
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): October 7, 2013

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

000-16731

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW, 3rd 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.

We are furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of the textual information from a PowerPoint presentation to be given at meetings with institutional investors or analysts. This information may be amended or updated at any time and from time to time through another Form 8-K, a later company filing, or other means. The PowerPoint presentation attached as Exhibit 99.1 to this Current Report on Form 8-K updates and replaces in its entirety all prior PowerPoint presentations filed by us.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 7.01 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in the Report that is required to be disclosed solely by Regulation FD.

We do not have, and expressly disclaim, any obligation to release publicly any updates or any changes in our expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

The text included with this Report on Form 8-K is available on our website located at www.therapeuticsmd.com, although we reserve the right to discontinue that availability at any time.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. presentation dated October 2013.

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: October 7, 2013

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. presentation dated October 2013.



TherapeuticsMD[®]



TXMD Corporate Overview

October 2013

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Forward-Looking Statements

This presentation includes forward-looking statements covered by the safe harbor provision of the Private Securities Litigation Reform Act of 1995, including predictions, estimates, and other information that might be considered forward-looking. While these forward-looking statements represent TherapeuticsMD, Inc.'s ("TherapeuticsMD," "we," "us," and "our") current judgment on what the future holds, they are subject to risks and uncertainties, many of which are outside our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements.

You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. Please keep in mind that we are not obligating ourselves to revise or publicly release the results of any revision to these forward-looking statements in light of new information, future events, or otherwise.

Throughout this presentation, we will attempt to present some important factors relating to our business that may affect our predictions. You should also review our most recent Form 10-K, Form 10-Q, our Form 8-K, and our other filings with the Securities and Exchange Commission, for a more complete discussion of these factors and other risks, particularly under the heading "Risk Factors." A PDF copy of our press releases and financial tables can be viewed and downloaded on the TherapeuticsMD website: www.therapeuticsmd.com/InvestorRelations.aspx.



TherapeuticsMD[®]



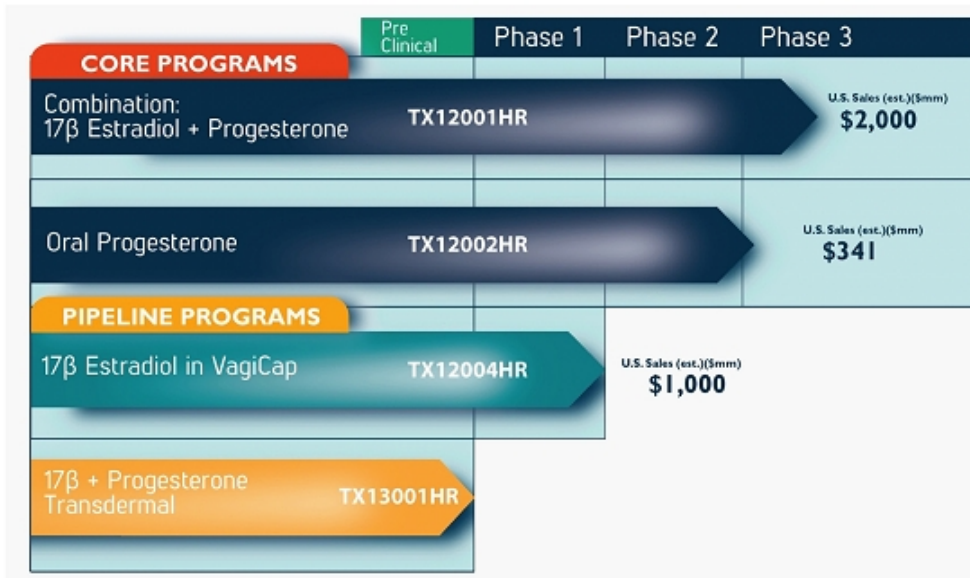
Company Overview

TXMD Company History

- ❏ **Founded in May of 2008**
- ❏ **Originally a prenatal vitamin company**
- ❏ **Recently listed on NYSE MKT under “TXMD”**
- ❏ **Shares outstanding: 145 million**
- ❏ **Well-capitalized – approximately \$64.4 million in cash; no debt**
- ❏ **Strong board with blue-chip institutional holders**
 - ❏ Gov. Tommy Thompson, Jules Musing, Ernest Mario (investor)
 - ❏ Wellington, Fidelity, Franklin Templeton, RA Capital, UBS O’Connor, Broadfin
 - ❏ Member of the Russell 2000

Innovative Women's Healthcare Company

Two late-stage 505(b)(2) proposed hormone therapy ("HT") products targeting a multi-billion dollar U.S. market ⁽¹⁾⁽²⁾



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(1) Phast Prescription Monthly by Source Healthcare Analytics.

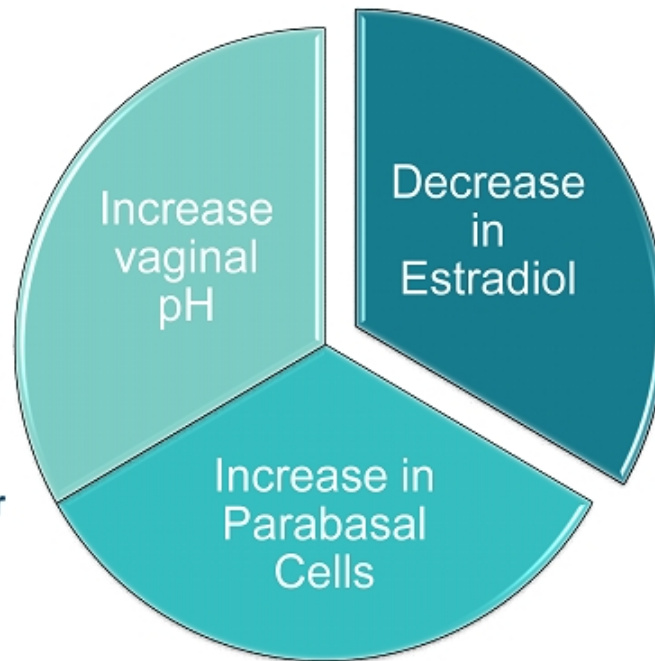
(2) Estimates per: Dr. Loyd Allen Jr., Editor-in-Chief of the International Journal of Pharmaceutical Compounding; Tom Murry, Executive Director of the Pharmaceutical Compounding Accreditation Board; and Wulf Utian, Consultant on Gynecology and Women's Health at The Cleveland Clinic and Executive Director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

TherapeuticsMD®

Vulvar / Vaginal Atrophy (VVA)

Mechanism of Vulvovaginal Atrophy

- ❏ **Decreased Estradiol levels cause a reduction in superficial cells**
- ❏ **Parabasal cells increase**
- ❏ **Vagina changes from acidic to basic (increased pH)**
- ❏ **Burning, dyspareunia, UTI, itching are the most common symptoms**
- ❏ **Chronic condition that requires ongoing therapy for the rest of a woman's life**



VVA Market

- ❏ **The North American Menopause Society (NAMS) Position Statement** “Management of Symptomatic Vulvovaginal Atrophy (VVA),” ... affecting ***nearly 50% of women***; ... ***low-dose vaginal estrogen is the preferred treatment*** and may be continued as long as the symptoms are present.⁽¹⁾
- ❏ ASD analysis indicates that the global postmenopausal vaginal atrophy therapeutics market was worth ***\$1.6 Billion in 2011***⁽²⁾
- ❏ Market is expected to grow at a CAGR of 8.5% during 2011-2019 to ***\$3.1 Billion in 2019***⁽²⁾

US Sales - Vulvar / Vaginal Atrophy

Product	Compound	U.S. Sales (est.) (\$mm) ⁽¹⁾⁽²⁾	Problems
Premarin® Cream	Conjugated equine vaginal estrogen	\$350	<ul style="list-style-type: none"> ❑ Equine source ❑ Non-bioidentical ❑ Messy ❑ Reusable plungers
Vagifem® Tablets	Vaginal estradiol	\$286	<ul style="list-style-type: none"> ❑ Messy
Estring® Insert		\$77	<ul style="list-style-type: none"> ❑ Reusable plungers
Femring® Insert		\$23	<ul style="list-style-type: none"> ❑ Difficult to use
Estrace® Cream		\$264	<ul style="list-style-type: none"> ❑ Continuous-use device
Total Sales		\$1,000	

US Sales Grew 22% 6/12-6/13⁽³⁾

Market is expected to grow at a CAGR of 8.5% during 2011-2019 to \$3,144.3M in 2019⁽⁴⁾

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- (1) Phasel Prescription Monthly by Source Healthcare Analytics.
 (2) Based on last twelve months sales through June 30, 2013.
 (3) Source Healthcare Analytics
 (4) GlobalData 2/12 report https://www.wasdreports.com/news.asp?pr_id=420

Leading Estrogen Products vs. TXMD

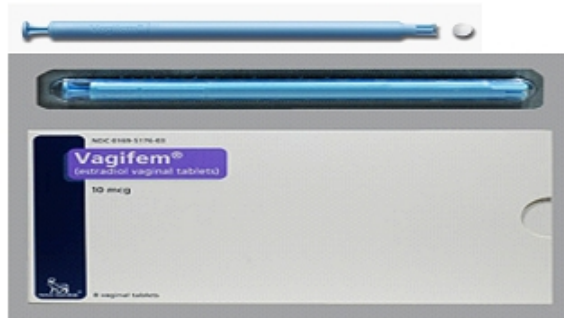


TXMD Solution

"vagiCap™"

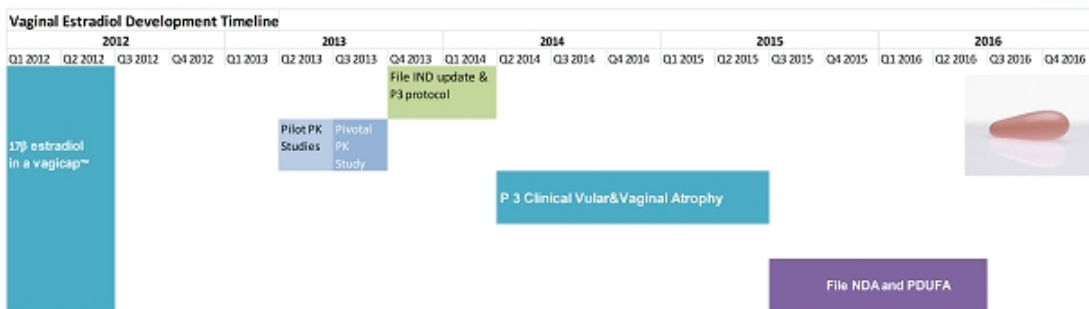


- ❏ Less messy than creams and burning sensation eliminated
- ❏ Easier to use, not requiring a long-term device
- ❏ Flexibility of dosing with 0.01 mg & 0.025 mg



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Estradiol Vaginal Suppository – P1 Update 8-22-2013



Study – Estradiol	Cost (\$mm)	Phase 3 Trial
Phase 3	\$14.4	<ul style="list-style-type: none"> ☒ Trial: 12 weeks ☒ Sites: 30-40 ☒ Subjects: 375-400 <ul style="list-style-type: none"> – 2 active arms (150 per arm) - 10mcg & 25mcg – 100 placebo
Total	\$15.6	<ul style="list-style-type: none"> ☒ Endpoints <ul style="list-style-type: none"> – Cell change – Lowering of pH – Lowering of most bothersome symptoms

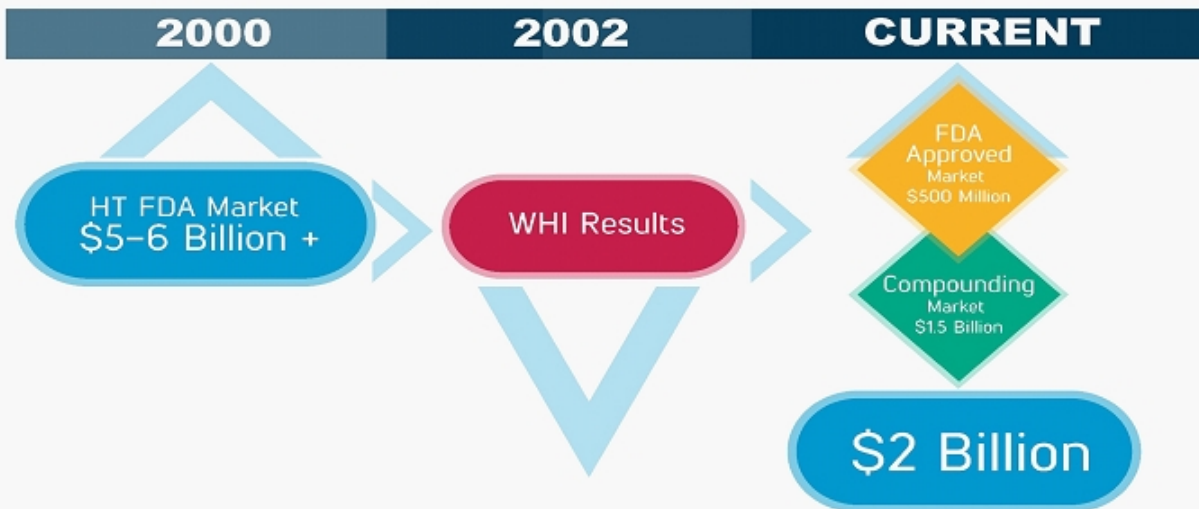


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Combination Product

History of Hormone Therapy



Women's Health Initiative (WHI)

- Hormone Therapy is linked to Cardiovascular, Cancer and other risks
- Estrogen + **Progestin** (Prempro) arm had a 24% increase in breast cancer vs. Estrogen alone

(1) Phast Prescription Monthly by Source Healthcare Analytics.

(2) Estimates per: Dr. Loyd Allen Jr., Editor-in-Chief of 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").

Bioidentical Progesterone vs. Non-Bioidentical Progestin

Side Effect ⁽¹⁾	Bioidentical Natural Progesterone	Non-Bioidentical Progestins (MPA, NETA, drospirinone)
Breast cancer	More favorable profile (E3N-EPIC study)	Increased risk
Cardiovascular	More favorable profile (PEPI trial)	Increased risk of MI, stroke, VTE
Lipid profile	More favorable profile (PEPI trial)	Less favorable effects on lipid profile (cholesterol, HDL, 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
Quality of life	Improvement in symptoms and overall satisfaction with bioidentical progesterone HT compared to MPA regimen ⁽³⁾	

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⁽¹⁾ Alone or in combination with estrogen

⁽²⁾ Caufriez, Anne, Rachel Leproult, Mirella L'Hermite-Balle, Hsu, Myriam Karkhah, and Georgina Copinschi. "Progesterone Prevents Sleep Disturbances and Modulates GH, TSH, and Melatonin Secretion in Postmenopausal Women." *J Clin Endocrinol Metab* 95.4 (2013): 914-23.

⁽³⁾ Fazzaroli, Pia, and Wiro. "Comparative of Regimens Containing Oral Micronized Progesterone or Medroxyprogesterone Acetate on Quality of Life in Postmenopausal Women: A Cross-Sectional Survey." *J Womens Health Gen Based Med* 9.4 (2000): 381-87.

Estradiol vs. Conjugated Estrogens

JAMA September 30, 2013

- **CEEs (Premarin)** were associated with a **higher incident of venous thrombosis and myocardial infarction** than oral estradiol ⁽¹⁾

JAMA October 3, 2013

- **Breast Cancer Risk persists for 13 years** after discontinuation of CEE ⁽²⁾

Menopause September 2013

- **“Oral estradiol may be associated with a lower risk of stroke ... compared with conventional-dose oral CEE”** ⁽³⁾

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

(2) Menopausal Hormone Therapy and Health Outcomes During the Intervention and Extended Poststopping Phases of the Women's Health Initiative Randomized Trials Manson et al.

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

Latest Position Statements

British Menopause Society, 2013

North American Menopause Society, 2012

- ❏ “HRT prescribed before the age of 60 has a favorable benefit/risk profile.” (1)
- ❏ “Recent evidence suggests that HRT regimens containing **progesterone** can minimize the metabolic impact and reduce the risk of thromboembolism.” (1)
- ❏ In a large observational cohort study of French teachers, after five years of use estrogen–**progesterone** combination, HRT was found to be associated with a significantly lower relative risk (neutral for ‘ever use’ of HRT) than for other types of combined HRT (RR 1.7–2.0).” (1)
- ❏ “Data from a large observational study suggest that EPT with micronized **progesterone** carries a low risk of breast cancer with short-term use.” (2)

Novel Drug Design

❏ **Converted (API) from solid / crystalline to a New Liquid Drug Form**

- ❏ Estrace (RLD) is a tablet — 0.5 mg, 1.0 mg, and 2.0 mg
- ❏ Prometrium (RLD) is in suspension — 100 mg and 200 mg

❏ **New solubilized drug form**

- ❏ Achieves FDA requirements of uniformity and stability
- ❏ Improved functional effects (improved bioavailability, reduced variability, food effect, lowest effective dose, reduced side-effect profile)
- ❏ Enabling new combinations, routes and dosages (creams, patches, etc.)



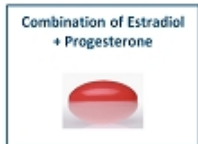
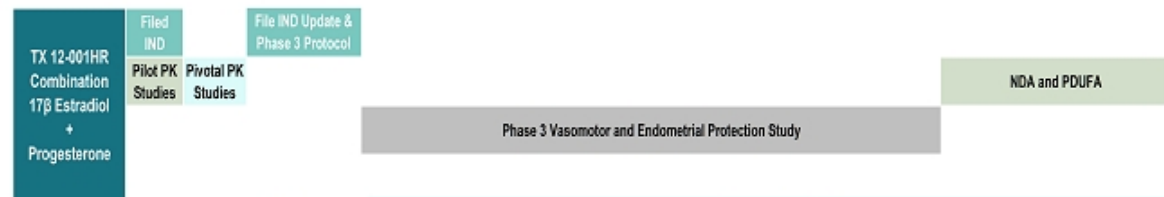
✔ **Meet PK 505(b)(2) thresholds**

TX 12-001HR Combination Potential Benefits

Drug Improvement	General Benefits	Patient Benefits
Receive FDA approved indication	<ul style="list-style-type: none"> FDA indication / safety and quality assurance 	<ul style="list-style-type: none"> Insurance coverage Safety, quality, and stability
New lower effective doses	<ul style="list-style-type: none"> Reduced blood levels Better side effect profile 	<ul style="list-style-type: none"> Improved safety
Improved safety profile vs. non-bioidentical progestin	<ul style="list-style-type: none"> Reduced breast cancer risk Improved cardiovascular and lipid profile 	<ul style="list-style-type: none"> Confidence in treatment regimen
No peanut oil	<ul style="list-style-type: none"> Non-allergenic Excellent for all patient profiles 	<ul style="list-style-type: none"> No worries about potential allergies
Combined pill vs. 2 pills (E+P sold separately today)	<ul style="list-style-type: none"> Less risk of dosing errors 	<ul style="list-style-type: none"> One co-pay Increased compliance

TX 12-001HR Combination— Phase 3 Study

	2012		2013E				2014E				2015E				2016E			
	Q3 '12	Q4 '12	Q1 '13	Q2 '13	Q3 '13	Q4 '13	Q1 '14	Q2 '14	Q3 '14	Q4 '14	Q1 '15	Q2 '15	Q3 '15	Q4 '15	Q1 '16	Q2 '16	Q3 '16	Q4 '16

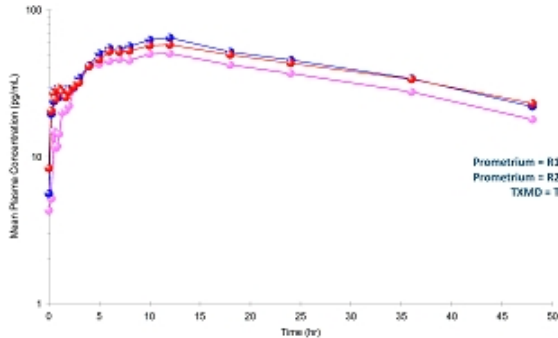


Phase 3 Trial

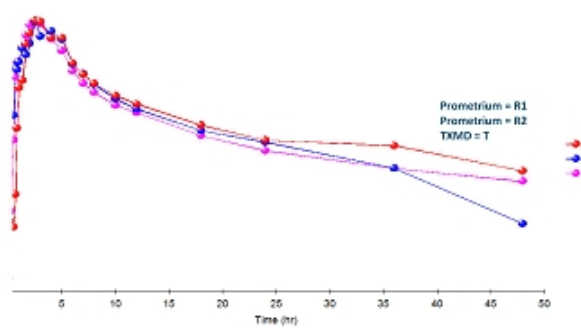
- 📄 **Study:** 12 month study with 12 week VMS
- 📄 **Sites:** ~50 (14 sites active)
- 📄 **Subjects:** 1,550
 - 4 active arms (350 per arm):
[1.0mg/100mg, 0.5mg/100mg, 0.5mg/50mg, 0.25mg/50mg]
 - 1 placebo arm (150)
- 📄 **Estimated cost:** \$20-\$25 million
- 📄 **Endpoints**
 - Vasomotor: number and severity of hot flashes (4 week and 12 weeks)
 - Endometrial safety: incidence of endometrial hyperplasia (12 months)

TXMD 2/200mg E2+P *Single* Gel-Tab vs. Separate 2mg Estrace® tablet + 200mg Prometrium® Capsule

- Based on C_{max} and AUC, both estradiol and progesterone showed relative bioequivalence (N=62)
- Progesterone, delivered in TXMD formulation, had significant reduction of variance between subjects



95% Confidence Interval for PK Parameter



95% Upper Confidence Limit for PK Parameter

Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C_{max}	0.88	0.344	-0.040
AUC_{0-t}	0.93	0.409	-0.089

Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C_{max}	1.16	1.179	-0.785
AUC_{0-t}	1.05	0.956	-0.542




Combination Transdermal Development

2013				2014				2015				2016			
Q1 2013	Q2 2013	Q3 2013	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016
Combination 17 β estradiol + progesterone				Pilot Preclinical Studies		Pilot PK Studies		File IND			File IND Update				
									Pivotal PK and clinical Study						

Study – Combination	Cost (\$mm)	Details
CMC / Delivery Development	\$5.0	<ul style="list-style-type: none"> Formulation testing; Pilot PK w/ multi measures – blood, saliva, capillary
Preclinical pilot/PK	\$1.5	<ul style="list-style-type: none"> Multi PK measures w/ endometrial biopsy
Pivotal PK w/ clinical	\$3.5	<ul style="list-style-type: none"> Patch and topical cream development
Total	\$10.0	

FDA Approved Products in Use Lack Innovation

All FDA approved products in use contain ***non-bioidentical*** progestins

Product	Progestin	U.S. Sales (est.) (\$mm)	Intl Sales (\$mm) ⁽⁴⁾	Company
17β Estradiol + NETA / Drospirenone (Activella / FemHRT / Angeliq / others)	<i>Non-bioidentical</i>	\$222 ⁽¹⁾⁽²⁾		  
Premarin + MPA (Prempro / Premphase)	<i>Non-bioidentical</i>	\$313 ⁽¹⁾⁽²⁾		
Estradiol + Progesterone (custom compounded)	Untested Bioidentical	\$1,500 ⁽³⁾		Not FDA approved
Total Oral Combination Sales		\$2,000	\$489	

Notes: All FDA approved combination products in use contain a non-bioidentical progestin.

(1) Phast Prescription Monthly by Source Healthcare Analytics.

(2) Based on last twelve months sales through June 30, 2012, and estimated sales from July 1 through December 31, 2012.

(3) Estimate per Wulf Utian, Executive Director Emeritus and Honorary Founding President of NAMS.

(4) IMS Data (Euro Conversion at 1.2875)



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***New Lower Dose
Progesterone***

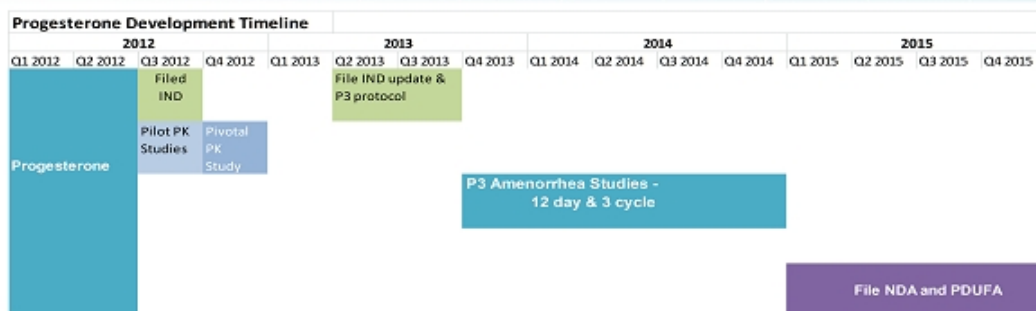
TX 12-002HR Progesterone Highlights

- ❏ Conducted PK studies in accordance with FDA requirements
- ❏ TXMD 150 mg test dose found to be bioequivalent to 200 mg Prometrium®

Product Goals

- ❏ Lower first-pass effect, less metabolites = 25% Increase in bioavailability
- ❏ Lower blood level = TXMD target dose 225mg vs. 400mg Prometrium®
- ❏ Non-allergenic = removed peanut oil





TX 12-002HR Progesterone— Phase 3 Study



Phase 3 Trial

- ☒ Trial: 1 study, 3 cycles – estrogen priming and 2 progesterone treatment cycles
- ☒ Sites: 10-15 each
- ☒ Subject: 180
 - 3 arms (60 per arm): 225mg, 300mg, Placebo
- ☒ Estimated cost: \$5-\$8 million
- ☒ RLD = 400 mg
- ☒ Endpoints = Withdrawal bleeding and secretory change

Natural Progesterone Dominates

Product	Progestin	U.S. Sales (est.) (\$mm) ⁽¹⁾⁽²⁾	INTL Sales ⁽³⁾	Company	Generic Available
Provera[®] (medroxyprogesterone acetate)	Non-bioidentical	\$26		 MERCK	✓
Aygestin[®] (norethindrone acetate)	Non-bioidentical	\$46		 TEVA	✓
Prometrium[®] (micronized progesterone)	Bioidentical	\$269		 Abbott A Promise for Life  BESINS HEALTHCARE	✓
Total Oral Progestin Sales		\$341	\$600		

Extensive Patent Filings - Therapeutics

Title	Application(s)	Earliest Filing Date	Projected Expiry ⁽¹⁾	Status
<i>Oral Combination Therapeutics</i>				
Natural E+P HT Combination	<ul style="list-style-type: none"> ➤ US Provisional ➤ US Non-Provisional ➤ PCT 	23-Nov-2011	Nov-2032	<i>US – Case under Accelerated Exam; Final Office Action received; Interviewed at USPTO</i> <i>PCT – Int'l Search Report received</i>
Natural Combination HT and Formulations	<ul style="list-style-type: none"> ➤ US Non-Provisional ➤ PCT 	18-June-2012	Nov-2032	<i>US – Awaiting First Office Action</i> <i>PCT – Awaiting Int'l Search Report</i>
<i>Vaginal Suppository Applications (VVA)</i>				
Soluble Estradiol Capsule for Vaginal Insertion	<ul style="list-style-type: none"> ➤ US Provisional ➤ PCT 	21-Dec-2012	Nov-2032	<i>PCT – Awaiting Int'l Search Report</i>
<i>Oral Solo Therapeutics</i>				
Progesterone Formulations	<ul style="list-style-type: none"> ➤ US Provisional ➤ PCT 	20-Jun-2012	Nov-2032	<i>PCT – Awaiting Int'l Search Report</i>
Estradiol Formulations	<ul style="list-style-type: none"> ➤ US Provisional 	18-Jun-2012	Expired	<i>Not Applicable</i>
<i>Transdermal Applications</i>				
Transdermal HT Combination	<ul style="list-style-type: none"> ➤ US Provisional ➤ PCT 	26-Jan-2012	Nov-2032	<i>PCT – Int'l Search Report received</i>
Transdermal HT	<ul style="list-style-type: none"> ➤ US Non-Provisional ➤ PCT 	18-June-2012	Nov-2032	<i>US – Awaiting First Office Action</i> <i>PCT – Awaiting Int'l Search Report</i>

Extensive Patent Filings - Other

Title	Application(s)	Earliest Filing Date	Projected Expiry ⁽¹⁾	Status
<i>Opera Software</i>				
System and Method of Ongoing Evaluation Reporting and Analysis	➤ US Non-Provisional	17-Sept-2009	Sept-2029	<i>US – Allowed</i>
System and Method for Distributor Reporting and Analysis	➤ US Non-Provisional	17-Sept-2009	Sept-2029	<i>US – Awaiting First Office Action</i>

Experienced Management and Drug Development Team

Management

Robert Finizio
Chief Executive Officer

vitaMed

John Milligan

President

HT

Julia Amadio

Chief Product Officer

Corporate

Dan Cartwright

Chief Financial Officer

Dr. Brian Bernick

Chief Medical Officer and Director

Jason Spitz

Vice President, Marketing

Board Members and Early Investors

Tommy Thompson

Chairman

Former Sec HHS & Gov of Wisc

Cooper Collins

Director

CEO, Pernix

Nick Segal

Director

Seavest Capital Partners

Mario Family Partnership

Ernest Mario
Former CEO of Glaxo

Jules Musing

Former Sr. Executive Johnson & Johnson

Drug Development Team

- 📄 **Julia Amadio and James Pickar, M.D., F.A.C.O.G.**
 - Led development and launch of Prempro®, Premphase®, CombiPatch®, Alesse®, and Crinone®, among others
- 📄 **Lisa Rarick, M.D. and Daniel Shames, M.D.**
 - Former division Director of Reproductive and Urologic Products for FDA CDER
- 📄 **Fred Sancilio, Ph.D.**
 - Former founder and president of AAI and the innovator of multiple hormone products
- 📄 **Steve Fontana, J.D.**
 - Author of the original estradiol patents
- 📄 **Bill Mulholland, J.D.**
 - Lead patent attorney; previously, IP counsel at Pfizer

Proven team with a successful track record of creating shareholder value and developing some of the most successful products in the HT and birth control space

TherapeuticsMD

Investment Highlights

- | | |
|---|---|
| 1 | Novel late-stage hormone therapy candidates |
| 2 | Clear pivotal trial endpoints / low risk regulatory pathway |
| 3 | Compelling, growing market opportunity, especially with recent concerns regarding compounders |
| 4 | Recently completed \$33 million equity financing |
| 5 | Robust, growing patent estate |