

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): April 8, 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, 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 Q2 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: April 8, 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 Q2 2014.

The logo for TherapeuticsMD, featuring the company name in a dark teal font with a registered trademark symbol. The background of the slide is a light blue grid pattern with a gradient from top to bottom.

NYSE MKT: TXMD Corporate Overview

Q2 - 2014

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Forward-Looking Statements

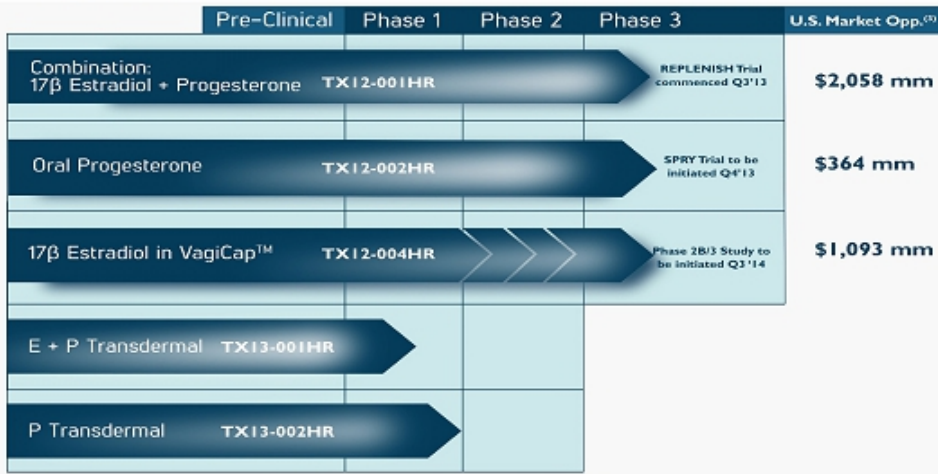
This presentation includes forward-looking statements covered by the safe harbor provision of the Private Securities Litigation Reform Act of 1995, including predictions, estimates, and other information that might be considered forward-looking. While these forward-looking statements represent TherapeuticsMD, 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 5, 2014, Forms 10-Q, our Forms 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.

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").

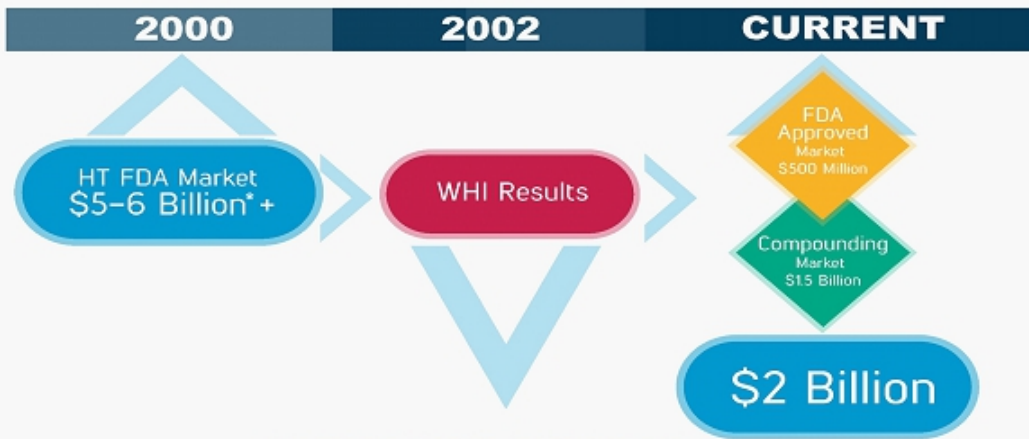
(3) Estimated U.S. sales



TherapeuticsMD[®]

Combination Product
TX 001-HR 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 WuF 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, 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⁾ [Cachler, Jane, Rachel Epprecht, Sabrina L'Heureux-Gale, Lisa Myrland-Kerthoff, and George Espinola. "Progesterone Prevents Sleep Disturbances and Modulates GH, TSH, and Melatonin Secretion in Perimenopausal Women." J Clin Endocrinol Metab 96.4\(2008\): 814-25.](#)
⁽³⁾ [Pozzatti, Pauc, and Wilks. "Comparison of Regimens Containing Oral Microcrystalline Progesterone or Medroxyprogesterone Acetate on Quality of Life in Postmenopausal Women: A Cross-Sectional Survey." J Womens Health Gender 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**

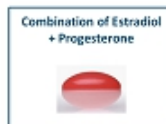
TXMD Novel Drug Design

❏ **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**

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RLD = Reference Listed Drug
API = Active Pharmaceutical Ingredient

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TX 001-HR 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



Phase 3 Vasomotor and Endometrial Protection Study

Filed
IND

File IND Update &
Phase 3 Protocol

Pilot PK
Studies

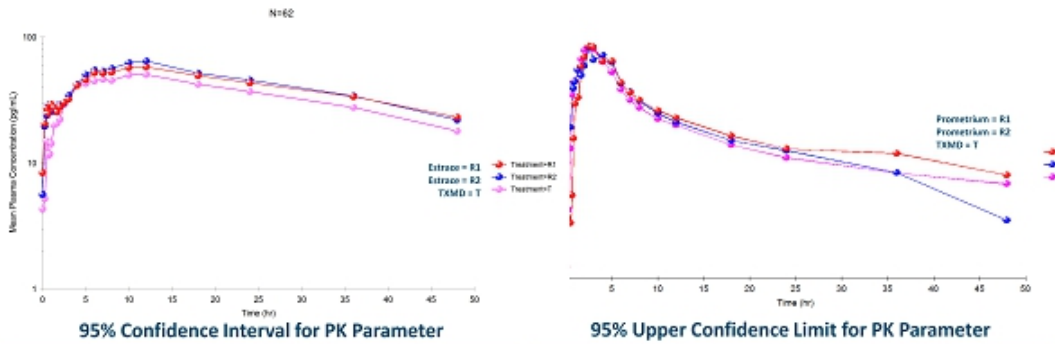
Pivotal PK
Studies

NDA and PDUFA

- ❏ 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		File IND		File IND Update		
				Pilot Studies		Phase 1 PK and clinical Study				
P Transdermal				Pilot Preclinical Studies		Pilot Studies		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	

Notes:

- (1) PHAST Prescription Monthly by Source Healthcare Analytics.
- (2) Based on last twelve months sales through December 31, 2013.
- (3) Estimate per Wolf 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

Establishes requirements for traditional compounding pharmacies and larger-scale outsourcing facilities.

Prohibits compounding of essential copies of an FDA approved & marketed drug except in limited circumstances:

Traditional compounding pharmacies may not compound essential copies regularly or in inordinate amounts, or unless there is a change in the compounded drug that produces a significant difference for an individual patient.

Outsourcing facilities may not compound essential copies unless the approved drug appears on the drug shortage list, or unless there is a change in the compounded drug that produces a clinical difference for an individual patient.

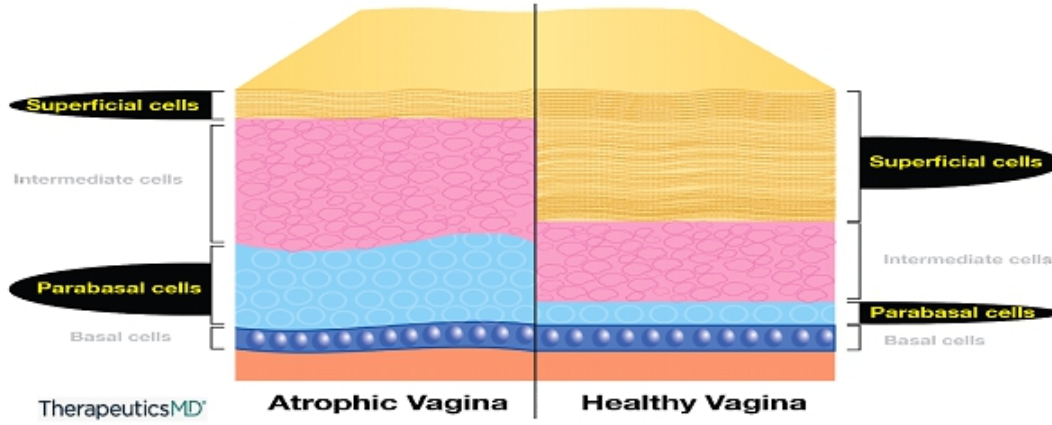
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Vulvar / Vaginal Atrophy (VVA)

Vulvar/Vaginal Atrophy

❏ Mechanism: Low Levels of Estradiol impact on the Vagina

- ❏ Reduction in superficial cells
- ❏ Parabasal cells increase
- ❏ Vagina changes from acidic to basic (increased pH)
- ❏ Most common symptoms: Vaginal Dryness, Dyspareunia, Itching/Irritation, Dysuria, Bleeding with Sexual Activity



VVA US Sales – Currently No Generics

Product	Compound	US(\$mm) Sales ₂₀₁₂	WAC Price ₂₀₁₂
Premarin® Cream	Equine vaginal estrogen	\$389	\$201*
Vagifem® Tablets	Vaginal Estradiol	\$316	\$193*
Estrace® Cream	Vaginal Estradiol	\$284	\$152*
Total		\$1,100 mm	

US Sales Grew 22% from June 2012-2013^[1]

ASD analysis - global market is expected to grow to **\$3.1 Billion 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.
 [4] GlobalData 2/12 report https://www.asdreports.com/news.asp?pr_id=420

US Sales – Large and Growing

“VVA market revenue has more than doubled since 2008”

	Total Number of Prescriptions	US Sales
2008	5,030,472	\$505,917,525
2009	5,370,763	\$630,210,685
2010	5,381,069	\$681,598,442
2011	5,425,240	\$768,532,546
2012	5,550,504	\$900,519,871
2013	5,832,186	\$1,100,833,171

Leading Estrogen Products vs. TXMD

Current Approved Estrogen Products - ~ \$1.1 BILLION In Sales



TXMD Solution: VagiCap™



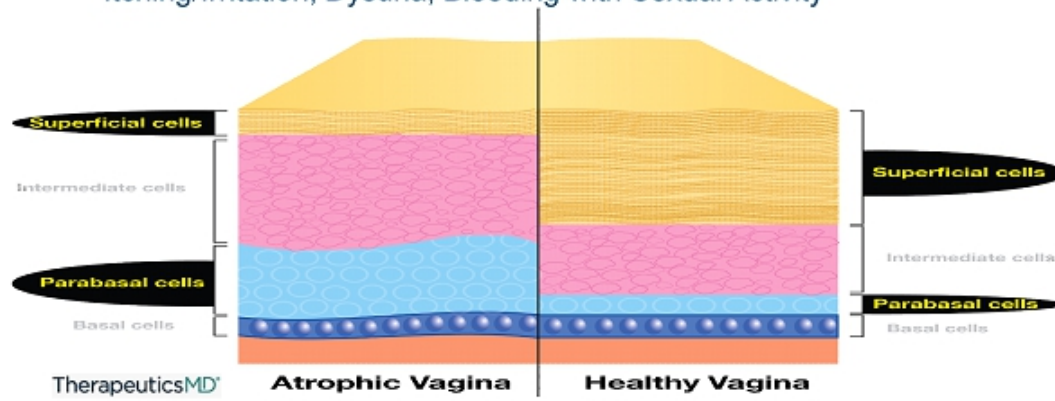
- ❑ Deliver an elegant patient experience
- ❑ Eliminate reusable plungers
- ❑ Less messy than creams
- ❑ Burning sensation eliminated
- ❑ Simple-to-use / no placement issues
- ❑ Quick dissolution
- ❑ Does not require a long-term device

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Vulvar/Vaginal Atrophy

How to Measure Efficacy – FDA Guidance for Phase 3

1. Statistical increase in superficial cells
 2. Statistical decrease in parabasal cells
 3. Statistical changes in vaginal pH from basic to acidic (decrease pH)
- Reduce most bothersome symptoms: Vaginal Dryness, Dyspareunia, Itching/Irritation, Dysuria, Bleeding with Sexual Activity



TX 004-HR Positive Phase 1

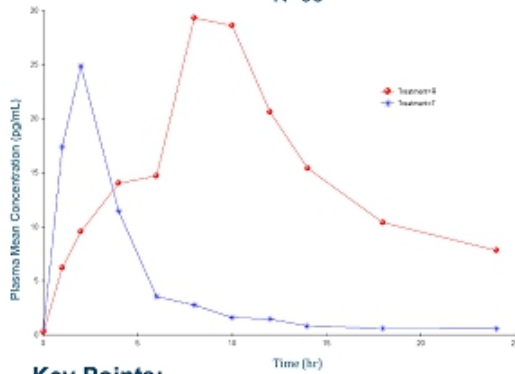


- ❏ **48 postmenopausal women with symptoms of VVA**
- ❏ **Randomized 10µg dose of TX 004-HR or placebo**
 - ❏ Self-administered 1x daily for two-week period
- ❏ **Phase 3 (12 weeks) endpoints measured in phase 1 study (2 weeks)**
- ❏ **As compared to placebo, women treated with TX 004-HR showed:**
 - ❏ Statistically significant decreases in parabasal cells ($p < 0.0001$)
 - ❏ Significant increases in superficial cells ($p = 0.0002$)
 - ❏ Statistically significant decreases in vaginal pH ($p = 0.0002$)
 - ❏ Significant reduction in the atrophic effects on epithelial integrity and vaginal secretions
 - ❏ Not powered for most bothersome symptom (positive trends)

VagiCap vs. Vagifem

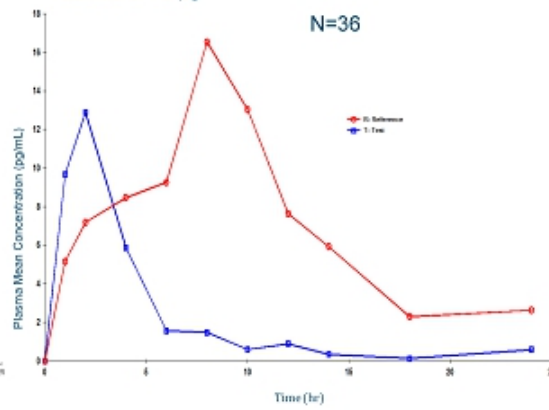
Estradiol 25 µg

N=36



Estradiol 10 µg

N=36



Key Points:

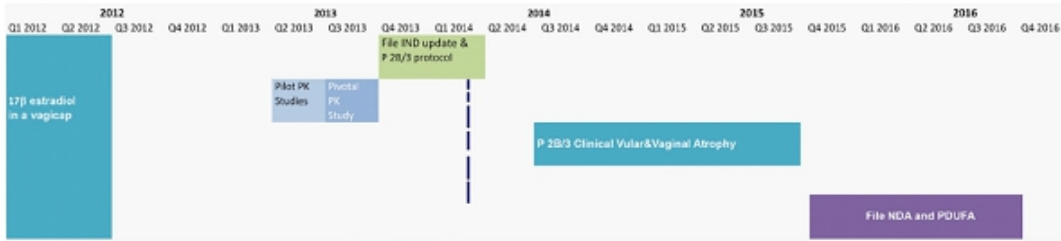
- Tmax ~ 2hours with VagiCap and ~8 hours with Vagifem
- Systemic absorption AUC (0-24 hrs) is 2-3 fold lower with Vagicap relative to Vagifem
- Suggests more drug is reaching target tissue and less drug is reaching systemic circulation

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What does this mean? *Next Generation VVA Product*

- ❏ **Early data suggests more Solubilized Estradiol is reaching target tissue and less is spilling over into blood (less systemic exposure) compared to Vagifem**
- ❏ **New technology potentially enabling new lower effective doses (4&10mcg) without the risk of systemic exposure**
- ❏ **10 mcg dose achieves Phase 3 endpoints (other than most bothersome symptom) in only 14 days**
- ❏ **Quick dissolving gelcap enabling an elegant / positive user experience**

Estradiol Vaginal Suppository

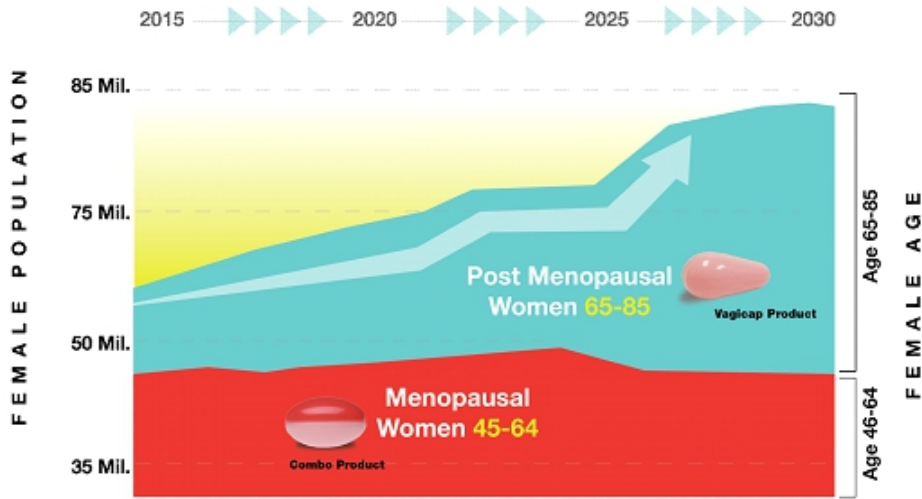


Phase 2B/3 Study 2014

- 📅 12 weeks
- 📅 Designed to enroll 150-200 subjects in each arm
 - Multiple Active Arms (4 mcg, 10 mcg, 25 mcg)
 - Placebo (n=100)
- 📅 Endpoints:
 - Cell change
 - Lowering of pH
 - Evaluation of Adverse Vaginal Effects (Dyspareunia and Dryness)

Hormone Therapy Market Opportunity

US Population



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

Milestones

2014	VVA:	Rabbit Irritation Study Results	Q2
	E+P Transdermal:	File IND for P and E+P Transdermal	Q2/Q3
	E+P Transdermal:	PK Results for P and E+P Transdermal	Q2/Q3
	E+P Oral:	International Menopausal Society Replenish Trial Poster Session	Q2
	Compounding Market:	Symphony Health Report on BHRT Size of Market	Q3
	Estradiol VagiCap:	Commence Phase 2b/III VVA Trial	Q3
	Oral Progesterone:	Complete patient enrollment: Spry Trial	Q4
2015	E+P Oral:	Complete patient enrollment: Replenish Trial	Q4
	IP / Patents	Annual IP Update to Patent Portfolio	Q4
	Oral Progesterone	Report P III/Spry Trial Results	Q1
	Estradiol VagiCap:	Complete Patient Enrollment	Q2
	Estradiol VagiCap	Report P III/VVA Trial Results	Q3
	Estradiol VagiCap:	File NDA for TX-12-003 HR in VVA	Q3
	Combination E+P:	Report Replenish Trial results	Q4
Combination E+P:	File NDA for TX-12-001HR E+P	Q4	

Key Statistics

NYSE MTK: TXMD

Recent market price ¹	\$5.04
Shares outstanding ²	145 million
Market capitalization ¹	\$730 Billion
Cash & equivalents ²	\$54 million
Debt ³	\$0.00 million

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¹ Based upon closing price April 7, 2014
² As at December 31, 2013

The logo for TherapeuticsMD, featuring the company name in a dark blue, sans-serif font. The 'MD' is stylized with a square symbol over the 'D'.

TherapeuticsMD[®]

Investor Contacts

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561-961-1900

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Lisa M. Wilson
President

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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."

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The 2012 Hormone Therapy Position Statement of The North American Menopause Society, Menopause: The Journal of The North American Menopause Society Vol. 18, No. 3, pp. 257-271

The 2013 British Menopause Society & Women's Health Concern recommendations on hormone replacement therapy, Menopause Int, published online May 23, 2013

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Experienced Management and Drug Development Team

Management					Drug Development Team				
Robert Finizio <i>Chief Executive Officer</i>					<ul style="list-style-type: none"> ▣ Julia Amadio and James Pickar, M.D., F.A.C.O.G. <ul style="list-style-type: none"> – Led development and launch of Prempro®, Premphase®, CombiPatch®, Alesse®, and Crinone®, among others ▣ Lisa Rarick, M.D. and Daniel Shames, M.D. <ul style="list-style-type: none"> – Former division Director of Reproductive and Urologic Products for FDA CDER ▣ Fred Sancilio, Ph.D. <ul style="list-style-type: none"> – Former founder and president of AAI and the innovator of multiple hormone products ▣ Marlan Walker, J.D. <ul style="list-style-type: none"> – Lead Patent Attorney ▣ Steve Fontana, J.D. <ul style="list-style-type: none"> – Author of the original estradiol patents 				
vitaMed	HT	Corporate							
John Milligan <i>President</i>	Julia Amadio <i>Chief Product Officer</i>	Dan Cartwright <i>Chief Financial Officer</i>	Dr. Sebastian Mirkin <i>Chief Medical Officer</i>	Dr. Joel Krasnow <i>Chief Scientific Officer</i>					
Board Members and Early Investors									
Tommy Thompson <i>Chairman</i> <i>Former Sec HHS & Gov of Wisc</i>	Cooper Collins <i>Director</i> <i>Pernix</i>	Nick Segal <i>Director</i> <i>Seavest Capital Partners</i>	Mario Family Partnership <i>Ernest Mario</i> <i>Former CEO of Glaxo</i>	Jules Musing <i>Former Sr. Executive</i> <i>Johnson & Johnson</i>					

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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