UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): January 9, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230-405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on January 9, 2018 and at subsequent meetings with investors or analysts.

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

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated January 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 9, 2018

THERAPEUTICSMD, INC.

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

Exhibit 99.1


TXMD Overview
January 2018
TherapeuticsMD®
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TherapeuticsMD.com
THER-0086 01/18

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 are 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 Current Reports on Form 8-K, and include the following: our ability to resolve the deficiencies identified by the FDA in our new drug application for our TX-004HR product candidate and the time frame associated with such resolution; whether the FDA will approve the amended NDA for our TX-004HR product candidate and whether such approval will occur by the PDUFA target action date; our ability to maintain or increase sales of our products; our ability to develop, protect and defend our intellectual property; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; whether the FDA will accept and approve the NDA for our TX-001HR product candidate; the length, cost and uncertain results of our clinical trials; the potential of 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 and other 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.

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

	TX-004HR	TX-001HR
		
Proposed Indication	Moderate to severe dyspareunia, a symptom of VVA, due to menopause	Moderate to severe hot flashes due to menopause
Condition Description	VVA due to Menopause	Menopause
Active Ingredients	Bio-Identical 17 β-Estradiol	Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone
Form	Vaginal softgel capsule	Oral softgel capsule
Key Value Proposition	Easy to use, negligible systemic exposure, designed to support long-term use	Potential first and only bio-identical FDA-approved combination product
Affected US Population	32 million women[1,2]	36 million women[3]
US TAM Opportunity	>$20B[5]	>$25B[4,5]
Status	NDA resubmitted Nov. 29, 2017 PDUFA Target Action Date: May 29, 2018	NDA submitted Dec. 28, 2017 Expected PDUFA Target Action Date: Oct. 2018

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
2) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.
3) Derived from U.S. Census data
4) Based on pre-WHI annual scripts of FDA-approved HT products
5) Based on market pricing of current FDA-approved HT products

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Significant Catalysts Within Next 12 Months

TX-004HR

December 2017
Acceptance of the NDA for TX-004HR

May 29, 2018
PDUFA target action date for TX-004HR

3Q 2018
Potential launch of TX-004HR*

December 2017
Submission of the NDA for TX-001HR

March 2018
Receipt of 74-Day Filing Letter acknowledging acceptance of the NDA for TX-001HR

October 2018
Potential approval of the NDA for TX-001HR**

1Q 2019
Potential launch of TX-001HR**

TX-001HR

*Assumes approval on or before PDUFA target action date of May 29, 2018
**Assumes 10-month 505(b)(2) review timeline

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Complete Financing Strategy In Place

Phase 1	Phase 2	Phase 3
Equity Financing	**Term Loan Debt Financing**	**Partnership Opportunities**
▪ $68.6M equity offering, closed on September 28th ▪ Secures near term financing needs for TX-004HR launch, if approved ▪ Strengthens Phase 2 debt financing negotiating position	▪ Targeting commitments of $150M-$200M in debt financing in 1Q18 ▪ Anticipate first draw of debt financing following approval of TX-004HR or TX-001HR ▪ Secures medium term financing needs for TX-004HR and TX-001HR launches, if approved	▪ Potential for upfront payments and royalty revenue streams to further support additional product opportunities

Phase 1 and Phase 2 provide potential access to ~$300M of capital to support commercialization of TX-004HR and TX-001HR*

*Includes cash and cash equivalents on hand

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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

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

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

Christine Miller, PharmD.
Chief Regulatory and Quality Officer

- 30+ years of regulatory, quality, and drug development experience
- Sr. Vice President, Drug Development at Sirion Therapeutics
- VP of Regulatory Affairs and Quality Assurance at Santarus
- Global Vice President, Regulatory Affairs at Bausch and Lomb

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

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®

Christian Bloomgren
VP, Sales

- 16+ years of experience in the pharmaceuticals and biotech
- Created a national sales channel, led the Specialty Diagnostics business at ViaCell, Inc.
- Product launch and sales management roles at Eli Lilly & Company and KV Pharmaceutical
- Served as an Officer in the United States Air Force

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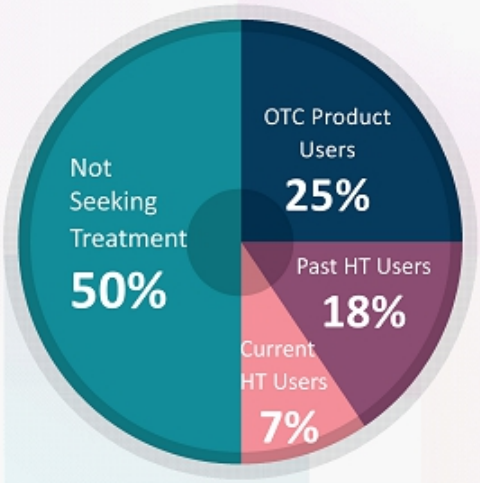
Current US VVA Market Overview



>$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.S1469
* 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	DUCHESNAY USA	amag
FDA Approval	1984	1978	1999	1996	2013	2016
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			Approval Without Dryness Data	Week 12

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

*Onset of Action = First efficacy observation

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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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[4]	Patient Count[5]	Patient Share[5]
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.
4) Symphony Health Solutions PHAST Data powered by IDV; Annual 2016
5) IMS SDI's Total Patient Tracker; Annual 2016

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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

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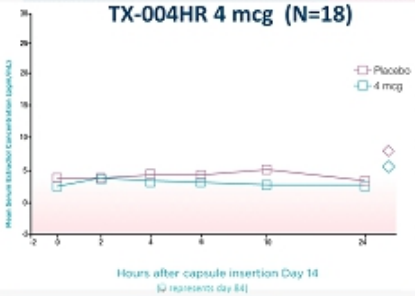
Co-Primary and Key Secondary Efficacy Endpoints

	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

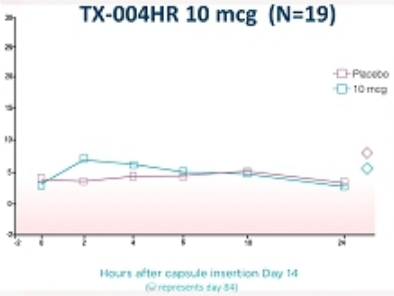
Arithmetic Mean Estradiol Serum Concentrations – Unadjusted

TX-004HR 4 mcg (N=18)



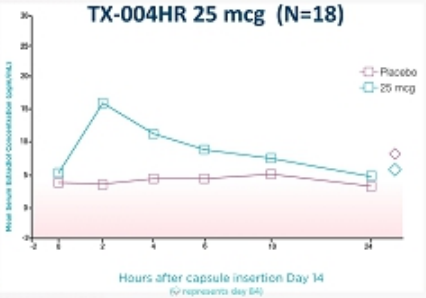
Hours after capsule insertion Day 14

TX-004HR 10 mcg (N=19)



Hours after capsule insertion Day 14

TX-004HR 25 mcg (N=18)



Hours after capsule insertion Day 14

	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 Approval and Launch Timelines

- Sales force build and preparedness
- Payer pipeline discussions
- Launch planning

- **PDUFA date - May 29th**
- Continued payer outreach to secure broad coverage

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

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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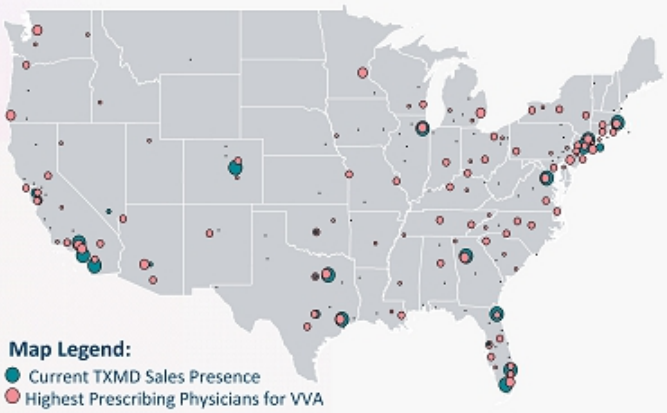
Foundation Already Built for a Strong Launch

TXMD Sales Force Currently in OB/GYN Offices

- 40% overlap with current prenatal vitamins business
- Currently calling on VVA targets with disease awareness campaign
- Planned sales force of 150 in place prior to launch
- Partnership with inVentiv, leading contract sales organization
- Operational and analytic systems



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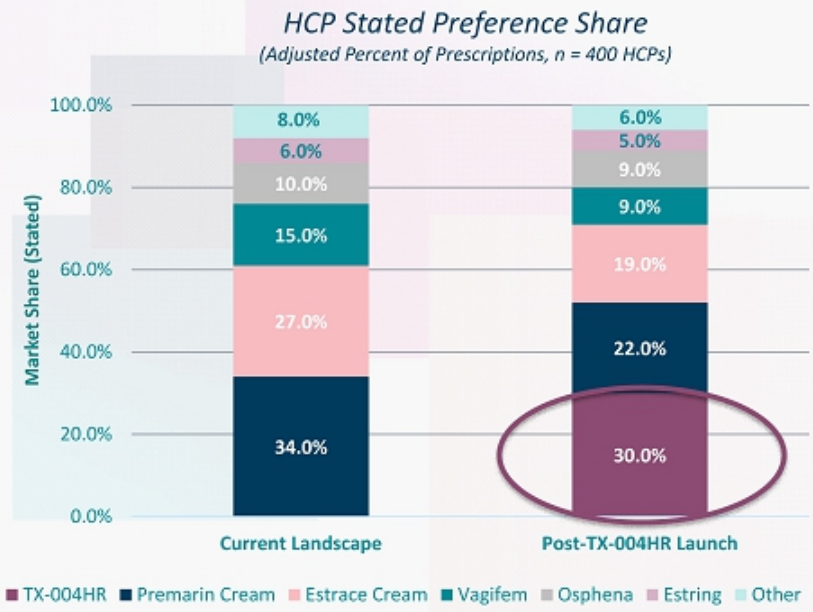
HCPs Estimate Giving TX-004HR 30% Market Share



- 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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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* 2014:8 23-30 doi:10.4137/CMRH.S14498
REJOICE Trial Results

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Increasing Compliance Through National Care Model Represents TXMD Core Competency

Prenatal Vitamins Market	VVA Market
▪ Market Dynamics: ▪ No Drug Claims ▪ 9 month condition	▪ Market Dynamics: ▪ Clinical and physical product differentiation ▪ Chronic, progressive condition
▪ Industry Average Patient Compliance: ▪ 2.5 fills per pregnancy	▪ Industry Average Patient Compliance: ▪ Vaginal Creams: 1.5 fills per year ▪ Vaginal Tablets: 3.5 fills per year
▪ TXMD Compliance with National Care Model: ▪ 8 fills per pregnancy	▪ Potential Compliance with National Care Model: ▪ Greater than 4 fills per year

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Market Share Gains and Fills Per Year Drive 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%

TX-004HR Net Revenue at Year 5
>$400 Million
4 Fills Per Year

- Pricing at parity to Vagifem
- Zero price increases
- Zero market growth

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

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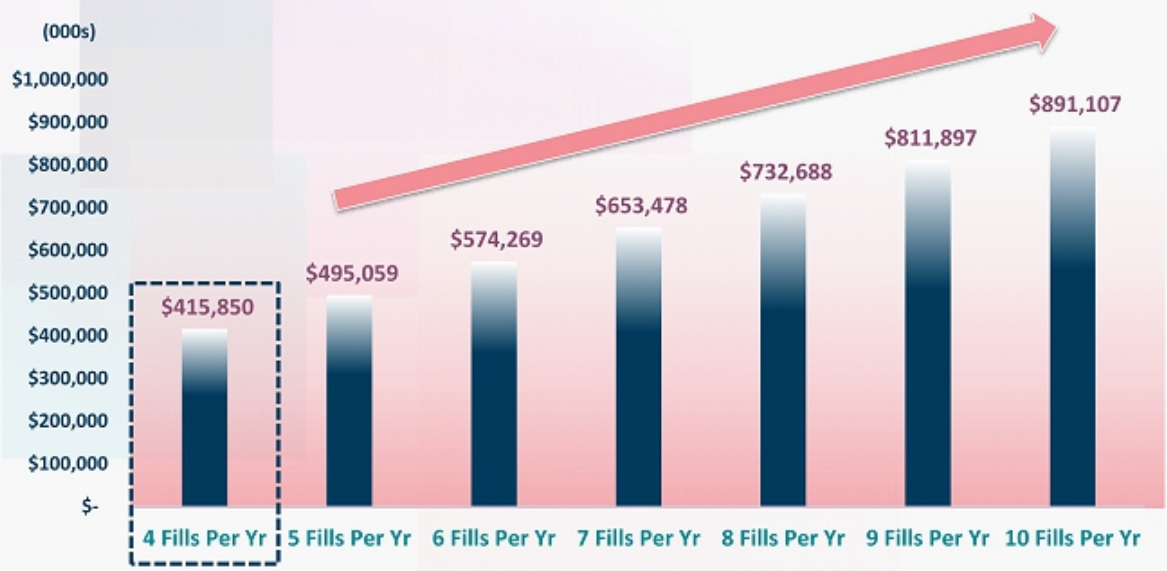
Incremental Fills Per Year Drives Significant Upside to TX-004HR Net Revenues

- Each incremental fill per year adds >$75M to TX-004HR net revenues



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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	9,508,973	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	5,442,846	Preferred	Covered	Covered	Preferred	Preferred
Health Care Service Corporation	5,135,711	Preferred	Covered	Covered	Covered	Preferred
Department of Veterans Affairs (VHA)	4,803,318	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)	2,201,309	Covered	Covered	Covered	Preferred	Covered
Blue Shield of California	1,834,377	Preferred	Preferred	Covered	Preferred	Preferred
Prime Therapeutics	1,885,924	Preferred	Covered	Covered	Covered	Preferred
Blue Cross and Blue Shield of Florida, Inc.	1,851,938	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?

- Overall low cost category compared to other therapeutic areas
- Importance of providing choice for women
- Prior authorizations and step edits are not economically favorable for payers and do not currently exist
- **Cost of a prior authorization runs between $80-$140 per patient per year depending on payer**

Favorable Payer Dynamics: No Substitution Across Branded Products

Case Study: Yuvafem Authorized Generic Launch (Year 1)

- Yuvafem launch in October 2016

	VVA TRx Market Share (%) Oct 2015-Sept 2016	VVA TRx Market Share (%) Oct 2016-Sept 2017	Gains (Losses)
Vagifem	29.2%	9.3%	(19.9%)
Yuvafem	-	19.7%	19.7%
Total	29.2%	29.0%	(0.2%)

- Yuvafem continues to take market share from **only** Vagifem
- Total Vagifem and Yuvafem TRx have lost 20 bps of VVA TRx market share to other branded products
- No substitution or cannibalization of other branded products

Symphony Health Solutions PHAST Data powered by IDV
Vagifem and Yuvafem (authorized generic of Vagifem)

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TX-001HR
Combination
Estrogen + Progesterone
(E+P) Program
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26

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/

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 treatment options:
      - 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 Estrogen/Ineffective Progesterone leads to increased risk of endometrial hyperplasia / cancer

ACOG | ENDOCRINE SOCIETY | NAMS The North American Menopause Society | INTERNATIONAL MENOPAUSE SOCIETY

1) Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee, Number 532, August 2012 (Reaffirmed 2014, Replaces No. 387, November 2007 and No. 322, November 2005).

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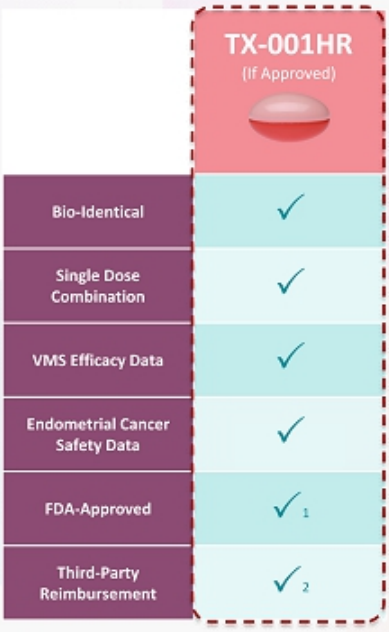
TX-001HR – Potential Best in Class Therapy



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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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

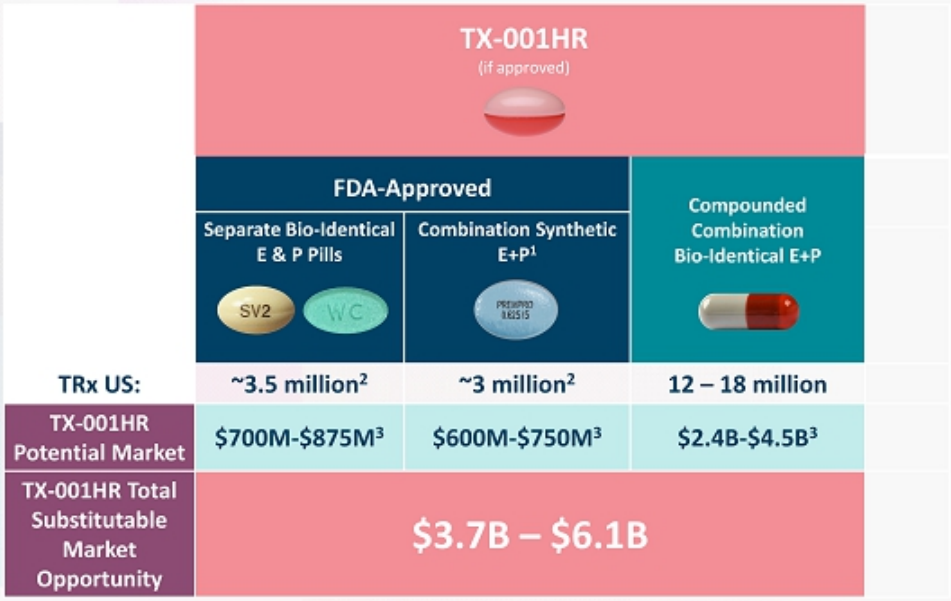
[Ŧ]Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

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**

Multi-Billion Dollar Total Substitutable Market Opportunity



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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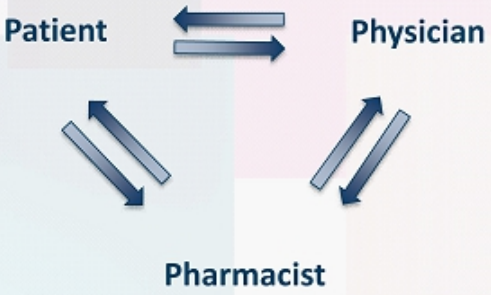
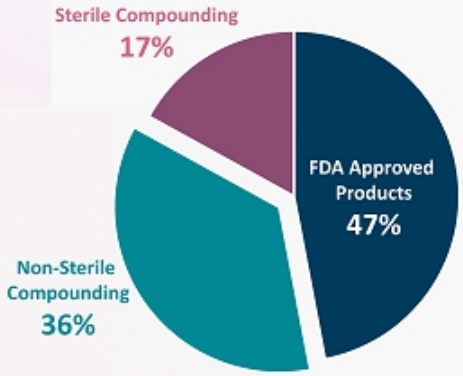
Understanding the Compounding Pharmacy

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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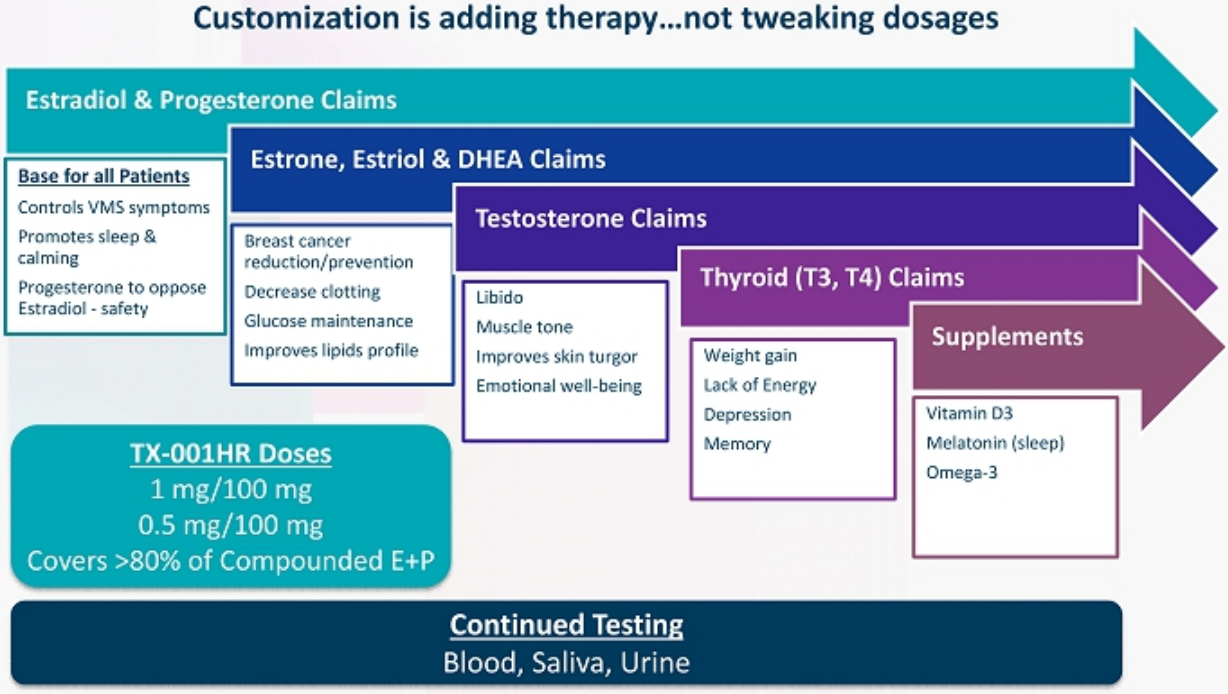
Compounding Pharmacy Menopausal Treatment Paradigm

Customization is adding therapy…not tweaking dosages



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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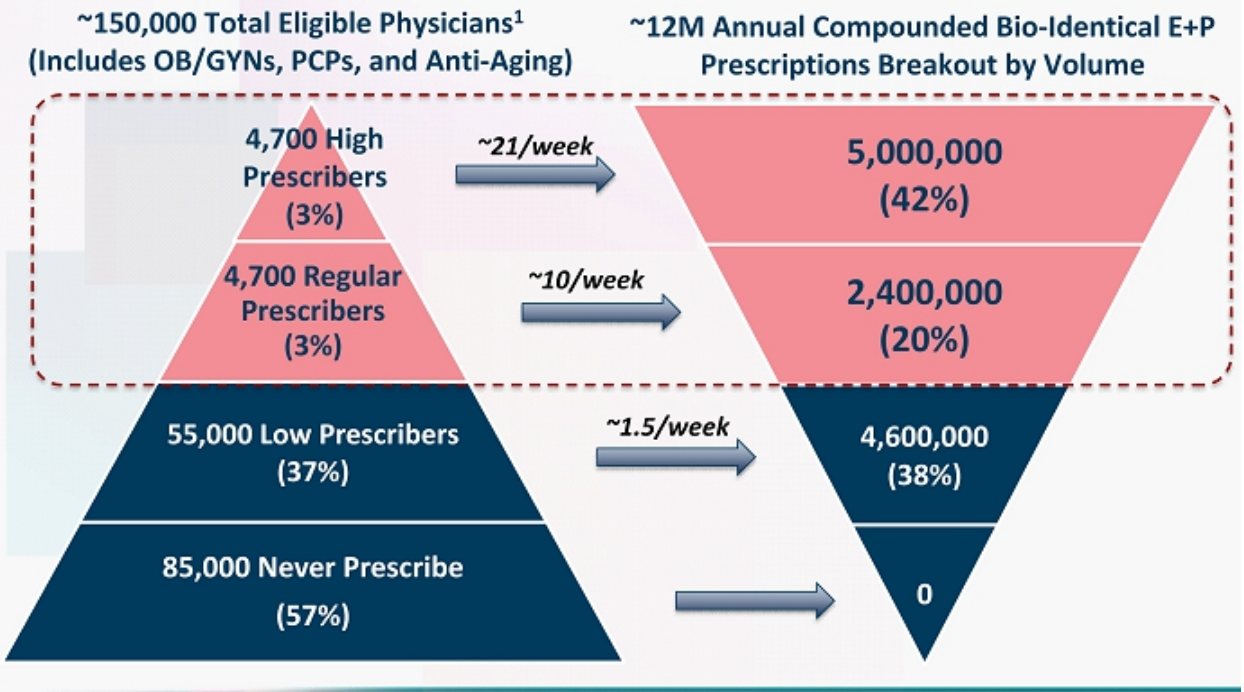
Small Number of Physicians Account for Large Percentage of the Compounded BHRT Market



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

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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

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	>400 Pharmacies with Prescription Data	>500,000 prescriptions annually

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Adverse Reimbursement and Regulatory Environments Continue to Erode Independent Pharmacy Margins

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

EXPRESS SCRIPTS®

OPTUM®

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

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

December 1, 2019: *USP-800 implementation will set new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs*[4,5]

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

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

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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 1Q19
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) December 2019 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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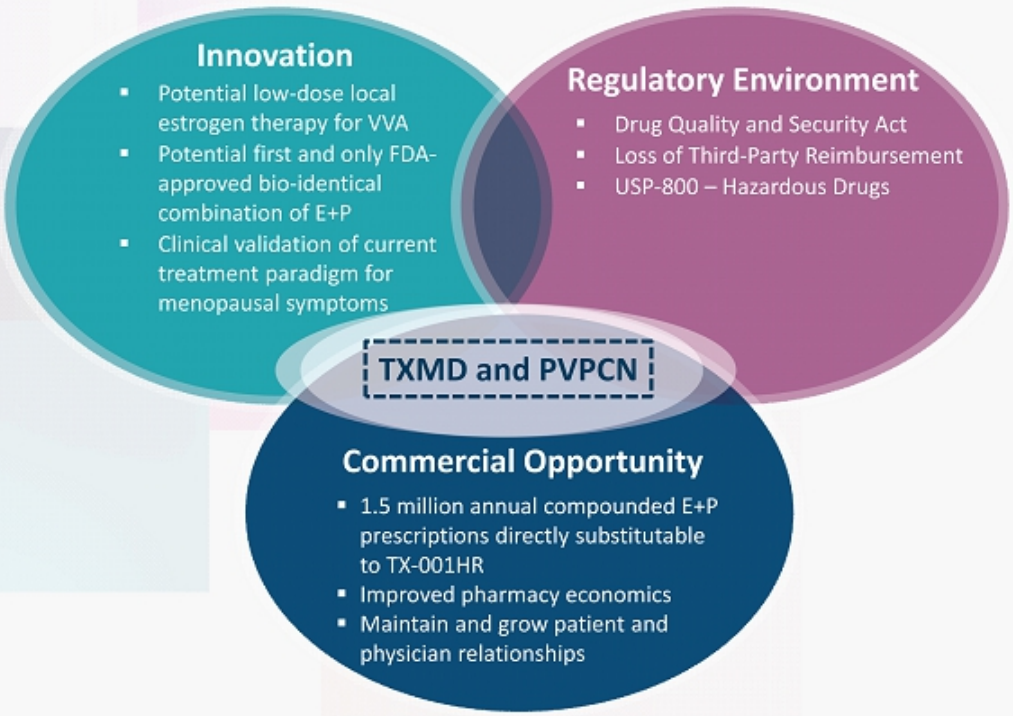
PVPCN Distribution Agreement Rationale



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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: Financial Snapshot

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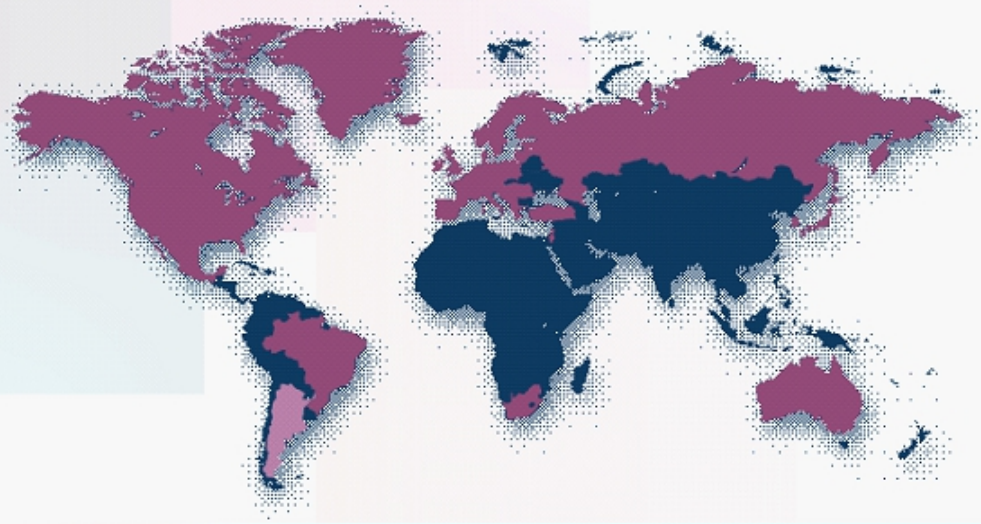
Worldwide Patent Filings*

Strong IP Portfolio with 158 Patent Applications, including 82 international filings, and 18 issued U.S. patents



*Not all patent filings filed in all jurisdictions.

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Appendix

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Women's Health Initiative Observational Study

- First ever study to evaluate the long-term safety of women using **only** U.S. FDA-approved vaginal estrogen products
  - 2,953 users of vaginal estrogen without progestin with an intact uterus
  - Median duration of use of 2-3 years and median duration of follow-up of 7.2 years, representing over 21,000 patient years of data
  - Risks of breast cancer, endometrial cancer, colorectal cancer, stroke, and pulmonary embolism/deep vein thrombosis were not statistically significant between vaginal estrogen users and nonusers
    - *11 total cases of endometrial cancer*

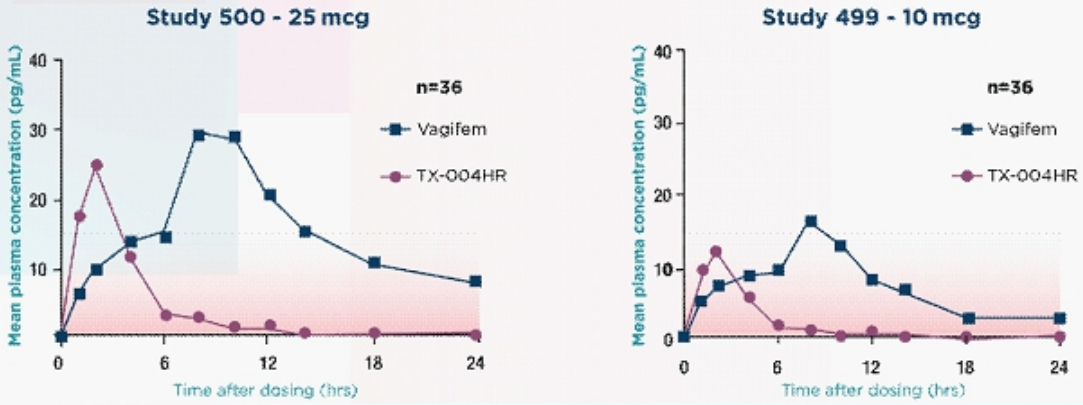
Breast cancer, endometrial cancer, and cardiovascular events in participants who used vaginal estrogen in the Women's Health Initiative Observational Study

Carolyn J. Crandall, MD, MS,[1] Kathleen M. Hovey, MS,[2] Christopher A. Andrews, PhD,[3] Rowan T. Chlebowski, MD, PhD,[4] Marcia L. Stefanick, PhD,[5] Dorothy S. Lane, MD, MPH,[6] Jan Shifren, MD,[7] Chu Chen, PhD,[8] Andrew M. Kaunitz, MD,[9] Jane A. Cauley, DrPH,[10] and JoAnn E. Manson, MD, DrPH[11]

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

Key Findings

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



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

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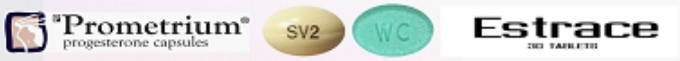
FDA-Approved Separate Bio-Identical E & P Substitutable Market Opportunity

- 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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