

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): March 4, 2014

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, 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.

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 March 2014.

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: March 4, 2014

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 March 2014.

The logo for TherapeuticsMD, featuring the company name in a dark blue, sans-serif font. The 'MD' is stylized with a white outline and a registered trademark symbol (®) to its upper right.The main title of the presentation, 'NYSE MKT: TXMD Corporate Overview', displayed in a bold, dark blue, sans-serif font. The text is centered within a light blue, grid-patterned background.

Q1 - 2014

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Forward-Looking Statements

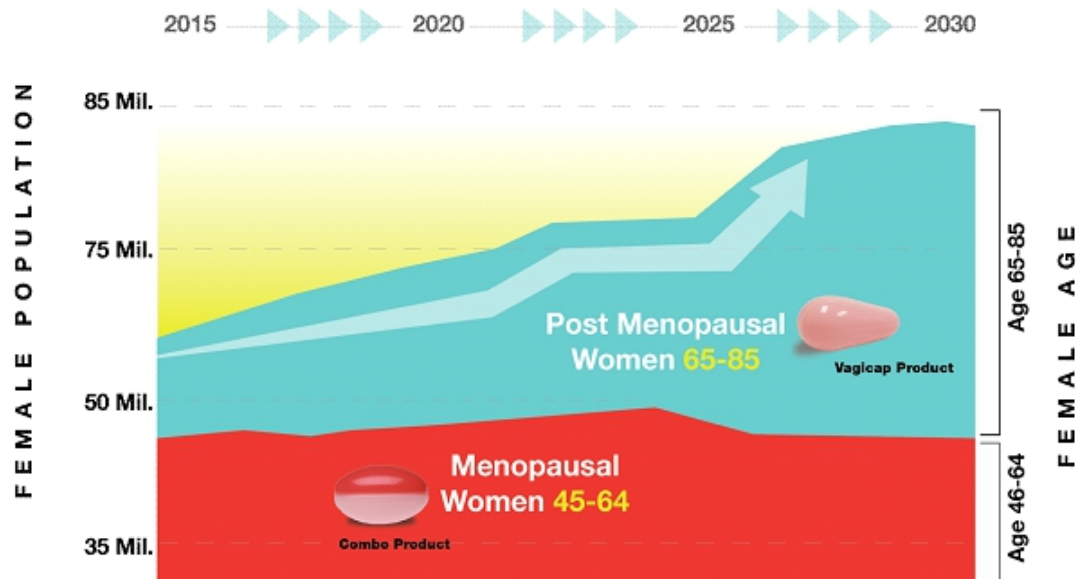
This presentation includes forward-looking statements covered by the safe harbor provision of the Private Securities Litigation Reform Act of 1995, including predictions, estimates, and other information that might be considered forward-looking. While these forward-looking statements represent TherapeuticsMD, 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 filed on March 12, 2013, 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.

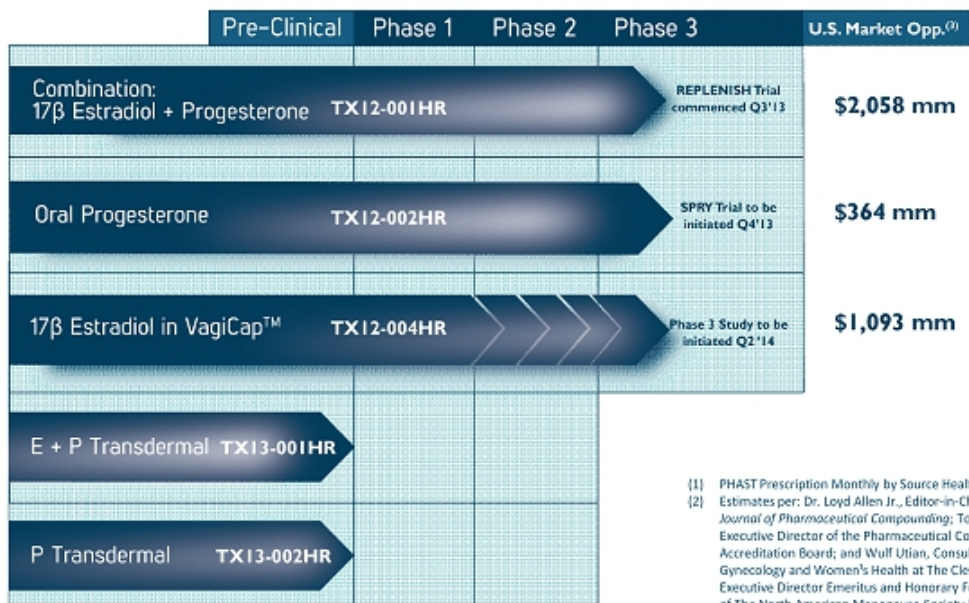
Hormone Therapy Market Opportunity

US Population



Pipeline

Two late-stage 505(b)(2) hormone therapy (“HT”) product candidates targeting multi-billion dollar U.S. markets ⁽¹⁾⁽²⁾



- (1) PHAST Prescription Monthly by Source Healthcare Analytics.
- (2) Estimates per: Dr. Loyd Allen Jr., Editor-in-Chief, *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").
- (3) Estimated U.S. sales

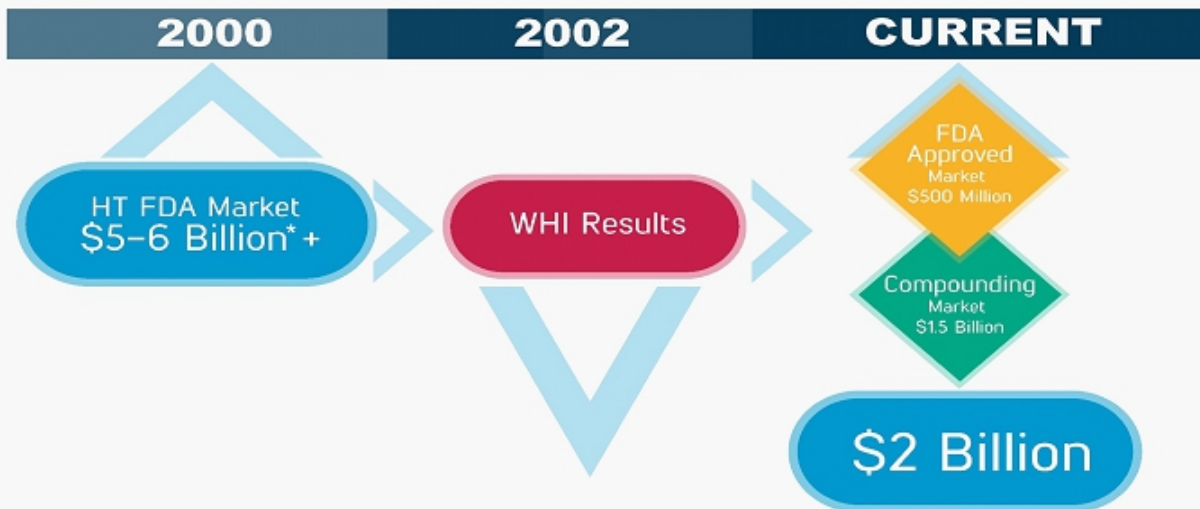
TherapeuticsMD



TherapeuticsMD[®]

Combination Product
TX 12-001HR E+P

History of Hormone Therapy



Women's Health Initiative (WHI)

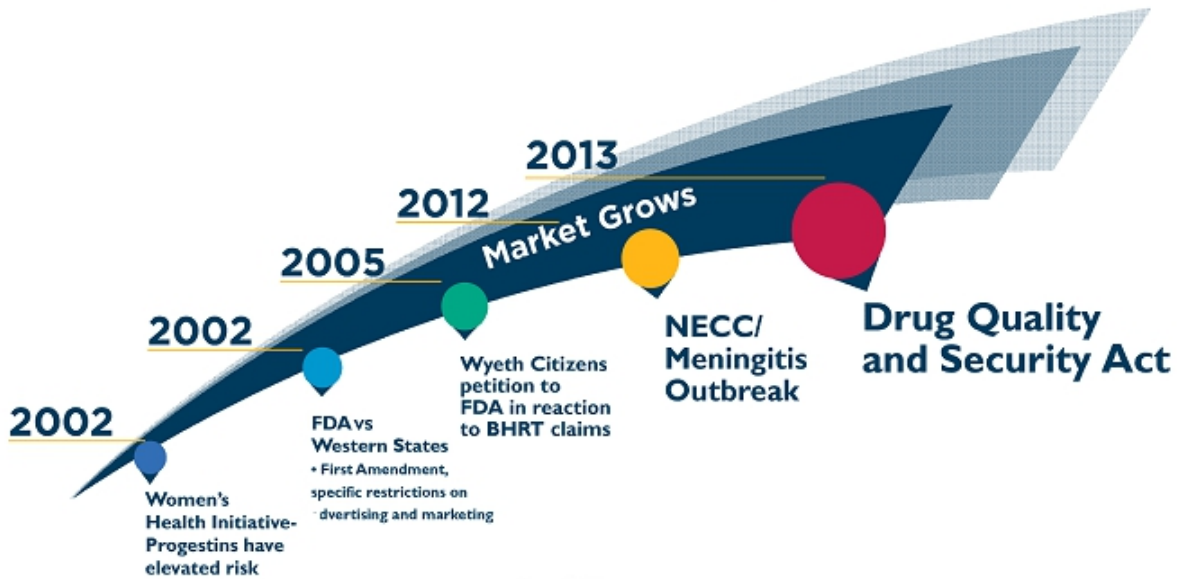
- Hormone Therapy is linked to Cardiovascular, Cancer and other risks
- Estrogen + **Progestin** (Prempro) arm had a 24% increase in breast cancer vs. Estrogen alone

(1) PHAST Prescription Monthly by Source Healthcare Analytics. 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").

History of Compounding

📌 Bio-identical Hormone Replacement (BHRT)



Bioidentical Progesterone vs. Non-Bioidentical Progestin

Side Effect ⁽¹⁾	Bioidentical Natural Progesterone	Non-Bioidentical Progestins (MPA, NETA, drospirone)
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 Karimkhani, and Georgios Copinschi. "Progesterone Prevents Sleep Disturbances and Modulates GH, TSH, and Melatonin Secretion in Postmenopausal Women." *J Clin Endocrinol Metab* 95.4 (2011): 914-23.

⁽³⁾ Fazzaroli, Pia, and Wafa. "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

Journal of the American Medical Association

September 30, 2013

CEEs (Premarin) were associated with a higher incidence of venous thrombosis and myocardial infarction than oral estradiol

Journal of the American Medical Association

October 3, 2013

Breast Cancer Risk persists for 13 years after discontinuation of CEE

Menopause

September 2013

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

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

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

(3) 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

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8

TXMD 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, well tolerated)
- ❏ Enabling new combinations, routes and dosages (creams, patches, etc.)



✔ **Meet PK 505(b)(2) thresholds**

TX 12-001HR E+P — Phase 3 Study

Combination of Estradiol
+ Progesterone



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

Filed
IND

File IND Update &
Phase 3 Protocol

Pilot PK
Studies

Pivotal PK
Studies



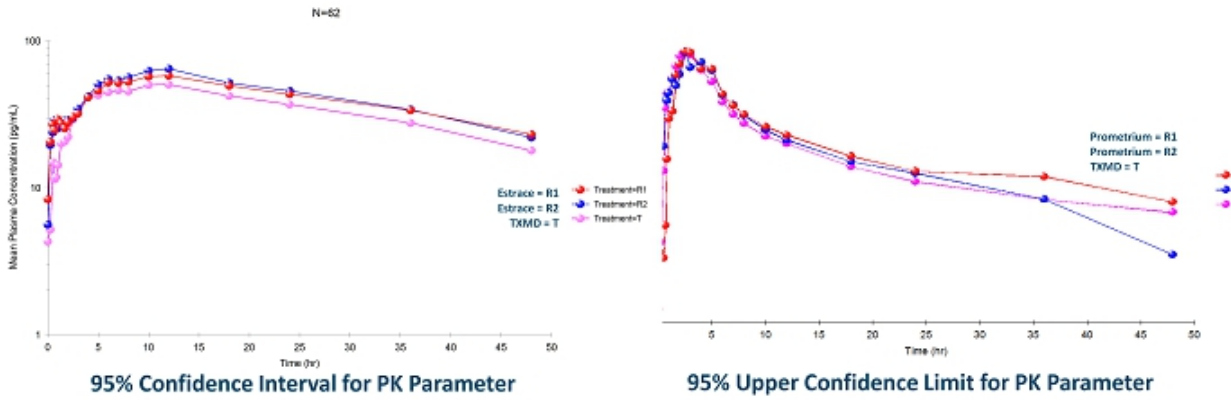
NDA and PDUFA

Phase 3 Vasomotor and Endometrial Protection Study

- ❏ **Pivotal Phase 3 clinical trial initiated Q3 '13: The REPLENISH Trial**
- ❏ **Designed to enroll 1,750 subjects at ~70 sites**
 - ❏ Four active arms (N=400/ arm)
 - ❏ Placebo arm (N=150)
- ❏ **12-month study with 12 week VMS**
- ❏ **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 versus Separate 2mg Estrace[®] tablet + 200mg Prometrium[®] Capsule

Based on C_{max} and AUC, both estradiol and progesterone showed relative bioequivalence (N=62)



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

Transdermal Development

2013				2014				2015			
Q1 2013	Q2 2013	Q3 2013	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	
E+P Transdermal				Pilot Preclinical Studies		Pilot Studies		File IND	File IND Update		
									Phase 1 PK and clinical Study		
P Transdermal				Pilot Preclinical Studies		Pilot Studies		File IND	File IND Update		
									Phase 1 PK and clinical		

Enormous E+P HT Market Opportunity

- All in-market FDA-approved combination products contain **non-bioidentical** progestins
- Today's FDA-approved combination products lack innovation

Product	Progestin	U.S. Sales (est.)	Intl Sales (4)	Company
17β Estradiol + NETA / Drospirenone (Activella / FemHRT / Angeliq / others)	Non-bioidentical	\$ 230 mm ⁽¹⁾⁽²⁾		
Premarin + MPA (Prempro / Premphase)	Non-bioidentical	\$ 328 mm ⁽¹⁾⁽²⁾		
Estradiol + Progesterone (custom compounded)	Untested Bioidentical	\$1,500 mm ⁽³⁾		Not FDA approved
Total Oral Combination Sales		\$2,058 mm	\$489 mm	

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Notes:

- (1) PHAST Prescription Monthly by Source Healthcare Analytics.
- (2) Based on last twelve months sales through December 31, 2013.
- (3) Estimate per Wulf Utian, Executive Director Emeritus and Honorary Founding President of NAMS.
- (4) IMS Data

Drug Quality and Security Act

☒ Signed by President on 11/27/13

☒ Bill Highlights

- ☒ Prohibits compounding of essentially a copy of an FDA approved & marketed drug
- ☒ Prohibits compounding of certain drug products, including those identified by regulation as being ***demonstrably difficult to compound*** such as complex dosage forms and biologics
- ☒ FDA-approved drugs that are not in shortage cannot be compounded without a medical need



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Vulvar / Vaginal Atrophy (VVA)

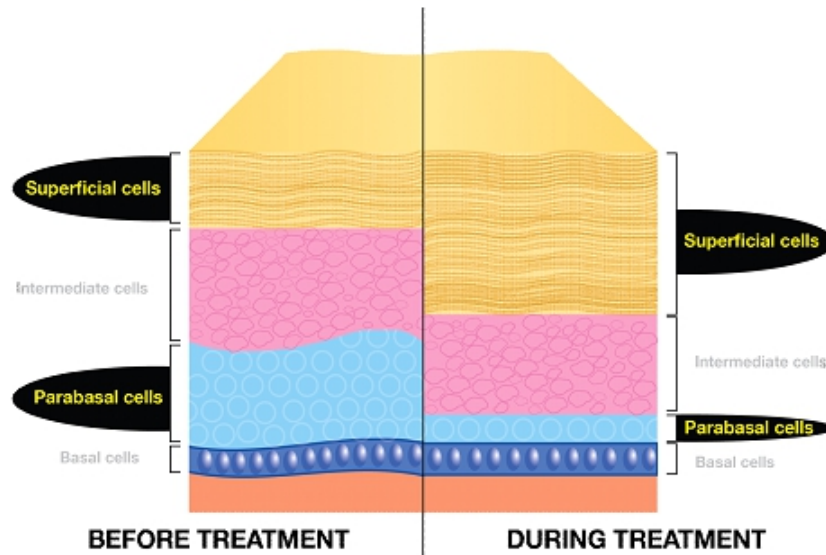
Vulvar/Vaginal Atrophy

Mechanism:

- Decreased estradiol levels cause a reduction in superficial cells
- Parabasal cells increase
- Vagina changes from acidic to basic (increased pH)

Most common symptoms: Burning, dyspareunia, UTI & itching

Chronic condition; requires ongoing therapy for the rest of a woman's life



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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	\$389	<ul style="list-style-type: none"> ☒ Equine source ☒ Non-bioidentical ☒ Messy ☒ Reusable plungers
Vagifem® Tablets	Vaginal estradiol	\$316	☒ Messy
Estring® Insert		\$81	☒ Reusable plungers
Femring® Insert		\$23	☒ Difficult to use
Estrace® Cream		\$284	☒ Continuous-use device
Total Sales		\$1,093 mm	

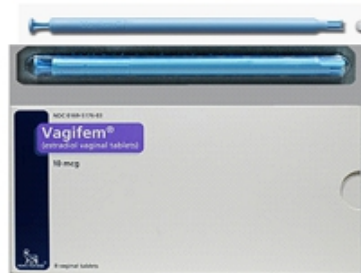
US Sales Grew 22% from June 2012-2013⁽³⁾

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

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- (1) PHAST Prescription Monthly by Source Healthcare Analytics.
 (2) Based on last twelve months sales through December 31, 2013.
 (3) Source Healthcare Analytics/W
 (4) GlobalData 2/12 report https://www.asdreports.com/news.asp?pr_id=420

Leading Estrogen Products vs. TXMD



TXMD Solution: VagiCap™

- ❑ Less messy than creams
- ❑ Well tolerated
- ❑ Easier to use
- ❑ Does not require a long-term device
- ❑ Flexibility of dosing
 - ❑ 0.01 mg
 - ❑ 0.025 mg



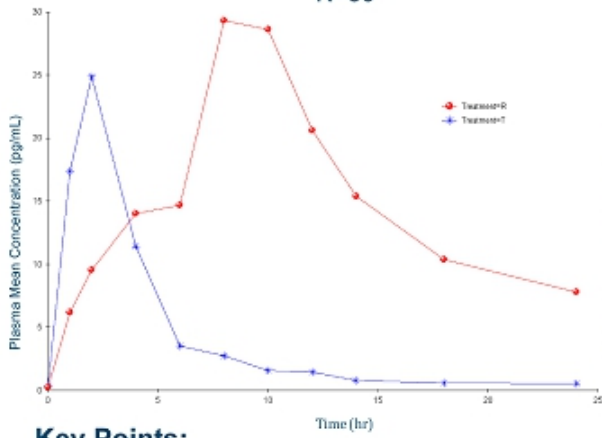
TX 12-004-HR Positive Phase I Study Outcomes

- ❖ **48 postmenopausal women with symptoms of VVA**
- ❖ **Randomized to receive 10µg dose of TX 12-004-HR or placebo VagiCap**
 - ❖ Self-administered 1x daily for two-week period
- ❖ **As compared to placebo, women treated with TX 12-004-HR showed:**
 - ❖ Statistically significant improvements in the Maturation index
 - ❖ Included significant decreases in parabasal cells ($p < 0.0001$)
 - ❖ Significant increases in superficial cells ($p = 0.0002$)
 - ❖ Significant increases in intermediate cells ($p = 0.0017$)
 - ❖ Statistically significant decreases in vaginal pH ($p = 0.0002$)
 - ❖ Significant reduction in the atrophic effects on epithelial integrity and vaginal secretions

VagiCap vs. Vagifem

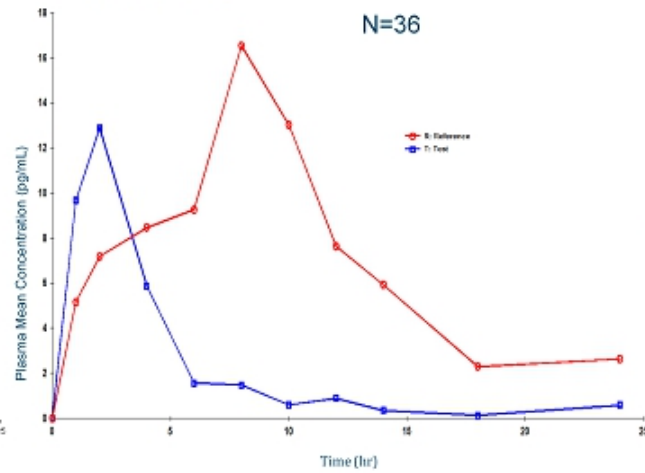
Estradiol 25 µg

N=36



Estradiol 10 µg

N=36



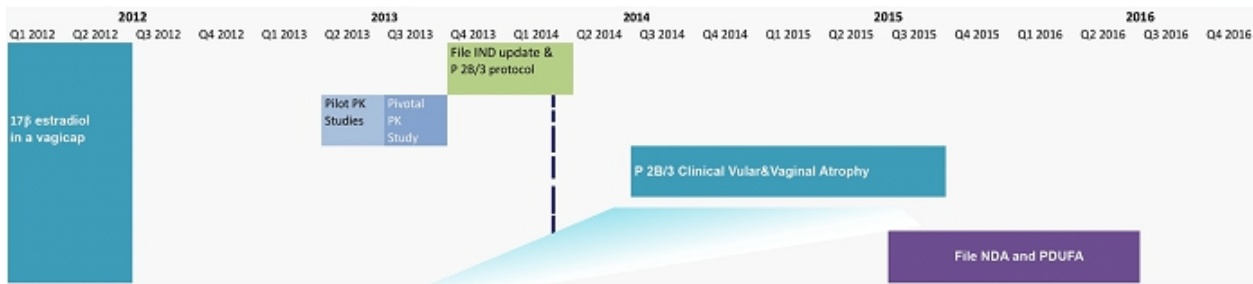
Key Points:

- T_{max} ~ 2 hours with VagiCap and ~8 hours with Vagifem
- Systemic absorption AUC (0-24 hrs) is 2-3 fold lower with Vagicap relative to Vagifem
- More drug is reaching target tissue and less drug is reaching systemic circulation

VagiCap Product Goals

- Next Generation product to treat VVA - well tolerated, achieve expected clinical endpoints
- Achieve significantly lower or negligible systemic estrogen exposure
- Obtain a new indication under the FDA's new VVA guidance
- Deliver an elegant patient experience
- Simple-to-use / placement of the product with patient-friendly attributes
- Quick dissolution (2 hours)
- Easier absorption and less residue compared to current solutions

Estradiol Vaginal Suppository



Phase 2B/3 Study 2014

- 📅 **12 weeks**
- 📅 **Designed to enroll 250-300 subjects in each arm**
 - Multiple Active Arms
 - Placebo (n=100)
- 📅 **Endpoints:**
 - Cell change
 - Lowering of pH
 - Evaluation of Adverse Effects



TherapeuticsMD[®]

*Lower Dose
Progesterone
TX 12-002HR*

TX 12-002HR Progesterone Highlights

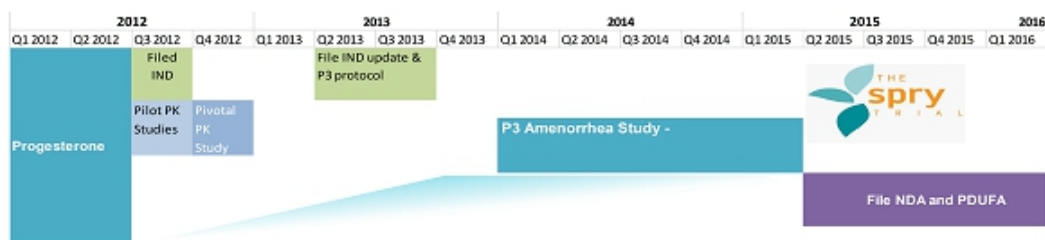
❏ Conducted PK studies in accordance with FDA requirements

- ❏ 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®
- ❏ Removed peanut oil





TX 12-002HR Progesterone— Phase 3 Study



Phase 3 Study : The SPRY Trial

- ❏ Three cycles – estrogen priming
- ❏ Two progesterone treatment cycles
- ❏ Designed to enroll 180 subjects in three arms
 - 2 active arms (225mg, 300mg)
 - Placebo
- ❏ 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 mm		 MERCK	✓
Aygestin[®] (norethindrone acetate)	Non-bioidentical	\$48 mm		 TEVA	✓
Prometrium[®] (micronized progesterone)	Bioidentical	\$290 mm		 Abbott A Promise for Life  BESINS HEALTHCARE	✓
Total Oral Progestin Sales		\$364 mm	\$600 mm		

Extensive Patent Filings

	Filed	Provisional	Non-Provisional	Issued
U.S.	25	8	17	2
Ex-U.S.	6			

- ❏ Oral combination therapeutics
 - ❏ Bioidentical E+P HT combination
 - ❏ Natural combination HT and formulations
- ❏ Oral solo therapeutics
 - ❏ Progesterone formulations
- ❏ Vulvovaginal atrophy pessary
- ❏ Pipeline applications
- ❏ Opera reporting and analysis software

Key Statistics

NYSE MTK: TXMD

Recent market price ¹	\$6.12
Shares outstanding ²	145 million
Market capitalization ¹	\$887.4 million
Cash & equivalents ²	\$54 million
Debt ³	\$0.00 million

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¹Based upon closing price February 14, 2014

²As at December 31, 2013



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Investor Contacts

Dan Cartwright
Chief Financial Officer
TherapeuticsMD, Inc.
561-961-1930

Dan.Cartwright@TherapeuticsMD.com

Lisa M. Wilson
President

In-Site Communications, Inc.
917-543-9932

lwilson@insitecony.com

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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. Sebastian Mirkin

Chief Medical Officer

Dr. Joel Krasnow

Chief Scientific Officer

Board Members and Early Investors

Tommy Thompson
Chairman

Former Sec HHS & Gov of Wisc

Cooper Collins
Director

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
- ❏ **Marlan Walker, J.D.**
 - Lead Patent Attorney
- ❏ **Steve Fontana, J.D.**
 - Author of the original estradiol patents

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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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.”
- ❏ “Recent evidence suggests that HRT regimens containing **progesterone** can minimize the metabolic impact and reduce the risk of thromboembolism.”
- ❏ 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).”
- ❏ “Data from a large observational study suggest that EPT with micronized **progesterone** carries a low risk of breast cancer with short-term use.”

