

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): June 3, 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.)

951 Broken Sound Parkway NW, Suite 320  
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1911

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](http://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 June 2013.

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**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: June 3, 2013

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

## EXHIBIT INDEX

Exhibit  
Number

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Description

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99.1 [TherapeuticsMD, Inc. presentation dated June 2013.](#)



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**Investor Presentation**

*June 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 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 SEC filings, press releases and financial tables can be viewed and downloaded on the TherapeuticsMD website: [www.therapeuticsmd.com/InvestorRelations.aspx](http://www.therapeuticsmd.com/InvestorRelations.aspx).



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*Company Overview*

# TXMD Company History

- ❏ **Founded in May of 2008**
- ❏ **Originally a prenatal vitamin company**
- ❏ **Recently listed on NYSE MKT under “TXMD”**
- ❏ **Shares outstanding: approximately 130 million**
- ❏ **Approximately \$40 million in cash; no long-term debt**
- ❏ **Strong board with blue-chip institutional holders**
  - ❏ Gov. Tommy Thompson, Jules Musing, Ernest Mario (investor)



RA CAPITAL



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# Innovative Women's Healthcare Company

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

- Bioidentical combination of estradiol + progesterone and lower-dose bioidentical progesterone
- Set to begin pivotal Phase 3 clinical trials

	2013E	2014E	2015E	2016E	U.S. Sales (est.)(\$mm) <sup>(1)(2)</sup>
Combination: 17β Estradiol + Progesterone					\$2,000
Oral Progesterone					\$300

## Novel estradiol pipeline product in development

17β Estradiol in VagiCap™				\$800
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■ Phase 3 Plan     ■ Expect to File NDA and PDUFA

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<sup>(1)</sup> Phast Prescription Monthly by Source Healthcare Analytics.

<sup>(2)</sup> 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").

# History of Hormone Therapy

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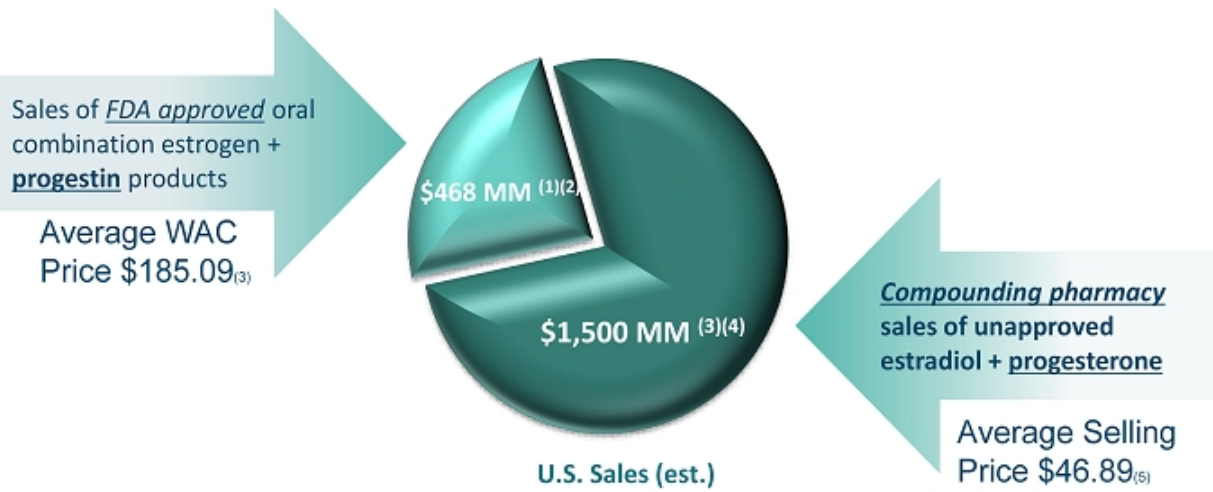
## ❏ 2002 Women's Health Initiative (WHI) Study

- ❏ Lower doses = lower side effect profile
- ❏ Estrogen + *Progestin* (Prempro) arm had a 22% increase in breast cancer vs. Estrogen alone arm

## ❏ Resulting Hormone Prescribing Trends

- ❏ Start with the lowest effective dose
- ❏ Progesterone (bioidentical) popularity over Progestins (non-bioidentical)
- ❏ Bioidentical (exact molecular structure of human Estrogen and Progesterone) sales sky rocket

# HT Combination Market Landscape



 **Significant demand**

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- (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) Dr. Loyd Allen Jr., Editor-in-Chief of the International Journal of Pharmaceutical Compounding, stated the U.S. drug compounding market is \$10-\$12 billion; and Tam Murry, Executive Director of the Pharmaceutical Compounding Accreditation Board, said HT for post-menopausal women is by far the largest of four primary segments served by the compounding industry.
- (5) 134 Compounding Pharmacies Survey in 34 States

# Bioidentical Progesterone vs. Non-Bioidentical Progestin

📊 The Market understands the benefits of bioidentical HT

Side Effect <sup>(1)</sup>	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 <sup>(2)</sup>	No benefit on sleep properties
Quality of life	Improvement in symptoms and overall satisfaction with bioidentical progesterone HT compared to MPA regimen <sup>(3)</sup>	

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<sup>(1)</sup> Alone or in combination with estrogen.

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

<sup>(3)</sup> Fazzaroli, Pia, and Wafa. "Comparison 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.

# 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 of API(s)
- ❏ Enabling new combinations, routes, and dosages



**Meet PK 505(b)(2) thresholds**

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RLD = Reference Listed Drug  
API = Active Pharmaceutical Ingredient

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# Building an Extensive Patent Estate

## ❏ Novel Drug Form Based Approach

- ❏ Solubilized API in combination and stand-alone drug products for HT indications
- ❏ Enabling platform technology for delivery of bioidenticals to variety of dosage forms and routes of administration (softgel oral, suppository, transdermal, etc.)

## ❏ Multi-layered Patent Strategy

- ❏ Novel dosage forms, improved PK profiles (lowest effective dose, increased bioavailability) relative to RLD, reduced side effect profile, and formulation advancements (solvent systems, chemical stability, ratios, ranges, and functional effects)

# Senate HELP Bill 959 on Compounding

## ❏ New England Compounding Center

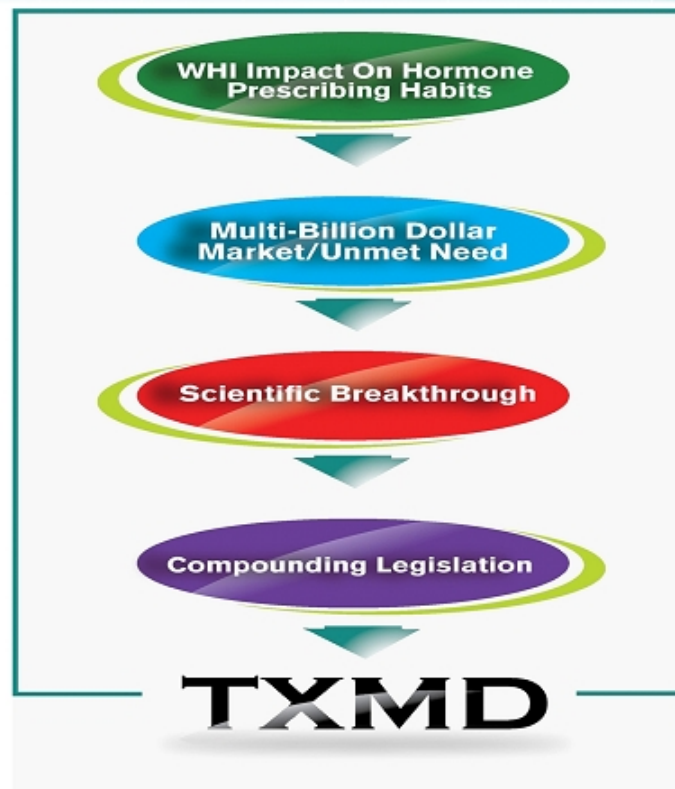
- ❏ Response to Meningitis outbreak, killed 50 and made over 700 patients sick
- ❏ Multiple other cases of unsafe drug sales by other compounding pharmacies

## ❏ Senate Bill Highlights <sup>(1)</sup>

- ❏ Establishes clear FDA oversight funded by compounding pharmacy registration fees
- ❏ “Prohibits compounding of certain drug products, including those identified by regulation as being demonstrably difficult to compound (such as complex dosage forms and biologics), marketed FDA-approved drugs that are not in shortage”

# Market Forces Converge

- External market changing events
  - WHI
  - Proposed legislative changes
- Internal scientific breakthrough
- Significant shifts favor TXMD



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# Why Hormone Therapy?

- ❏ **HT is projected to be the largest growth segment in the overall women's health drug market**
- ❏ **Demographics driving strong growth fundamentals**
  - ❏ By 2015, nearly half the women in America will be of menopausal age <sup>(1)</sup>
  - ❏ Women will spend more than a third of their life in menopause and post-menopause
- ❏ **Very attractive commercial dynamics**
  - ❏ Segment of the market that lacks innovation
  - ❏ Relatively little promotional activity in the space
  - ❏ Opportunity to capture market share





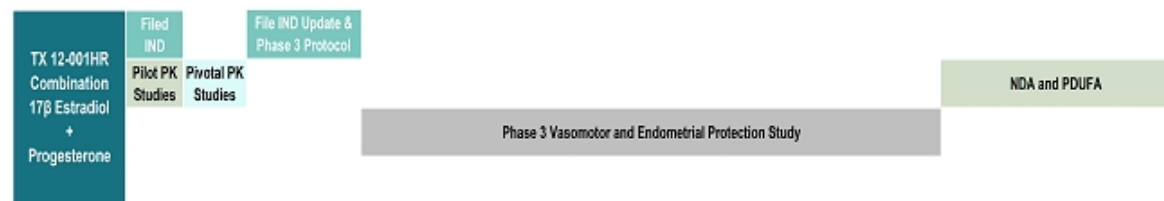
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***Combination Product***

# TX 12-001HR Combination— Proposed 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**

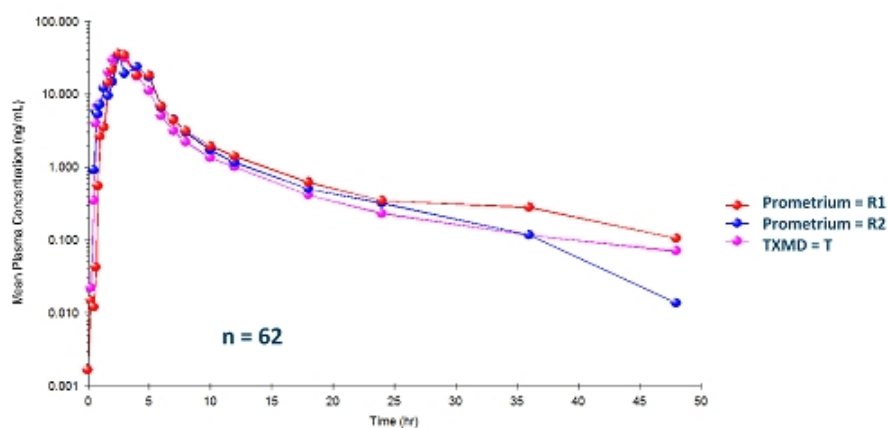
- ▣ Study: 12 month study with 12 week VMS
- ▣ Sites: ~50
- ▣ Subjects: 1,550
  - 4 active arms (350 per arm)
  - 1 placebo arm (150)
- ▣ Estimated cost: \$20-\$25 million
- ▣ Endpoints
  - Vasomotor: number and severity of hot flashes (4 week and 12 weeks)
  - Endometrial safety: incidence of endometrial hyperplasia (12 months)

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**Conduct Phase 3 study**

# TX 12-001HR Estradiol 2 mg / Progesterone 200 mg (combination) vs. Estrace® 2 mg + Prometrium® 200 mg (separate tablets)

## Progesterone Results (1)

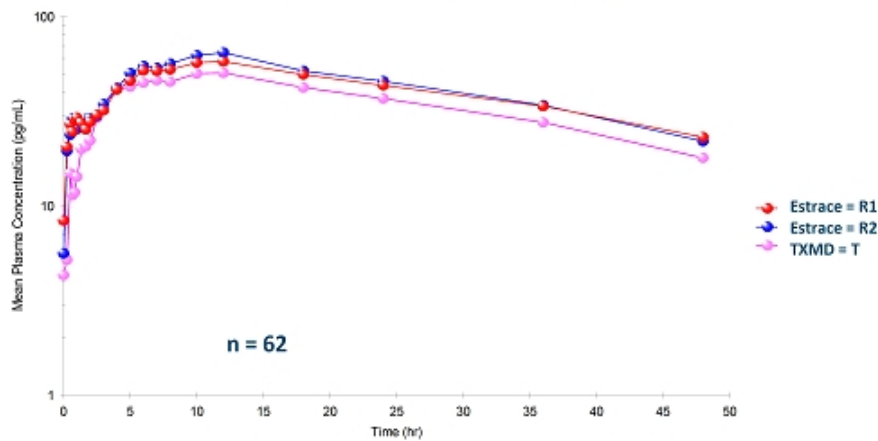


### 95% Upper Confidence Limit for PK Parameter

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

# TX 12-001HR Estradiol 2mg / Progesterone 200 mg (combination) vs. Estrace® 2m g + Prometrium® 200 mg (separate tablets)

## 17β Estradiol Results (1)



### 95% Confidence Interval 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

# TX 12-001HR Combination Potential Benefits

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

# 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) <sup>(4)</sup>	Company
<b>17β Estradiol + NETA / Drospirenone</b> (Activella / FemHRT / Angeliq / others)	<b>Non-bioidentical</b>	<b>\$178</b> <sup>(1)(2)</sup>		  
<b>Premarin + MPA</b> (Prempro / Premphase)	<b>Non-bioidentical</b>	<b>290</b> <sup>(1)(2)</sup>		
<b>Estradiol + Progesterone</b> (custom compounded)	<b>Untested Bioidentical</b>	<b>1,500</b> <sup>(3)</sup>		<b>Not FDA approved</b>
<b>Total Oral Combination Sales</b>		<b>\$1,968</b>	<b>\$489</b>	



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***New Lower Dose  
Progesterone***



# TX 12-002HR Progesterone— Proposed Phase 3 Study

	2012		2013E				2014E				2015E			
	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



**Phase 3 Trial**

- ☞ Trial: 2 studies; 12 days, 3 cycles
- ☞ Sites: 10-15 each
- ☞ Subject: 180
  - 3 arms (60 per arm)
- ☞ Estimated cost: \$5-\$8 million
- ☞ RLD = 400 mg
- ☞ Endpoints
  - Withdrawal bleeding and secretory change

# TX 12-002HR Progesterone Candidate

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





## Summary evaluations of baseline-corrected Progesterone results for a theoretical 150 mg test capsule vs. 200 mg Prometrium® capsule

Parameter	Point Estimate T/R Ratio	Within Subject Std. Deviation	Upper 95% Confidence Bound
C <sub>max</sub>	1.03	1.133	-0.747
AUC <sub>0-t</sub>	0.96	0.891	-0.465

# TX 12-002HR Progesterone— Potential Benefits

Drug Improvement	General Benefits	Patient Benefits
New lower effective doses	<ul style="list-style-type: none"><li>Lower first-pass metabolites</li><li>Better side effect profile</li></ul>	<ul style="list-style-type: none"><li>Less somnolence</li><li>Improved safety</li></ul>
Improved safety profile vs. non-bioidentical progestin	<ul style="list-style-type: none"><li>Reduced breast cancer risk</li><li>Improved cardiovascular profile</li><li>Improved lipid profile</li></ul>	<ul style="list-style-type: none"><li>Confidence in treatment regimen</li></ul>
No peanut oil	<ul style="list-style-type: none"><li>Non-allergenic</li><li>Excellent for all patient profiles</li></ul>	<ul style="list-style-type: none"><li>No worries about potential allergies</li></ul>

# Natural Progesterone Dominates

Product	Progestin	U.S. Sales (est.) (\$mm) <sup>(1),(2)</sup>	INTL Sales (3)	Company	Generic Available
<b>Provera<sup>®</sup></b> (medroxyprogesterone acetate)	<b>Non-bioidentical</b>	\$26		 MERCK	✓
<b>Aygestin<sup>®</sup></b> (norethindrone acetate)	<b>Non-bioidentical</b>	45		 TEVA	✓
<b>Prometrium<sup>®</sup></b> (micronized progesterone)	<b>Bioidentical</b>	247		 <b>Abbott</b> A Promise for Life  BESINS HEALTHCARE	✓
<b>Total Oral Progestin Sales</b>		<b>\$318</b>	<b>\$600</b>		



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*Other Programs*

# TX 12-004HR Estradiol Product— Vulvar / Vaginal Atrophy


Product	Compound	U.S. Sales (est.) (\$mm) <sup>(1)(2)</sup>	Problems
Premarin <sup>®</sup> Cream	Conjugated equine vaginal estrogen	\$265	<ul style="list-style-type: none"> <li>❑ Equine source</li> <li>❑ Non-bioidentical</li> <li>❑ Messy</li> <li>❑ Reusable plungers</li> </ul>
Vagifem <sup>®</sup> Tablets Estrace <sup>®</sup> Cream	Vaginal estradiol	\$558	<ul style="list-style-type: none"> <li>❑ Messy</li> <li>❑ Reusable plungers</li> <li>❑ Difficult to use</li> <li>❑ Continuous-use mechanical device</li> </ul>
<b>Total Sales</b>		<b>\$823</b>	

# TX 12-004HR Proposed Estradiol Vaginal Suppository—Proposed Phase 3 Study

	2013E				2014E				2015E				2016E			
	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



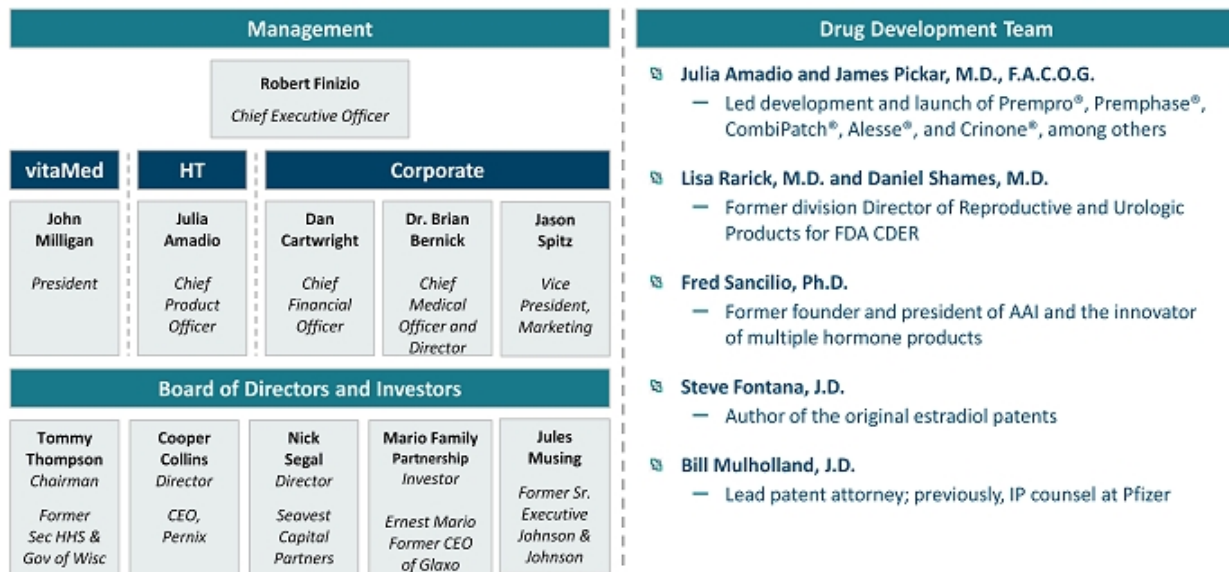
Estradiol



**Phase 3 Trial**

- 🔍 Trial: 12 weeks
- 🔍 Sites: 30-40
- 🔍 Subjects: 375-400
  - 2 active arms (150 per arm)
  - 100 placebo
- 🔍 Endpoints
  - Cell change
  - Lowering of pH
  - Lowering of most bothersome symptoms

# Experienced Management and Drug Development Team

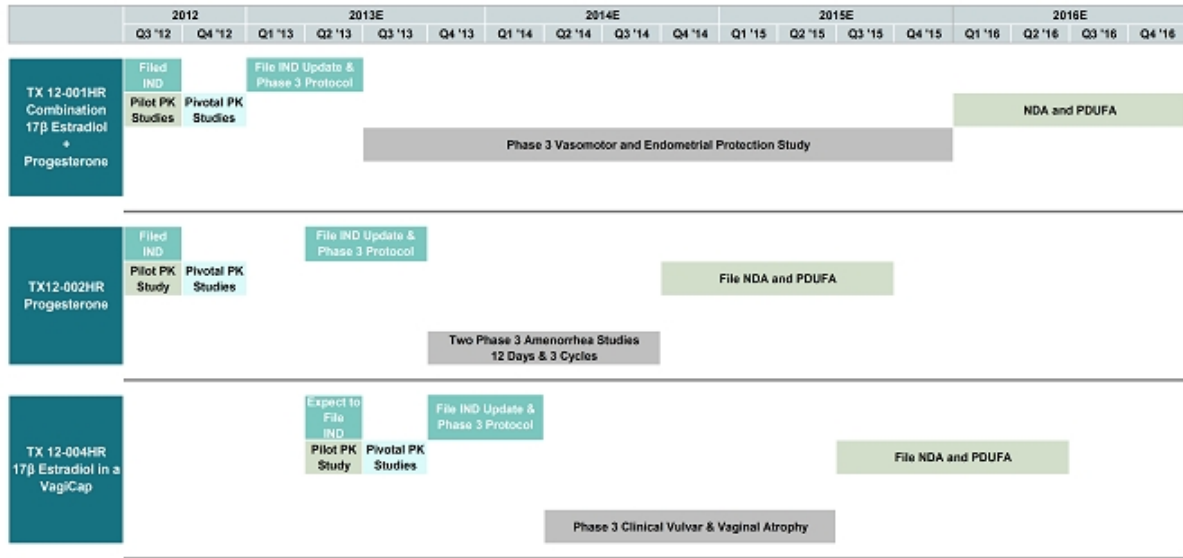


Proven team with a successful track record of creating shareholder value and developing some of the most successful products in the HT and birth control space

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# Potential Milestones



# 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 \$50 million equity financing  |
| 5 | Robust, growing patent estate   |

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