TherapeuticsMD®

TXMD Overview

August 2016

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 FDA will accept and, if accepted, approve the company's new drug application for its TX-004HR product candidate; the length, cost and uncertain results of our clinical trials; potential adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership.

Yuvvexy™ (TX-004HR), 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

Compelling Investment Opportunity

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

- Well-known chemical entities with established safety and efficacy thresholds
- Large U.S. markets with favorable competitive and regulatory dynamics
- Additional early stage pipeline candidates
- Strong global IP portfolio with 135 patent applications and 17 issued U.S. patents

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

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

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

Investigational Pipeline

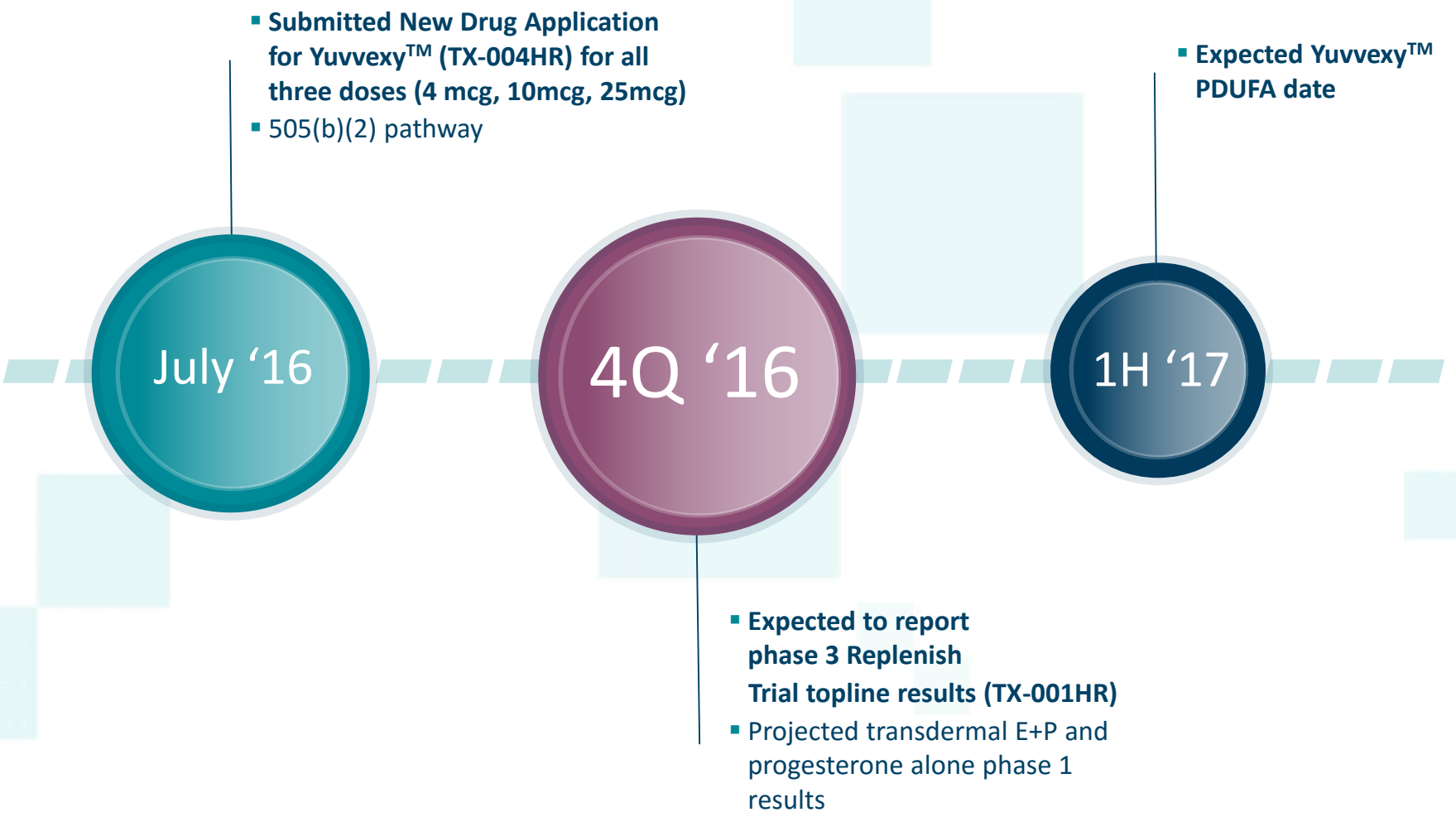
Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA Filing

Yuvvexy™ (17ß-estradiol Vaginal Softgel Capsule)	TX-004HR	07/07/2016
Oral Combination: 17ß-estradiol + Progesterone	TX-001HR	Q4 2016
Transdermal Progesterone	TX-005HR	Q4 2016
Transdermal 17ß-estradiol + Progesterone	TX-006HR	Q4 2016

Rejoice TRIAL

Replenish TRIAL

Key Accomplishments and Anticipated Milestones



Yuvvexy™

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

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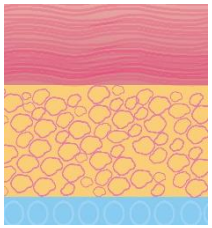
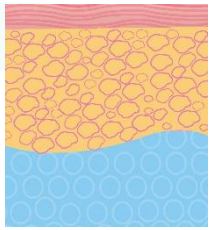
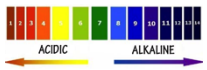
Overview – Vulvar and Vaginal Atrophy (VVA)

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

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

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

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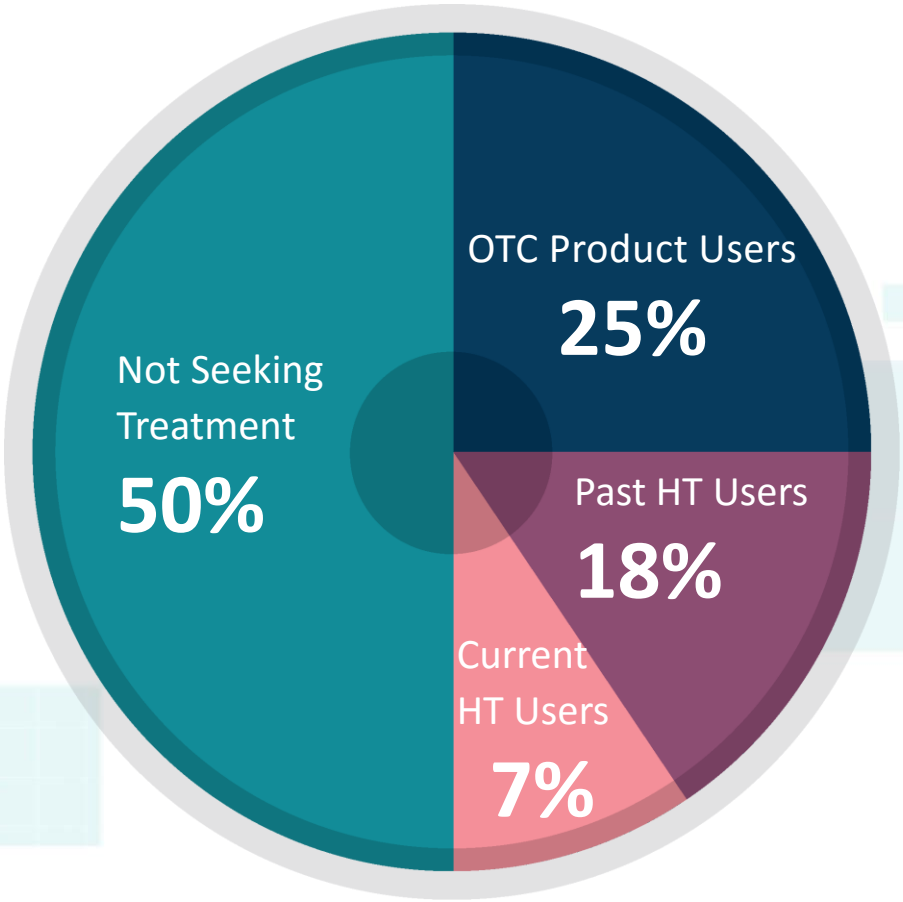
Current VVA Market Overview



32MM Women with VVA Symptoms[1,2]

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

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

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

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
2) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.
3) IMS Health Plan Claims (April 2008-Mar 2011).
4) TherapeuticsMD "EMPOWER" Survey, 2016
5) Based on current FDA-approved market pricing
** Not treated with an FDA approved Rx product. OTC products do not effectively treat the underlying pathological causes of VVA and therefore do not halt or reverse the progression of this condition.

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Current FDA-Approved VVA Competitive Landscape

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

Product[2]	Company	Compound	2015 TRx (000) [1]	2015 U.S. Sales ($MM)[1]	WAC Price[3]
Premarin® Cream	**Pfizer**	Conjugated equine vaginal estrogen	1,615	$502	$288.40
Vagifem® Tablets	**Novo Nordisk**	Vaginal estradiol	1,620	$456	$382.86*
Estrace® Cream	**Allergan**	Vaginal estradiol	1,548	$420	$263.81
Osphena® Tablets	**Shionogi**	Oral SERM	263	$66	$530.07
Estring® Ring	**Pfizer**	Vaginal estradiol ring	284	$91	$310.44
Total			**5,330**	**$1,535**	

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Femring data is excluded due to VMS indication.
3) Medi-Span Price Rx Basic as of 4/01/16. * for 18 tablets ($170.16 WAC for 8 tablets)
4) GlobalData July 2013 report GDHC54PIDR.

Current FDA-Approved VVA Product Use Falls Short

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

1) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23-30 doi:10.4137/CMRH.S14498
2) IMS Health Plan Claims (April 2008-Mar 2011).
3) TherapeuticsMD "EMPOWER" Survey, 2016

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Yuvvexy™ – TX-004HR

- Small, digitally inserted, rapidly dissolving softgel capsule
- No applicator
- Proposed dose packaging to optimize compliance and convenience
- ***Submitted NDA on July 7, 2016 under 505(b)(2) pathway***

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

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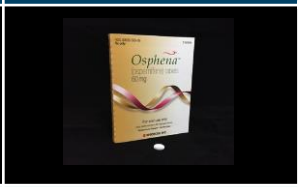
Yuvvexy™ – Potential Best In Class VVA Therapy

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

*Onset of Action = First efficacy observation

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

Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?400706572

Yuvvexy™ - Designed for Long Term Compliance

Current Market

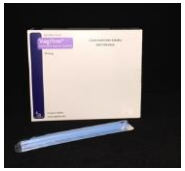
Vaginal Creams:

Mean Duration of Use: 1.5 Months[2]

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

Vaginal Tablets:

Mean Duration of Use: 3.5 Months[2]



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

Yuvvexy

- Muco-adhesive, Dissolves Quickly and Completely
- No Applicator and No Dose Preparation
- Onset-of-Action (Efficacy observed at 2 weeks)
- Negligible Systemic Exposure
- 95% Patient Satisfaction in a Market with Historically Low Compliance Rate

Potential Long Term Usage

Rejoice TRIAL

1) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23-30 doi:10.4137/CMRH.S14498
2) Portman, D, et al. One Year Treatment Persistence with Local Estrogen Therapy in Postmenopausal Women Diagnosed as Having Vaginal Atrophy. *Menopause.* 2015; 22 (11) 1197-203
3) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.

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

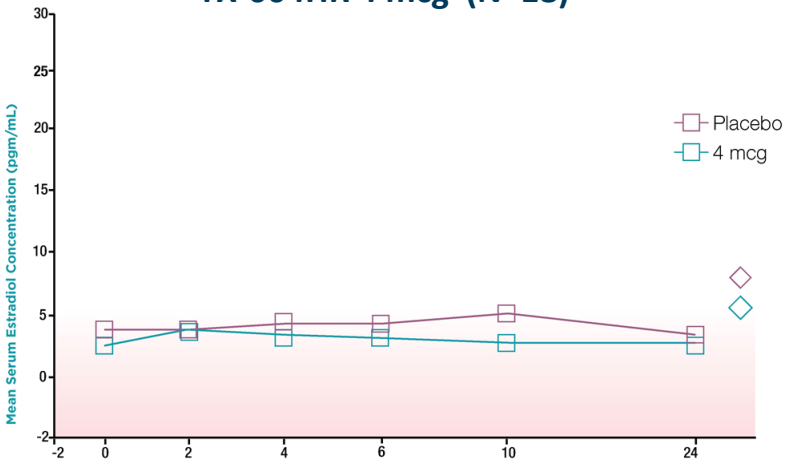
	4 mcg	10 mcg	25 mcg
Superficial Cells	<0.0001	<0.0001	<0.0001
Parabasal Cells	<0.0001	<0.0001	<0.0001
Vaginal pH	<0.0001	<0.0001	<0.0001
Severity of Dyspareunia	0.0149	<0.0001	<0.0001
Severity of Vaginal Dryness	0.0014	<0.0001	<0.0001

MMRM P-value vs placebo

LS = Least Squares

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

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



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

LS Mean Change from Baseline to Week 12

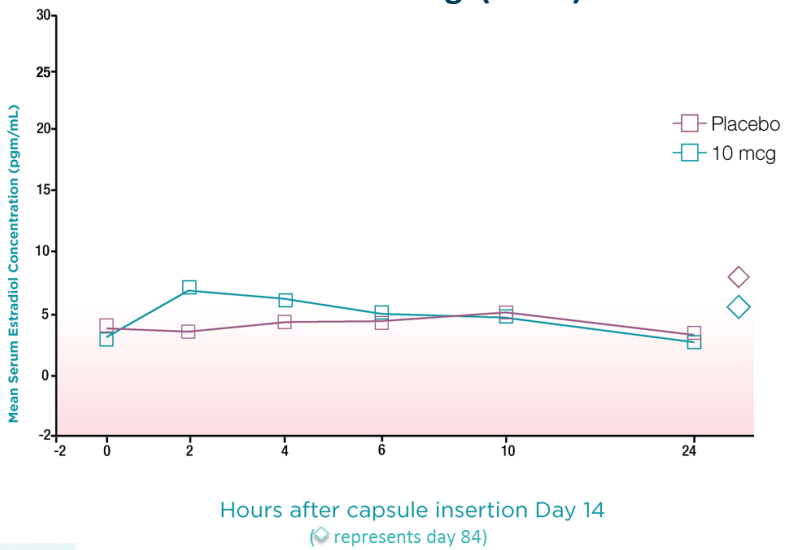
4 mcg	LS Mean Change from Baseline to Week 12		P-value
	4 mcg	Placebo	
Superficial Cells	17%	6%	<0.0001
Parabasal Cells	-41%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.5	-1.3	0.0149
Severity of Vaginal Dryness	-1.27	-0.97	0.0014

MMRM P-value vs placebo

LS = Least Squares

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

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



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

LS Mean Change from Baseline to Week 12

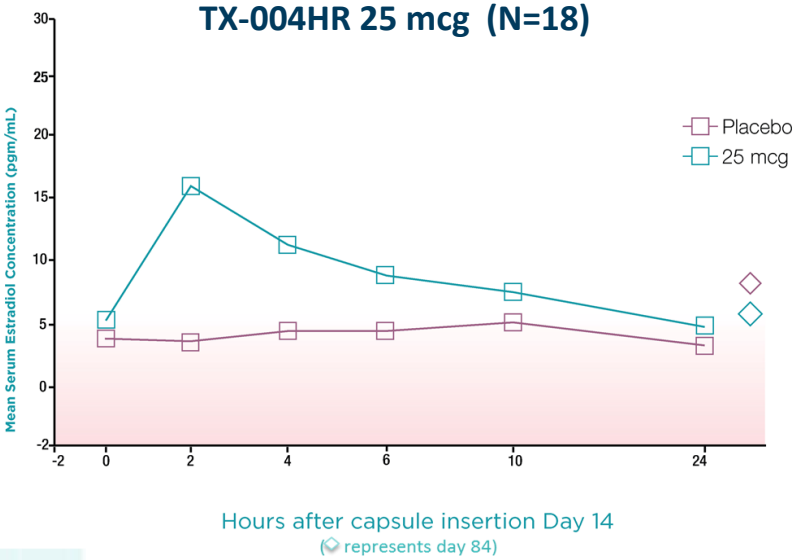
10 mcg	LS Mean Change from Baseline to Week 12		P-value
	10 mcg	Placebo	
Superficial Cells	17%	6%	<0.0001
Parabasal Cells	-44%	-7%	<0.0001
Vaginal pH	-1.4	-0.3	<0.0001
Severity of Dyspareunia	-1.7	-1.3	<0.0001
Severity of Vaginal Dryness	-1.47	-0.97	<0.0001

MMRM P-value vs placebo

LS = Least Squares

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

Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
TX-004HR 25 mcg (N=18)



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

LS Mean Change from Baseline to Week 12

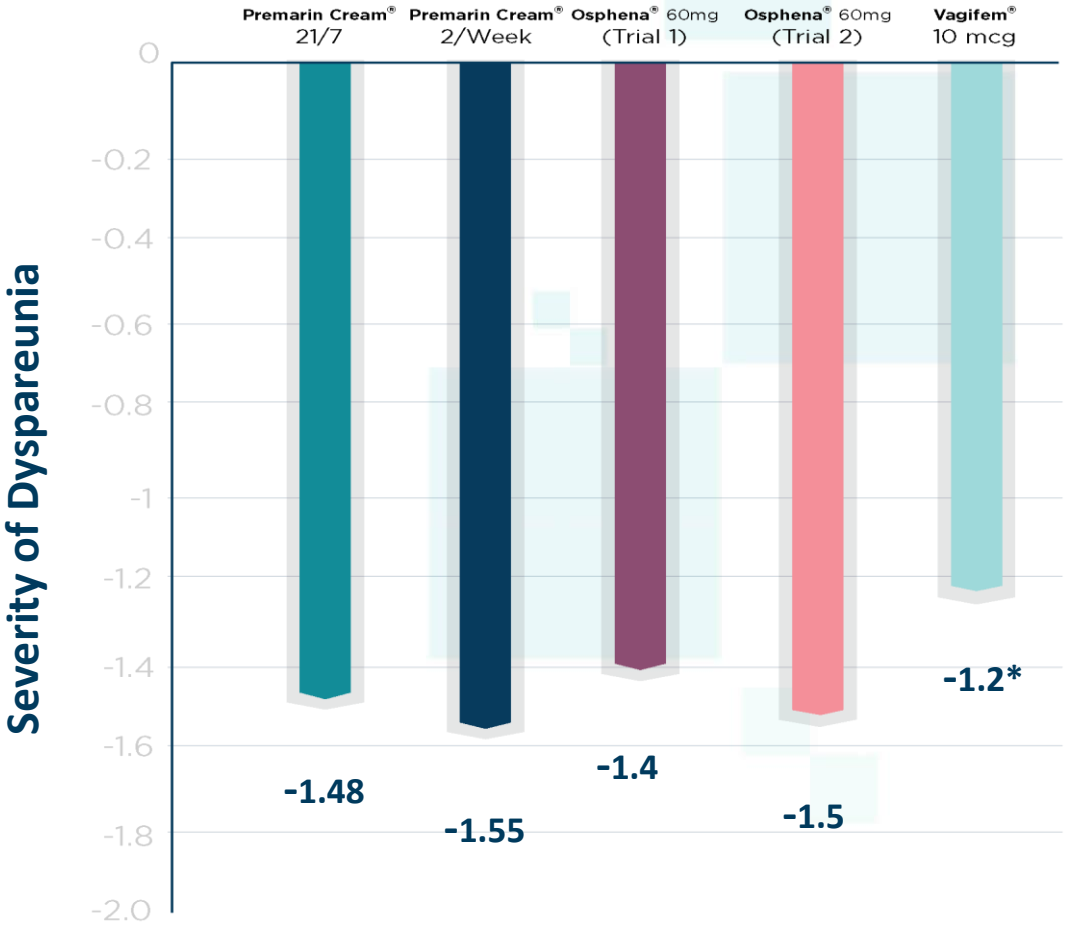
25mcg	LS Mean Change from Baseline to Week 12		P-value
	25 mcg	Placebo	
Superficial Cells	23%	6%	<0.0001
Parabasal Cells	-46%	-7%	<0.0001
Vaginal pH	-1.3	-0.3	<0.0001
Severity of Dyspareunia	-1.7	-1.3	<0.0001
Severity of Vaginal Dryness	-1.47	-0.97	<0.0001

MMRM P-value vs placebo

LS = Least Squares

Unadjusted Change From Baseline Severity Score Dyspareunia

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



*Composite score of most bothersome symptoms, including dyspareunia

Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

Dyspareunia and Vaginal Dryness By Study Visit

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

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

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

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

LS = Least Squares

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

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

*Onset of Action = First efficacy observation

Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
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Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

Yuvvexy™ Qualitative Attributes

Ease of Use

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

Overall p-value = 0.035

Patient Satisfaction

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

Overall p-value <0.0001

Preferred vs Competition

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

LS = Least Squares

Physical and Clinical Attributes Enable Market Expansion

	Yuvvexy™ Attributes Could Address Perceived Shortcomings of Current Products	Yuvvexy™ Market Opportunity
Current HT Users	▪ Negligible systemic profile may give comfort for long term use ▪ REJOICE data: first efficacy observation for dyspareunia and dryness at two weeks ▪ No applicator ▪ No mess	**Market Share Gain**
Past HT Users	▪ REJOICE data: 70%-95% patient satisfaction ▪ Ease of use could lead to less discontinuation ▪ Negligible systemic profile may give comfort for long term use ▪ Two week efficacy may increase refill rates past month 1	**Reintroduce HT**
OTC Product Users	▪ Negligible systemic profile may alleviate fear of HT ▪ Dose pack helpful to physicians likely to prescribe HT ▪ Could eliminate need to see a specialist ▪ Ease of use profile	**New HT Users**
Not Seeking Treatment	▪ Dose pack may reduce time for patient education on product use, making physicians more likely to initiate VVA conversation ▪ Could eliminate need to see a specialist ▪ Negligible systemic profile may enable access to a new demographic	**New HT Users**

REJOICE Trial Results

Favorable Regulatory Dynamics Driven by Change in Treatment Paradigm

Removal of Black Box Warning

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

Citizen's Petition Supporters:

Academy of Women's Health; Endocrine Society; NAMS The North American Menopause Society; NPWH Nurse Practitioners in Women's Health Caring for Women; ISSWSH International Society for the Study of Women's Sexual Health, Inc.; The American Society for Reproductive Medicine; AMWA; ACOG The American Congress of Obstetricians and Gynecologists

Estrogen use in Breast Cancer Survivors

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

ACOG The American Congress of Obstetricians and Gynecologists

Changing Perception on Use of Estrogen

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

Harvard Medical School; NIH National Heart, Lung, and Blood Institute; International Menopause Society; Women's Health Initiative; Yale University School of Medicine; NAMS The North American Menopause Society

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

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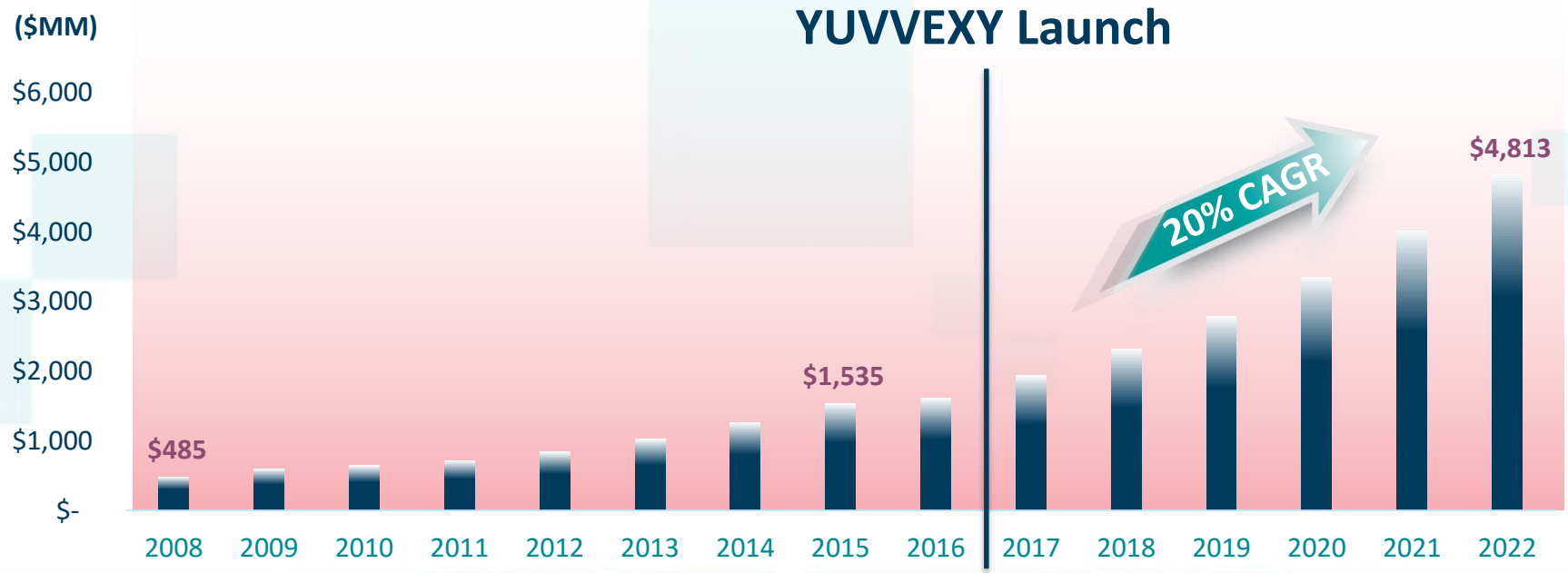
Future VVA HT Market

TherapeuticsMD VVA Market Goals

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

Increase in market penetration and duration of use could lead to market size increase of >100% by 2022



1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) GlobalData July 2013 report GDHC54PIDR.

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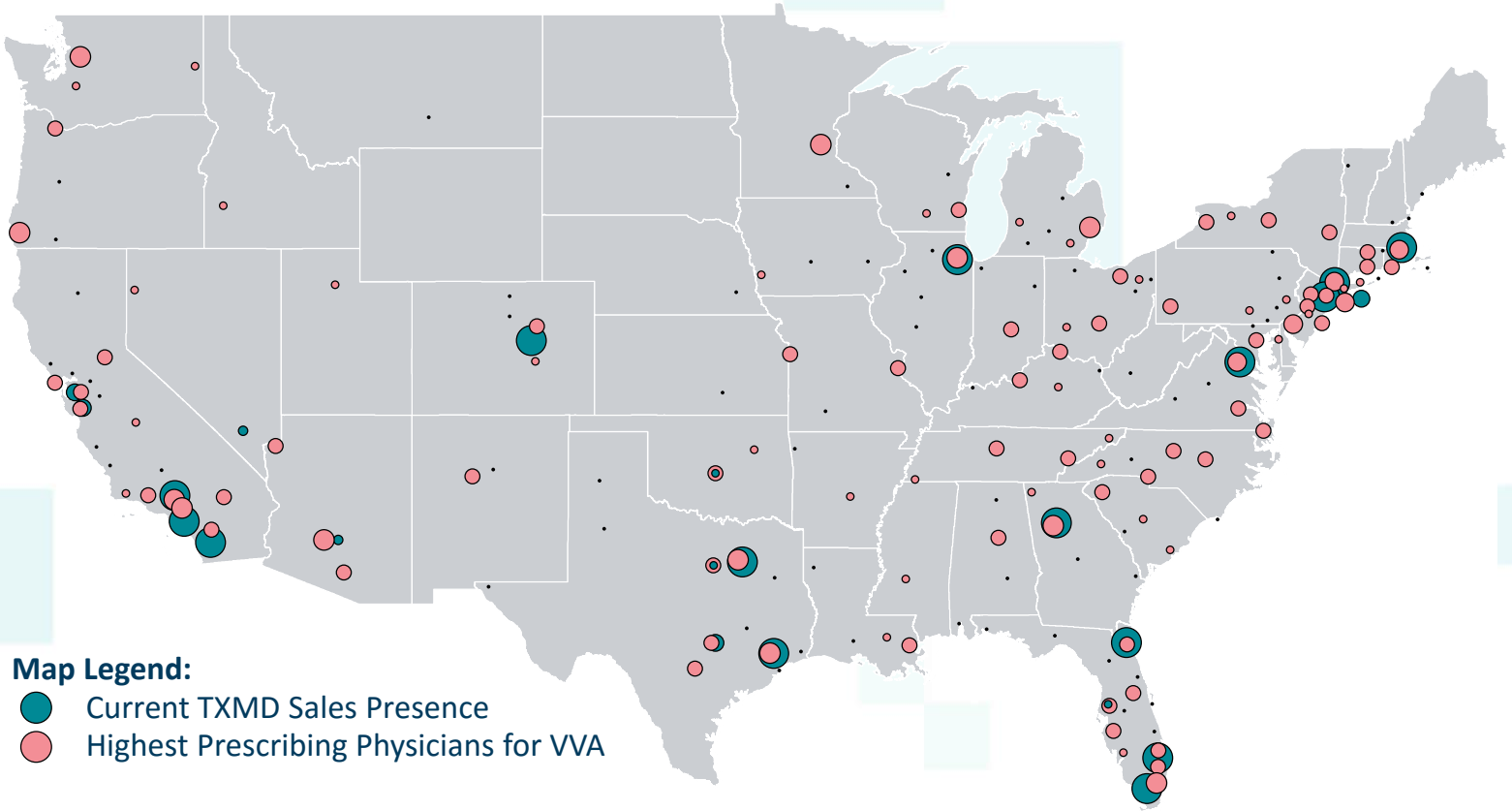
Foundation Built for a Strong Launch

Operational leverage of OB/GYN relationships in key markets



50 Sales Representatives; Planned Increase to 150 With Launch of Yuvvexy

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

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Menopause Overview

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

- Average age of menopause 51 years[1]
- Women will spend approximately half of their lives in this state

May result in physical and emotional symptoms[1]

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

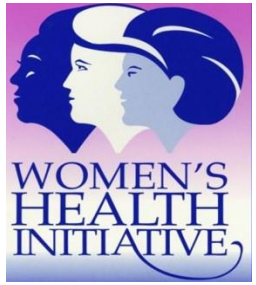
Long history of Estrogen (E) and Progesterone (P) use

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

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

Evolution of U.S. HT Market Post WHI Study

- **July 2002 - Women's Health Initiative (WHI) study showed that synthetic hormones increased the risk of breast cancer, stroke, heart attack and blood clots**

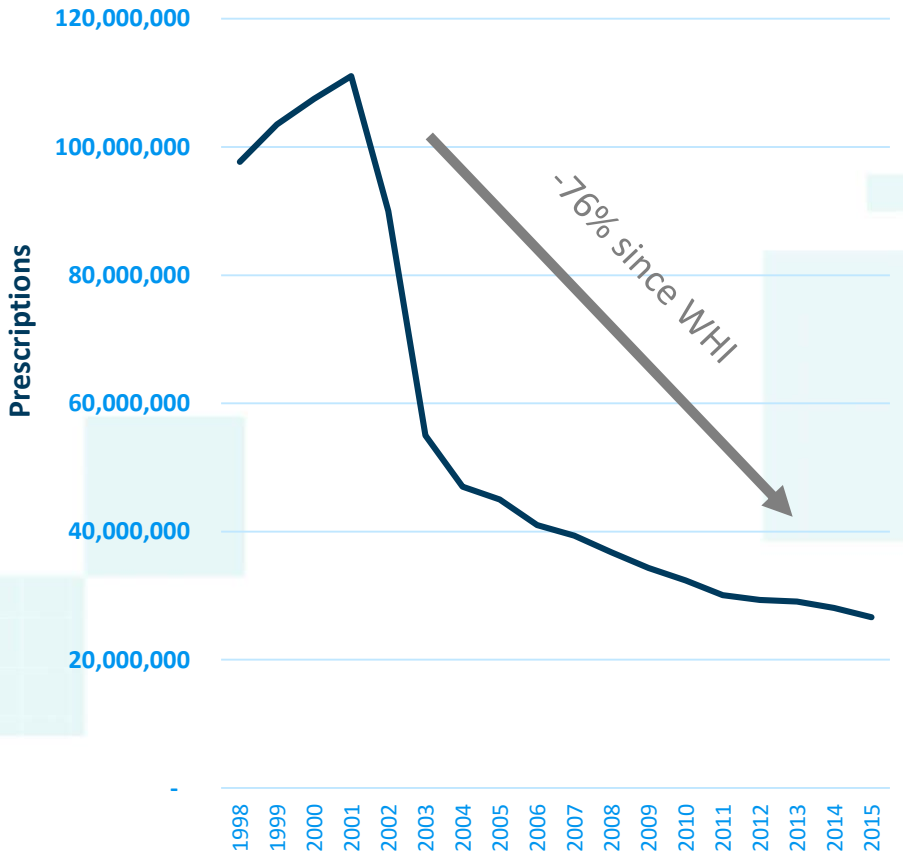


- **Post WHI, women shifted to Bio-Identical Hormone Therapy (BHT) containing Natural Estradiol (E2) and Natural Progesterone (P4) as a safer alternative**
  - All FDA-approved combination hormone products contain a synthetic progestin and not a natural progesterone
  - 110MM+ scripts of FDA-approved HT prescribed annually before 2002, declining to ~25MM in 2015[1]
- **Compounding filled the need and demand for BHT**
  - 30MM scripts (1-2.5MM women) of Compounded BHT prescribed annually in the U.S. currently[2,3]
- **No FDA-approved BHT combination product of E2 + P4**

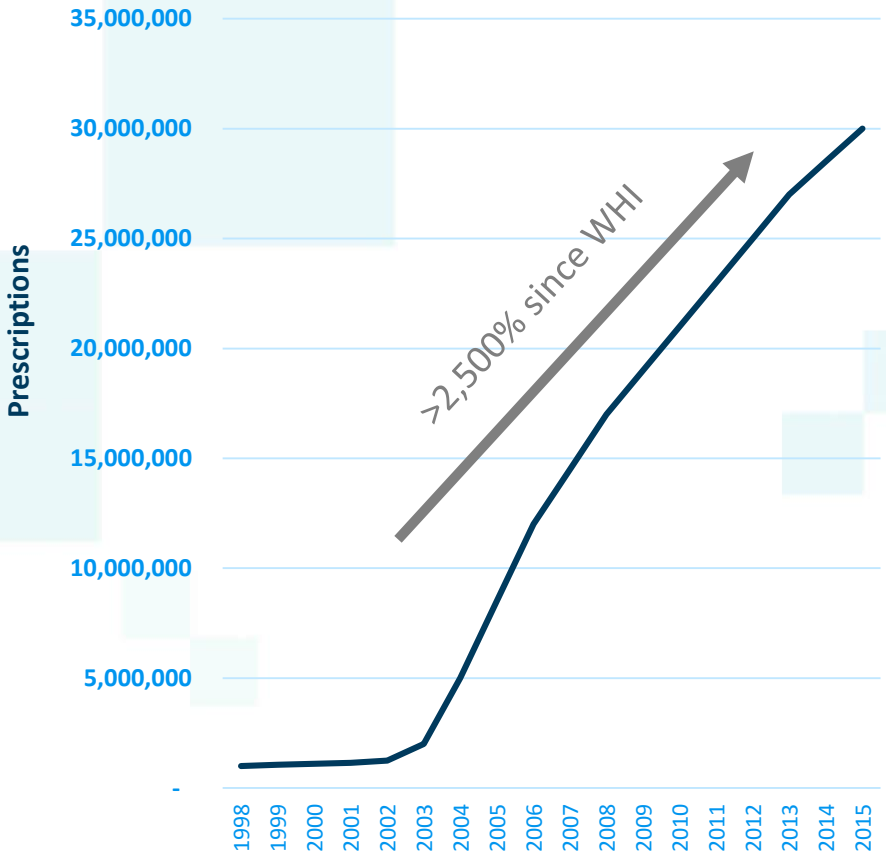
1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. *Menopause,*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

Bio-Identical Hormones Are What Women and Doctors Want

FDA-Approved Synthetic and Separate E&P Market[1]



Compounded Bio-identical Hormone Therapy Market[2,3]



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

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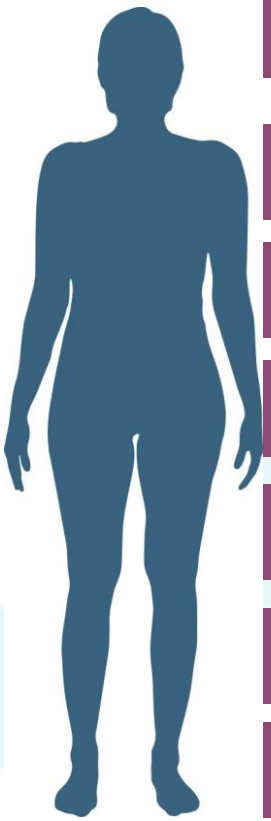
Compounded Bio-Identical HT: Why Has It Been So Successful?



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

1) Freeman E, Rickels K, Sondheimer S J. et al. A double-blind trial of oral progesterone, alprazolam and placebo in treatment of severe premenstrual syndrome. *JAMA*. 1995;274:51–57.
2) Fournier A, Berrino F, Clavel-Chapelon F. Unequal risks for breast cancer associated with different hormone replacement therapies: results from the E3N cohort study. Breast Cancer Res Treat. 2008;107:103–111.
3) Writing Group for the PEPI Trial . Effects of estrogen or estrogen/progestin regimes on heart disease. Risks factors in postmenopausal women. *JAMA*. 1995;273:199–208.
4) The Writing Group for the PEPI Trial . Effects of hormone replacement therapy on endometrial histology in postmenopausal woman. The postmenopausal estrogen/progestin interventions (PEPI) trial. *JAMA*. 1996;275:370–375.
5) Hodis HN, et al. "Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol" AHA 2014; Abstract 13283.
6) Regidor, P-A, et al. Progesterone in Peri- and Postmenopausal: A Review. *Geburtshilfe Frauenheilkd.* 2014 Nov; 74 (11): 995-1002.

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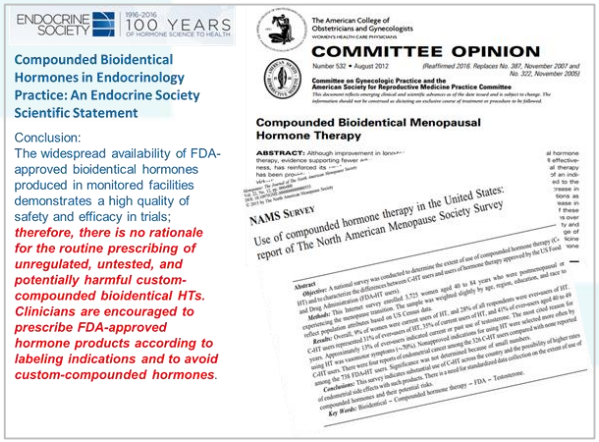
But…..Compounded Products Pose Significant Risks

- **Medical Societies' global consensus statement declares that the use of Custom-Compounded HT is not recommended[1]**
- **ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products[2]**
  - Lack of efficacy and safety data
  - Lack of Good Manufacturing Practices (GMP)
  - Variable purity
  - Variable content uniformity
  - Variable potency (under/over dose)
  - Lack of stability
  - Unopposed E / Ineffective P leads to increased risk of endometrial hyperplasia / cancer



ENDOCRINE SOCIETY 1916-2016 100 YEARS OF HORMONE SCIENCE TO HEALTH

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

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

The American College of Obstetricians and Gynecologists

COMMITTEE OPINION

Number 532 • August 2012 (Reaffirmed 2016. Replaces No. 387, November 2007 and No. 322, November 2005)

Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee

Compounded Bioidentical Menopausal Hormone Therapy

ABSTRACT: Although improvement in [illegible] therapy, evidence supporting fewer [illegible] has been reinforced by [illegible]

NAMS Survey

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

Abstract

Objective: A national survey was conducted to determine the extent of use of compounded hormone therapy (C-HT) and to characterize the differences between C-HT users and users of hormone therapy approved by the US Food and Drug Administration (FDA-HT users).

Methods: This Internet survey enrolled 1,725 women aged 40 to 84 years who were postmenopausal or experiencing the menopause transition. The sample was weighted slightly by age, region, education, and race to reflect population attributes based on US Census data.

Results: Overall, 9% of women were current users of HT, and 38% of all respondents were ever-users of HT. C-HT users represented 31% of ever-users and 3% of current users of HT, and 41% of ever-users aged 40 to 49 years. Approximately 13% of ever-users indicated current or past use of testosterone. The most cited reasons for using HT was transient symptoms (~70%). Nonapproved indications for using HT were selected more often by C-HT users. There were few reports of endometrial cancer among the 336 C-HT users compared with some reported among the 778 FDA-HT users. Significant use of C-HT across the country and the possibility of higher rates of endometrial side effects with such products. There is a need for standardized data collection on the extent of use of compounded hormones and their potential risks.

Conclusion: [illegible] – FDA – Testosterone.

Key Words: Bioidentical – Compounded hormone therapy

ACOG THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

ENDOCRINE SOCIETY

NAMS THE NORTH AMERICAN MENOPAUSE SOCIETY

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE 19 44

INTERNATIONAL MENOPAUSE SOCIETY

1) Villiers, T.J. et al. Global Consensus Statement on Menopausal Hormone Therapy, *Climacteric*, June 2013, Vol. 16, No. 3 : Pages 316-337.
2) 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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Rationale for TX-001HR

Target Goals	Preliminary Supportive Data
Meet patient demand for bio-identical hormones	Potential for first and only FDA-approved natural estradiol plus natural progesterone combination softgel capsule
Meet FDA requirements for safe, effective, and clinically validated products	Multiple FDA guidance documents released about unsafe use of compounded hormones
New lower effective dose	Broad range of doses being evaluated in Phase 3 Replenish Trial
Labeling differentiation	Potential bio-identical terminology as both hormones similar to those produced by the ovary

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

Q1 ’15 | Q2 ’15 | Q3 ’15 | Q4 ’15 | Q1 ’16 | Q2 ’16 | Q3 ’16 | Q4 ’16 | Q1 ’17 | Q2 ’17 | Q3’17 | Q4’17 | Q1’18

Phase 3 Vasomotor & Endometrial Safety

NDA Prep/Filing/PDUFA

- **Phase 3 Trial[1]: ~100 U.S. sites**
- **Subjects: ~1750 fully enrolled as of October 2015**
  - Four active arms (N=400/arm)
    - Estradiol 1 mg/Progesterone 100 mg
    - Estradiol 0.5 mg/Progesterone 100 mg
    - Estradiol 0.5 mg/Progesterone 50 mg
    - Estradiol 0.25 mg/Progesterone 50 mg
  - Control arm: Placebo (N=150)
- **12-month study with 12-week VMS substudy endpoints:**
  - Vasomotor substudy: number and severity of hot flashes (4 weeks and 12 weeks)
  - Endometrial safety: incidence of endometrial hyperplasia (12 months)
- **As of August 4, 2016, approximately 1,642 subjects have exited the trial and the incidence of endometrial hyperplasia is less than 1%**

Replenish TRIAL

Topline results expected in the fourth quarter of 2016

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

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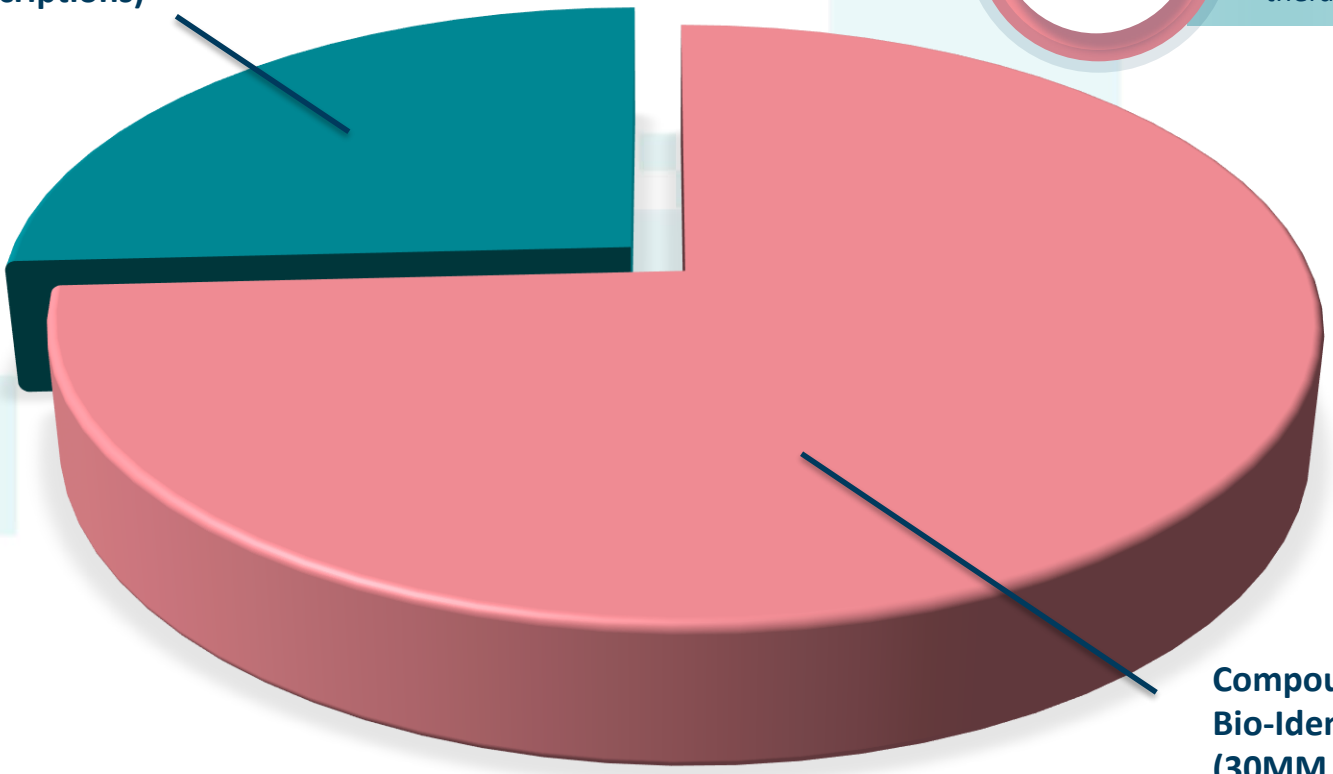
Total HT Market = 38+MM Prescriptions

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

1-2.5MM[3]

U.S. women using custom-compounded menopausal hormone therapy



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

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

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Potential First and Only FDA-Approved Bio-Identical Combination Product

Products	FDA Approved						Compounded E+P	If Approved
	Separate E+P	Activella® FemHRT® Angeliq®	Generic 17β + Progestins	Prempro® Premphase®	Duavee®	Brisdelle®		TX – 001HR
		Allergan, Bayer, novo nordisk	TEVA	Pfizer	Pfizer	noven PHARMACEUTICALS, INC.	25,000 compounding pharmacies	TherapeuticsMD™
Bio-Identical	✓	✗	✗	✗	✗	✗	✓	✓
Safety Data with Endometrial Cancer Data	✗	✓	✓	✓	✓	✓	✗	✓
Combination	✗	✓	✓	✓	✓	✓	✓	✓
FDA-Approved	✓	✓	✓	✓	✓	✓	✗	✓[3]
Reimbursement	✓	✓	✓	✓	✓	✓	✗	✓[4]
Market Size	$520MM	$28MM	$218MM	$302MM	$30MM	$38MM	$4.5B[2]	---

1) 2015 US Sales, per IMS Health Plan Claims (April 2008-Mar 2011)
2) $150 average net monthly cost based on WAC, net of rebates/discounts, of existing FDA-approved hormone therapy combination products
3) NDA to be submitted assuming successful results of Replenish trial
4) Reimbursement anticipated if FDA-approved

Adverse Reimbursement Changes for Compounded Drugs

CVS CAREMARK

May 30, 2014: *CVS/Caremark forces compounding pharmacies to include NDC numbers for each ingredient used and two scientifically valid studies in peer-reviewed journals supporting clinical efficacy of the additional ingredients*[1]

EXPRESS SCRIPTS®

June 3, 2014: *ESI launches a "Compound Management Solution," creating a list of excluded ingredients that eliminated almost 95% of all compound claims*[1]

OPTUM®

July 2014: *Optum initiates a comprehensive compound management program, including prior authorizations and step therapy for all compounded prescriptions*[2]

TRICARE®

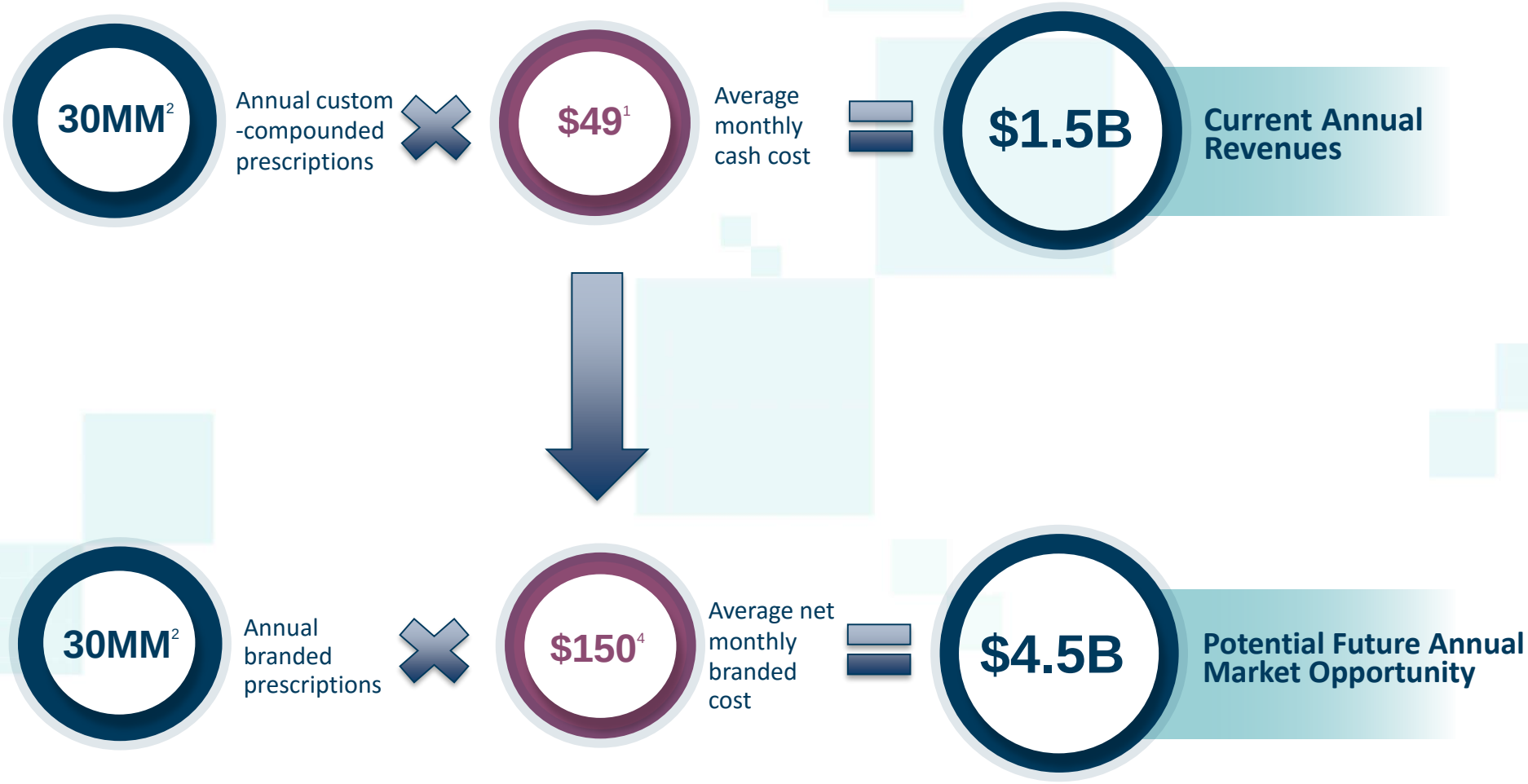
May 1, 2015: *Tricare initiates changes to their compounded medication coverage policy, effectively utilizing Express Scripts' compounded screening process and slashed costs by 74% within one month*[3]

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

June 2016: *Report released that Medicare Part D spending on compounded drugs rose 625% in the past decade. Beginning in February 2017, CMS is adding new screening requirements, blocking any reimbursement for prescriptions from unapproved providers*[4]

1. http://www.iacprx.org/general/custom.asp?page=CCIns161314
2. http://www.optum.com.br/content/optum/en/optumrx/pharmacy-insights/restoring-trust-compound-medications.html
3. http://www.militarytimes.com/story/military/benefits/health-care/2015/06/18/tricare-compounded-medications-update-defense-health-agency-dha-prescription-express-scripts/28914815/?from=global&sessionKey=&autologin=
4. https://www.statnews.com/pharmalot/2016/06/22/medicare-compounded-drugs-fraud/

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



1. Pinkerton, J.V. Compounded bio-identical hormone therapy: identifying use trends and knowledge gaps among U.S. women. *Menopause,* Vol.22, No.9, 2015
2. Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA Approved MHT Has Increased http://press.endocrine.org/doi/abs/10.1210/endo-meetings.2015.RE.5.FRI-124#sthash.PySEhZ9P.dpuf
3. *Obstetrics & Gynecology* 2015;Vol 125, No. 5, p. 98S (Supplement), May 2015
4. $150 average net monthly cost based on WAC, net of rebates/discounts, of existing FDA-approved hormone therapy combination products

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Regulatory Environment Continues to Favor FDA-Approved Products

October 2012
Contaminated compounded drugs made at NECC kill 77 people nationwide

November 2013
Congress enacted **Drug Quality and Security Act (DQSA)**

2014
Creation of **"Do Not Compound"** list and established Pharmacy Compounding Advisory Committee

2015
Initiated formation of **"Difficult to Compound"** list, including addition of hormones

2016
USP-800 finalized, addressing hazardous drugs including hormones

July 2016
Released draft guidance documents, outlining protocol for commercially available drugs and unsanitary conditions

July 2018
Final implementation of **USP-800**

1) http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2) http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf

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Regulatory Tailwinds for FDA-Approved Products

Drug Quality and Security Act (DQSA)[1]

- Prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortages
- Requires collaboration between the FDA and state boards of pharmacy to inspect, enforce, and take action against compound pharmacies
- Anticipate significant impact on compounding upon FDA approval of first bio-identical combination hormone therapy product

USP 800 – Hazardous Drugs[2,3]

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

1) http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2) http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf

Compounding Pharmacies Need An FDA-Approved Product

	Compounded BHT 	TX-001HR (if approved) 
Third-Party Reimbursement	No	Yes
Required Capital Expenditure to Dispense	Yes	No
Manufacturing and Compliance Investment	Yes	No
Legal & Regulatory Risk	Yes	No

If approved, compounding pharmacies who dispense TX-001HR achieve:

Higher Revenues → Lower Costs → Increased Profits

TX-001HR Could Fulfill Therapeutic Gap For All Participants

Patients

- Meet demand for natural bio-identical hormone therapy
- Assurance of safety and efficacy
- Reduction of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at all pharmacies and not just compounding pharmacies

Physicians

- First and only FDA-approved bio-identical combination hormone therapy
- Clinically validated dose regimens
- Eliminates 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
- Lower legal and regulatory costs and risk

FDA/Regulatory Bodies

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

TXMD: Financial Snapshot

Listing Exchange

TXMD
LISTED
NYSE MKT

Debt

$0MM

Shares Outstanding

196.5MM
(as of August 1, 2016)

Cash

$166.5MM
(as of June 30, 2016)

Worldwide Patent Filings*

Strong IP Portfolio with 135 Patent Applications, including 72 international filings, and 17 issued U.S. patents

*Not all patent filings filed in all jurisdictions.

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THANK YOU!

Appendix

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Seasoned Management Team with a Proven Track Record of Commercial Execution

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

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

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

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

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

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

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

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

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

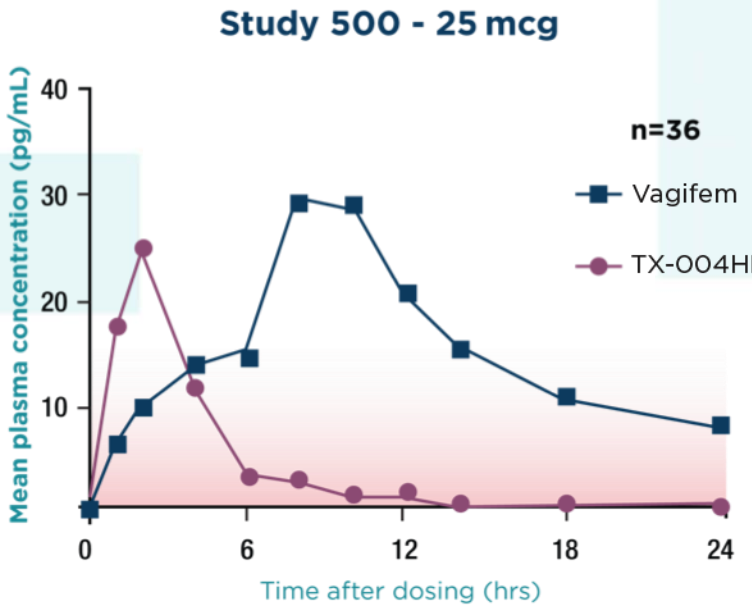
- Former Director of Corporate Development at Anthem
- Lead the Cigna and Amerigroup transactions
- Investment banker in healthcare coverage at Bank of America Merrill Lynch
- Executed over $60bn in deal value

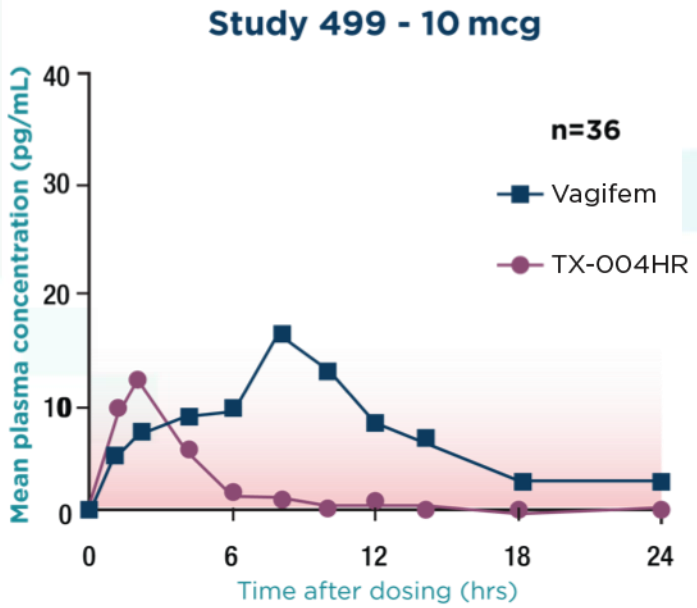
Supported by a team of regulatory consultants with decades of FDA experience

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

Key Findings

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





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

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