TherapeuticsMD®

TXMD Overview

January 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 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.

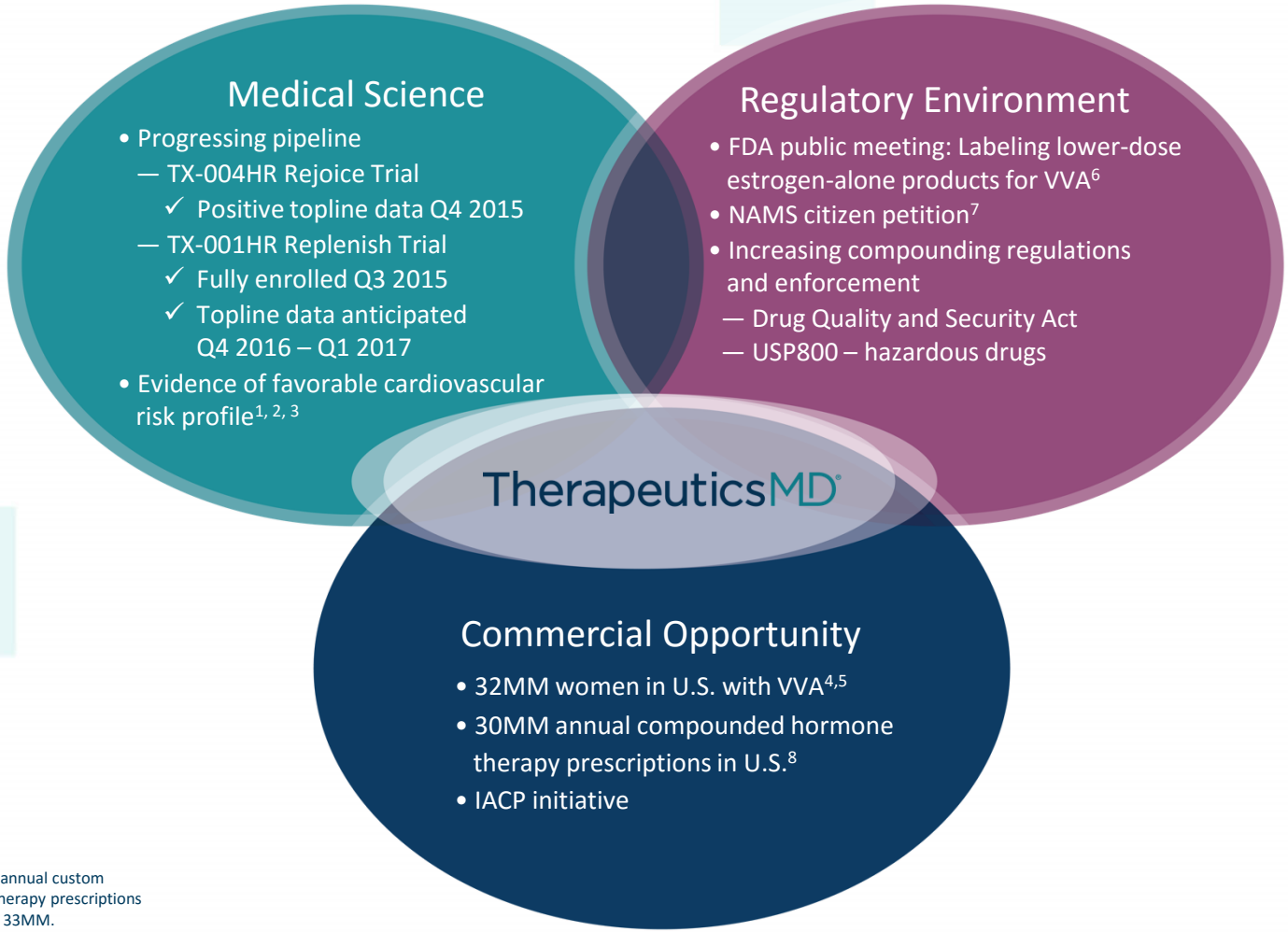
PDF copies of press releases and financial tables can be viewed and downloaded at our website: www.therapeuticsmd.com/pressreleases.aspx.

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

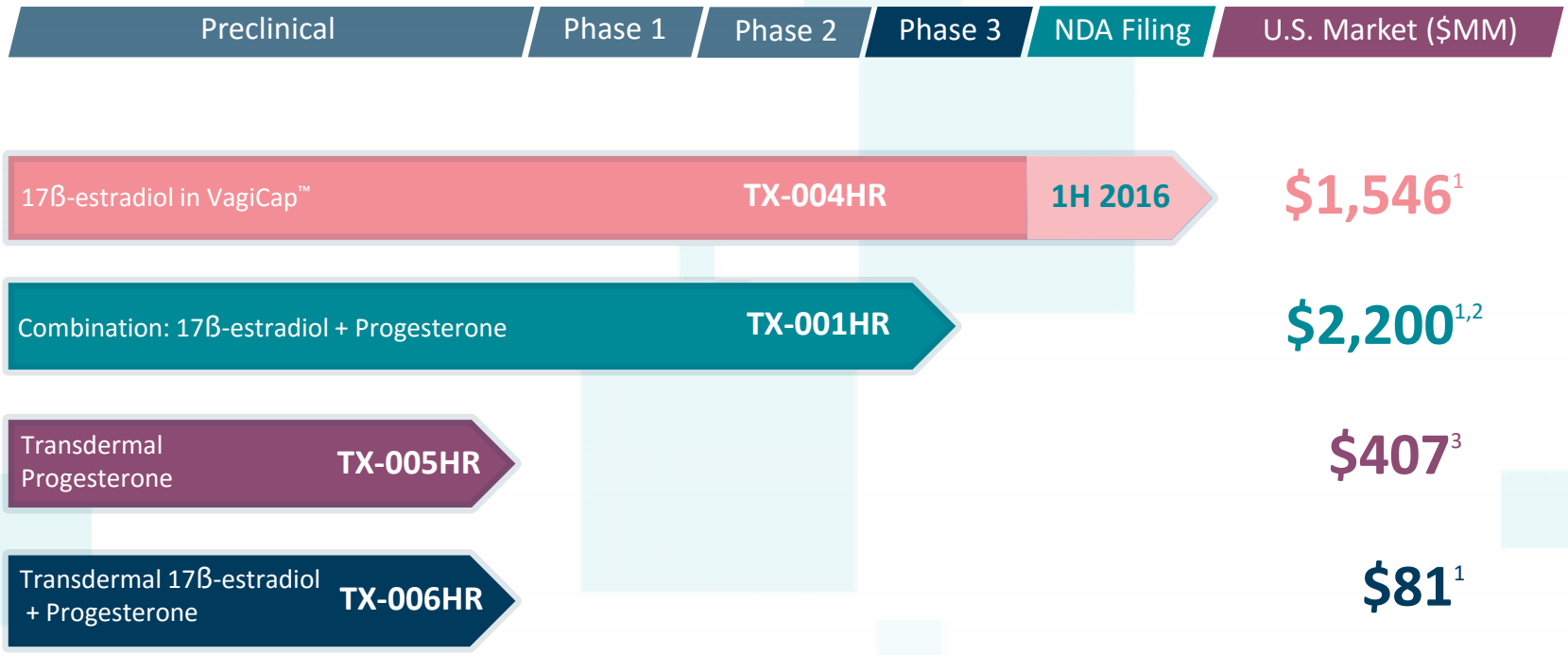
Unique Confluence of Factors



* The reported number of annual custom compounded hormone therapy prescriptions is estimated at 26MM to 33MM.

1) 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.
2) Hodis HN, et al. "Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol" AHA 2014; Abstract 13283.
3) Abstract 13283: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol;HN Hodis, et al. *Circulation*. 2014; 130:A13283.
4) 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.
5) 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.
6) https://federalregister.gov/a/2015-24509, last accessed November 10, 2015
7) www.menopause.org/forms/nams-citizens'-petition, last accessed November 10, 2015
8) Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA Approved MHT Has Increased - See more at: http://press.endocrine.org/doi/abs/10.1210/endo-meetings.2015.RE.5.FRI-124#sthash.PySEhZ9P.dpuf

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.

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Management with Deep Experience in Women's Health

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

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

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

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

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

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

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

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

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

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

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

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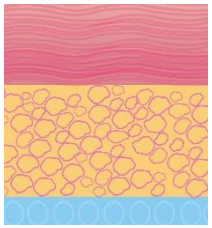
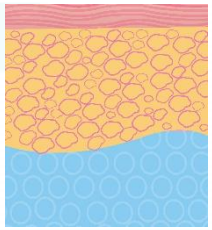
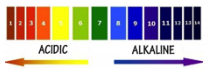
Overview – Vulvar and Vaginal Atrophy (VVA)

- 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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VVA Market – Established and Growing

- U.S. sales more than doubled since 2008[1]
- Global market expected to be $2.1 billion in 2022[4]
- Currently no generic competition
- 32 million U.S. women currently experiencing VVA symptoms[5,6]

Product[2]	Company	Compound	TRx[1] 12 Month Rolling (000)	U.S. Sales ($MM)[1] 12 Month Rolling	WAC Price[3]
Premarin® Cream	**Pfizer**	Equine vaginal estrogen	1,774	$511	$263.52
Vagifem® Tablets	**Novo Nordisk**	Vaginal estradiol	1,851	$463	$351.54*
Estrace® Cream	**Allergan**	Vaginal estradiol	1,751	$406	$240.05
Osphena® Tablets	**Shionogi**	Oral SERM	280	$67	$158.00
Estring®	**Pfizer**	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 11/6/15. * for 18 tablets ($156.54 WAC for 8 tablets)
4) GlobalData July 2013 report GDHC54PIDR.
5) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
6) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):

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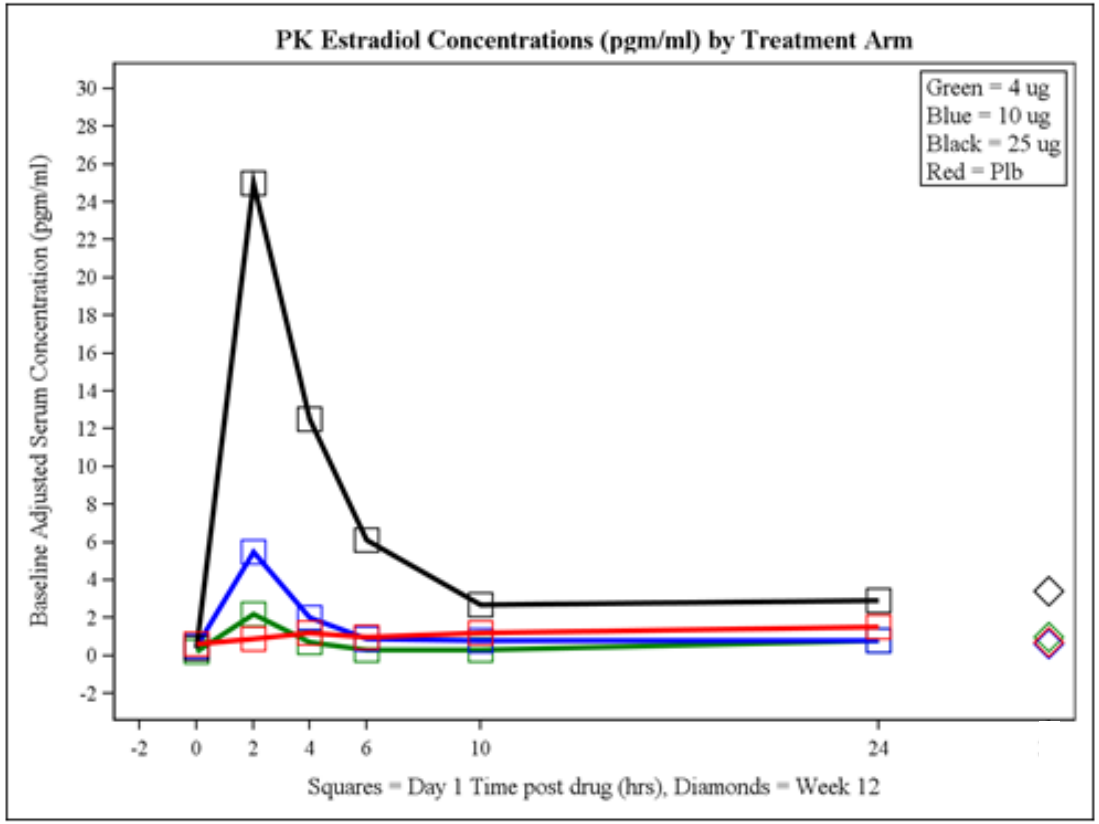
Statistical Significance of Results for Co-Primary Endpoints Mean Change from Baseline to Week 12 Compared to Placebo

	25 µg	10 µg	4 µg
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	0.0001	0.0001	0.0255

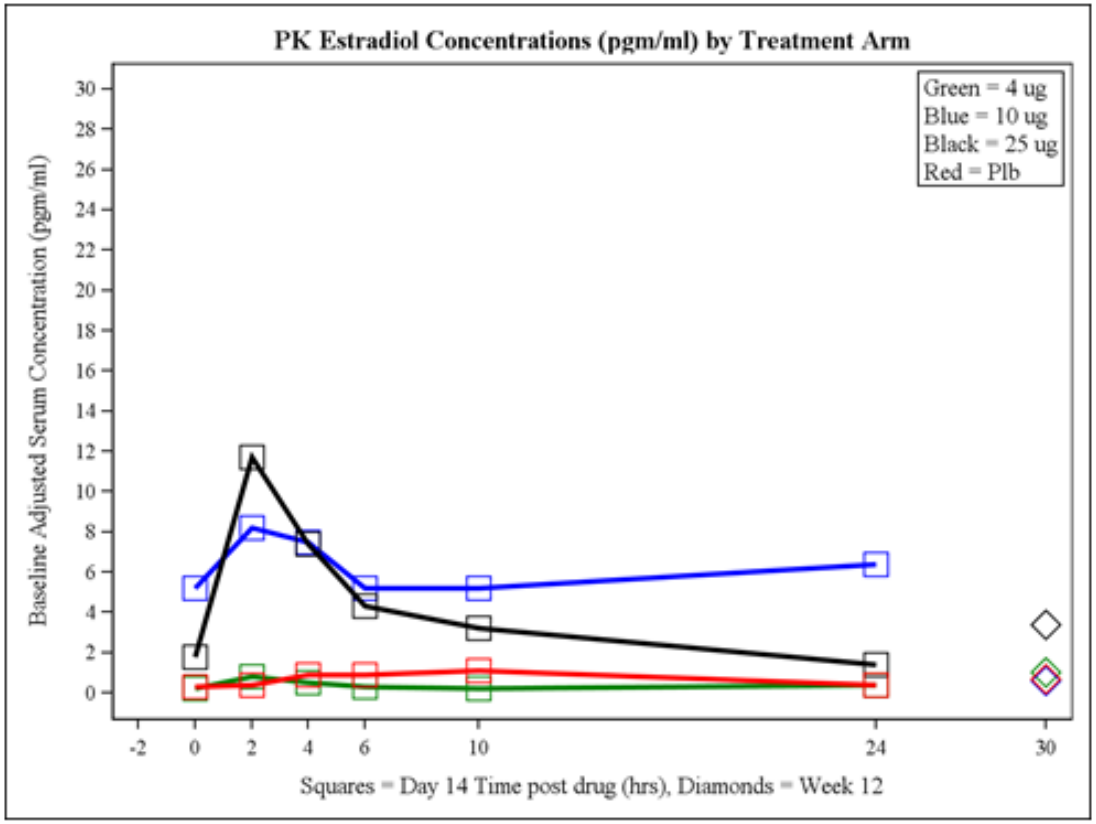
Statistical Significance of Mean Change from Baseline Severity of Dyspareunia by Study Visit

	25 µg	10 µg	4 µg
Week 2	0.0284	0.0026	0.0407
Week 6	0.0001	0.0012	0.0123
Week 8	< 0.0001	< 0.0001	0.0005
Week 12	0.0001	0.0001	0.0255

Baseline Adjusted Mean Estradiol Concentration Day 1



Baseline Adjusted Mean Estradiol Concentration Day 14



VVA Market Dynamics Ready for New Product

Why?

Only 2.3MM U.S. women treated with Rx product[1]

Vaginal Creams

- Messiness[2]
- Re-usable applicator
- Long-term safety[2]
- Dose preparation by user required[3]

Mean treatment duration

46 days[4]

Vaginal Tablets

- Efficacy[2]
- Applicator
- Long-term safety[2]
- Systemic absorption[2]

Mean treatment duration

103 days[4]

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.* 2015; 22 (11) 1197-203.

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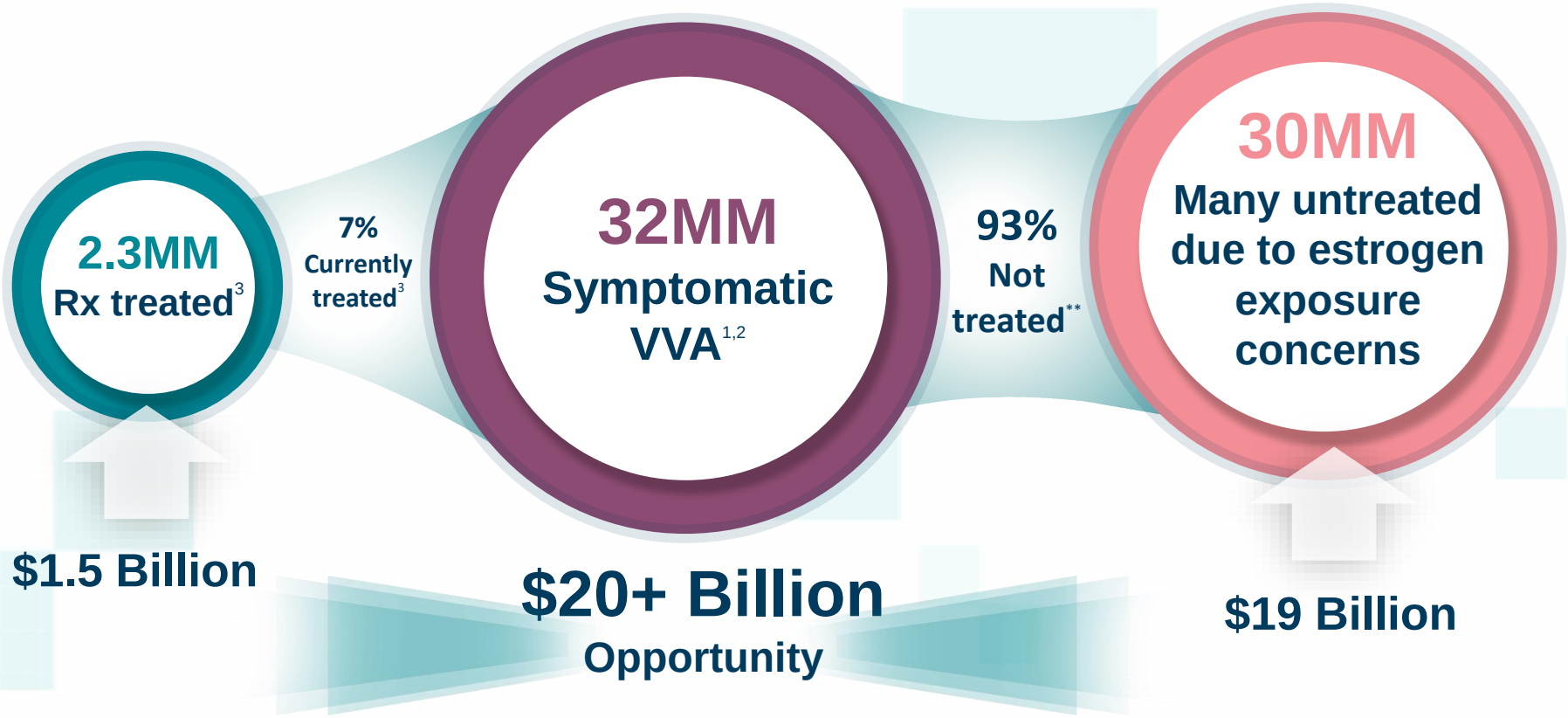
30MM Women with VVA Untreated**



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.

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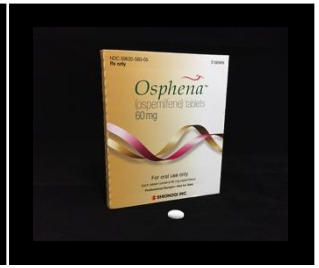
Current Products for the Treatment of VVA

Product Characteristic	Vagifem®	Premarin® Cream	Estrace® Cream	Osphena®
Design				
Cream		✓	✓	
Applicator	✓	✓	✓	Oral SERM Daily Use

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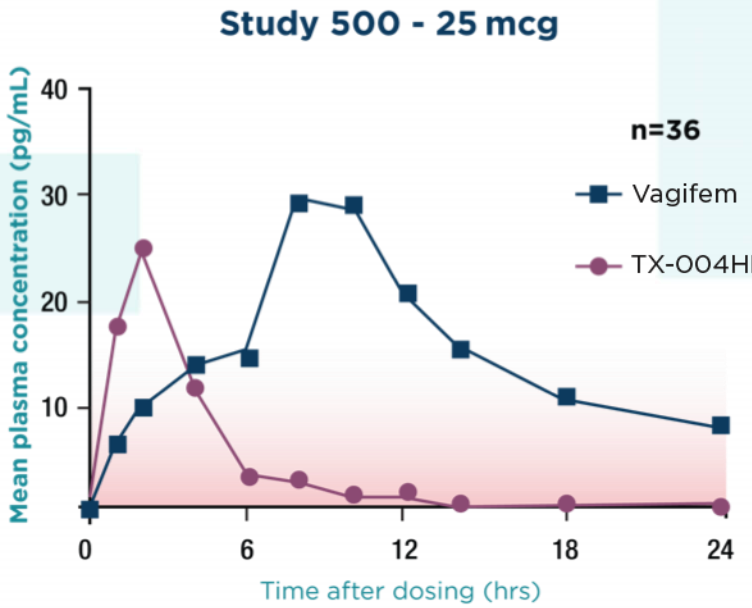
TX-004HR – Target Product Profile

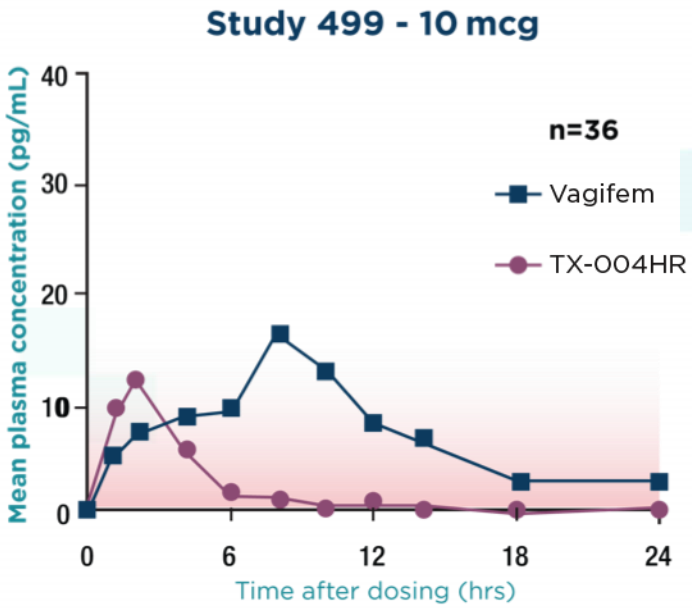
Target Goals	Phase 3 Supportive Data
Efficacy	Phase 3 data demonstrated statistical significance for all 3 doses on the 4 co-primary endpoints
Low systemic exposure	Negligible to low systemic absorption with 4 mcg, 10 mcg and 25 mcg observed in phase 1 and 3
Fast onset of action	Efficacy observed at Day 14 in phase 2 and 3
New lower effective dose	Phase 3 evaluated broad range of doses, including 4, 10, and 25 mcg; 4 mcg potential new lowest strength dose
Improved user experience	Phase 3 data included patient satisfaction; 95% said “easy to use”
Safety	Phase 3 data suggests no clinically significant differences vs. placebo; no drug-related serious adverse events

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 AUC (0-24 hours) is 2- to 3-fold lower with TX-004HR relative to Vagifem





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TX-004HR Phase 3 PK Studies

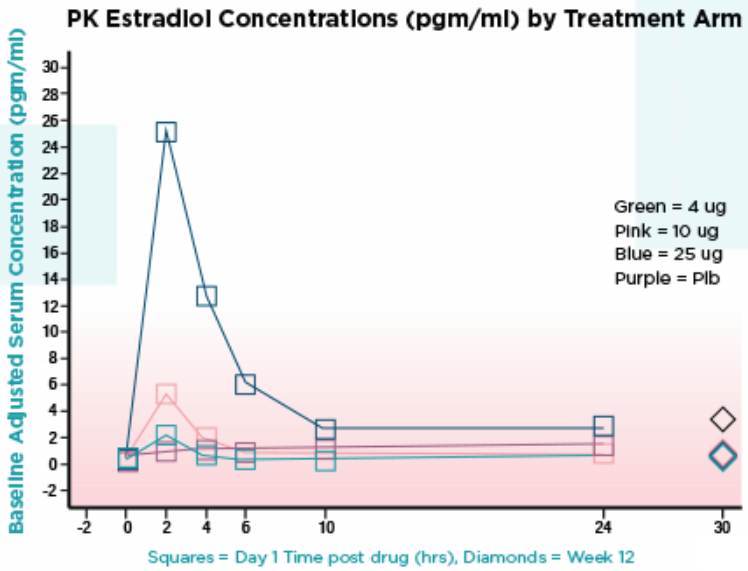
Key Findings

- Negligible to low systemic absorption for all three doses
- Supportive of the previous phase 1 trial data

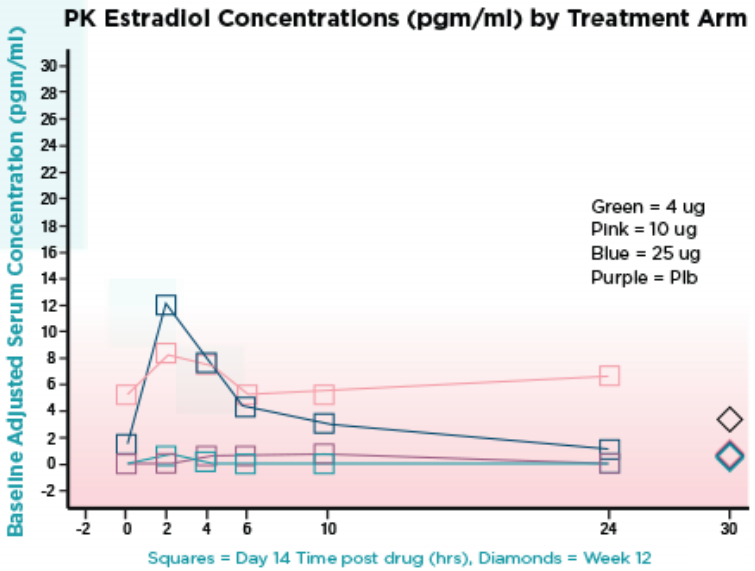
Rejoice Trial (Phase 3)

Baseline Adjusted Mean Estradiol Concentration Day 1 & Day 14

Day 1



Day 14



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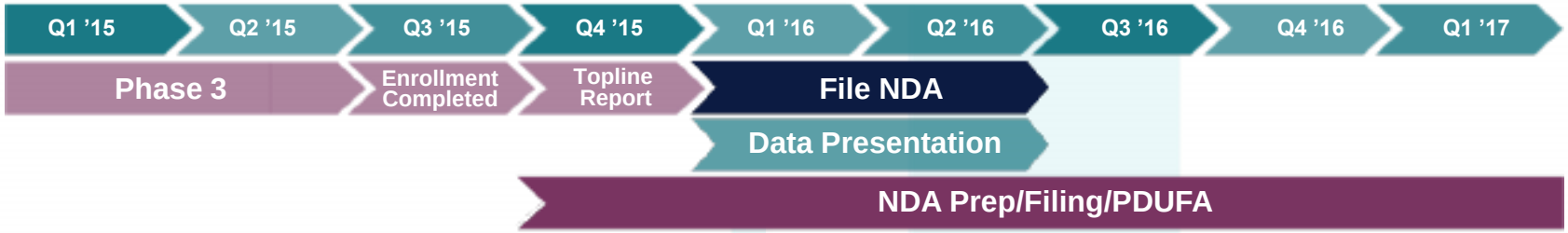
TX-004HR Vaginal Estradiol U.S. Launch Timeline



- **Phase 3 Trial[1]: 12 Week Double-blinded, Placebo Controlled**
- **Subjects: 764, in 89 Sites across the United States and Canada**
  - 3 active arms: 4 mcg (191), 10 mcg (191), 25 mcg (190)
  - 192 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
  - Reduction in atrophic effects on epithelial integrity and vaginal secretions[4]
  - FSFI (Female Sexual Function Index), acceptability survey

1) NCT02253173; https://clinicaltrials.gov/ct2/show/NCT02253173?term=rejoice&rank=1, last accessed November 3, 2015.
2) Each arm (4 mcg, 10 mcg, and 25 mcg) tested against each co-primary endpoint.
3) The FDA has previously indicated to us that in order to approve the drug based on a single trial, the trial would need to show statistical significance at the 0.01 level or lower for each endpoint, and that a trial that is merely statistically significant at a higher level may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial.
4) 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.

Black Box Warning

Current Black Box Warning[1]:

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

Estrogen-Alone Therapy

Endometrial Cancer

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding *[see Warnings and Precautions (5.3)].*

Cardiovascular Disorders and Probable Dementia

Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or *dementia [see Warnings and Precautions (5.2, 5.4), and Clinical Studies (14.2, 14.3)].*

The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo *[see Warnings and Precautions (5.2), and Clinical Studies (14.2)].*

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily CE (0.625 mg) -alone, relative to placebo*. It is unknown whether this finding applies to younger postmenopausal women* [see Warnings and Precautions (5.4), Use in Specific Populations (8.5), and Clinical Studies (14.3)].

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Estrogen Plus Progestin Therapy

Cardiovascular Disorders and Probable Dementia

Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia *[see Warnings and Precautions (5.2, 5.4), and Clinical Studies (14.2, 14.3)].*

The WHI estrogen plus progestin substudy reported increased risks of DVT, pulmonary embolism (PE), stroke and myocardial infarction (MI) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral CE (0.625 mg) combined with medroxyprogesterone acetate (MPA) [2.5 mg], relative to placebo *[see Warnings and Precautions (5.2), and Clinical Studies (14.2)].*

The WHIMS estrogen plus progestin ancillary study of the WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women *[see Warnings and Precautions (5.4), Use in Specific Populations (8.5), and Clinical Studies (14.3)].*

Breast Cancer

The WHI estrogen plus progestin substudy also demonstrated an increased risk of invasive breast cancer [see Warnings and Precautions (5.3), and Clinical Studies (14.2)].

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA, and other combinations and dosage forms of estrogens and progestins.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

1. Premarin Vaginal Cream prescribing information. http://labeling.pfizer.com/showlabeling.aspx?id=132

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Black Box Warning Citizen Petition

A Citizen Petition organized by the North American Menopause Society (NAMS) to be submitted to FDA and supported by[1]:

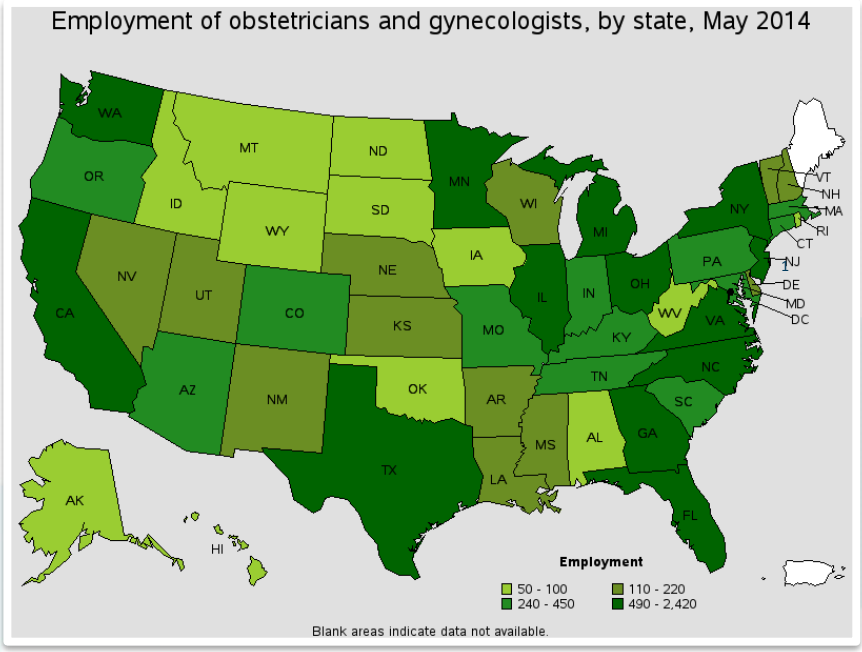
- Endocrine Society
- American Congress of Obstetricians and Gynecologists
- American Medical Women's Association
- American Society for Reproductive Medicine
- Academy of Women's Health
- Society for Women's Health Research
- Nurse Practitioners in Women's Health
- American Association of Nurse Practitioners
- Society for Women's Health Research
- International Society for the Study of Women's Sexual Health
- Others

FDA Scientific Workshop on Labeling "Lower" Dose Estrogen-Alone Products for Symptoms of VVA - November 10, 2015[2]

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

1. Form Letter Comment from North American Menopause Society. http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-3275-0060
2. 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

Sales Expansion



- 21,740 Total OB/GYNs
- 16,820 OB/GYN Physicians in GYN offices

Current vitaMedMD Sales Force

- 32 territories

Sales Expansion

1. http://www.bls.gov/oes/current/oes291064.htm

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

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Menopause Overview

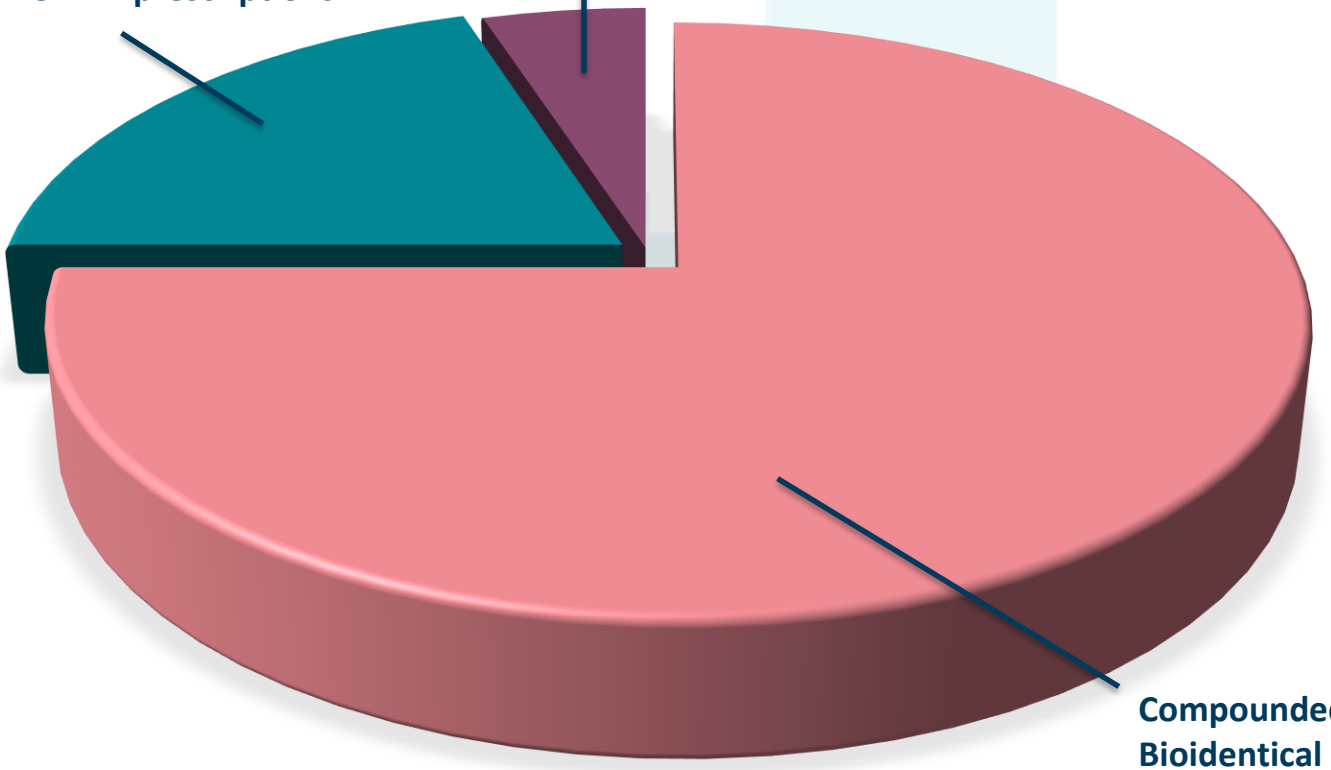
- Menopause represents the natural life-stage transition when women stop having periods
- May result in physical and emotional symptoms
  - Average age of menopause 51 years[1]
  - Hot flashes due to lower estrogen levels
  - Estrogen given to reduce hot flashes
  - Estrogen causes uterus to thicken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

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

Total Addressable Market = 40 MM prescriptions

Combined use of FDA-approved Estrace®
& Prometrium® 1.5 – 2.5 MM prescriptions[1]

FDA-approved Single-pill Combination
E+P (synthetic) 7-8 MM prescriptions[1]



Compounded
Bioidentical E+P
30MM prescriptions[2,3]

1) Symphony Health Solutions PHAST 2.0 Prescription Monthly Data, 12 months as of June 30, 2015.
2) The reported number of annual custom compounded hormone therapy prescriptions is estimated at 26MM to 33MM
3) Pinkerton, J.V. 2015. *Menopause,* Vol.22, No.9, pp 0-11.

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FDA-Approved Hormone Therapy Market Size

FDA-Approved Product	Non-Bioidentical	U.S. Sales ($MM)[1]	Company
17β-estradiol + NETA / DSP Activella® / FemHRT® / Angeliq®	**Non bio-identical containing progestins**	**$37**	Allergan, Bayer, novo nordisk®
Generic 17β + Progestins	**Non bio-identical containing progestins**	**$230**	Teva Pharmaceuticals
Premarin + MPA Prempro® / Premphase®	**Non bio-identical CEE + progestin**	**$339**	Pfizer
Premarin + SERM Duavee®	**Non bio-identical CEE + SERM**	**$19**	Pfizer
Paroxetine Brisdelle®	**SSRI non-hormonal**	**$36**	Noven Therapeutics, LLC
Total FDA-Approved Oral Combination Sales		**$661**	

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

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.[1]

Pinkerton, J.V. Menopause Hormone Therapy (MHT) Usage: FDA-Approved MHT has decreased while compounded non-FDA-approved MHT has increased, ENDO, 2015.[2]

Archer, D.F., et al. Prevalence of Use and Cost of Compounded Menopausal Hormone Therapy (CMHT) 2015 ACOG, presentation, May, 2015.[3]

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

30MM[2] Annual custom -compounded prescriptions

$49[1] Average monthly cash cost

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

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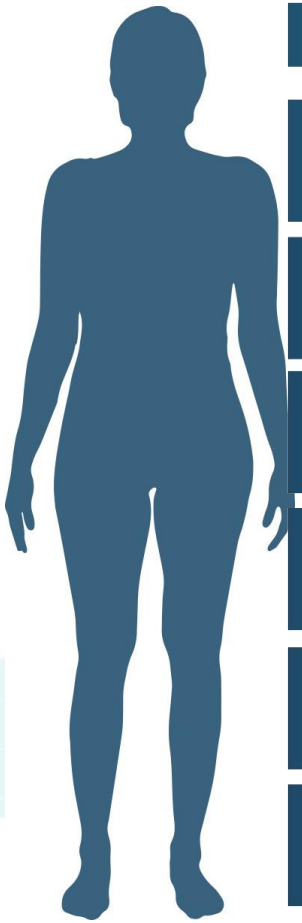
Evidence Supports Bio-identical Progesterone Favorable Clinical Profile Compared to Synthetic Progestins



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	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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Evidence Supports Bio-identical Progesterone 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

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

— *Circulation,* November 2014

Oral estradiol may be associated with a lower risk of stroke … compared with conventional-dose oral CEE.[2]

— *Menopause,* September 2014

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

— *Cochrane Collaboration,* 2015

1) Smith et al. Lower Risk of Cardiovascular Events in Postmenopausal Women Taking Oral Estradiol Compared with Oral Conjugated Equine Estrogens (CEE) .
2) Shufelt et al. Hormone Therapy Dose, Formulation, Route of Delivery, and Risk of Cardiovascular Events in Women: Findings from the Women's Health Initiative Observational Study.
3) Abstract 13283: Testing the Menopausal Hormone Therapy Timing Hypothesis: The Early versus Late Intervention Trial with Estradiol;HN Hodis, et al. *Circulation*. 2014; 130:A13283.
4) Cochrane Collaboration; HT for preventing cardiovascular disease in postmenopausal women; Boardmen HMP, et al., 2015.

Medical Societies Express Concern Over Compounded Hormones

- ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products[1]
  - Lack of Good Manufacturing Practices (GMP)
  - Variable purity
  - Variable content uniformity
  - Variable potency (under/over dose)
  - Not approved for efficacy and safety
  - Lack of stability data
- Medical societies' global consensus statement declares that the use of custom-compounded hormone therapy is not recommended[2]

1) Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee, Number 532, August 2012 (Reaffirmed 2014, Replaces No. 387, November 2007 and No. 322, November 2005).
2) Villiers, T.J. et al. Global Consensus Statement on Menopausal Hormone Therapy, *Climacteric*, June 2013, Vol. 16, No. 3 : Pages 316-337.

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Compounding Regulations and Enforcement

Drug Quality and Security Act (DQSA)[1]

- Prohibits compounding of essential copies of 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

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

TX-001HR – Target Product Profile

Target Goals	Preliminary Supportive Data
Meet patient demand for bio-identical hormones	Potential for first FDA-approved natural estradiol plus natural progesterone combination softgel capsule
New lower effective dose	Broad range of doses being evaluated in phase 3
Labeling differentiation	Bio-identical terminology as both hormones similar to those produced by the ovary
Leverage data on natural progesterone and 17β-estradiol	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 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
  - 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)

Replenish TRIAL

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

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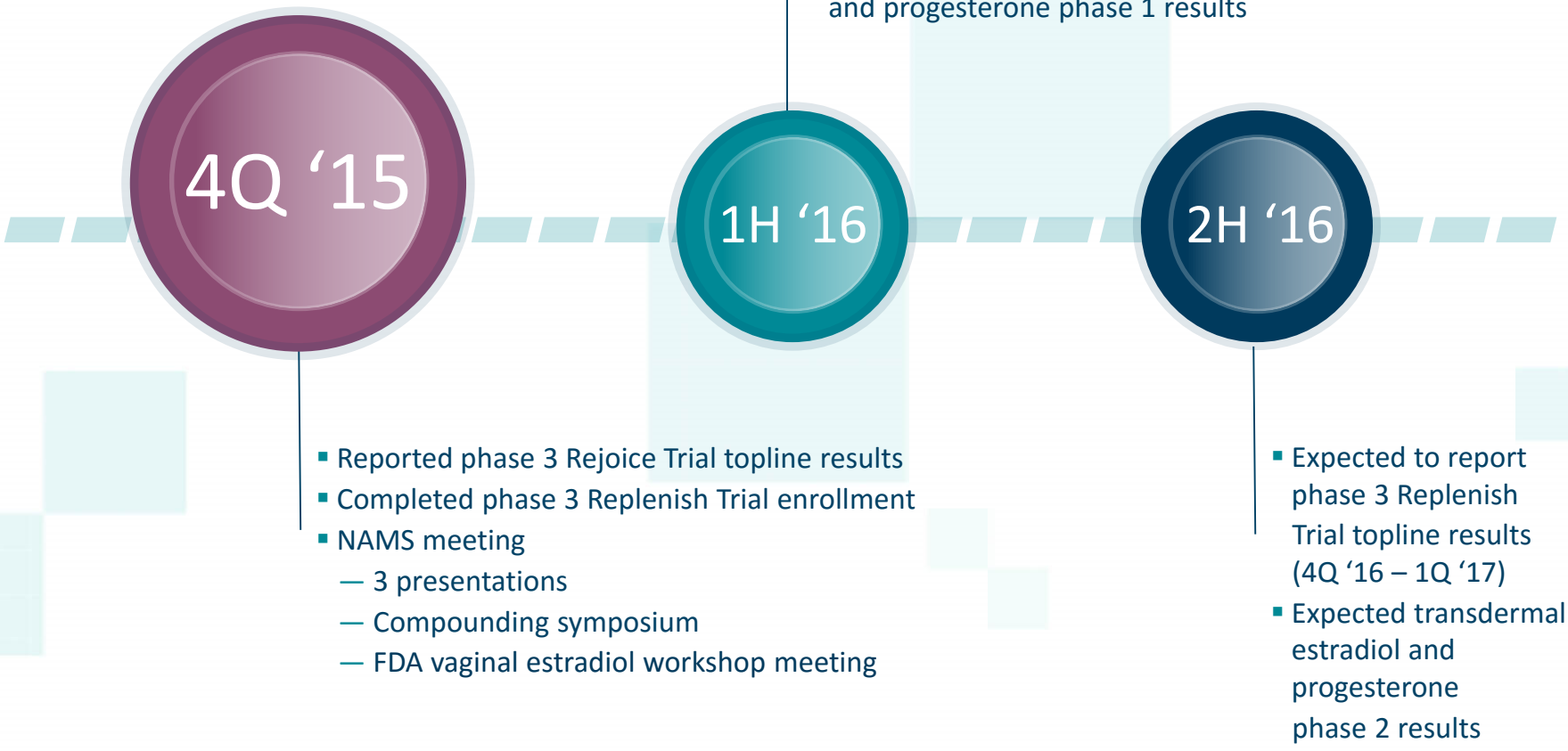
Key Milestones and Anticipated Milestones



Early Stage Pipeline | Transdermal Programs

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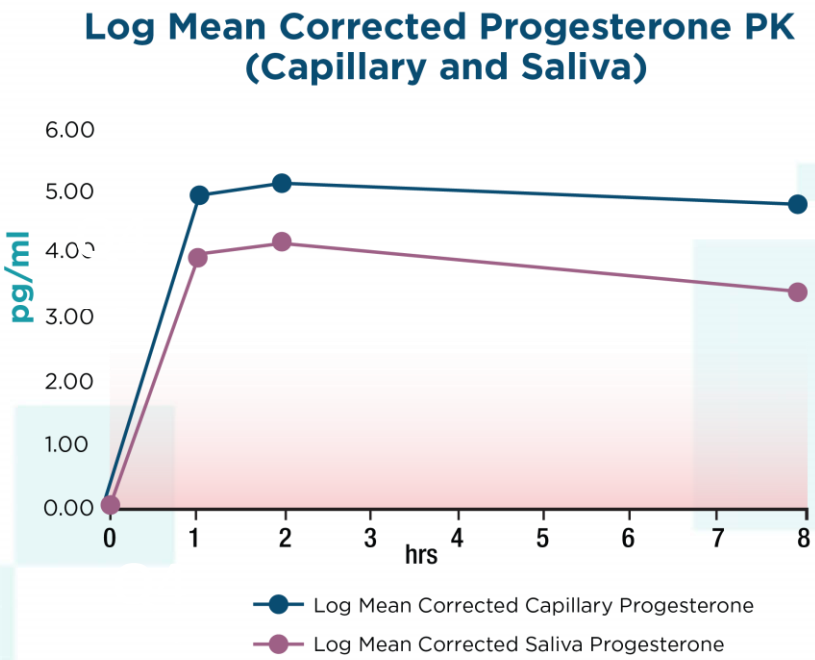
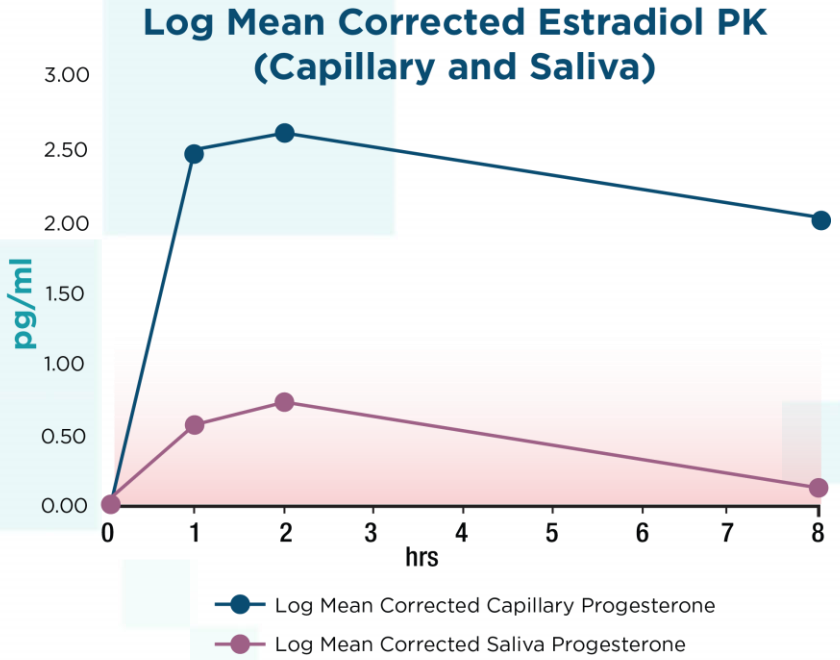
Why Transdermal?

- 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 Duration[1]





- Levels in the saliva and capillary samples are higher than in the serum, where it was not detectable[1]
- Consistent with published article from Du and Stanczyk 2013[2]

1) Data on file, TherapeuticsMD.
2) Du, Joanna Y. et al. *Menopause*. 2013, Vol.20, No.11, pp 1-7.

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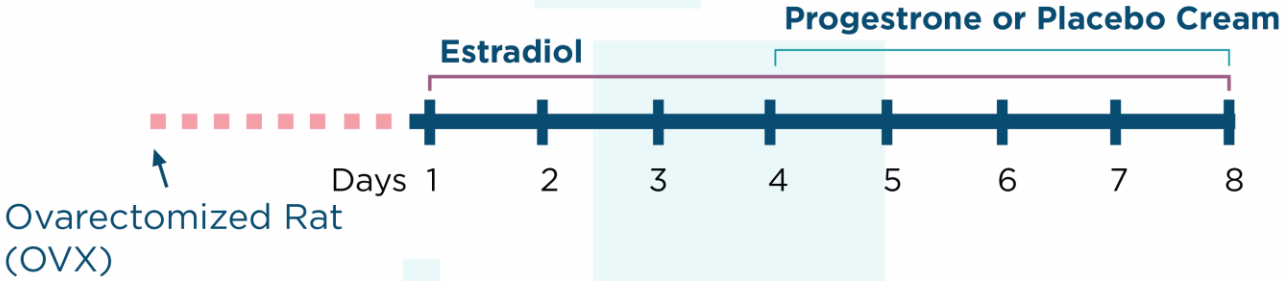
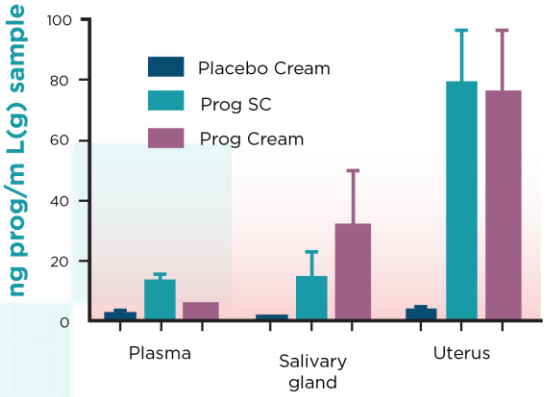
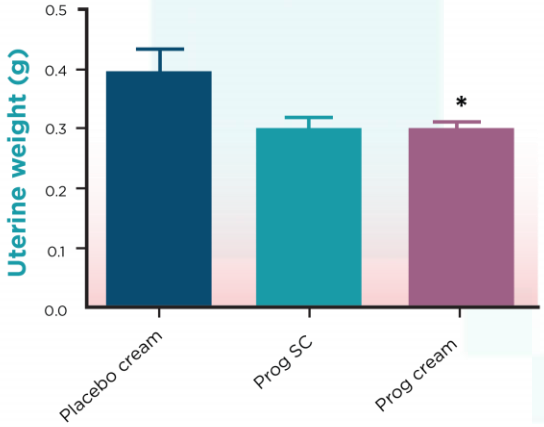
Proof of Concept Efficacy Study[1]



Progesterone Levels



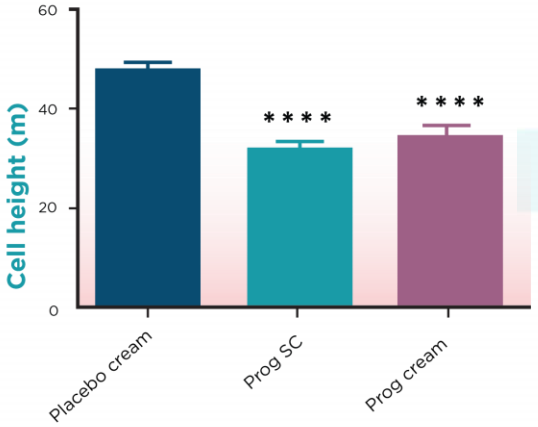
Uterine Weights



Mean ± SEM; n=8

* p=0.02 vs. Placebo Cream

Luminal Epithelial Cell Height



Mean ± SEM; n=8

**** p<0.0001 vs. Placebo Cream

1) Data on File, TherapeuticsMD.

Note: An ovarectomized rat (OVX) is a female rat whose ovaries have been removed.

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Transdermal Market Opportunity

Product (Combination E+P)	TRx[1] (000)	U.S. Sales ($MM)[1]	Company
Estradiol/Levonorgestrel (Climara Pro®)	111	**$23**	BAYER
Estradiol/Norethindrone Acet (CombiPatch®)	383	**$58**	NOVEN THERAPEUTICS, LLC
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**	NOVARTIS, Allergan, MEDA, BAYER, ASCEND THERAPEUTICS, NOVEN THERAPEUTICS, LLC, VERTICAL PHARMACEUTICALS, LLC, Perrigo
Total Estradiol Transdermal Sales	**5,674**	**$814**	

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

Intellectual Property | Update

TherapeuticsMD®

Growing Patent Portfolio

	Filed	Provisional	Non-Provisional	Issued
U.S.	**51**	16	21	14
Ex-U.S.	**61**			

- Ten 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
  - Soluble Estradiol Capsule for Vaginal Insertion
  - 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 Patent Applications Pending in 12 Jurisdictions Outside the United States

*Not all patent filings filed in all jurisdictions.

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vitaMedMD®

Manufacture and distribute prescription and over-the-counter (OTC) prenatal vitamins under the **vitaMedMD®** and **BocaGreenMD®** brand names.

- National sales force
- Distribution to drug wholesalers and retail pharmacies
- Insurance adjudication

Investment Rationale

Investment Rationale

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
- Unique, large, and growing U.S. markets with favorable competitive dynamics
- Additional early stage pipeline candidates
- Strong foreign IP portfolio with 61 patent applications pending in 12 foreign jurisdictions

2 Growing U.S. commercial business marketing prescription and OTC prenatal vitamins

- Strong customer base of OB/GYNs and other women's health specialists
- 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

TXMD: Financial Snapshot

Listing Exchange

TXMD
LISTED
NYSE MKT

Debt

$0MM

Shares Outstanding

177.9MM

(as of Dec. 31, 2015)

Cash

$81.1MM

(as of Sept. 30, 2015)

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THANK YOU!

Appendix

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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% 2009-2014[1]
- 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 Phase 2 Study
Patient Experience Secondary Endpoint

n = 49

Patient Experience Survey Results Summary[1]

- 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

1) Kingsberg, Sheryl. “Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap™). Presented at the 2015 ISSWSH Annual Meeting, Feb 20, 2015.