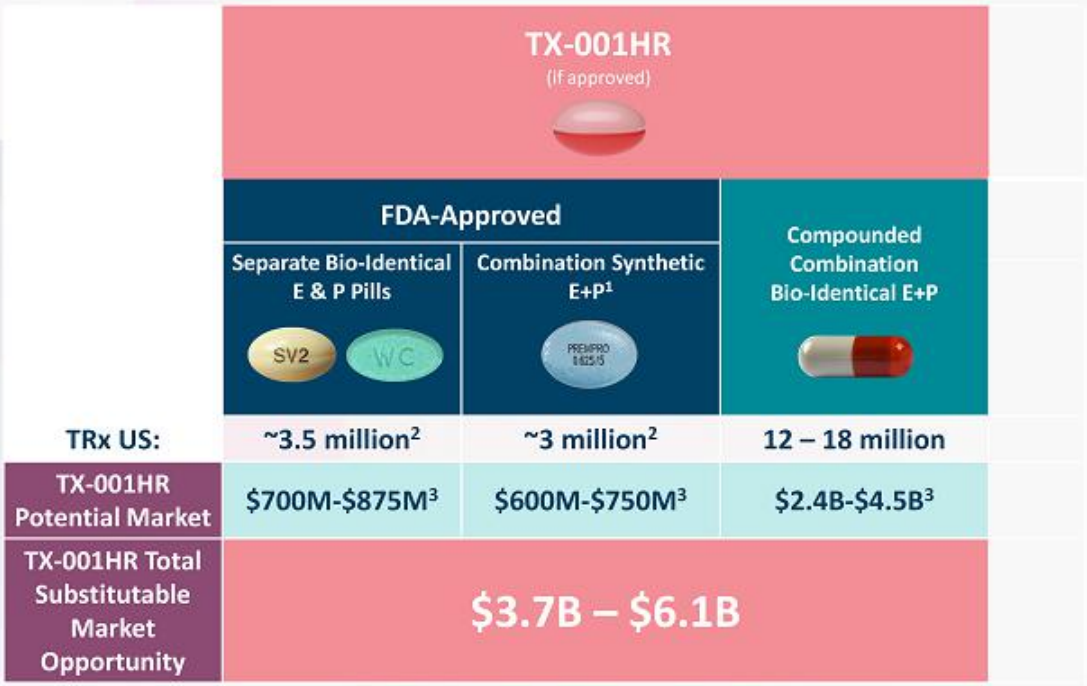
Multi-Billion Dollar Total Substitutable Market Opportunity



TRx US:	~3.5 million[2]	~3 million[2]	12 – 18 million
TX-001HR Potential Market	$700M-$875M[3]	$600M-$750M[3]	$2.4B-$4.5B[3]
TX-001HR Total Substitutable Market Opportunity	$3.7B – $6.1B		

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®, Brisdelle®
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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TXMD has the Most Comprehensive Body of Research Available Quantifying the Compounded BHRT Space

	Date	Purpose	Size
Consumer Survey Harris Interactive	July 2013	15 question Internet Survey to identify % of women going or having been through menopause and quantify symptoms and treatments utilized especially HRT	1,100 women age 45 to 60 with 801 completed survey
Consumer Survey Rose Research	April 2014	30 question Internet Survey to identify % of women using or who have used HRT and quantify (FDA approved vs Compounded) along with 40 detailed chats	17,825 women age 40 and over with 2,044 reporting use of HRT completing full survey
Physician Survey Rose Research	July 2014	20 question Internet Survey to identify prescribing patterns and volume of HRT for different groups of physicians (PCP, OBGYN, GYN & Wellness/Anti-aging) & reaction to our E+P drug candidate	762 physicians of which 440 qualified as prescribing HRT to women
Pharmacy Survey Rose Research	Dec. 2014	31 question Internet Survey to benchmark compounding metrics of community and compounding pharmacies including quantity, type and form of HRT	500+ community and compounding pharmacists (excluded national chain and hospital)
Consumer Survey Rose Research	July 2016	43 multi-part question survey to analyze the patient decision and use experience of women using these products to support product adoption and switch assumptions and to identify key drivers that promote adoption/switch	2,474 women (1,894 FDA approved users and 556 compounded users)
Physician Survey Rose Research	July 2016	21 multi-part question survey designed to analyze the physician treatment decision and prescribing preferences related to these products to support product adoption and switch assumptions and to identify key drivers that promote adoption/switch	600 HCPs (300 OBGYN & 300 PCP)
Pharmacy Survey Health Research & Analytics (an affiliate of Pharmacy Times)	Aug. 2016	52 multi-part question survey to compare trends in business of compounders since 2014 and to confirm size of compounding market specifically focusing on compounded estradiol and progesterone products	191 pharmacies: Focus on pharmacies that have at least 20% of business coming from compounding services (75% of responders)
Big Three Consulting Firm	Oct. 2016	Retained top-tier consulting firm to provide an independent opinion on the size of the E+P addressable compounding market	Includes additional physician survey data
BIO-IGNITE	Nov. 2016	Physical outreach to compounding pharmacy networks as well as independent pharmacies to quantify E+P scripts flowing through pharmacies that have interest in TXMD partnership	To date, >662 pharmacies: 2M E+P scripts

Methodologies to Quantify Compounded E+P Segments

Simple Extrapolation	Addressable %	Top-Tier Consultant Validation	BIO-IGNITE™
• Simple extrapolation from survey data applying average reported addressable prescriptions to universe of pharmacies that compound • Independent community pharmacies that compound = 14,500 • Compounding focused pharmacies = 3,500	• Quantify overall compounded hormone therapy market within compounding pharmacies • Apply percentage addressable E+P prescriptions to overall CBHRT market	• Segment pharmacies by size using prescription volume • Calculate average metrics based on category given dispersion in pharmacy size and business • Apply average metrics by category • Independent community pharmacies that compound = 14,500 • Compounding focused pharmacies = 3,500	• Outreach to individual compounding pharmacies and compounding pharmacy networks that are interested in working with TXMD • As an indication of interest, pharmacies provide E+P addressable prescriptions their pharmacies fill today
~14M E+P Prescriptions	**~12M E+P Prescriptions**	**~12M E+P Prescriptions**	**>12M E+P Prescriptions**

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Learnings from Our Research:

Problems Using Physician and Consumer Data to Quantify BHRT Market Size

- **Physician Survey Data:**
  - 67% of prescribers of compounded BHRT believe it is FDA-approved
  - Difficult to capture the population of compounded BHRT prescribers:
    - Prescribers are dispersed across specialties: OBGYN, PCP, and Wellness/Integrative
    - 3% of prescribers account for over 40% of compounded prescription volume
    - Internet panels of physicians are weighted toward high FDA-approved prescribers which under-represents prescribers of compounded products
- **Consumer Survey Data:**
  - 78% of patients believe their compounded products are FDA-approved
    - Example: Compounded products and FDA-approved products look very similar when they receive it from pharmacy
    - Physicians and pharmacists do not refer to products as compounded or FDA-approved
  - Distinguishing feature of consumer data is over half of menopausal women get their HRT prescription filled at an independent community pharmacy vs. chain or retail pharmacy

Pharmacies are only group with clear understanding of what is being dispensed

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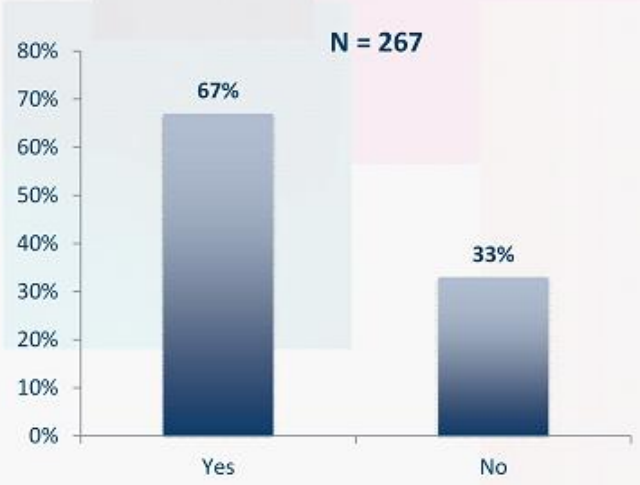
Compounded BHRT Market is Difficult to Extrapolate Using Physician Data

3 Primary Reasons

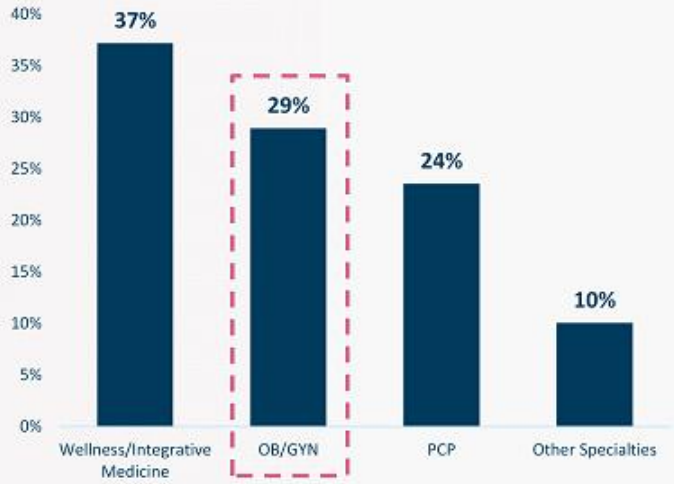
1 **67% of physicians who prescribe compounded BHRT falsely believe that these are FDA approved**

Are prescription compounded hormone replacement therapy products made by the compounding pharmacy FDA-approved?



2 **Prescribers are dispersed among 4 specialties with many high volume writers outside of OB/GYNs**

Weighted average based on script volume



2016 Physician Survey – Rose Research

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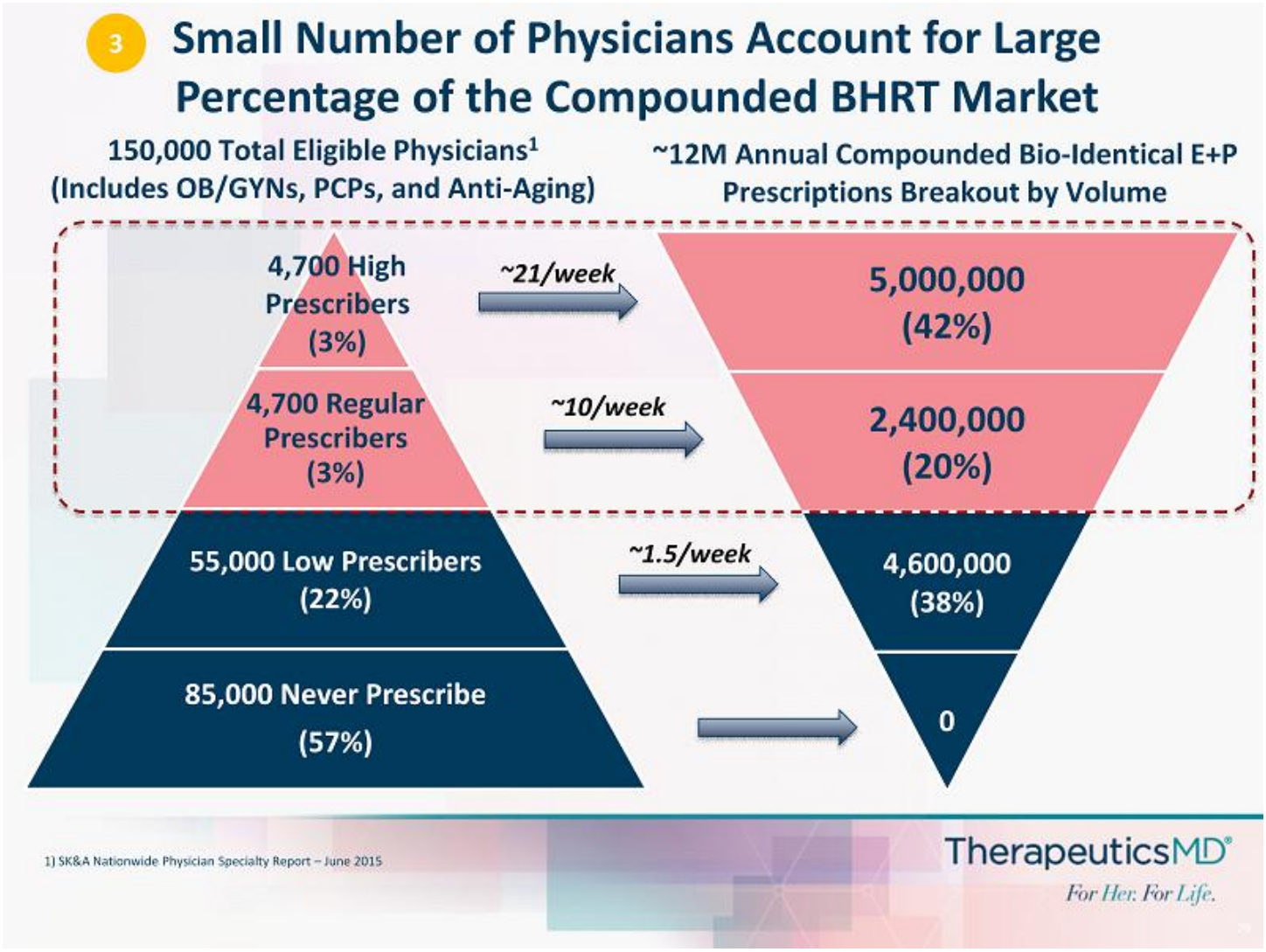
3
Small Number of Physicians Account for Large Percentage of the Compounded BHRT Market
150,000 Total Eligible Physicians[1]
(Includes OB/GYNs, PCPs, and Anti-Aging)
~12M Annual Compounded Bio-Identical E+P Prescriptions Breakout by Volume
4,700 High Prescribers (3%)
~21/week
5,000,000 (42%)
4,700 Regular Prescribers (3%)
~10/week
2,400,000 (20%)
55,000 Low Prescribers (22%)
~1.5/week
4,600,000 (38%)
85,000 Never Prescribe (57%)
0
1) SK&A Nationwide Physician Specialty Report – June 2015
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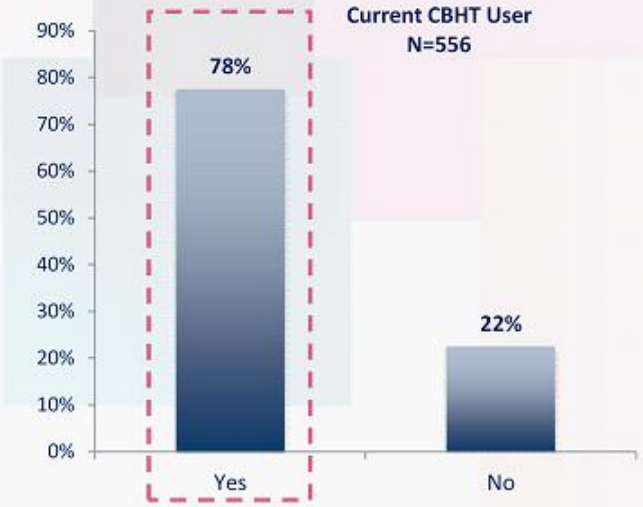
Compounded BHRT Market is Difficult to Extrapolate Using Consumer Data

2 Primary Reasons

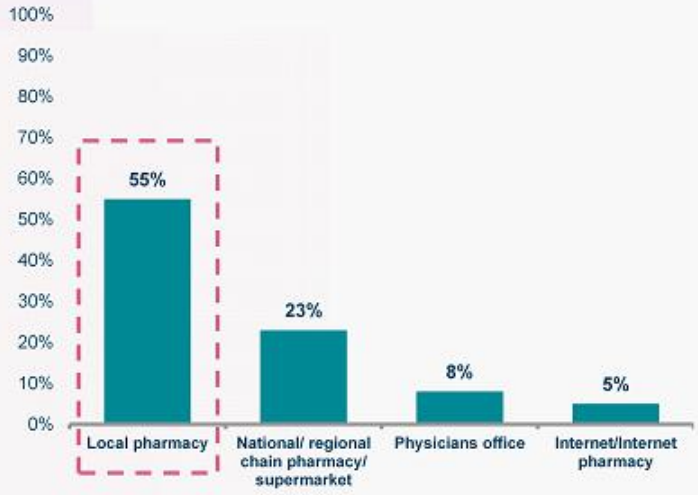
1 **78% of compounded BHRT patients falsely believe that their prescription is FDA-approved**

Do you believe that the product made specifically for you by your compounding pharmacy is FDA-approved?



2 **More than half of menopausal women purchased their hormone therapy at a "local pharmacy"**

Where was your therapy obtained?



2016 Consumer Survey – Rose Research

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Methodologies to Quantify Compounded E+P Segments

Simple Extrapolation	Addressable %	McKinsey Approach	BIO-IGNITE™
• Simple extrapolation from survey data applying average reported addressable prescriptions to universe of pharmacies who compound • Independent community pharmacies that compound = 14,500 • Compounding focused pharmacies = 3,000	• Quantify overall compounded hormone therapy market within compounding pharmacies • Apply percentage addressable E+P prescriptions to overall CBHRT market	• Segment pharmacies by size using prescription volume • Calculate average metrics based on category given dispersion in pharmacy size and business • Apply average metrics by category	• Outreach to individual compounding pharmacies and compounding pharmacy networks that are interested in working with TXMD • As an indication of interest, pharmacies provide E+P addressable prescriptions their pharmacies fill today
~14mm E+P Prescriptions	~12mm E+P Prescriptions	~12mm E+P Prescriptions	>12mm E+P Prescriptions

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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

~3.5M Potential Prescriptions for TX-001HR (if approved)
Market Opportunity = $700M-875M[2]

- This regimen carries **significant risk** of endometrial hyperplasia/cancer if the patient is non-compliant with regular progesterone use
  - Side effects of progesterone including 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

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FDA-Approved Combination Synthetic E+P Substitutable Market Opportunity

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

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Conclusions

- **Total E+P market size of $3.7B - $6.1B**
  - 12 – 18 million compounded E+P scripts
  - 6.5 million FDA-approved E+P scripts
- **Large, readily convertible compounded E+P market**
  - Meaningful economic incentives for compounding pharmacies to convert patients to TX-001HR
  - Regulatory incentives provide meaningful tailwinds
  - Compounding pharmacy partnerships enables rapid adoption

Launch Strategies & Case Studies

Joseph Auci
VP, Managed Care, Distribution, and Policy

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Understanding the Traditional Retail Pharmacy

Transactional Relationship

Patient feels sick

↓

Patient visits Physician

↓

Physician writes Rx

↓

Patient picks up Rx from Pharmacy

Traditional Retail Pharmacies
% of Business (by Prescription Units)

CVS, Walgreens, Duane Reade, …

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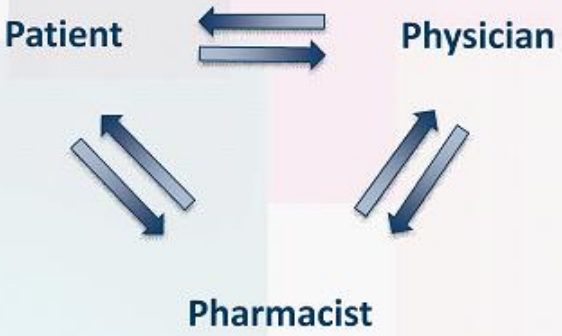
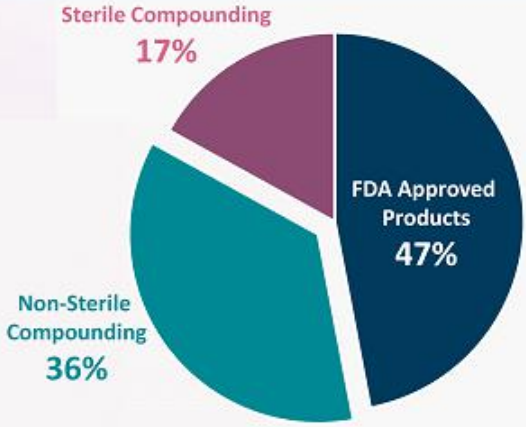
Understanding the Compounding Pharmacy

Collaborative Relationship



Compounding Pharmacies % of Business (by Prescription Units)



N = 3,000-3,500 Compounding Focused Pharmacies[1,2,3]

(1) 2013 National Community Pharmacists Association Digest: Financial Benchmarks (Sponsored by Cardinal Health)
(2) NCPA Community Pharmacy Compounding Survey (November 2012)
(3) NPI Database: using taxonomy codes

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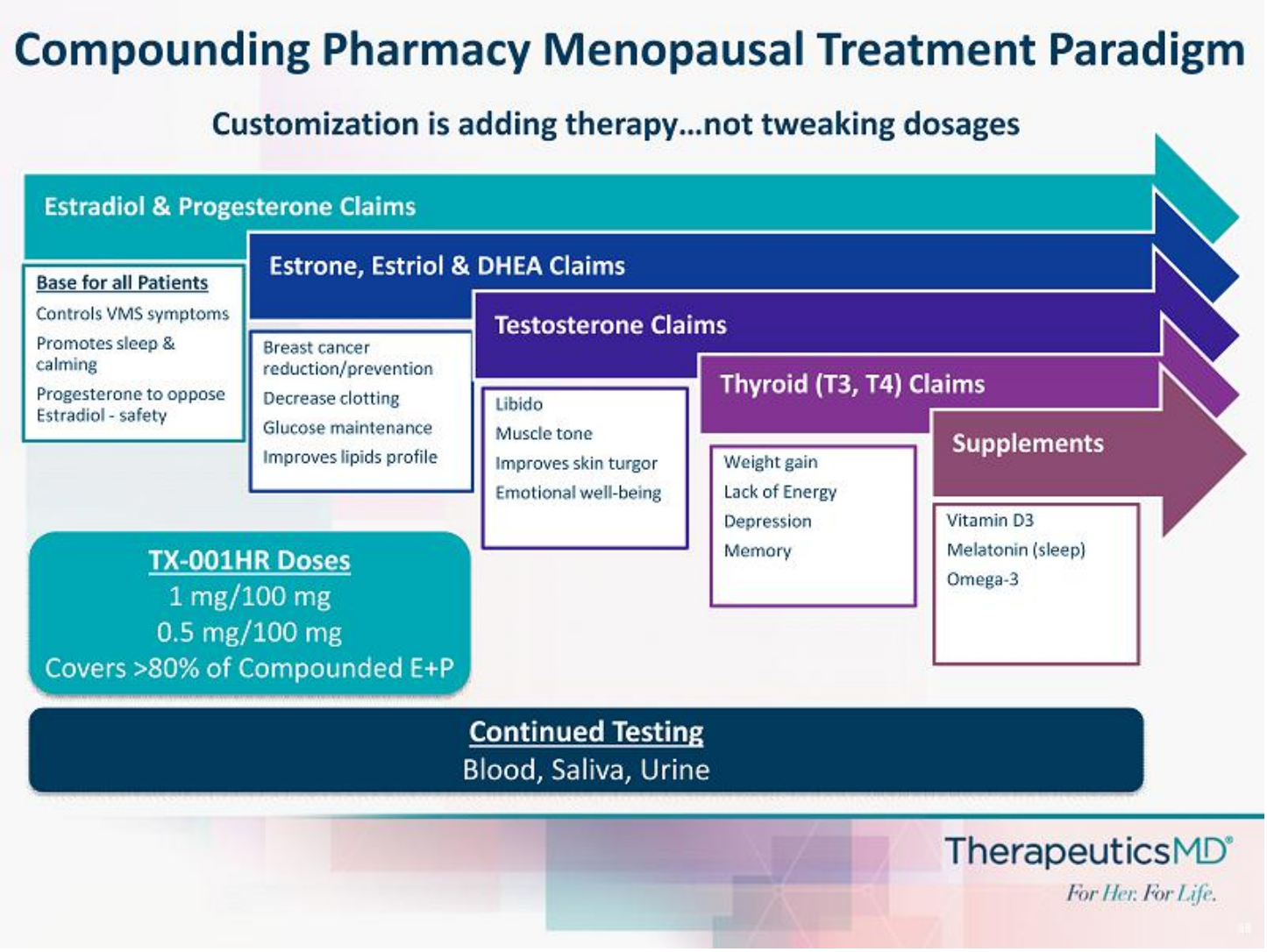
Compounding Pharmacy Menopausal Treatment Paradigm
Customization is adding therapy…not tweaking dosages
Estradiol & Progesterone Claims
Base for all Patients
Controls VMS symptoms
Promotes sleep & calming
Progesterone to oppose Estradiol - safety
Estrone, Estriol & DHEA Claims
Breast cancer reduction/prevention
Decrease clotting
Glucose maintenance
Improves lipids profile
Testosterone Claims
Libido
Muscle tone
Improves skin turgor
Emotional well-being
Thyroid (T3, T4) Claims
Weight gain
Lack of Energy
Depression
Memory
Supplements
Vitamin D3
Melatonin (sleep)
Omega-3
TX-001HR Doses
1 mg/100 mg
0.5 mg/100 mg
Covers >80% of Compounded E+P
Continued Testing
Blood, Saliva, Urine
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BIO-IGNITE™

Compounding Pharmacy Partnership Strategy

BIO-IGNITE™ is an outreach program to quantify the number of compounded bio-identical estradiol and progesterone prescriptions currently dispensed by the 3,000-3,500 high-volume compounding pharmacies, and qualify their interests in distributing our hormone product candidates, if approved.

Phase 1:
Understand and identify the high volume pharmacies and prescribers that have developed a specialty focus around women's menopausal health

Phase 2:
Work with these specialists to transition patients from unapproved compounded therapies to an FDA-approved treatment

Compounded E+P Conversion Strategy

Objective

- Collaborate to expand utilization of BHRT for menopausal women
- Convert the majority of compounded preparations for E+P to TX-001HR

Tactics

- **Create a cooperative network**
  - Establish relationships with top BHRT compounding pharmacies to execute Rx transitions to approved product
  - Concentrate on high BHRT compounding geographies (e.g., CA, FL, NY, VA, TX and others)
- **Utilize typical pharmacy programs**
  - Programs for patient education and outreach
  - Programs to improve compliance and persistency
  - Patient adherence programs
  - Pharmacy Medical Therapy Management (MTM) programs
- **VitaCare™ Referral Approach**
  - Link VitaCare customer service hub to cooperative compounding network pharmacies to improve the patient care and experience

BIO-IGNITE Progress and Results

Partnerships with Large Pharmacy Network and Individual Pharmacies

Pharmacy Network and Individual Pharmacy Partners	# of Pharmacies	Combination Bio-Identical E+P Scripts
Premier Value Pharmacy Compounding Network	>300 Pharmacies In Network	~1,500,000 prescriptions annually
TXMD Outreach to Individual Pharmacies	362 Pharmacies with Prescription Data	~500,000 prescriptions annually

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TXMD Is Not Re-Inventing The Wheel

- Makena® Case Study
- Androgel® Case Study

Case studies are for example only and not indicate of how other products, including TX-004HR, may perform.

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Makena® Case Study: History

- **Makena® approved and launched in February 2011 by KV Pharmaceutical**
  - Planned to limit distribution and rely on FDA enforcement
- **FDA and CMS guidance on 3-31-2011 stated that there will be no government enforcement of making "essential" copies of a commercially available product**
  - DQSA had not yet been implemented
- Payers and state Medicaid plans publicly stated that only compounded product will be covered
  - Backlash on pricing was immediate and significant
- In response to significant pricing criticism, on April 1, 2011, KV reduced price from $1,500 per injection to $690 per injection
- Sales struggled and company began taking legal action against the FDA and numerous states (GA, AL, SC, TX & IL)
- **June 2012 - FDA submitted a "weak" statement recommending providers use Makena® over compounded product but no legal action**
  - KV Pharmaceutical subsequently won its lawsuit in GA and negotiated contracts with IL, SC, and TX
  - The company began signing additional contracts with payers in 2012 but sales did not significantly grow

Makena® Case Study: History

- **KV Pharmaceutical entered bankruptcy in August 2012 with less than 3% market share**
  - "Overall, the FDA's public stance on compounding 17P and failure to take enforcement action against compounding pharmacies combined with CMS reimbursement policies invited numerous compounders back into the market and resulted in substantial sales of compounded alternatives to Makena® and effective loss of the Company's orphan drug marketing exclusivity for the affected period of time. Moreover, limited reimbursement for Makena® under various State Medicaid programs had a severe negative impact on Makena® sales and the Company's overall business prior to the Petition Date"
- **September 2012 – New England Compounding Center meningitis breakout occurred**
- Most payers and physicians did not change their stance towards compounded product, but institutional sales began growing through negotiated contracts
  - Introduced difficult "buy and bill" opportunity with hospitals, clinics, and DOD
- KV Pharmaceutical emerged from bankruptcy in September 2013 and changed the company name to Lumara Health
- **Lumara Health achieved significant growth in 2014 through collaboration with compounding pharmacies**
  - Attained coverage never experienced before
  - Achieved patient and prescriber growth
- **Lumara Health is acquired by AMAG in November 2014 for over $1B ($675M upfront and $350M in sales milestones)**

Makena® Case Study: Collaboration Works

- Collaboration discussions begin with the compounding pharmacy community in 4Q13
- Initial distribution agreements finalized in 1Q14
- Broad distribution implemented in 2Q14 and growth significantly expanded
- 2Q14 volume growth of 38% q/q and 32% y/y
- 2Q14 sales growth of 59% q/q and 77% y/y

Volume and Sales Growth of Makena®

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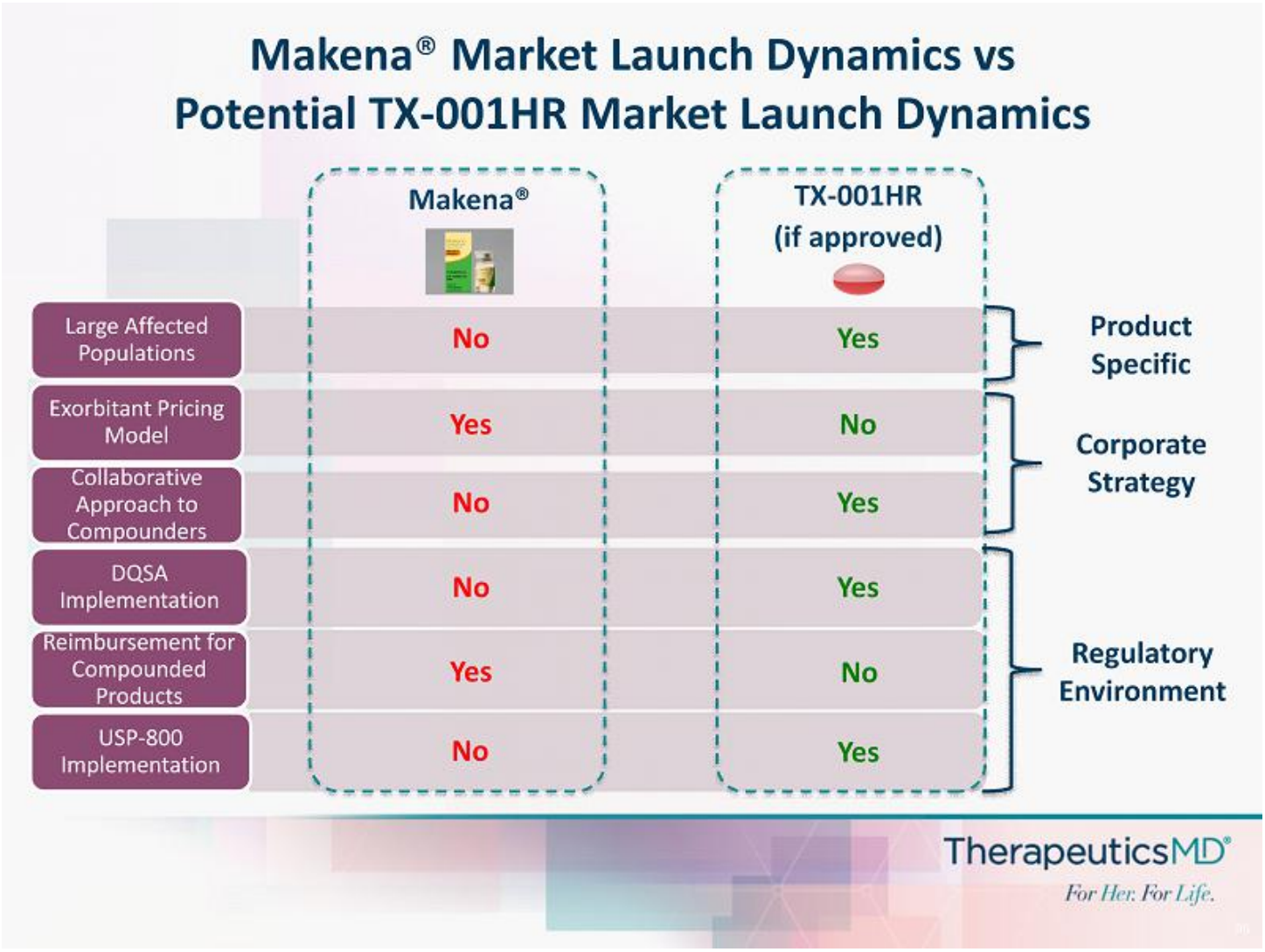
Makena® Market Launch Dynamics vs Potential TX-001HR Market Launch Dynamics
Makena®
TX-001HR (if approved)
Large Affected Populations
No
Yes
Product Specific
Exorbitant Pricing Model
Yes
No
Collaborative Approach to Compounders
No
Yes
Corporate Strategy
DQSA Implementation
No
Yes
Reimbursement for Compounded Products
Yes
No
USP-800 Implementation
No
Yes
Regulatory Environment
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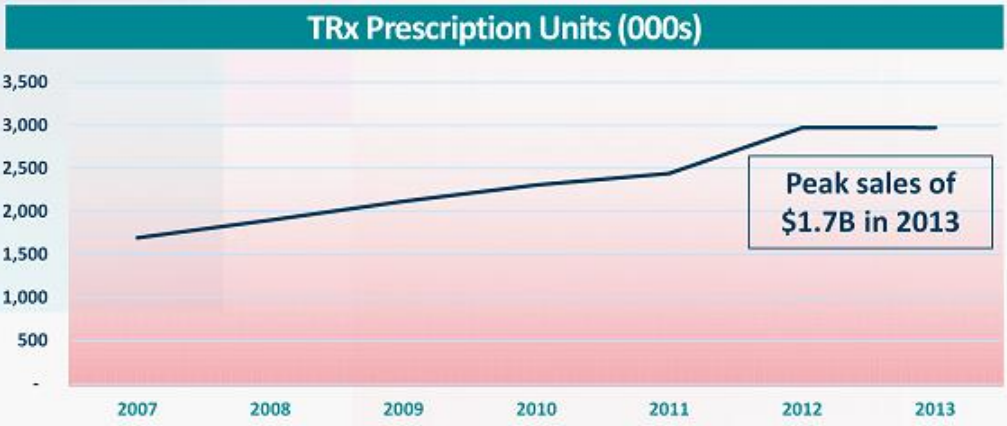
AndroGel® Case Study: Example of an FDA-Approved Drug Replacing an Unapproved Compounded Product

- Pre-2000, unapproved compounded bio-identical testosterone was heavily compounded whereas synthetic FDA-approved methyltestosterone sales were small
- In 2000, AndroGel® launched as the first FDA-approved bio-identical testosterone and became the leader in the category



Source: IMS, Symphony and EvaluatePharma

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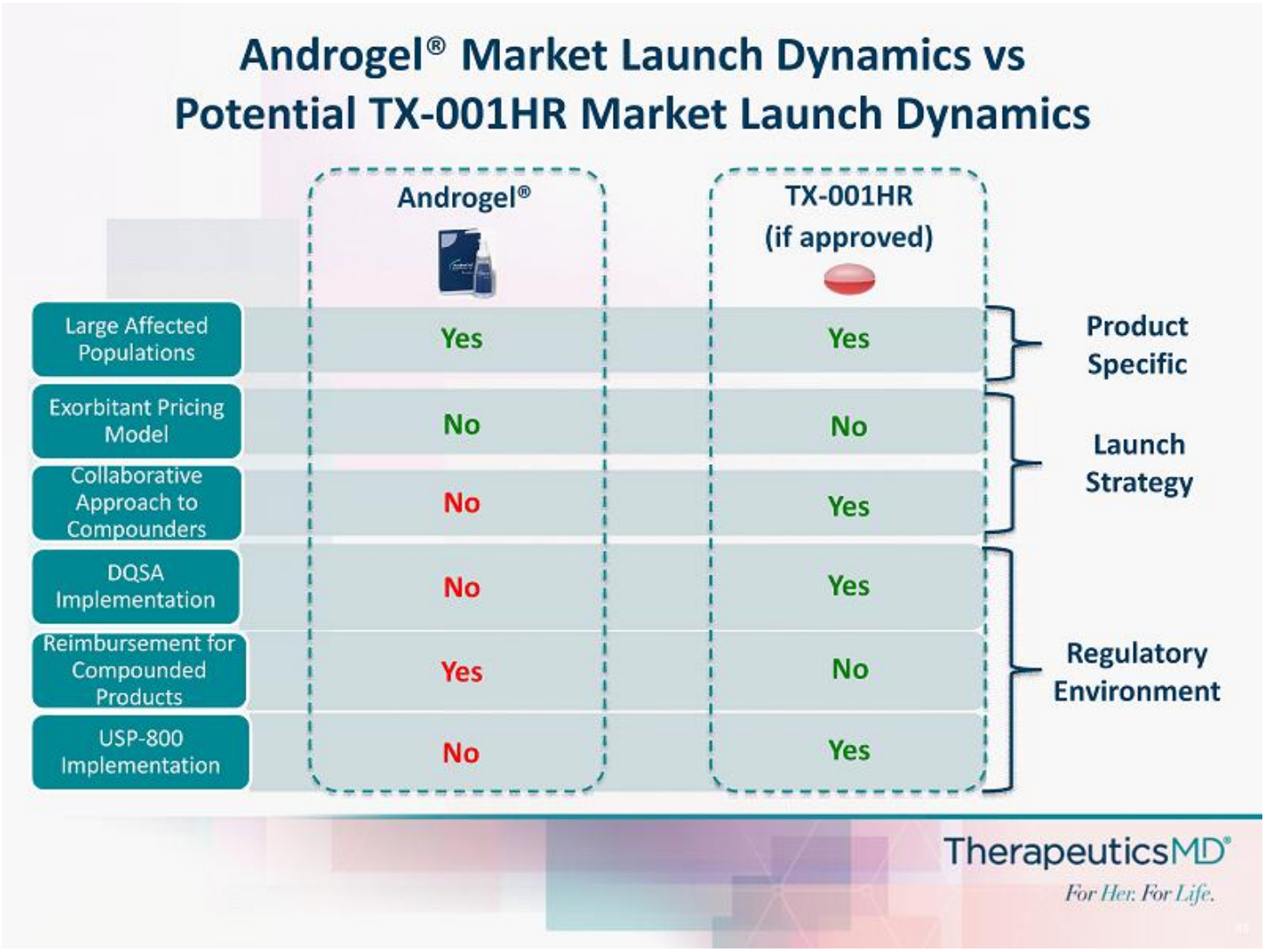
Androgel® Market Launch Dynamics vs Potential TX-001HR Market Launch Dynamics
Androgel®
TX-001HR (if approved)
Large Affected Populations
Yes
Yes
Exorbitant Pricing Model
No
No
Collaborative Approach to Compounders
No
Yes
DQSA Implementation
No
Yes
Reimbursement for Compounded Products
Yes
No
USP-800 Implementation
No
Yes
Product Specific
Launch Strategy
Regulatory Environment
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Numerous Other Examples of Prior Success

- **Multiple examples exist where replacing less effective or unapproved compounded options with FDA-approved treatments captured significant market share and became standards of care**

Previously Compounded Preparations Evolved to FDA-Approved Products

- Rectiv – nitroglycerin gel for treatment of anal fissures
- Mitocin – treatment of glaucoma
- Neudexta – treatment of pseudo bulbar affect disorder
- Rogaine – topical treatment for alopecia
- Cleocin Solution/Gel – topical treatment of acne vulgaris
- Endometrin – vaginal suppository formulation of progesterone
- Crinone & Prochieve – progesterone vaginal gel

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

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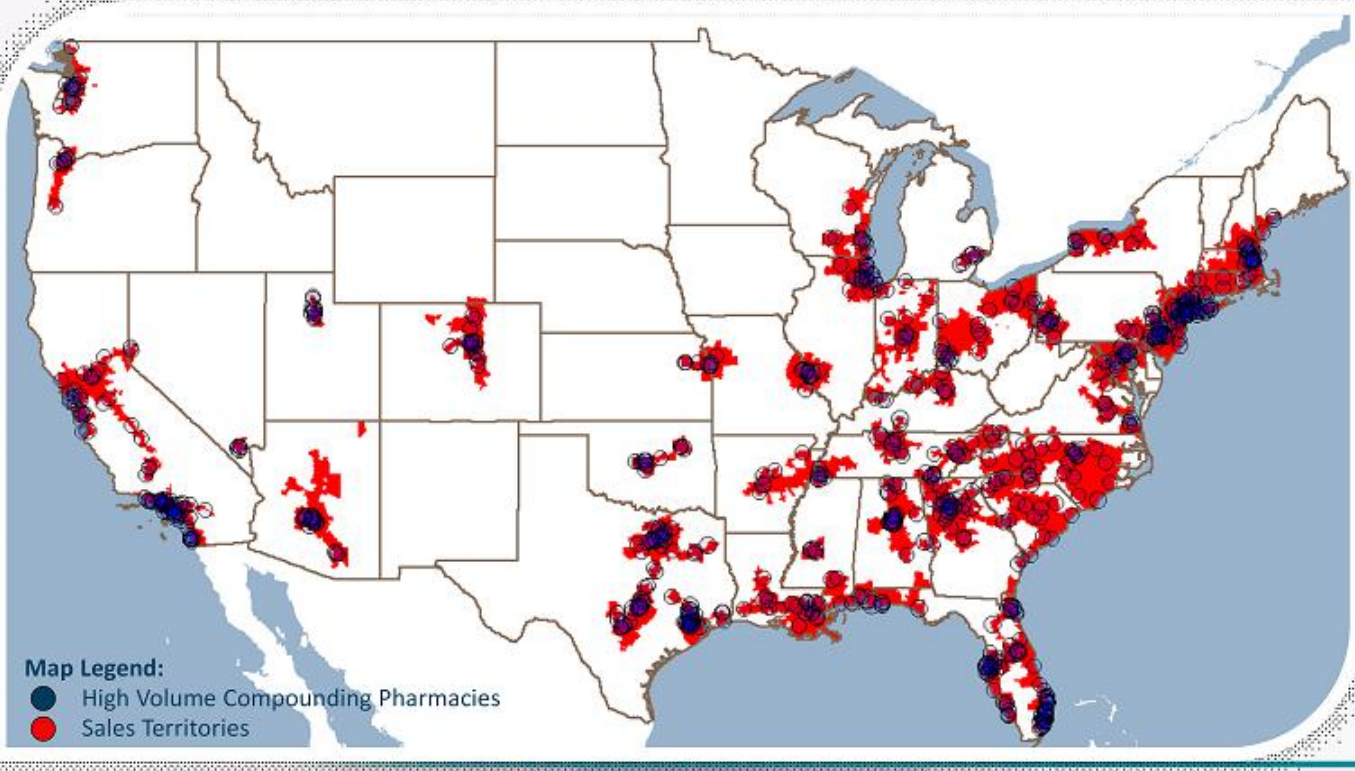
TXMD Salesforce Has High Overlap with Targeted Compounding Pharmacies to Drive Successful Conversion



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[DRAFT]

Compounding Regulatory Dynamics

David Miller, R.Ph.

- Former Executive VP and CEO for the International Academy of Compounding Pharmacists (2010-2015)
- Director of Pharmacy Affairs at Merck (1996-2010); involved in launch planning, distribution and stocking programs for more than a dozen products
- Advisor and committee member for American Pharmacists Association (APhA), National Community Pharmacists Association (NCPA), National Association of Chain Drug Stores (NACDS), National Alliance of State Pharmacy Associations (NASPA), and many others

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Regulatory Changes Have Constrained the Compounding Pharmacy Marketplace

Drug Quality & Security Act of 2013 gave the FDA unprecedented authority and enforcement, which represents an on-going risk burden for compounders

The FDA is actively enforcing DQSA and coordinating disciplinary action with state regulatory agencies[1]

- 350+ inspections of compounders
- Issued more than 130 warning letters and more than 30 letters referring inspectional findings to state Boards
- Oversaw about 100 recalls involving compounded drugs
- Worked with DOJ on civil and criminal enforcement
- Issued 18 draft guidances, seven final guidances, two proposed rules, a final rule, and a draft memorandum of understanding

Guidance documents and regulations introduce greater risk for compounders

- Prohibits duplication of commercially available products – limiting dose variation, dosage forms – including BHRT
- Prohibits compounding of "demonstrably difficult" products
- Mandates individual patient prescriptions and eliminates sales directly to prescribers – including BHRT
- Limits types of bulk ingredients used by compounders (e.g., positive list, negative list)

1) FDA's Human Drug Compounding Progress Report: Three Years After Enactment of the Drug Quality and Security Act, January 2017

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Elimination of Coverage and Reimbursement Slashed Compounding Revenue Stream

Questionable billing practices by compounders caused insurers and PBMs to terminate coverage in 2014, reducing revenue by ~90%

Uncontrolled billing by compounders drove the category to the third most PMPM spend for managed care by 2013[1]

- January 2013 – Optum became first PBM to phase in management of compound billing; costs continued to rise[2]
- May 2014 – CVS/Caremark mandated clinical support for all compounds, PAs, and terminated coverage for certain bulk ingredients
- July 2014 – Express Scripts eliminated thousands of bulk ingredients from coverage
- September 2014 – ESI extended prohibition on compounding to include therapeutic categories
- 2014/2015 – DOJ investigations into fraudulent billing to Tricare - $5 million in 2004 to $514 million in 2014[3]

Establishing a Well-Balanced Approach to Compound Drug Management. Presented at AMCP Nexus Program, October 2015.

1 *2014 Annual Drug Spend Trend Report,* Express Scripts. https://lab.express-scripts.com/lab/drug-trend-report/previous-reports
2 *Restoring trust for compounded medications,* Optum, February 2016, https://www.optum.com/resources/library/restoring-trust-compound-medications.html
3 *Controls Over Compounds At the Defense Department* - Report No. DODIG-2016-105, July 1 2016 http://www.dodig.mil/pubs/documents/DODIG-2016-105.pdf

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Mandatory USP-800 Compliance Creates New and Unplanned Expenses by July 2018

The cost burden of USP-800 will cause many compounders to exit the compounded hormone replacement market space

Initial investment of $100,000 to $750,000 per pharmacy

Ongoing costs of ~$10,000 to $25,000/month per pharmacy

To continue to compound hormones, which are considered hazardous drugs, all pharmacies must comply with new requirements for infrastructure, training, and testing.

- Investment in externally vented, physically separate, negative pressure environment with ante-room
- Dedicated equipment used only for compounding of hazardous drugs
- Personnel training with annual assessment, and documentation of competency
- Gowning and testing equivalent to sterile drug laboratories
- Every six months sampling of air quality and environmental containment at average cost of $400 per drug
- Development, review and ongoing compliance with NIOSH lists, internal assessments, and documentation

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What USP-800 Really Means

Compounding BHRT Today

Adolphe Pierre-Louis - Albuquerque Journal – 2/13/2017

Compounding BHRT after July 2018

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Compounding Pharmacy Economics

Richard Moon, PharmD, R.Ph.

Principal, Premier Value Pharmacy Compounding Network

- Represents one of the largest compounding pharmacy networks
- Owner of Pharmacy Innovations, a group of 7 specialty and compounding pharmacies throughout the United States
- Former IACP President, Treasurer, and Board Member

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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

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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

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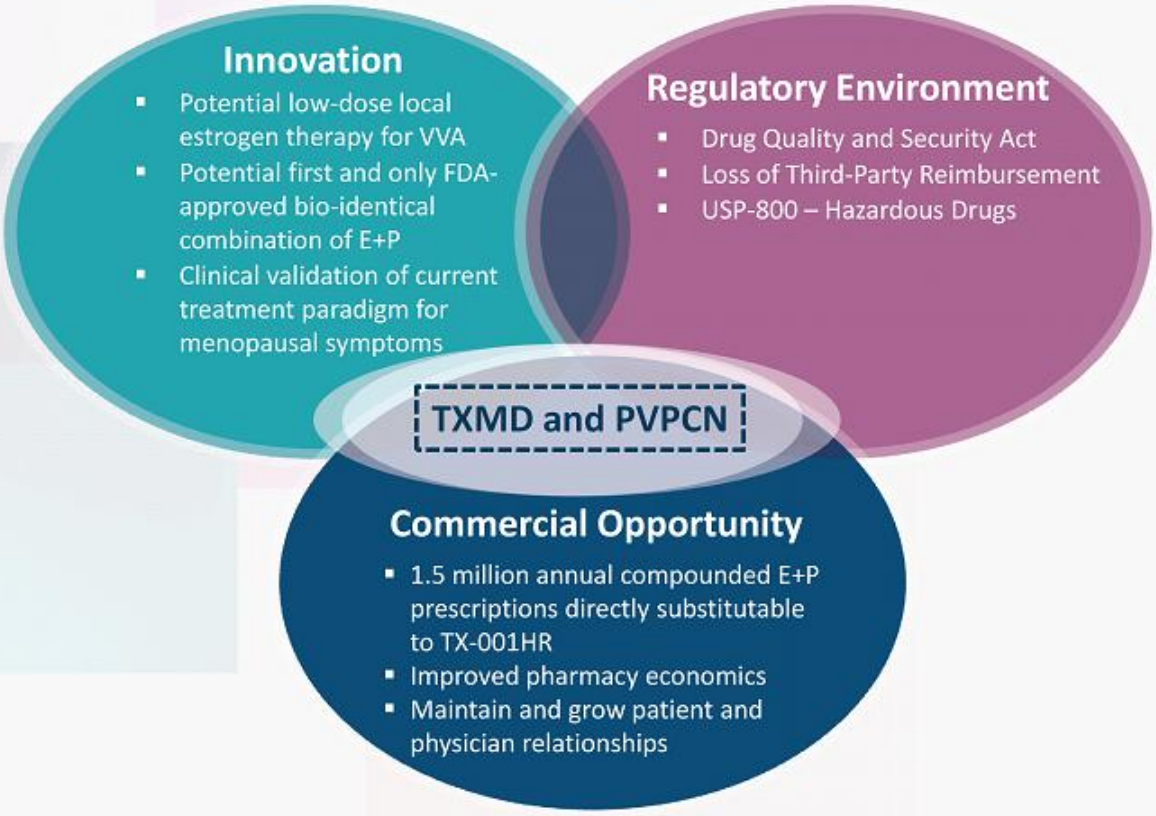
PVPCN Distribution Agreement Rationale



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Q&A

Panel

Joseph Auci

David Miller

Sebastian Mirkin, M.D.

Rich Moon

James Pickar, M.D.

John Walcyzk

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Closing Remarks

Robert Finizio
Chief Executive Officer

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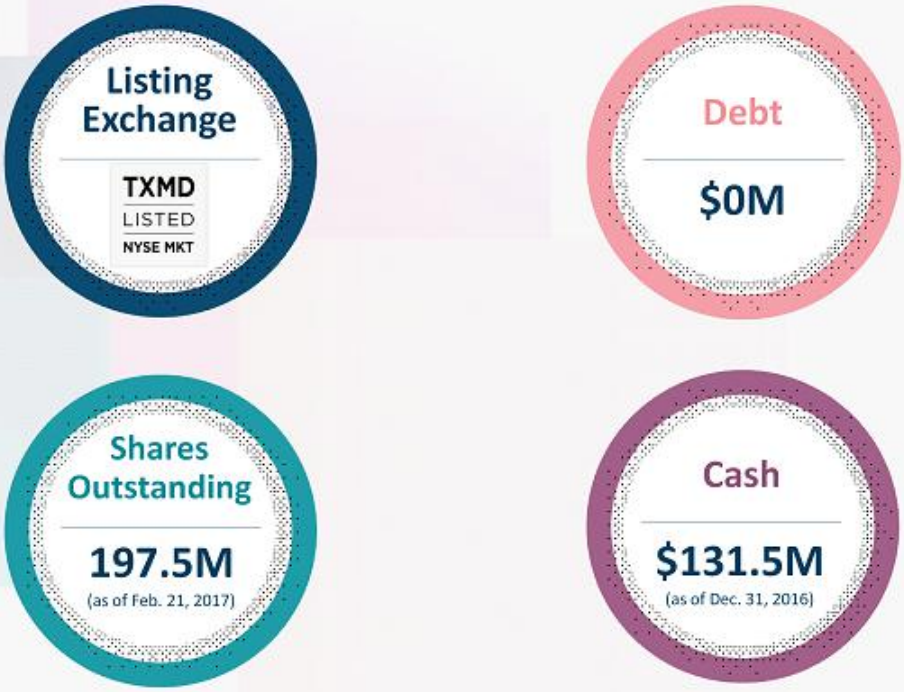
TXMD: Financial Snapshot



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Worldwide Patent Filings*

Strong IP Portfolio with 144 Patent Applications, including 74 international filings, and 17 issued U.S. patents

*Not all patent filings filed in all jurisdictions.

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