

TherapeuticsMD[®]

A Woman's Health Company

TXMD Overview

August 2015



www.TherapeuticsMD.com

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 our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop, protect and defend our intellectual property; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of our clinical trials; potential adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership.

PDF copies of press releases and financial tables can be viewed and downloaded at our website: <http://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 patented SYMBODA™ technology, developed to enable new bio-identical hormone combinations, forms and administration routes

Pipeline Targets Large Markets



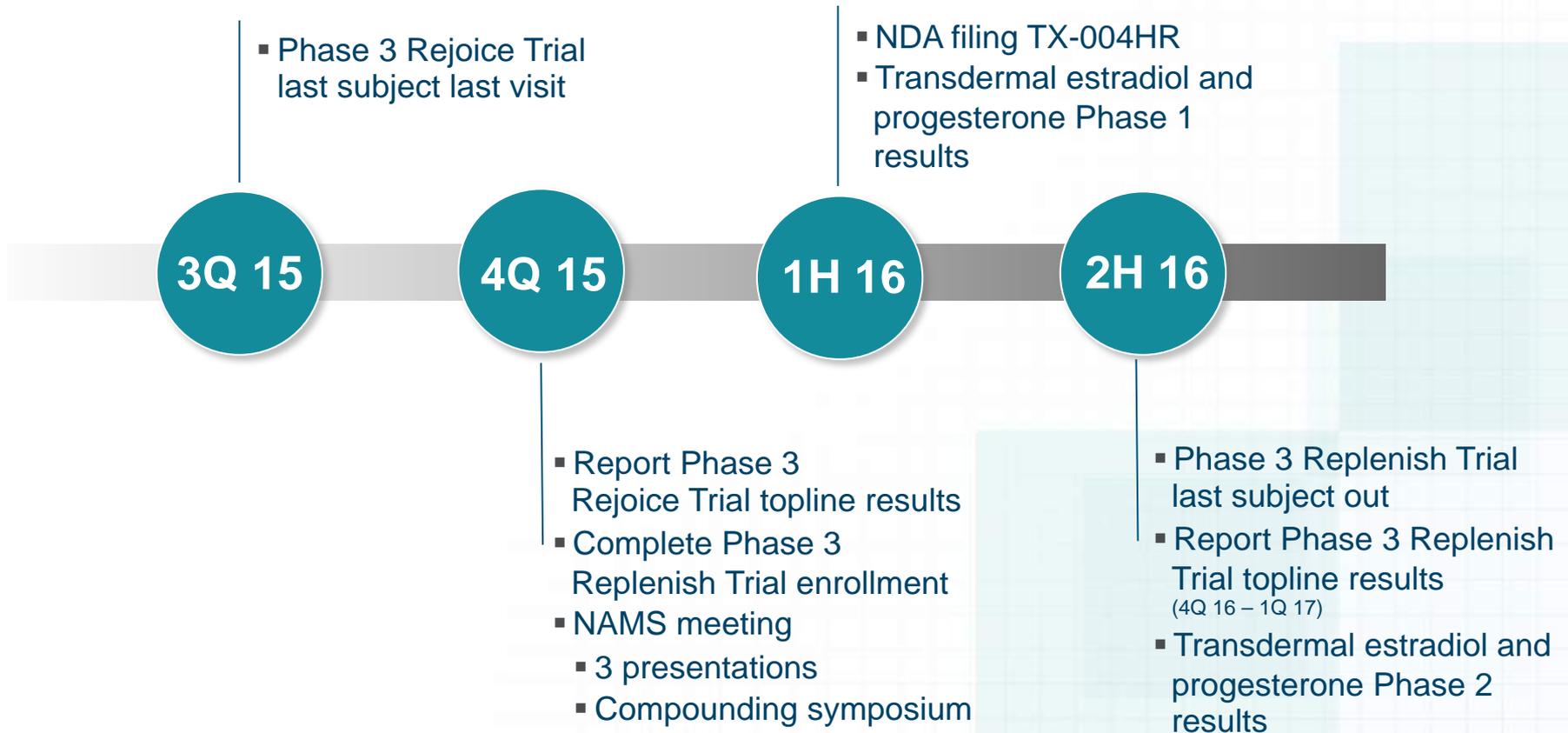
1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.

2) Pinkerton, J.V. 2015. *Menopause*, Vol.22, No.9, pp 0-11.

3) Estimated U.S. sales, based on half estradiol patch sales.

* In July 2014 we temporarily suspended enrollment in the Spry Trial and, in October we temporarily stopped it in order to update the Phase 3 protocol based on discussions with the FDA. We intend to update the Phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial.

Key Milestones



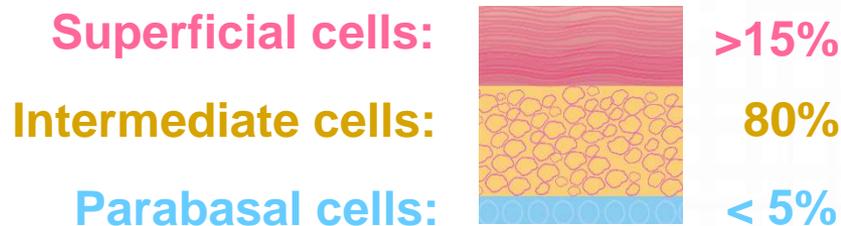
TX-004HR VVA Program



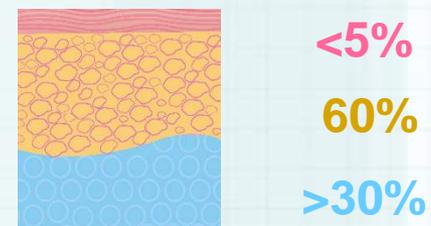
Overview – Vulvar and Vaginal Atrophy (VVA)

- Diagnosed in approximately 50% of postmenopausal women¹
- Most bothersome symptom commonly reported is dyspareunia¹
- FDA guidance for efficacy requirements:
 - Statistically significant increase in superficial cells
 - Statistically significant decrease in parabasal cells
 - Statistically significant change in vaginal pH
 - Statistically significant reduction in severity of dyspareunia

Healthy Vaginal Tissue



Atrophic Vaginal Tissue



VVA Market – Established and Growing

- U.S. sales more than doubled since 2008
- Global market expected to be \$2.1 billion in 2022⁴
- Currently no generic competition
- 32 million U.S. women currently experiencing VVA symptoms

Product ²	Compound	TRx ¹ 12 Month Rolling (000)	U.S. Sales (\$MM) ¹ 12 Month Rolling	WAC Price ³
Premarin® Cream	Equine vaginal estrogen	1,774	\$511	\$263.52
Vagifem® Tablets	Vaginal estradiol	1,851	\$463	\$306.00*
Estrace® Cream	Vaginal estradiol	1,751	\$406	\$240.05
Osphena® Tablets	Oral SERM	280	\$67	\$158.00
Estring®	Vaginal estradiol ring	336	\$99	\$283.66
Total		5,992	\$1,546	

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.

2) Femring data is excluded due to VMS indication.

3) Medi-Span Price Rx Basic as of 6/10/15. * for 18 tablets (\$136.00 WAC for 8 tablets)

4) GlobalData July 2013 report GDHC54PIDR.

All trademarks are the property of their respective owners.

VVA Market Dynamics – Ready for New Product

Only 2.3MM U.S. women treated with Rx product¹

Why?

Creams

- Messiness²
- Long-term safety²
- Dose preparation by user required³



Mean treatment duration
46 days⁴

Tablets

- Long-term safety²
- Systemic absorption²



Mean treatment duration
103 days⁴



Women primed for conversion to new product

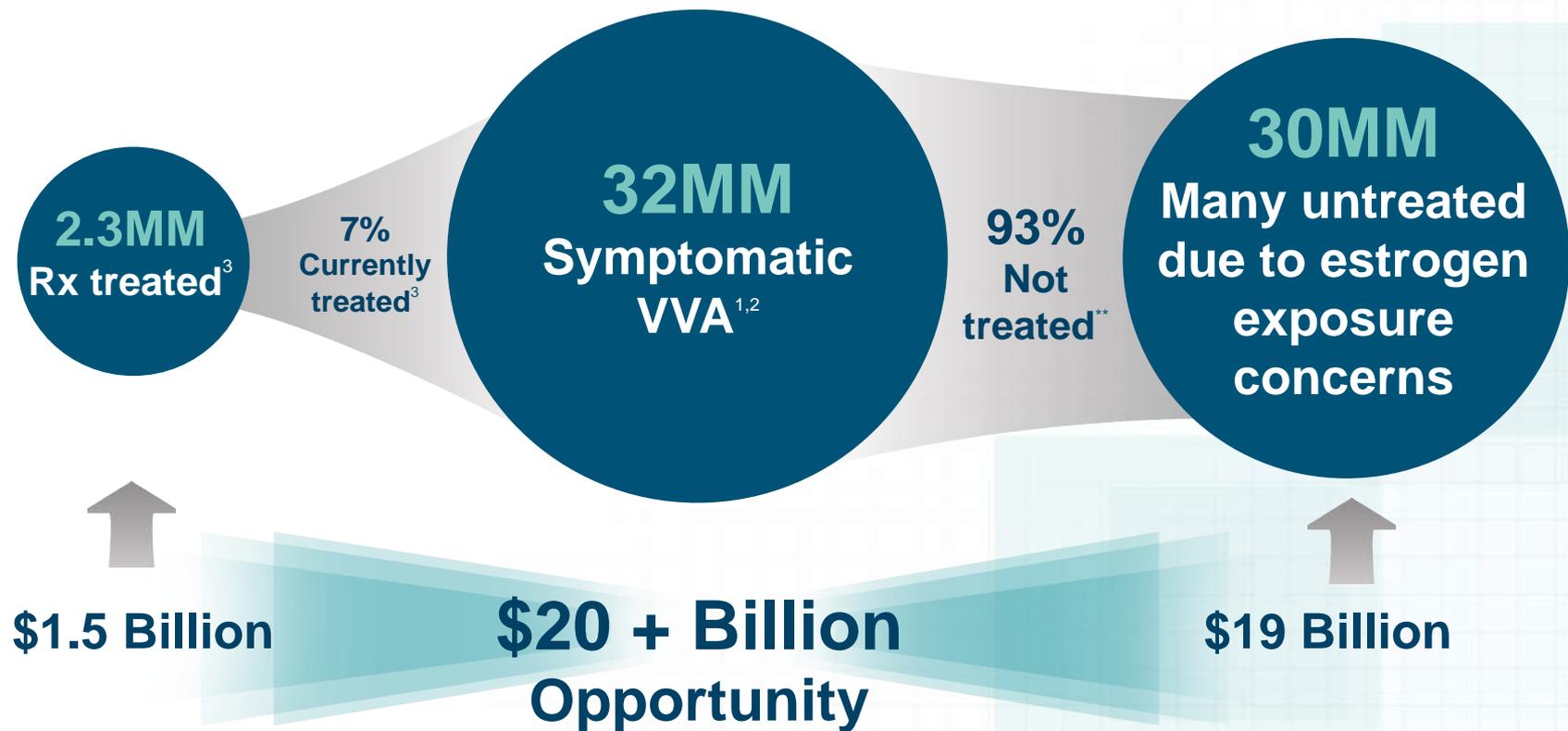
1) IMS Health Plan Claims (April 2008-Mar 2011).

2) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014;8 23-30 doi:10.4137/CMRH.S14498.

3) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.

4) Portman, D, et al. One Year Treatment Persistence with Local Estrogen Therapy in Postmenopausal Women Diagnosed as Having Vaginal Atrophy. *Menopause: The Journal of The North American Menopause Society* Vol. 22, No. 11, Published online ahead of print May 4, 2015.

30MM Women with VVA Untreated in U.S.**



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).

** 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.

Vagifem® 25 mcg to 10 mcg Market Share

Vagifem		
Year	2009	2014
Dosage Strength	25 mcg*	10 mcg*
Market Share ¹ (%)	40%	32%

- VVA market TRx increased 15% 2009-2014¹
- Vagifem had an 18% decrease of its own market share moving to 10 mcg only

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, Annual Data 2009-2014.

*Vagifem 25 mcg was discontinued on July 30, 2010. Vagifem 10 mcg was approved by the FDA November 25, 2009 and began shipping to pharmacies in Q1 2010.

TX-004HR – Target Product Profile

Target Goals

Preliminary Supportive Data

Lower systemic exposure

Phase 1 data with 10 mcg and 25 mcg suggest lower systemic absorption

Faster onset of action

Phase 2 demonstrated efficacy in 14 days

New lower effective dose

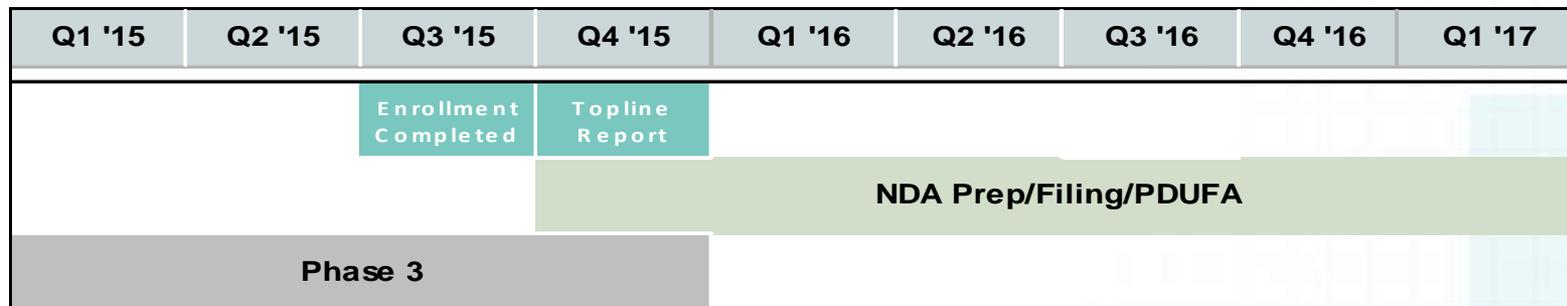
Phase 3 evaluating broad range of doses, including 4, 10 and 25 mcg

Improved user experience

Phase 2 showed patient satisfaction; 97% said “easy to use”

Target Product Profile being evaluated in ongoing Phase 3 Rejoice Trial

TX-004HR Vaginal Estradiol U.S. Launch Timeline



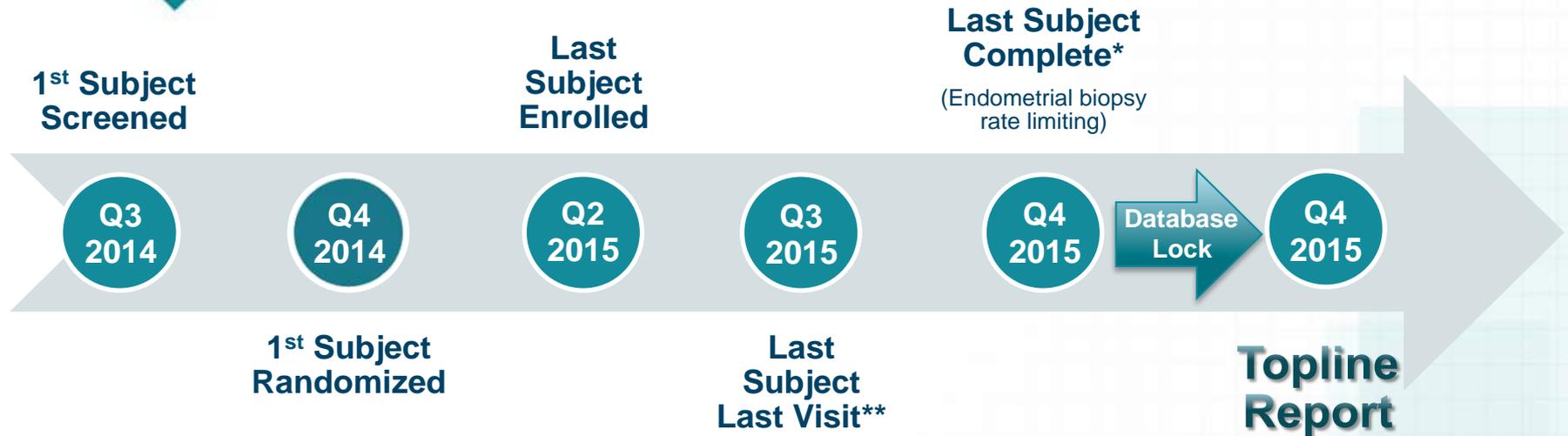
- **Phase 3 Trial¹: 12 weeks, ~100 sites**
- **Subjects: ~700 fully enrolled as of June 2015**
 - 3 active arms: 4 mcg, 10 mcg, 25 mcg (~175 per arm)
 - 175 placebo
- **FDA required Co-Primary Endpoints for Proposed Indication**
(from baseline to week 12 versus placebo)^{2,3}
 - Statistically significant increase in the % of vaginal superficial cells
 - Statistically significant decrease in the % of vaginal parabasal cells
 - Statistically significant change in vaginal pH
 - Statistically significant reduction in the severity of dyspareunia
- **Additional Endpoints**
 - PK measures Days 1, 14, 84
 - FSFI (Female Sexual Function Index), acceptability survey

1) NCT02253173; <https://clinicaltrials.gov/ct2/show/NCT02253173?term=rejoice&rank=1>.

2) Each arm (4 mcg, 10 mcg, and 25 mcg) tested against each co-primary endpoint.

3) The FDA has noted that a single, large, well-controlled clinical trial to support safety and efficacy should be sufficient to submit an NDA for TX-004HR for the proposed indication and that to support the indication in a single trial, evidence of efficacy for a given dose would need to show statistical significance of at least a .01 level.

TX-004HR Phase 3 Trial Timelines & Milestones



Last Subject Last Visit Details*

- Last subject last visit scheduled for Sept 2015
- Endometrial biopsy (EB) – 3 independent pathologists must read
- If insufficient tissue, repeat EB
- If insufficient tissue on repeat biopsy – transvaginal ultrasound (TVU) assessment
- If endometrium >4 mm on TVU, then hysteroscopy guided biopsy with specimens sent to all three pathologists

** A telephone interview is conducted at Week 14 (15 days after the last dose of investigational product as per study protocol).

TX-004HR Phase 2 Study

Double-blind and Placebo-controlled

Study Design

- 48 postmenopausal women with VVA (24 active, 24 placebo)
- Randomized 1:1 to 10 mcg; 1x daily for 2-week period
- Endpoints measured at 2 weeks; same endpoints to be measured in Phase 3 at 12 weeks

Co-primary Endpoint Results¹

- Increase in superficial cells 35% treatment vs. 4% placebo ($P=0.0002$)
- Decrease in parabasal cells 54% treatment vs. 4% placebo ($P<0.0001$)
- Decrease in vaginal pH -0.97 units for treatment vs. -0.34 units for placebo ($P=0.0002$)
- Numerical reduction of most bothersome symptoms

Secondary Endpoint Results

- Improved patient satisfaction, 97% said easy to use²
- Reduction in atrophic effects on epithelial integrity and vaginal secretions³

1) Pickar, J.H. et al, Pilot and Pharmacokinetic Studies of Solubilized Estradiol Administered Vaginally in a Softgel Capsule. *Menopause*. 2014; Vol.23, No.12, S-6, 1328.

2) Kingsberg, Sheryl. "Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap™)" presented 2015 Annual Meeting ISSWSH, Feb 20, 2015.

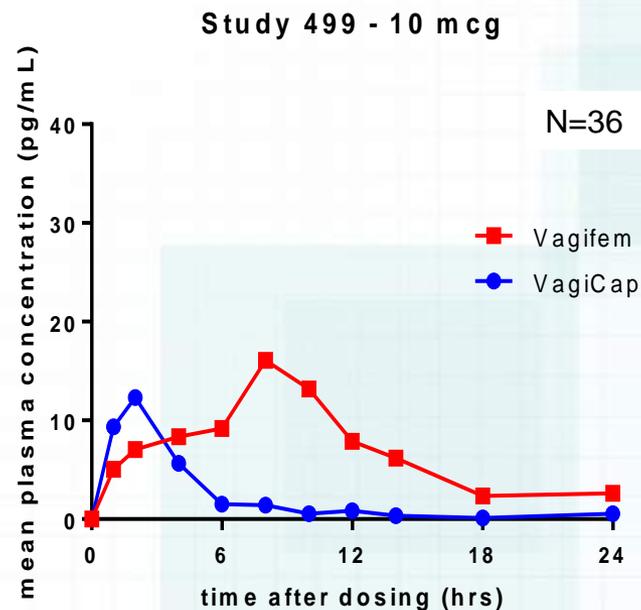
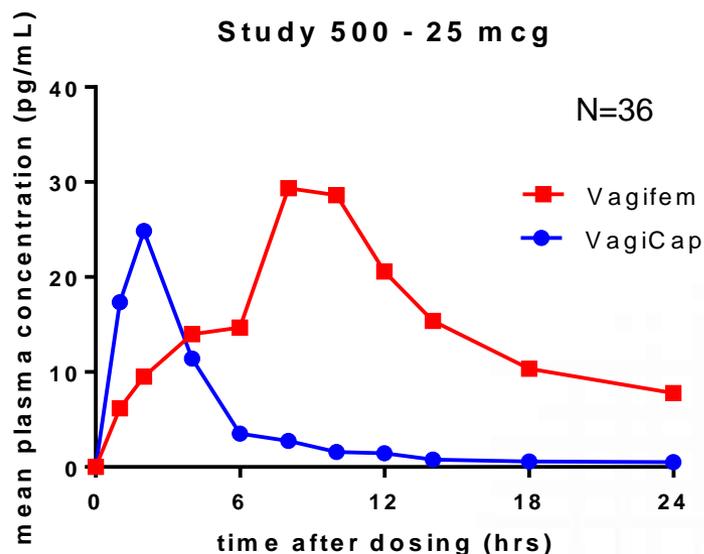
3) Constantine, G.D., "Vaginal Physical Examination Correlates with Vaginal Epithelial Cells and pH and Can Be Used to Assess Therapeutic Efficacy," FRI-126, ENDO2015.org, Endocrine Society Meeting and Expo Guide, p. 229.

TX-004HR vs. Vagifem®

Phase 1 Single Dose PK Studies

Key Findings

- T_{max} ~2 hours with TX-004HR and ~8 hours with Vagifem
- Systemic absorption AUC (0-24 hours) is 2- to 3-fold lower with TX-004HR relative to Vagifem



TX-001HR Combination Program



Menopause Overview

Menopause represents the natural life-stage transition when women stop having periods and may result in physical and emotional symptoms.

- Average age of menopause is 51 years¹
- Hot flashes are due to lower estrogen levels
- Estrogen is given to reduce hot flashes
- Estrogen causes the uterus to thicken (hyperplasia)
- Progesterone is given to non-hysterectomized women to prevent thickening of the uterus

FDA Approved Hormone Therapy Market Size

FDA-Approved Product		U.S. Sales (\$MM) ¹	Company
17β Estradiol + NETA / DSP Activella® / FemHRT® / Angeliq®	Non bio-identical containing progestins	\$37	  
Generic 17β + Progestins	Non bio-identical containing progestins	\$230	
Premarin + MPA Prempro® / Premphase®	Non bio-identical CEE + progestin	\$339	
Premarin + SERM Duavee®	Non bio-identical CEE + SERM	\$19	
Paroxetine Brisdelle®	SSRI non-hormonal	\$36	
Total FDA-Approved Oral Combination Sales		\$661	

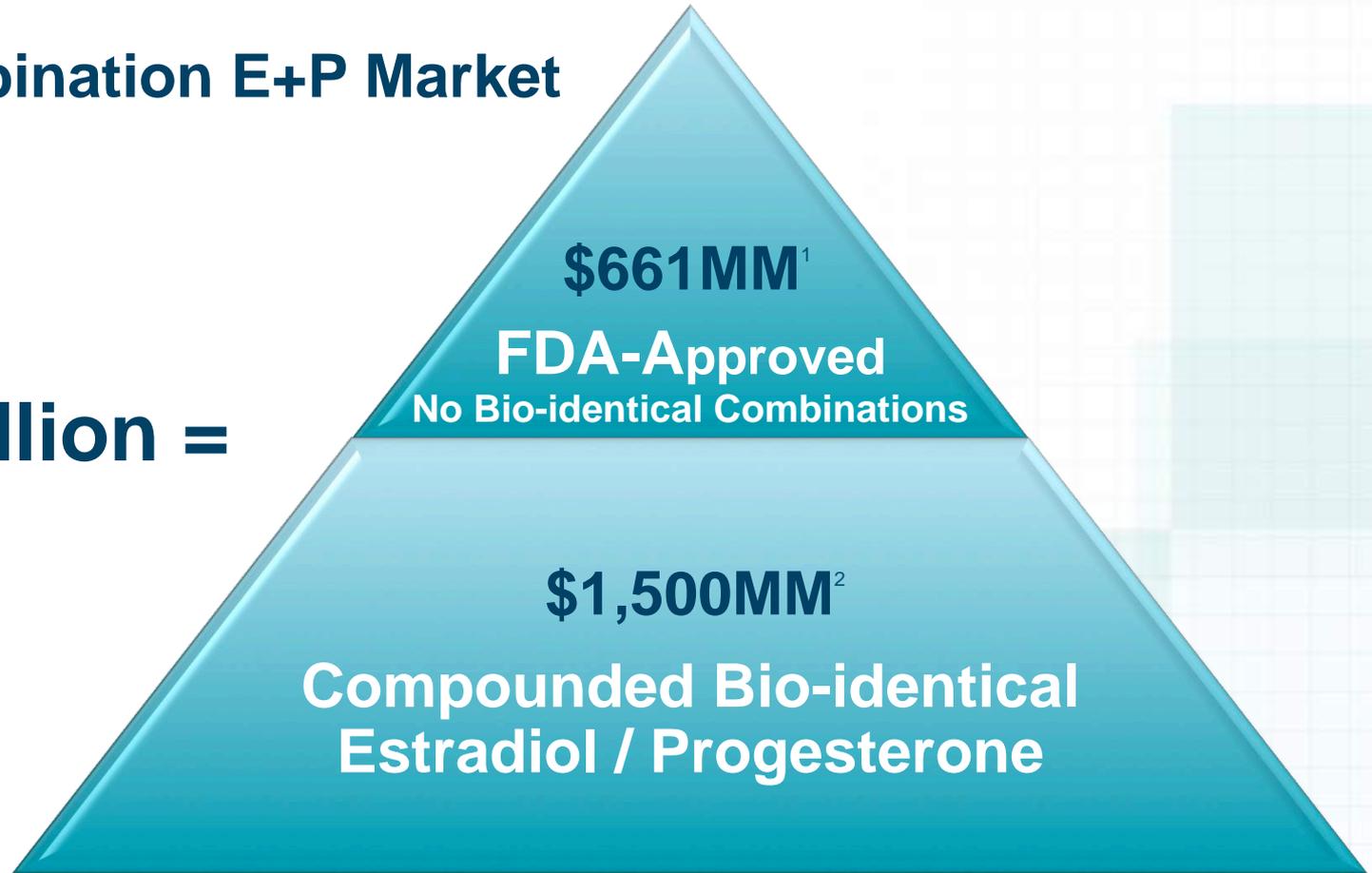
1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.

All trademarks are the property of their respective owners.

Hormone Therapy Market = Two Markets

Total Combination E+P Market

\$2.2 billion =



Number of U.S. Women Using Non-FDA-Approved Compounded HT



Pinkerton, J.V. Compounded bio-identical hormone therapy: identifying use trends and knowledge gaps among U.S. women. *Menopause* Vol.22, No.9, 2015.



Pinkerton, J.V. Menopause Hormone Therapy (MHT) Usage: FDA-Approved MHT has decreased while Compounded non-FDA-approved MHT has increased, ENDO, 2015.



Archer, D.F., et al. Prevalence of Use and Cost of Compounded Menopausal Hormone Therapy (CMHT) 2015 ACOG, presentation, May, 2015.

1-2.5MM

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

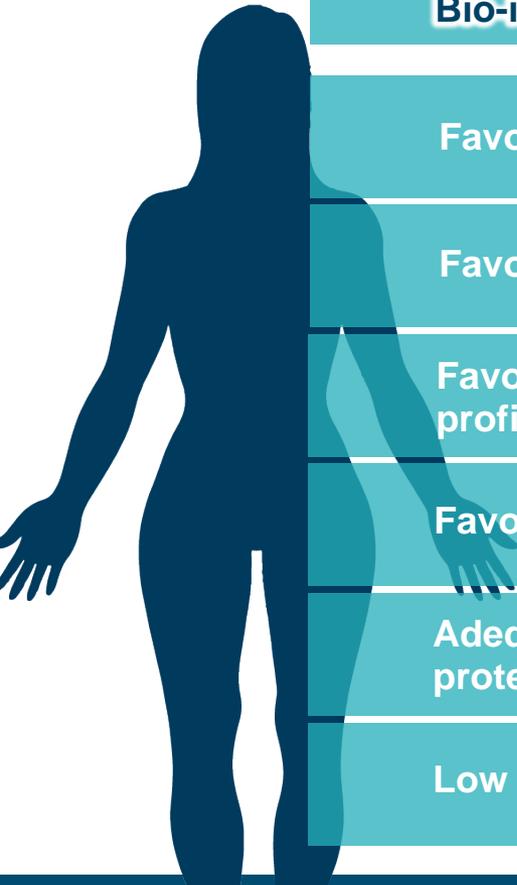
30MM*

Annual custom-compounded prescriptions

\$49

Average monthly cash cost

Evidence Supports Bio-identical Progesterone Favorable Clinical Profile Compared to Synthetic Progestins



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

22 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) Lorrain J, Lalumiere L G, Caron P. The effects of oral micronized progesterone on bleeding patterns, endometrial histology and bone density in postmenopausal woman on hormone replacement therapy. Int J Gynaecol Obstet. 1994;46:77-79.

Evidence Supports Bio-identical Estradiol Favorable Clinical Profile Compared to Conjugated Estrogens

“CEEs (Premarin) were associated with a higher incidence of venous thrombosis and myocardial infarction than estradiol.”¹

— *Journal of the American Medical Association*, September 2013

“Oral estradiol may be associated with a lower risk of stroke ... compared with conventional-dose oral CEE.”²

— *Menopause*, September 2014

The ELITE trial demonstrated that estradiol is cardioprotective when given during the early postmenopausal years.³

— *Circulation*, November 2014

Cochrane meta analysis demonstrated that estradiol is cardioprotective and reduced overall mortality when given 10 years before the onset of menopause.⁴

— Cochrane Collaboration, 2015

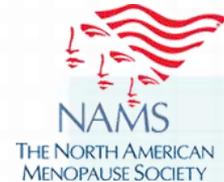
1) Smith *et al.* Lower Risk of Cardiovascular Events in Postmenopausal Women Taking Oral Estradiol Compared with Oral Conjugated Equine Estrogens (CEE) .

2) Shufelt *et al.* Hormone Therapy Dose, Formulation, Route of Delivery, and Risk of Cardiovascular Events in Women: Findings from the Women's Health Initiative Observational Study.

3) Abstract 13283: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol ;HN Hodis, et al.1 *Circulation*. 2014; 130:A13283.

4) Cochrane Collaboration; HT for preventing cardiovascular disease in postmenopausal women; Boardmen HMP, et al., 2015.

Medical Societies Express Concern Over Compounded Hormones



- ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA approved products¹
 - Lack of Good Manufacturing Practices (GMP)
 - Variable purity
 - Variable content uniformity
 - Variable potency (under/over dose)
 - Not approved for efficacy and safety
 - Lack of stability data
- Medical societies' global consensus statement declares that the use of custom-compounded hormone therapy is not recommended²

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

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

Compounding Regulations and Enforcement

Drug Quality and Security Act (DQSA)¹

- Prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortages
- Anticipate significant impact on compounding upon FDA-approval of first 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



TX-001HR – Target Product Profile

Target Goals

Meet patient demand for bio-identical hormones

New lower effective dose

Labeling differentiation

Leverage data on natural progesterone and 17β estradiol

Preliminary Supportive Data

Potential for FDA-approved first natural estradiol plus natural progesterone combination softgel

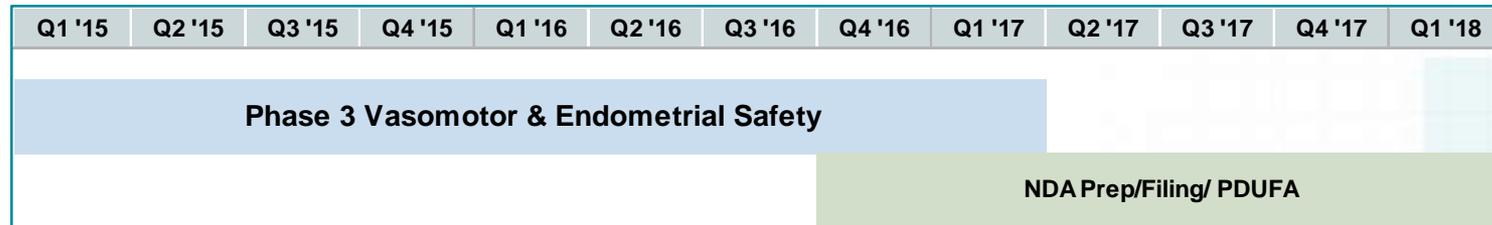
Broad range of doses being evaluated in Phase 3

Bio-identical terminology as both hormones similar to those produced by the ovary

Inclusion of progesterone/estradiol differences data via label negotiation

Target Product Profile being evaluated in ongoing Phase 3 Replenish Trial

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



- Phase 3 Replenish Trial to enroll 1,750 subjects at ~100 U.S. sites
 - 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
 - Placebo arm (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)



Early Stage Pipeline: Transdermal Programs

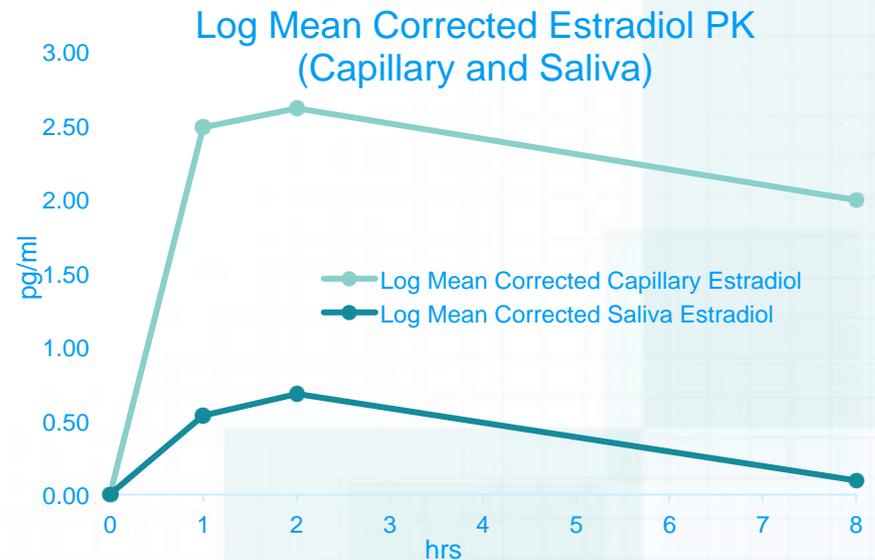
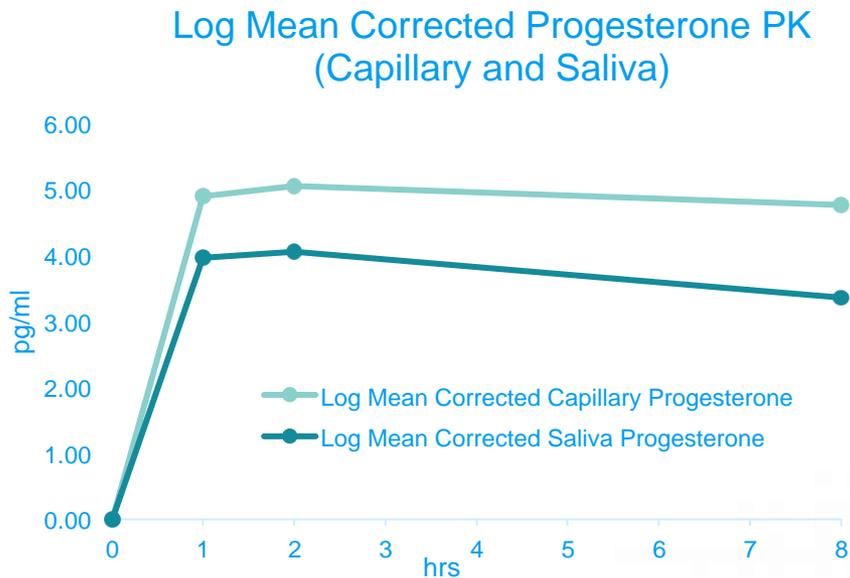


Why Transdermal?

- Transdermal delivery perceived safer due to a lower first-pass effect
- No FDA-approved transdermal progesterone
- New TXMD PK data suggest leveraging solubilized progesterone, show elevated and sustained transdermal levels
- Leveraging this technology creates an opportunity for new progesterone IP, products and novel dosage forms

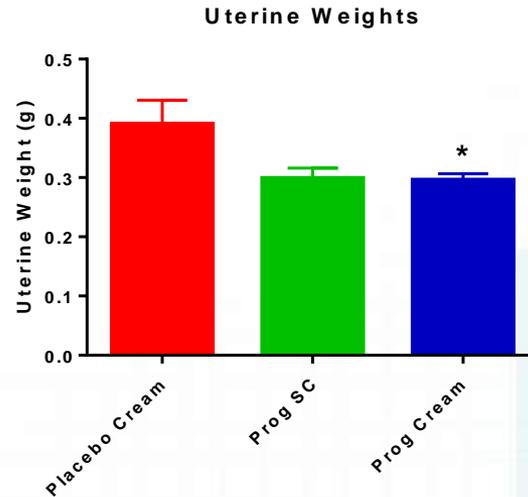
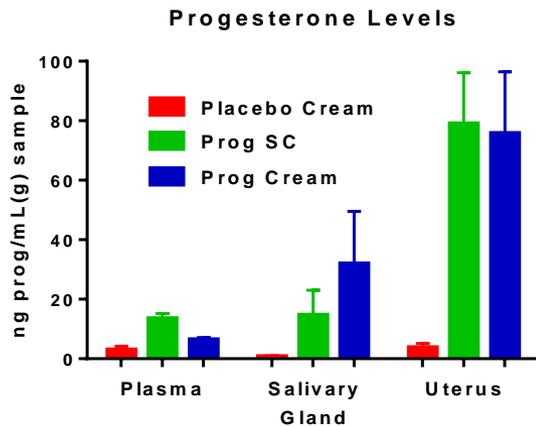
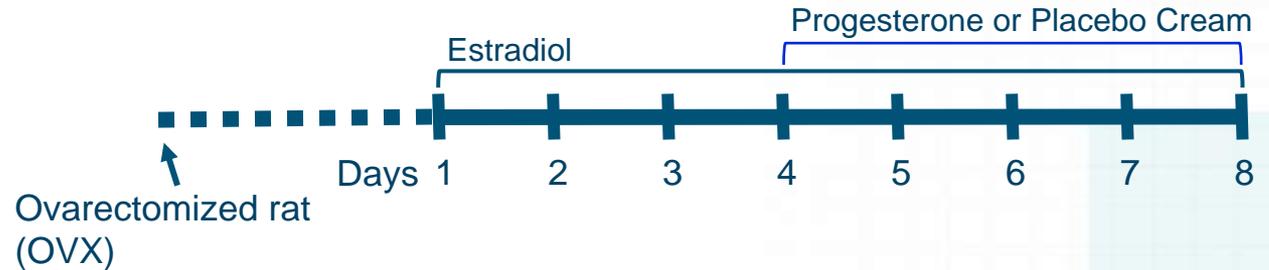
E+P Topical PK Results

New Formulation PK Data Suggest Sustained 8-hour Duration¹

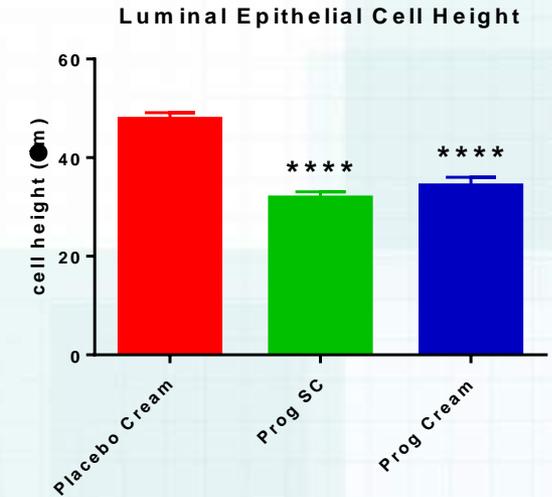


- Levels in the saliva and capillary samples are higher than in the serum, where it was not detectable¹
- Consistent with published article from Du and Stanczyk 2013²

Proof Of Concept Efficacy Study¹



Mean \diamond SEM; n=8
* p=0.02 vs. Placebo Cream



Mean \diamond SEM; n=8
**** p<0.0001 vs. Placebo Cream

Transdermal Market Opportunity

Product (Combination E+P)	TRx ¹ (000)	U.S. Sales (\$MM) ¹	Company
Estradiol/Levonorgestrel (Climara Pro [®])	111	\$23	
Estradiol/Norethindrone Acet (CombiPatch [®])	383	\$58	
Total Combination Transdermal Sales	494	\$81	

Product (Estradiol Only)	TRx ¹ (000)	U.S. Sales (\$MM) ¹	Company
Estradiol (Patch, Gel, Spray) (Alora [®] , Climara [®] , Estraderm [®] , Menostar [®] , Vivelle [®] , Vivelle-Dot [®] , Minivelle [®] ; Divigel [®] , Elestrin [®] , Estrogel [®] ; Evamist [®])	5,674	\$814	      
Total Estradiol Transdermal Sales	5,674	\$814	

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.

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Intellectual Property Update



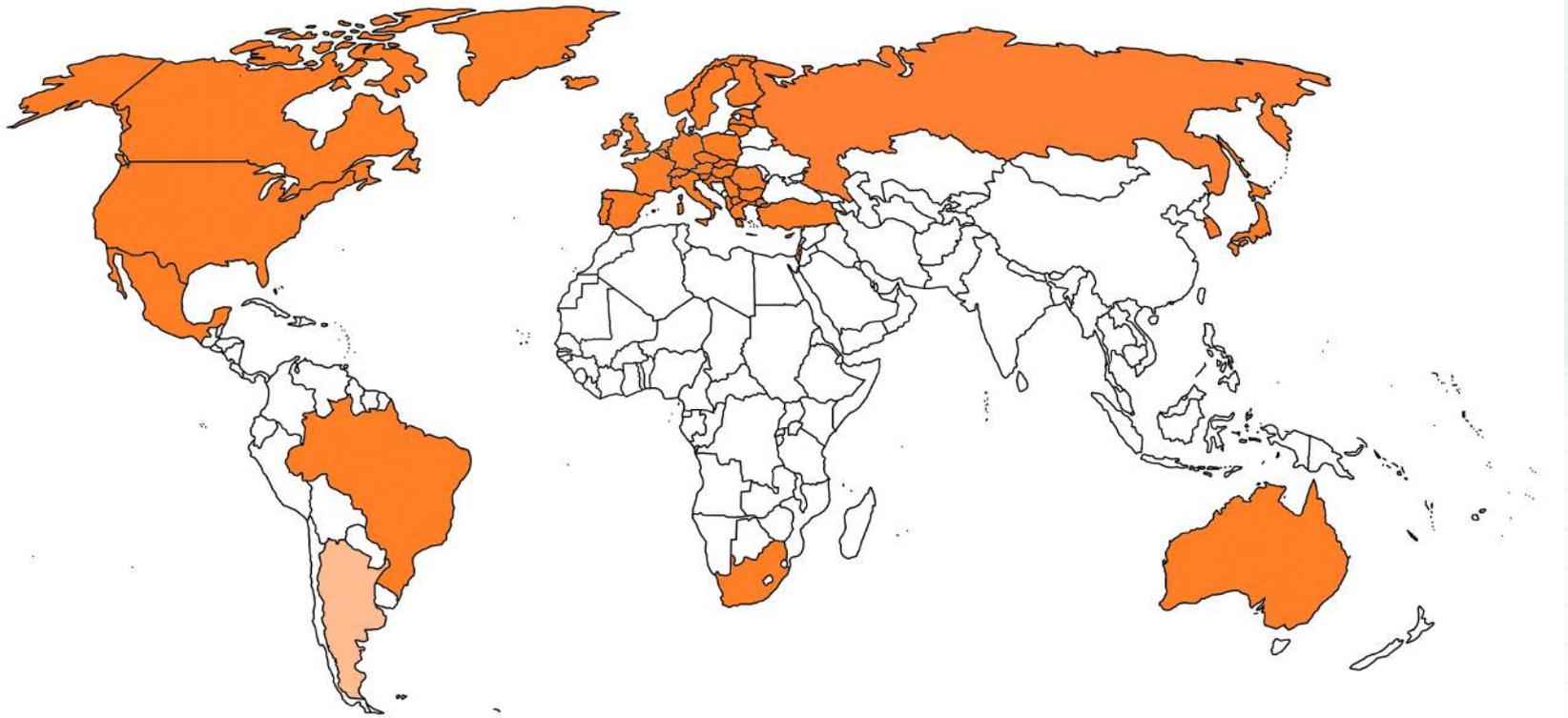
Growing Patent Portfolio

	Filed	Provisional	Non-Provisional	Issued
U.S.	48	15	22	11
Ex-U.S.	61			

- Seven new patents issued in 2015 strengthening competitive barriers to entry and building on layered coverage strategies
- Others issued:
 - Field spanning estradiol and progesterone pharmaceutical compositions and methods
 - OPERA reporting and analysis software patent
- Layered patent strategies
 - Field spanning pharmaceutical compositions and methods by family of estradiol and progesterone alone and in combination
 - Siloed strategy for each product

Worldwide Patent Filings*

Strong IP Portfolio with 61 Patents Pending in 12 Jurisdictions Outside the United States



Investment Rationale



TXMD

LISTED

NYSE MKT

Investment Rationale

- **Worldwide commercial rights for multiple hormone therapy products in Phase 3** and earlier stages:
 - Well-known chemical entities with established safety and efficacy thresholds; 505(b)(2)
 - Unique, large, and growing markets with favorable competitive dynamics (DQSA)
 - Additional early stage pipeline candidates
 - Strong foreign IP portfolio with 61 patent applications pending in 12 foreign jurisdictions
- **Growing U.S. commercial business** marketing prescription and OTC prenatal vitamins
 - Customer base of OB/GYNs and other women's health specialists
 - Recognized by Deloitte Technology Fast 500 as 41st in North America
- **Experienced management team** with proven development and commercial success in women's health

TXMD: Financial Snapshot

Listing Exchange

NYSE MKT

Shares outstanding

177.5 million (as of August 3, 2015)

Cash

\$67.2 million (as of June 30, 2015)

Financing net proceeds

\$32.2 million (offering July 10, 2015)

Debt

\$ 0 million

Thank You!

TherapeuticsMD[®]

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Appendix



TherapeuticsMD®

Long-Term Growth Opportunity

DIVERSE PRODUCT PORTFOLIO

- Two Phase 3 products
 - Trial completion for lead product expected Q4 2015
 - Complete enrollment for second product expected Q4 2015
- Pipeline of 8 novel products
- Expedited and cost effective development – 505(b)(2) pathway
- Unpartnered with worldwide rights

LARGE UNDERSERVED MARKETS

- Phase 3 products address ~85 million patients
- Unmet need for safe and effective treatments
- DQSA supports commercial opportunity
- Initial HT market opportunity >\$3.5B

WOMEN'S HEALTH EXPERTISE

- Experienced clinical team
- Existing commercial infrastructure
- Established customer relationships (OB/GYNs)

SYMBODA™ TECHNOLOGY

- Addresses key formulation and delivery challenges
- VagiCap™ – enhanced gelcap technology
- Transdermal portfolio in development
- 109 patents filed/granted

EFFICIENT FUNDING

- No debt
- \$200M raised publicly to date

TX-004HR Phase 2 Study

Patient Experience Secondary Endpoint

Patient Experience Survey Results Summary¹

- 97% reported “easy to use”
- 96% reported the TX-004HR softgel (VagiCap™) was “easy to insert”
- 94% reported “convenient to use”
- 0% experienced expulsion of capsule
- >60% “very satisfied”; 8% were “dissatisfied”
- 63% reported quality of life was “somewhat better” to “much better” after only 14 days of use

Subject to patient interpretation