

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

FORM 8-K

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

Date of Report (Date of earliest event reported): January 12, 2015

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW, Third Floor
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, at meetings with investors or analysts from time to time.

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

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. presentation dated January 2015.

SIGNATURES

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

Date: January 12, 2015

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated January 2015.

TherapeuticsMD®
Supporting Women's Health for Life

Investor Overview

JANUARY 2015



www.TherapeuticsMD.com

Forward-Looking Statements

This presentation by TherapeuticsMD Inc. (referred to as "we" and "our") may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

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>.

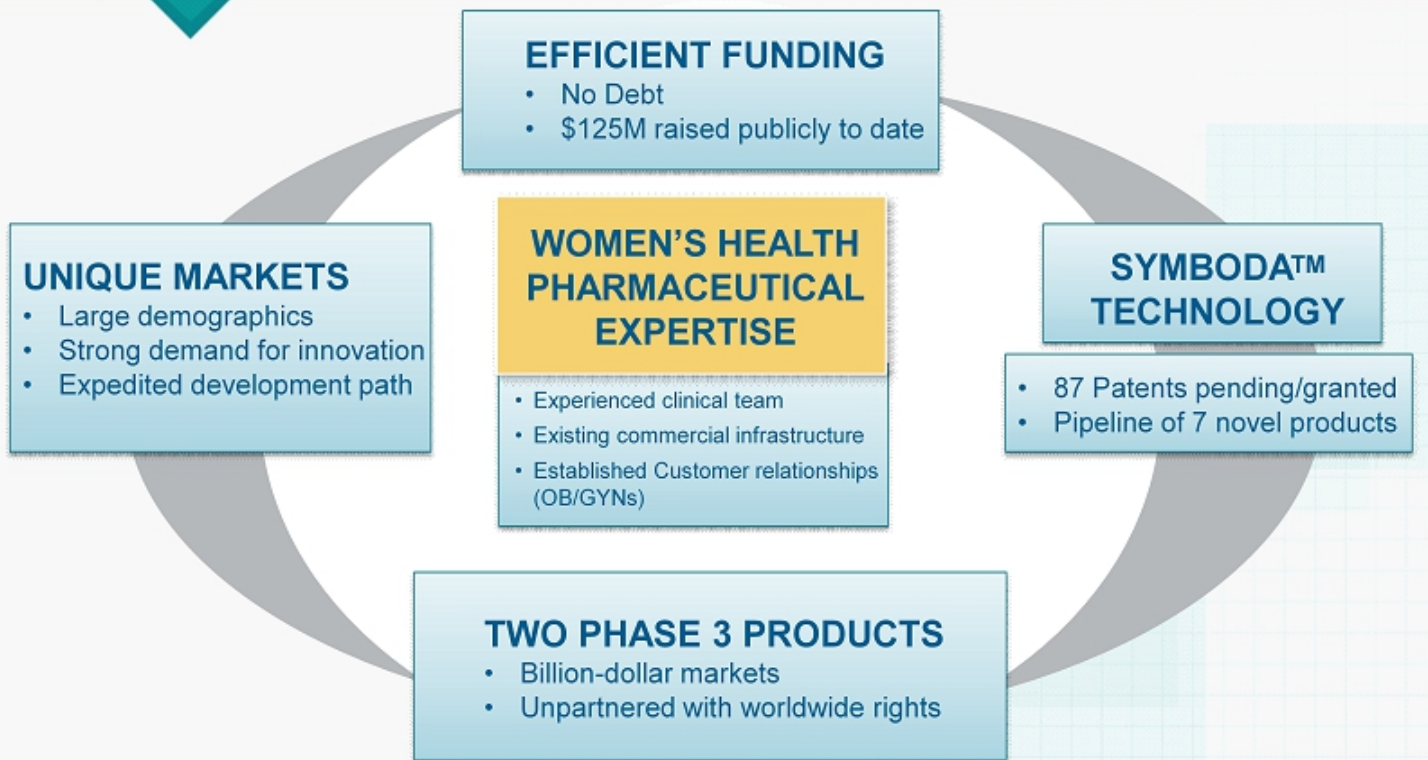
Our Mission

To develop treatments that promote women's health and address the unmet needs of this large, underserved market with innovative technology and first-to-market, FDA-regulated products.

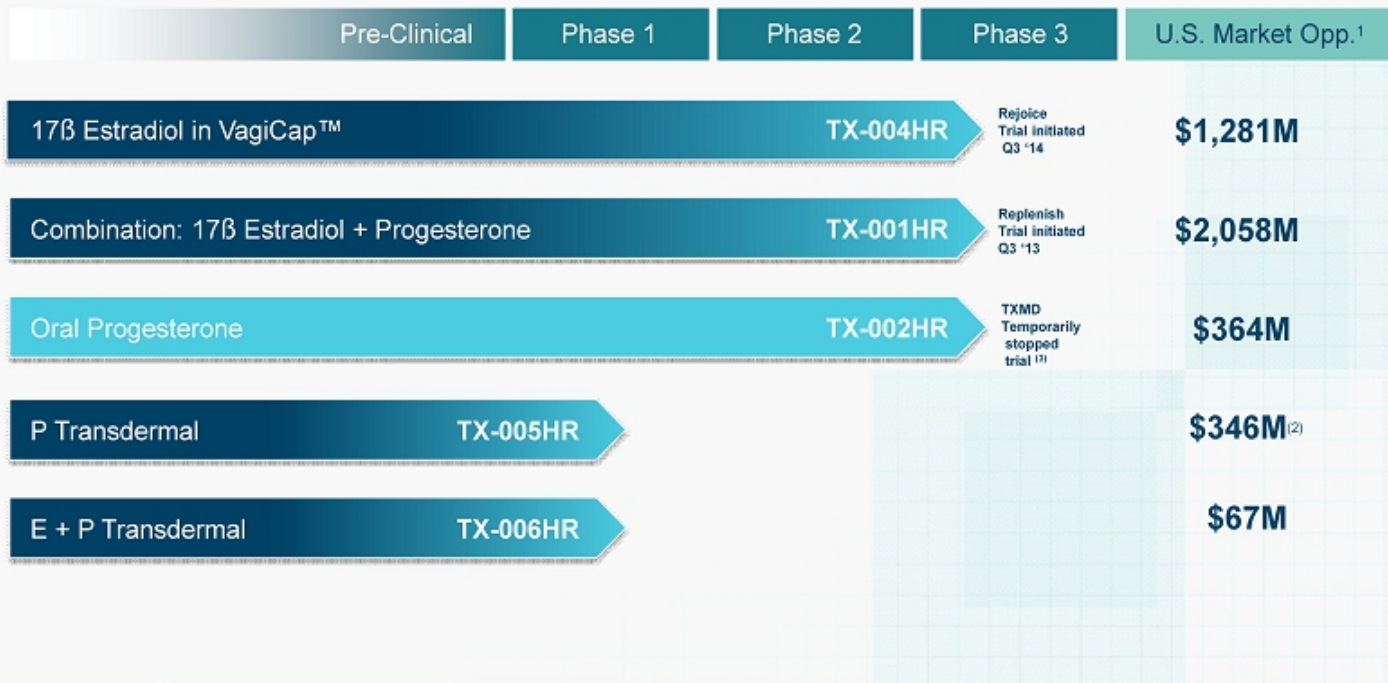


Our therapeutic portfolio of drug candidates is built on our SYMBODA™ technology platform, which enables new bio-identical hormone combinations, forms and administration routes.

TXMD: Long-Term Growth Opportunity



Pipeline Targets Large Markets



1) PHAST Prescription Monthly by Source Healthcare Analytics as of 10/14
 2) Estimated U.S. sales, based on half estradiol patch sales
 3) 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.

SYMBODA™ Enables The Combination

Reference Listed Drugs (RLD) Chemistry challenges

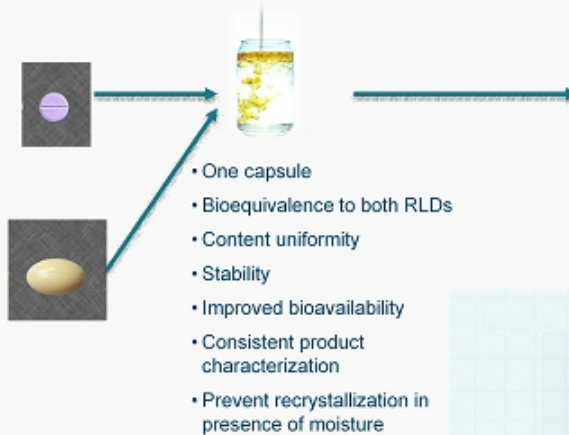
Estrace® 17β estradiol

- Hydrophobic
- Crystalline
- Small amounts
- Low doses 0.5-1 mg
- Low oral bioavailability

Prometrium® progesterone

- Large molecule
- High doses 100-200 mg
- Micronized
- Suspended in peanut oil
- 100% inter-/intra-subject variability
- Hydrophobic
- ~7% oral bioavailability

Formulation Challenges



Solution

- Lipid solubilized mixture of the two APIs
- Medium chain fatty acids
- C6 – C12
- Continuous estradiol solubilization
- Safety & efficacy in Phase 3

TX-004HR
VVA Program



TherapeuticsMD®
Supporting Women's Health for Life

Overview – Vulvar and Vaginal Atrophy (VVA)

- ❏ Diagnosed in approximately 50% of postmenopausal women using measure of vaginal pH levels⁽¹⁾
- ❏ Most bothersome symptoms include: dyspareunia, dryness, itching, irritation, dysuria, bleeding with sexual activity⁽¹⁾
- ❏ FDA guidance for efficacy requirements:
 - ❏ Statistical increase in superficial cells
 - ❏ Statistical decrease in parabasal cells
 - ❏ Changes in vaginal pH from basic to acidic
 - ❏ Statistical reduction in most bothersome symptom

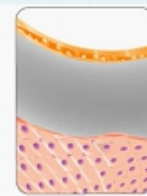
Healthy Vaginal Tissue

Superficial cells: >15%
Intermediate cells: 80%
Parabasal cells: < 5%



Atrophic Vaginal Tissue

<5%
60%
>10%



VVA Market – Established and Growing

- U.S. sales more than doubled since 2008
- Global market expected to be \$2.1 billion in 2022⁽⁴⁾
- Currently no generic competition

Product	Compound	TRx (MAT 9/14) ⁽¹⁾	U.S. Sales (\$M) ^{(1) (2)} (MAT 9/14)	WAC Price ⁽³⁾
Premarin® Cream	Equine Vaginal Estrogen	1,767,810	\$448	\$220.02
Vagifem® Tablets	Vaginal Estradiol	1,945,711	\$378	\$222.12
Estrace® Cream	Vaginal Estradiol	1,738,856	\$324	\$174.25
Osphena® Tablets	Oral SERM	176,455	\$40	\$158.00
Estring®	Vaginal Estradiol Ring	336,803	\$88	\$244.52
Total⁽³⁾		5,965,635	\$1,281	

- 1) PHAST Prescription Monthly by Symphony Health Solutions as of 10/14.
- 2) Femring data was excluded due to VMS indication - All trademarks are property of their respective owners
- 3) Medi-Span Price Rx Basic.
- 4) GlobalData July 2013 report GDHCS4PIDR

TX-004HR – Target Product Profile



Target Goals

Supportive Data

Lower Systemic Exposure

Phase 1 data with 10 mcg suggest lower systemic absorption

Faster Onset of Action

Demonstrated activity at 14 days in Phase 2

New Lower Effective Dose

Broad range of doses being evaluated in Phase 3, including 4, 10 and 25 mcg

Improved User Experience

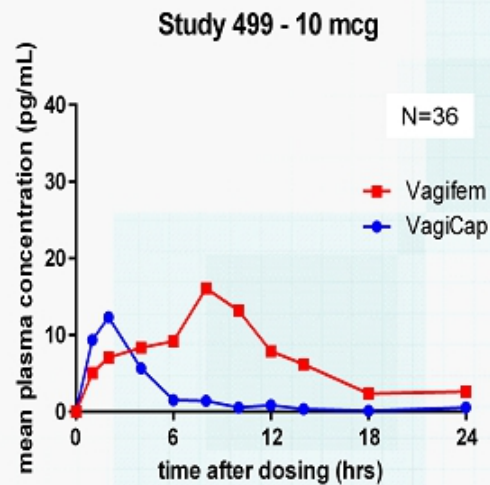
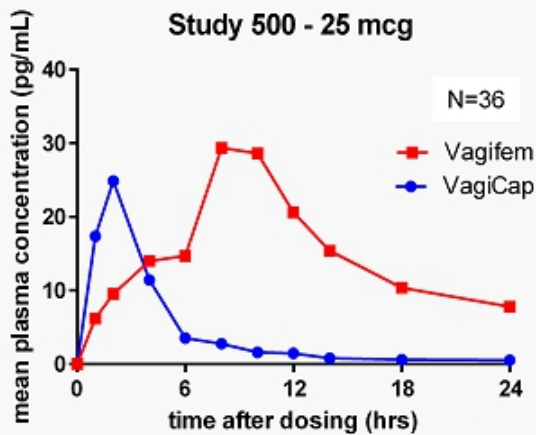
Phase 2 showed patient satisfaction; 97% said easy to use

VagiCap™ Target Product Profile being evaluated in ongoing Phase 3 Rejoice Trial

VagiCap™ vs. Vagifem® – Phase 1 Single Dose PK Studies

Key Findings

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



VagiCap™ Double-Blind, Controlled Phase 2 Study

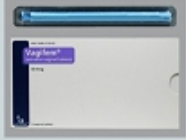


Study Design

- 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

Key Results

- 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)
- Reduction in atrophic effects on epithelial integrity and vaginal secretions
- Positive trend in reduction of most bothersome symptoms

TX-004HR – Potential Competitive Profile

Product Characteristic*	Vagifem	Premarin	Estrace
			
Design			
Burning		✓	
Discharge	✓	✓	✓
Cream		✓	✓
Quick Dissolution			
Applicator	✓	✓	✓
Placement Issues	✓		



TX-004HR Profile Goals

- Not a cream
- Improve ease of use/placement
- Quick dissolution
- Digital insertion/ no applicator
- Deliver elegant patient experience

OPERA Survey (n=178); TXV-1301 Survey (n=49)

*Perceived product characteristics reported by health care professionals and patients in separate surveys. Not based on head-to-head clinical comparisons or validated instruments.

Phase 3 – TX-004HR Vaginal Estradiol



	Q3 '14	Q4 '14	Q1 '15	Q2 '15	Q3 '15	Q4 '15	Q1 '16	Q2 '16	Q3 '16	Q4 '16
TX-004HR Estradiol VVA VagiCap	P3 Protocol			Enrolmt Cmpltd	Data Read					
						NDA and PDUFA				
		Phase 3 Study								



- 📌 **Trial: 12 weeks, Sites: ~100**
- 📌 **Subjects: ~700¹**
 - 3 active arms: 4 mcg, 10 mcg, 25 mcg (~175 per arm)
 - 175 placebo
- 📌 **Co-Primary Endpoints**
 - % change in superficial cells
 - % change in parabasal cells
 - Lowering of pH
 - Reducing dyspareunia as most bothersome symptom
- 📌 **Additional Endpoints**
 - PK measures Days 1,14, 84
 - FSFI (Female Sexual Function Index), acceptability survey

1) The FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance of at least a .01 level, and that a trial that is merely statistically positive may not provide sufficient evidence to support an NDA filing or approval of a drug candidate.

TX-001HR Combination Program



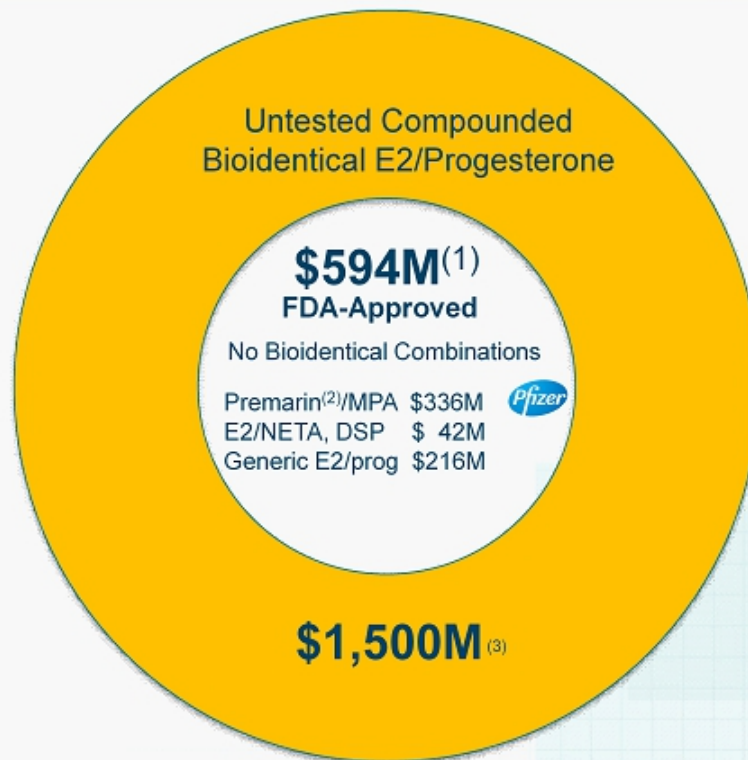
TherapeuticsMD[®]
Supporting Women's Health for Life

Indication Overview

Menopause is defined as the final menstrual period and is typically confirmed after an otherwise healthy woman has not had a period for 12 consecutive months.

- 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 prevent thickening in women with an intact uterus

HT Market = Two Markets



Total
Combo
Markets:
\$2,094M

1) PHAST by Symphony Health Solutions, last twelve months through Sept 2014, including Pfizer, Novo Nordisk, Actavis and other suppliers.
2) Premarin is a trademark of Pfizer Inc.
3) Pinkerton, J.V. Compounded bioidentical hormone therapy: Identifying use trends and knowledge gaps among U.S. women. 2014 Menopause. In press.

Compounded Market/Bioidentical HT



\$1-2B

- No FDA-approved bio-identical E+P combination
- Most users unaware custom-compounded products are unregulated
- DQSA reinforces regulation



Pinkerton, J.V. Compounded bioidentical hormone therapy: Identifying use trends and knowledge gaps among U.S. women. 2014 *Menopause*. In press.

1-2.5M

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

21-39M

Annual custom-compounded prescriptions

\$49

Average monthly cash cost

33%

Drug Quality and Security Act (DQSA)

- ❏ Spurred by public health scares, DQSA establishes clear FDA oversight of compounding pharmacies
- ❏ Prohibits compounding of essential copies of an FDA-approved and marketed drug except in limited circumstances such as drug shortages
- ❏ Recent FDA enforcement actions related to essential copies
- ❏ DQSA anticipated to have significant impact on market post-approval of first combination drug
- ❏ TXMD would look to distribute through compounding pharmacies once approved



TX-001HR – Differentiated Target Product Profile

Goals for Replenish Trial

Meet Patient Demand for Bio-identicals

Potential for FDA-approved natural estradiol plus natural progesterone combination pill

New Lower Effective Dose

Broad range of doses being evaluated in Phase 3, two of which would be a new lower effective dose

Labeling Differentiation

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

Leverage Data on Natural Progesterone

Inclusion of Progesterone differences data via label negotiation

Rationale for Natural Progesterone vs. Synthetic Progestins

Side Effect ⁽¹⁾	Bio-identical Natural Progesterone	Non-bioidentical Progestins (MPA, NETA, drospirinone)
Breast cancer	Neutral in breast cancer (E3N-EPIC study)	Increased risk
Cardiovascular	More favorable profile (PEPI trial, KEEPS, ELITE)	Increased risk of MI, stroke, VTE
Lipid profile	More favorable profile (PEPI trial)	Less favorable effects on lipid profile (cholesterol, LDL, triglycerides)
Glucose / insulin	Improved carbohydrate metabolism (PEPI trial)	Deterioration of glucose tolerance or hyperinsulemia or both
Sleep / mood	Improved sleep efficiency ⁽²⁾	No benefit on sleep properties

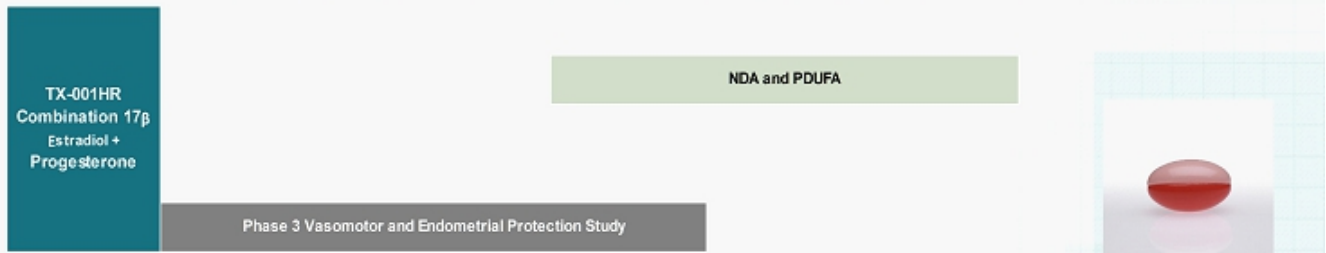
1) Alone or in combination with estrogen.

2) Cautriez, Anne, Rachel Leproult, Mireille L'Hermite-Balle'riaux, Myriam Kerkhofs, and Georges Copinschi. "Progesterone Prevents Sleep Disturbances and Modulates GH, TSH, and Melatonin Secretion in Postmenopausal Women." J Clin Endocrinol Metab 95.4 (2011): 614-23.

Phase 3 – TX-001HR (Estrogen + Progesterone)



				2015E				2016E				2017E			
Q2 '14	Q3 '14	Q4 '14	Q1 '15	Q2 '15	Q3 '15	Q4 '15	Q1 '16	Q2 '16	Q3 '16	Q4 '16	Q1 '17	Q2 '17	Q3 '17	Q4 '17	



📌 **Designed to enroll 1,750 subjects at ~ U.S. 100 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

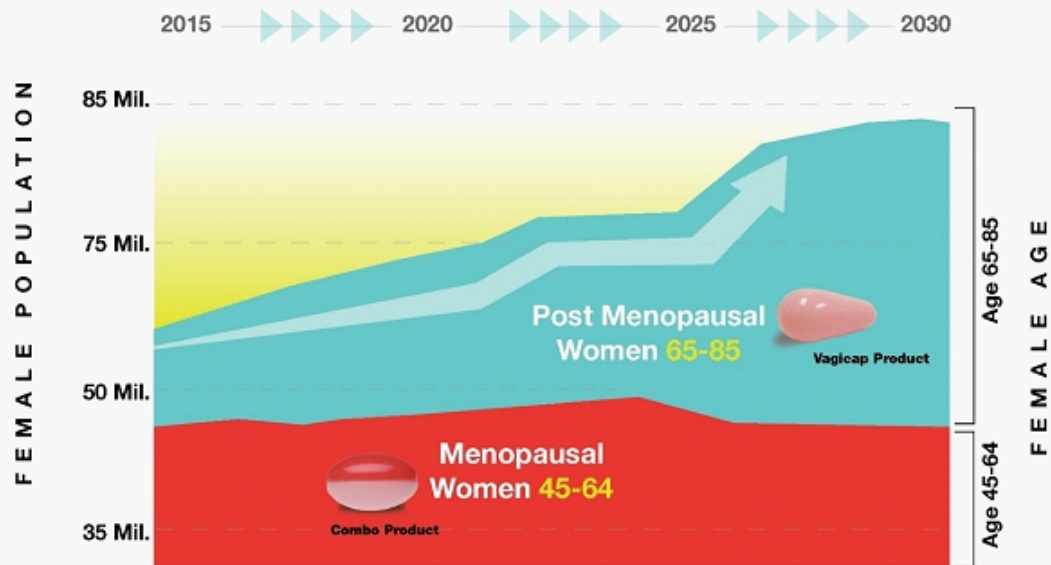
- 📌 Placebo arm (N=150)

📌 **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)

Growing Opportunity for Hormone Therapy

US Population



U.S. Census 2010

Transdermal Programs

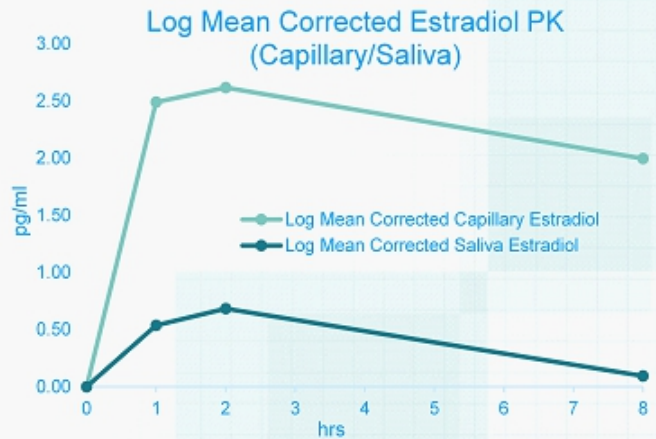
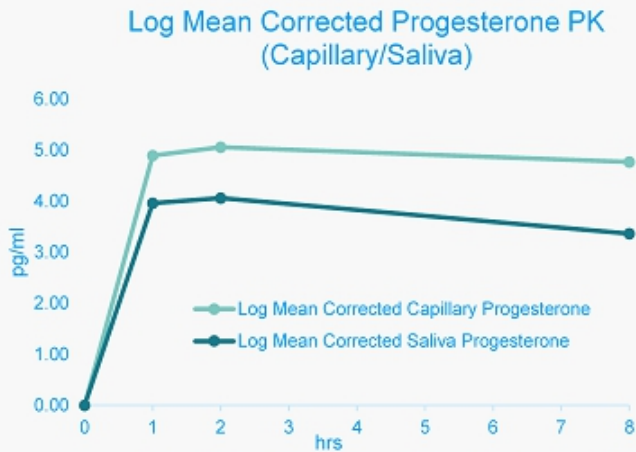


Why Transdermal?

- 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 Duration



- Levels in the saliva and capillary samples are higher than in the serum, where it was not detectable
- This is consistent with the published article from Du and Stanczyk 2013.¹

Transdermal Market Opportunity

Product (Combination E+P)	TRx ⁽¹⁾⁽²⁾	U.S. Sales (est.) ⁽¹⁾⁽²⁾	Company
Estradiol/Levonorgestrel (Climara Pro)	129,755	\$ 22.5M	 Bayer
Estradiol/Norethindrone Acet (CombiPatch)	408,598	\$ 44.0M	
Total Combination Transdermal Sales	538,353	\$ 66.5M	
Product (Estradiol Only)	TRx ⁽¹⁾⁽²⁾	U.S. Sales (est.) ⁽¹⁾⁽²⁾	Company
Estradiol (Patch, Gel, Spray) (Alora, Climara, Estraderm, Menostar, Vivelle, Vivelle-Dot, Minivelle; Divigel, Elestrin, Estrogel; Evamist)	5,762,725	\$ 692M	 Bayer  Watson  NOVARTIS  ASCEND PHARMACEUTICALS  MEDA  UPsher-Knowlton
Total Estradiol Transdermal Sales	5,762,725	\$ 692M	

1) PHAST by Symphony Health Solutions as of 10/14
 2) Based on last twelve months sales through September 30, 2014
 3) All trademarks are property of their respective owners

Intellectual Property Update



Growing Patent Portfolio

	Filed	Provisional	Non-Provisional	Issued
U.S.	37	13	24	4
Ex-U.S.	53			

- Two new patents issued; one on method of treating menopausal symptoms which strengthens competitive barriers to entry and builds on layered coverage strategies

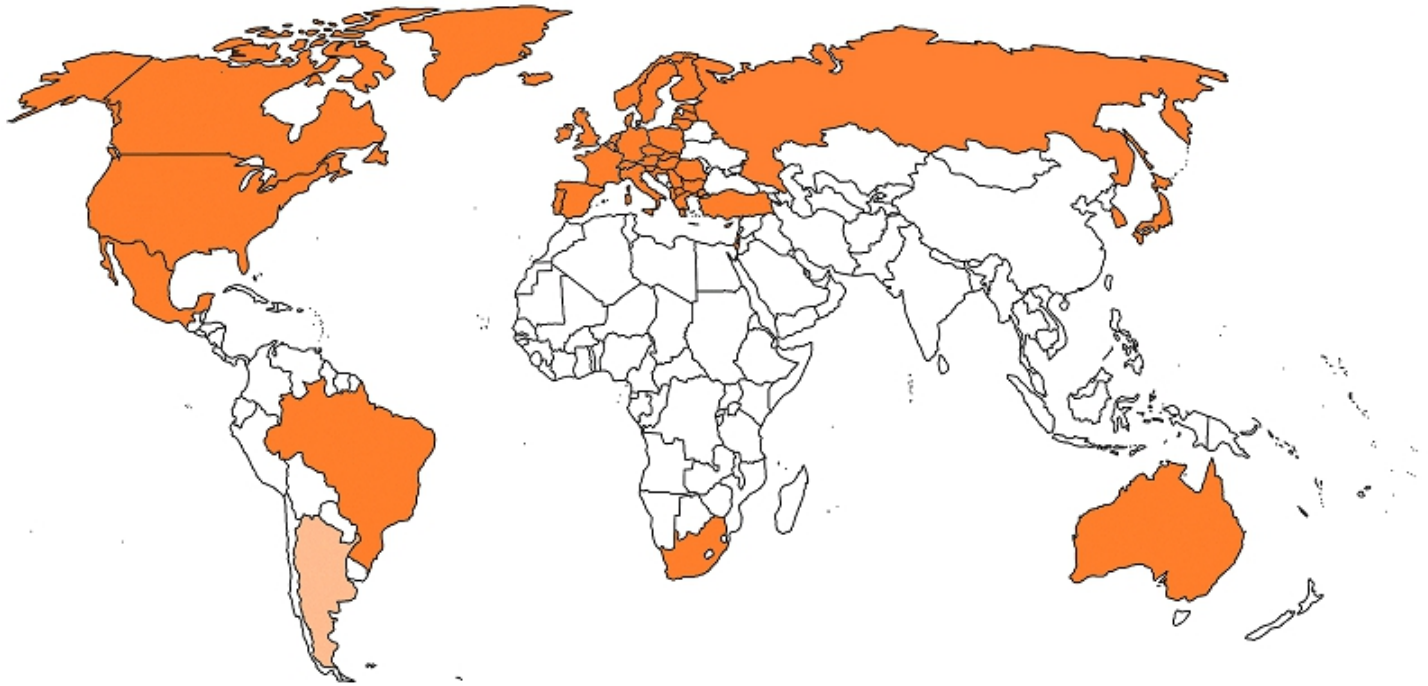
- Others issued:

- Field spanning estradiol and progesterone pharmaceutical compositions (SYMBODA™)
- OPERA reporting and analysis software patent

- Layered patent strategies

- Field spanning pharmaceutical compositions by family of estradiol and progesterone alone and in combination
- Siloed strategy for each product

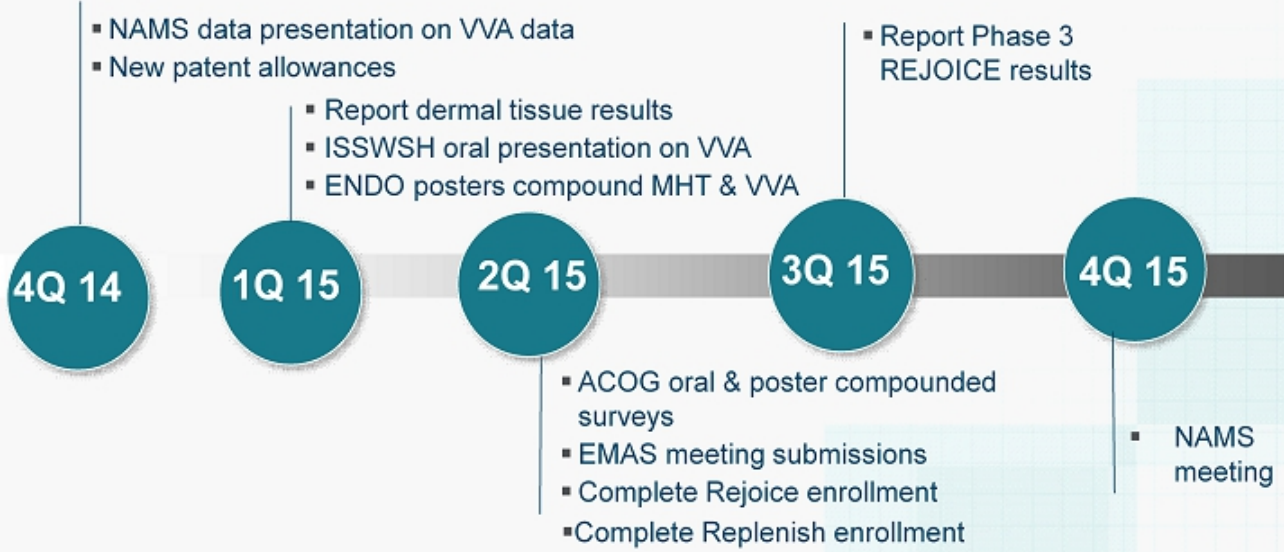
Worldwide Patent Filings*



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 IP Portfolio with 57 patents pending/issued in 19 countries
- ❏ **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

Key Milestones



TXMD: Financial Snapshot

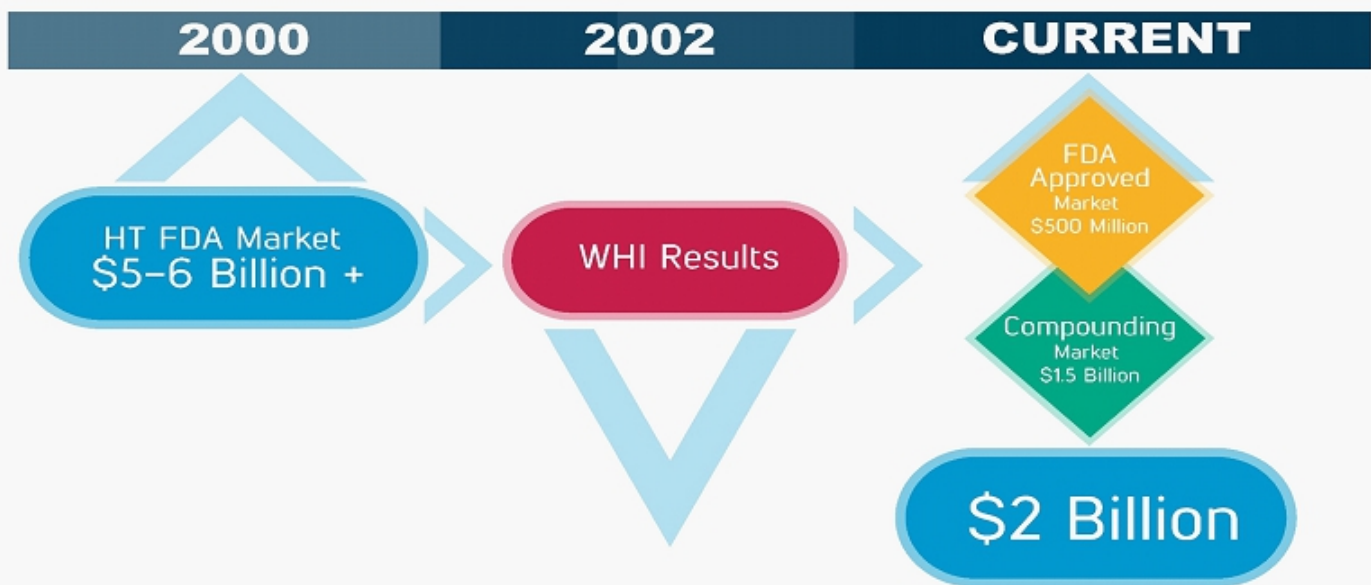
Listing Exchange	NYSE MKT
Shares outstanding	156 million (as of Nov. 4, 2014)
Cash	\$67 million (as of Sept. 30, 2014)
Debt	\$ 0 million

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Supporting Women's Health for Life

Thank You

www.TherapeuticsMD.com

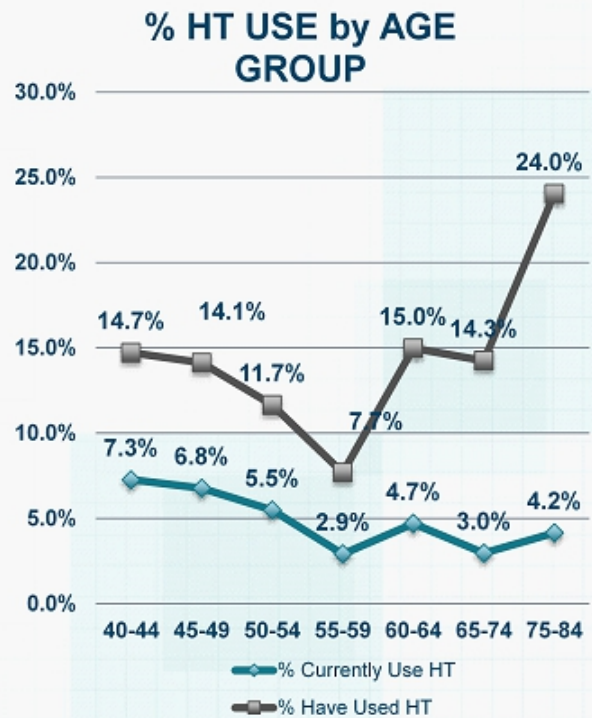
Evolution of Hormone Therapy Market



1) PHAST Prescription Monthly by Source Healthcare Analytics. Inflation Adjusted Number*
2) Estimates per: Dr. Loyd Allen Jr., Editor-in-Chief, the *International Journal of Pharmaceutical Compounding*; Tom Murry, Executive Director of the Pharmaceutical Compounding Accreditation Board; and Wulf Utian, Consultant on Gynecology and Women's Health at The Cleveland Clinic and Executive Director Emeritus and Honorary Founding President of The North American Menopause Society ("NAMS").

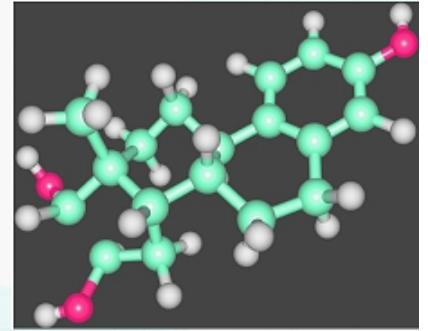
Hormone Therapy Use Is Increasing^{1,2}

- Post-WHI, expert consensus: HT before 60 has a favorable benefit/risk profile³
- Women using FDA-approved and compounded HT increasing:
 - Estimated 30% of use is compounded
 - Natural or “bioidenticals” preferred
- 83% of women believe hormone therapy helps treat their symptoms
- More younger women asking for HT



Current Demand For Natural Hormones

- ❏ Women actively requesting “bioidentical” hormone therapy (HT) containing natural estradiol and natural progesterone
- ❏ Compounded drugs are not approved by FDA, including requirements for safety, efficacy or manufacturing quality
- ❏ Emerging evidence of the advantages of natural hormones over synthetics



Current Evidence Shows Potential Advantages of Natural Estradiol

“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 2013

Dose Rationale: TX-001HR (Estradiol/Progesterone)

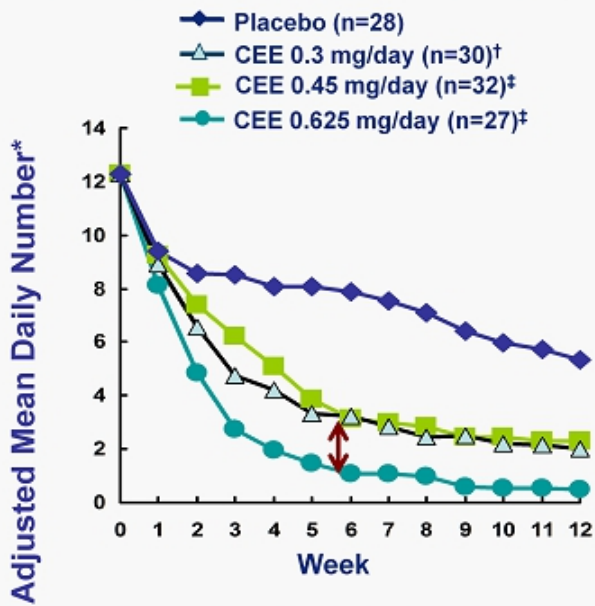
🔍 **Objective:** to provide the first FDA-approved natural estradiol/progesterone (combination) product with lowest effective doses

🔍 **Dose selection:** Four estradiol/progesterone combinations being evaluated based upon:

- Known effective doses of estradiol
 - 1 mg and 0.5 mg have established efficacy for the treatment of VMS
 - Estradiol 0.25 mg alone has not been shown to be effective; however, progesterone has been shown to have an additive effect, thus the combination of E/P may provide lowest effective dose
- To deliver a low dose of progesterone that provides endometrial safety with the lowest side effect profile (50 mg and 100 mg)
- To provide multiple doses for tapering and adjustment based on patient therapeutic response

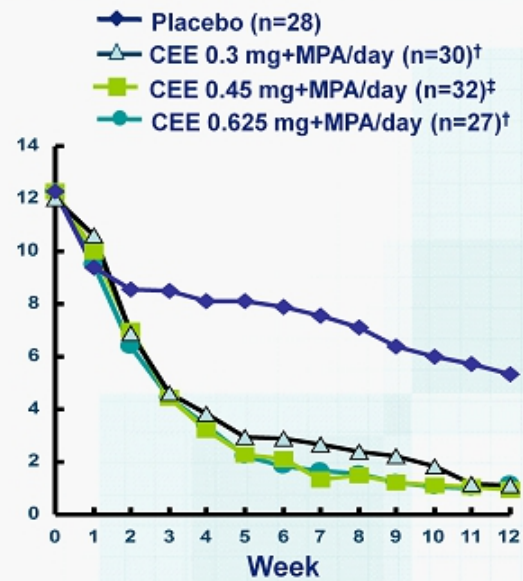
Women's HOPE Study Hot Flashes

Number of hot flashes (CEE-Alone)



Range of hot flashes at baseline=11.3-13.8.
^{*}Adjusted for baseline.
[†]P<0.05 by week 3 compared with placebo.
[‡]P<0.05 by week 2 compared with placebo.

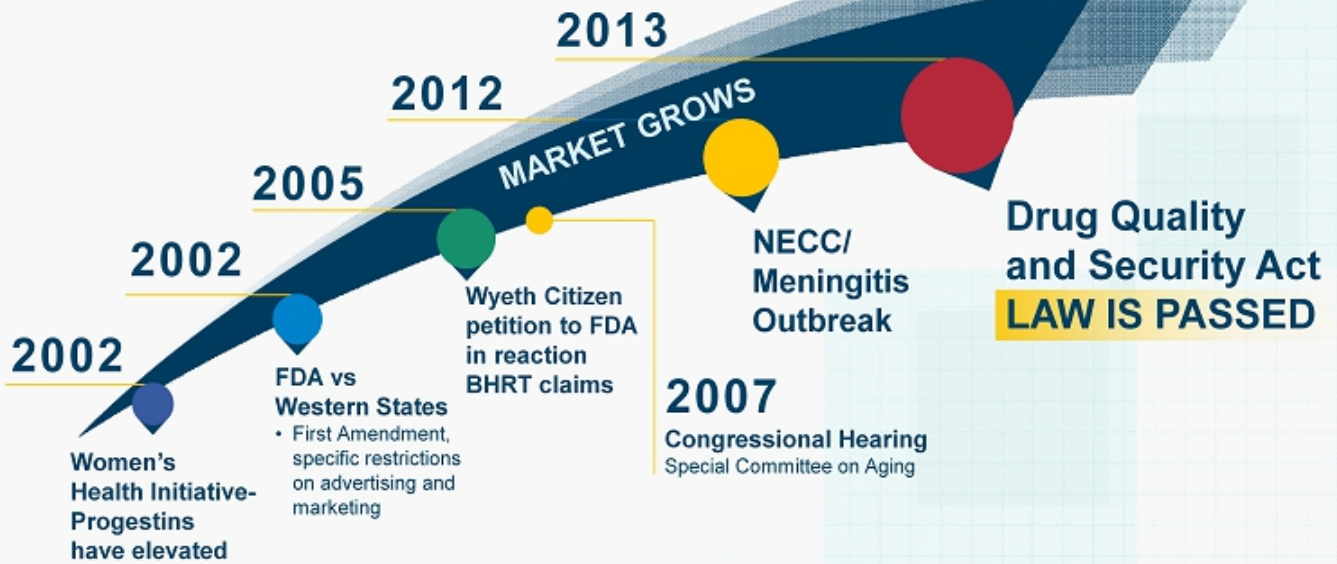
Number of hot flashes (CEE+MPA)



Range of number of hot flashes at baseline=11.3-13.8.
^{*}Adjusted for baseline.
[†]P<0.05 by week 3 compared with placebo.
[‡]P<0.05 by week 2 compared with placebo.





History of Compounding

Market Shift to Bioidentical Hormone Replacement (BHRT)



HT Market Size – Two Markets

Compounded Product	Progestin	U.S. Sales (Cash Pay)	Company
Estradiol + Progesterone	Untested Bioidentical	\$1,500M ⁽³⁾	Various Compounding Pharmacies Not FDA-approved

FDA-Approved Product	Progestin	U.S. Sales (est.)	Company
17β Estradiol + NETA / DSP Activella / FemHRT / Angeliq)	Non-bioidentical	\$ 42M ⁽¹⁾⁽²⁾	  
Generic 17β + Progestins	Non-bioidentical	\$ 216M ⁽¹⁾⁽²⁾	
Premarin + MPA (Prempro / Premphase)	Non-bioidentical	\$ 336M ⁽¹⁾⁽²⁾	
Total FDA Approved Oral Combination Sales		\$ 594M	

Total Combination Market Sales \$ 2,094M

1) PHAST by Symphony Health Solutions as of 10/14
 2) Based on last twelve months sales through September 30, 2014
 3) Pinkerton, J.V. Compounded bioidentical hormone therapy: Identifying use trends and knowledge gaps among U.S. women. 2014 Menopause. In press.
 4) All trademarks are the property of their respective owners.