**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): September 26, 2016

**TherapeuticsMD, Inc.**
(Exact Name of Registrant as Specified in its Charter)

| **Nevada** | **001-00100** | **87-0233535** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

6800 Broken Sound Parkway NW, Third Floor
Boca Raton, FL 33487
(Address of Principal Executive Office) (Zip Code)

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01. Regulation FD Disclosure.**

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on September 26, 2016 and at subsequent meetings with investors or analysts.

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

**Item 9.01. Financial Statements and Exhibits.**

(d) *Exhibits.*

| Exhibit Number | Description |
|---|---|
| 99.1 | TherapeuticsMD, Inc. presentation dated September 2016. |

**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: September 26, 2016

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 September 2016. |

**Exhibit 99.1**


TherapeuticsMD®
TXMD Overview
September 2016
TherapeuticsMD.com
THER-0086 8/16

# Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as "we" and "our") may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believe," "hope," "may," "anticipate," "should," "intend," "plan," "will," "expect," "estimate," "project," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop, protect and defend our intellectual property; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefore; whether the FDA will accept and, if accepted, approve the company's new drug application for its TX-004HR product candidate; the length, cost and uncertain results of our clinical trials; potential adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership.

Yuvvexy™ (TX-004HR), TX-001HR, TX-005HR, and TX-006HR are investigational drugs and are not approved by the FDA. This non-promotional presentation is intended for investor audiences only.

*PDF copies of press releases and financial tables can be viewed and downloaded at our website: www.therapeuticsmd.com/pressreleases.aspx.*

# TherapeuticsMD® (TXMD)

**Innovative women's health company** exclusively focused on developing and commercializing products for women throughout their life cycles

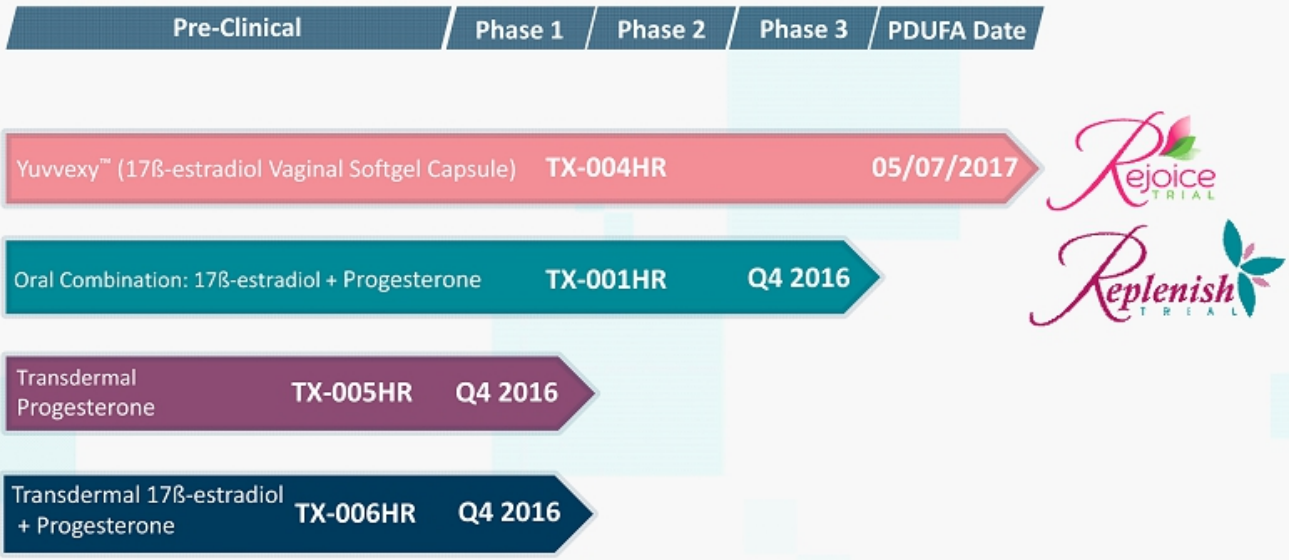
Drug candidate portfolio is built on **SYMBODA™** technology for the solubilization of bio-identical female hormones

# Two Late-Stage Women's Health Assets with Large Total Addressable Market Opportunities

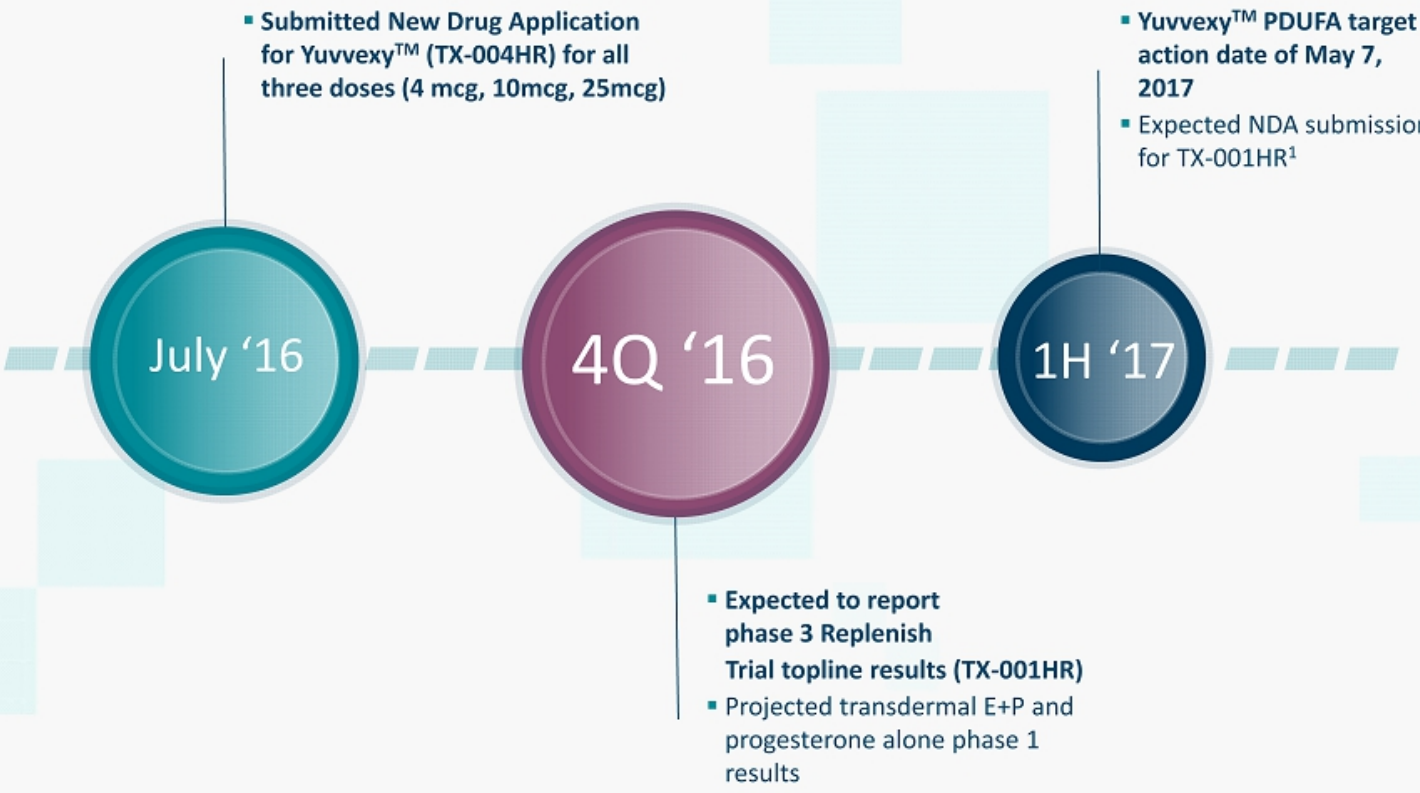
| | Yuvvexy™ | TX-001HR |
|---|---|---|
| |  |  |
| Proposed Indication | Moderate to Severe Dyspareunia, a Symptom of VVA, due to Menopause | Moderate to Severe Hot Flashes due to Menopause |
| Condition Description | VVA due to Menopause | Menopause |
| Active Ingredients | Bio-Identical 17 β-Estradiol | Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone |
| Form | Vaginal softgel capsule | Oral softgel capsule |
| Key Value Proposition | Negligible systemic exposure, early onset of action, ease of use | Potential first and only bio-identical FDA-approved combination product |
| Affected US Population | 32 million women[1,2] | 36 million women[3] |
| US TAM Opportunity | >$20B[5] | >$25B[4,5] |
| Status | NDA submitted July 7, 2016<br>PDUFA target action date: May 7, 2017 | Pivotal Phase 3 topline data expected 4Q 2016 |

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
2) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.
3) Derived from U.S. Census data
4) Based on pre-WHI annual scripts of FDA-approved HT
5) Based on current FDA-approved market pricing

# Investigational Pipeline



# Key Accomplishments and Anticipated Milestones



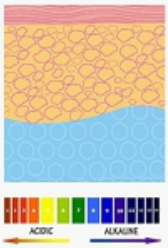

1) NDA to be submitted assuming successful results of Replenish trial


Yuvvexy™
TX-004HR | Vulvar and Vaginal Atrophy (VVA) Program
TherapeuticsMD®
7

# Overview – Vulvar and Vaginal Atrophy (VVA)

- **Chronic** and **progressive** condition characterized by thinning of vaginal tissue from decreased estrogen levels
- Diagnosed in approximately 50% of postmenopausal women[1]
- Primary symptom = dyspareunia
- Secondary symptoms include: dryness, itching, irritation, dysuria, bleeding with sexual activity
- Current treatments include: prescription creams, lubricants and tablets

| | Healthy Vaginal Tissue | Atrophic Vaginal Tissue |
|---|---|---|
| Superficial cells: | >15% | <5% |
| Intermediate cells: | 80% | 60% |
| Parabasal cells: | < 5% | >30% |
| pH: | < 5 | > 5 |


1) Kingsberg, Sheryl A., et al. "Vulvar and Vaginal Atrophy in Postmenopausal Women: Findings from the REVIVE (REal Women's Views of Treatment Options for Menopausal Vaginal ChangEs) Survey." International Society for Sexual Medicine 2013, no. 10, 1790-1799.

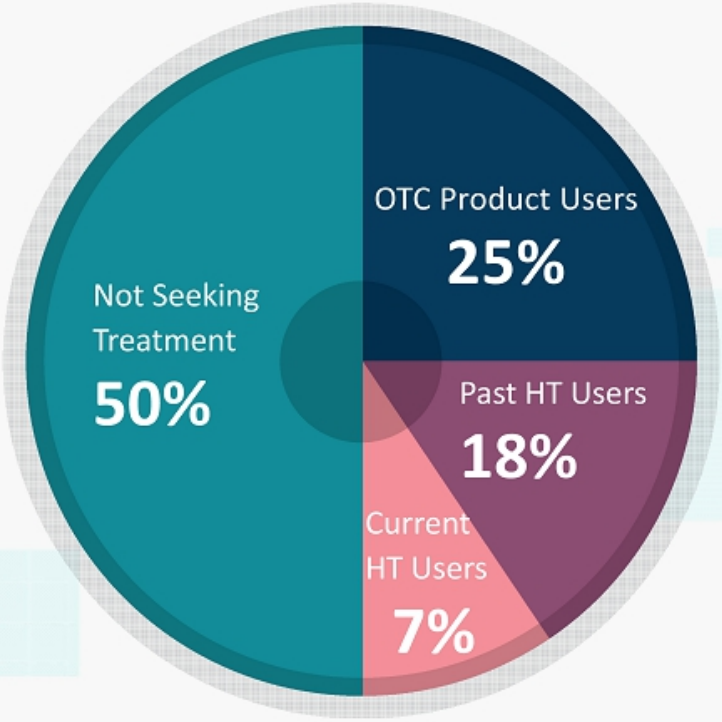
# Current FDA-Approved VVA Competitive Landscape

- U.S. sales more than doubled since 2008[1]
- Global market expected to be $2.1 billion in 2022[4]
- Currently no generic competition – Vagifem AG expected October 2016
- **7% current market penetration**

| Product[2] | Company | Compound | 2015 TRx (000)[1] | 2015 U.S. Sales ($MM)[1] | WAC Price[3] |
|---|---|---|---|---|---|
| Premarin® Cream | Pfizer | Conjugated equine vaginal estrogen | 1,615 | $502 | $288.40 |
| Vagifem® Tablets | Novo Nordisk | Vaginal estradiol | 1,620 | $456 | $382.86* |
| Estrace® Cream | Allergan | Vaginal estradiol | 1,548 | $420 | $263.81 |
| Osphena® Tablets | Shionogi | Oral SERM | 263 | $66 | $530.07 |
| Estring® Ring | Pfizer | Vaginal estradiol ring | 284 | $91 | $310.44 |
| **Total** | | | **5,330** | **$1,535** | |

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) Femring data is excluded due to VMS indication.
3) Medi-Span Price Rx Basic as of 4/01/16. * for 18 tablets ($170.16 WAC for 8 tablets)
4) GlobalData July 2013 report GDHCS4PIOR.

# Current VVA Market Overview




## 32MM Women with VVA Symptoms[1,2]

*~50% of women seek treatment for VVA[4]*

- 7%, or 2.3MM women, are currently being treated today with Rx hormone therapy (HT)[3]
- 18%, or 5.7MM women, have tried HT and were unsatisfied/unsuccessful[4]
- 25%, or 8MM women, use OTC products**, such as lubricants[4]

**>$20B Branded Total US Market Opportunity[5]**

1] The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
2] Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.
3] IMS Health Plan Claims (April 2008-Mar 2011).
4] TherapeuticsMD "EMPOWER" Survey, 2016
5] Based on current FDA-approved market pricing
** Not treated with an FDA approved Rx product. OTC products do not effectively treat the underlying pathological causes of VVA and therefore do not halt or reverse the progression of this condition.

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# Current FDA-Approved VVA Product Use Falls Short

| | Market Size | Perceived Product Shortcomings | VVA Market Opportunity |
|---|---|---|---|
| Current HT Users | 2.3MM Women[2]<br>7% of VVA Population | ▪ Long-term safety concerns[1]<br>▪ Efficacy[1]<br>▪ Messiness[1]<br>▪ Need for applicator[1] | >$1.5B |
| Past HT Users | 5.7MM Women[3]<br>18% of VVA Population | ▪ Unsatisfied / unsuccessful with past treatments<br>▪ Physical and clinical attributes of existing products | >$3B |
| OTC Product Users | 8MM Women[3]<br>25% of VVA Population | ▪ Do not effectively treat the underlying pathological causes of VVA<br>▪ Do not halt or reverse symptoms | >$5B |
| Not Seeking Treatment | 16MM Women<br>50% of VVA Population | ▪ Not aware that VVA is a treatable condition<br>▪ Estrogen exposure concerns | >$10B |

1) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23-30 doi:10.4137/CMRH.S14498
2) IMS Health Plan Claims (April 2008-Mar 2011).
3) TherapeuticsMD "EMPOWER" Survey, 2016

# Yuvvexy™ – TX-004HR

- Small, digitally inserted, rapidly dissolving softgel capsule
- No applicator
- Proposed dose packaging to optimize compliance and convenience
- ***PDUFA target action date of May 7, 2017***


0.69 x 0.3 inch



Prototype Maintenance Pack

YUVVEXY™ is an investigational drug and is not approved for use by the FDA.

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# Yuvvexy™ – Potential Best In Class VVA Therapy

| Products | Premarin® | Vagifem® | Estrace® | Osphena® | Yuvvexy® (if approved) |
|---|---|---|---|---|---|
| |  |  |  |  |  |
| | Pfizer | novo nordisk | Allergan | SHIONOGI | TherapeuticsMD |
| Method of Admin | Vaginal Cream | Vaginal Tablet | Vaginal Cream | Oral Tablet | Vaginal Capsule |
| Application | Reusable Vaginal Applicator | Vaginal Applicator | Reusable Vaginal Applicator | Oral Daily SERM | Digitally Inserted Softgel |
| Active Ingredient | 625 mcg/g CEEs | 10 mcg Estradiol | 100 mcg/g Estradiol | 60,000 mcg ospemifene | 4, 10, 25 mcg 17β-estradiol |
| Avg Maintenance Dose | 312.5 mcg 2x/week | 10 mcg 2x/week | 100 mcg 2x/week | 60,000 mcg daily | 4, 10, 25 mcg 2x/week |
| Onset of Action* Dyspareunia | Week 4+ | Week 8 | Approval Without Dyspareunia and Dryness Data | Week 12 | Week 2 |
| Onset of Action* Dryness | Not Demonstrated | | | Not Demonstrated | Week 2 |
| | | | | | Easy to Use |
| | | | | | Easy to Prescribe |
| | | | | | Negligible Systemic Exposure |

*Onset of Action = First efficacy observation

**Based on Product Prescribing Information**
**Not Head-to-Head Comparative Studies**


Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?400706572

# Yuvvexy™ - Designed for Long Term Compliance

## Current Market

### Vaginal Creams:

**Mean Duration of Use: 1.5 Months[2]**



| Reasons Women Stop |
|---|
| Messiness[1] |
| Reusable Applicator[1] |
| Long-term Safety[1] |
| Dose Preparation by User Required[3] |

### Vaginal Tablets:

**Mean Duration of Use: 3.5 Months[2]**

| Reasons Women Stop |
|---|
| Efficacy[1] |
| Applicator[1] |
| Long-term Safety[1] |
| Systemic Absorption[1] |

## Yuvvexy

- Muco-adhesive, Dissolves Quickly and Completely
- No Applicator and No Dose Preparation
- Onset-of-Action (Efficacy observed at 2 weeks)
- Negligible Systemic Exposure
- 95% Patient Satisfaction in a Market with Historically Low Compliance Rate

**Potential Long Term Usage**

Rejoice TRIAL


1) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23-30 doi:10.4137/CMRH.S14498
2) Portman, D, et al. One Year Treatment Persistence with Local Estrogen Therapy in Postmenopausal Women Diagnosed as Having Vaginal Atrophy. *Menopause*. 2015; 22 (11) 1197-203
3) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.


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# Co-Primary and Key Secondary Endpoints LS Mean Change from Baseline to Week 12 Compared to Placebo

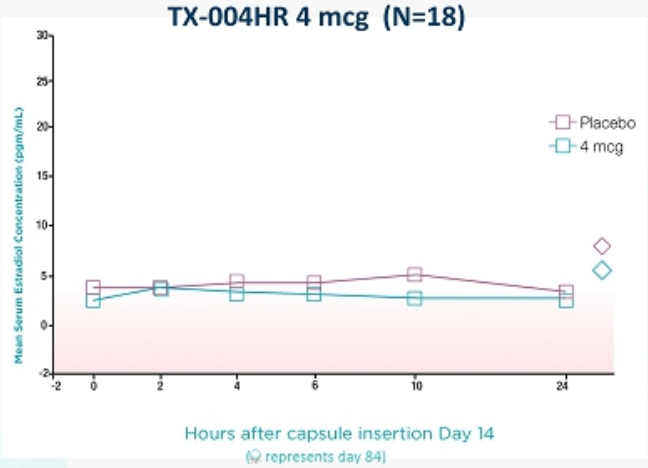
| | 4 mcg | 10 mcg | 25 mcg |
|---|---|---|---|
| Superficial Cells | <0.0001 | <0.0001 | <0.0001 |
| Parabasal Cells | <0.0001 | <0.0001 | <0.0001 |
| Vaginal pH | <0.0001 | <0.0001 | <0.0001 |
| Severity of Dyspareunia | 0.0149 | <0.0001 | <0.0001 |
| Severity of Vaginal Dryness | 0.0014 | <0.0001 | <0.0001 |

MMRM P-value vs placebo

LS = Least Squares

# Co-Primary and Key Secondary Efficacy Endpoints
# TX-004HR 4 mcg

### Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
### TX-004HR 4 mcg (N=18)




| | $AUC_{0-24}$ (pg.h/mL) | $C_{avg(0-24)}$ (pg/mL) |
|---|---|---|
| 4 mcg | 87.22 (42.77) | 3.634 (1.78) |
| Placebo | 104.16 (66.38) | 4.34 (2.76) |
| P-value vs Placebo | 0.3829 | 0.3829 |

### LS Mean Change from Baseline to Week 12

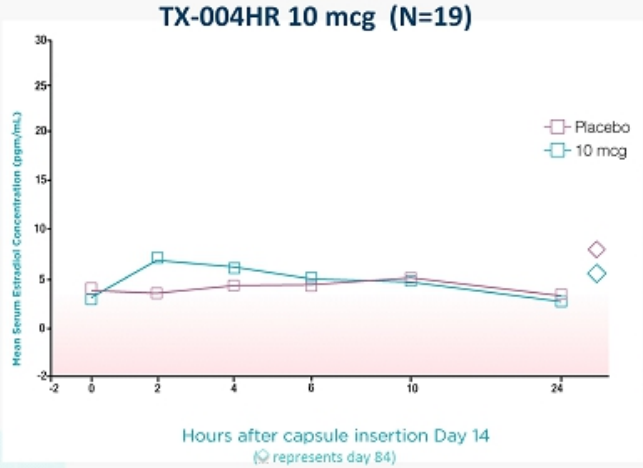
| 4 mcg | LS Mean Change from Baseline to Week 12 | | P-value |
|---|---|---|---|
| | 4 mcg | Placebo | |
| Superficial Cells | 17% | 6% | <0.0001 |
| Parabasal Cells | -41% | -7% | <0.0001 |
| Vaginal pH | -1.3 | -0.3 | <0.0001 |
| Severity of Dyspareunia | -1.5 | -1.3 | 0.0149 |
| Severity of Vaginal Dryness | -1.27 | -0.97 | 0.0014 |

MMRM P-value vs placebo

LS = Least Squares

# Co-Primary and Key Secondary Efficacy Endpoints
# TX-004HR 10 mcg

### Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
### TX-004HR 10 mcg (N=19)




| | $AUC_{0-24}$ (pg.h/mL) | $C_{avg(0-24)}$ (pg/mL) |
|---|---|---|
| 10 mcg | 110.14 (54.57) | 4.58 (2.27) |
| Placebo | 104.16 (66.38) | 4.34 (2.76) |
| P-value vs Placebo | 0.7724 | 0.7724 |

### LS Mean Change from Baseline to Week 12

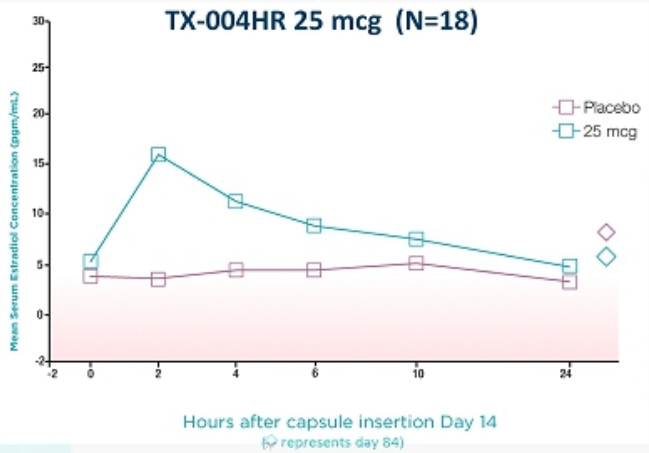
| 10 mcg | LS Mean Change from Baseline to Week 12 | | P-value |
|---|---|---|---|
| | 10 mcg | Placebo | |
| Superficial Cells | 17% | 6% | <0.0001 |
| Parabasal Cells | -44% | -7% | <0.0001 |
| Vaginal pH | -1.4 | -0.3 | <0.0001 |
| Severity of Dyspareunia | -1.7 | -1.3 | <0.0001 |
| Severity of Vaginal Dryness | -1.47 | -0.97 | <0.0001 |

MMRM P-value vs placebo

LS = Least Squares

# Co-Primary and Key Secondary Efficacy Endpoints
# TX-004HR 25 mcg

## Arithmetic Mean Estradiol Serum Concentrations - Unadjusted




| | $AUC_{0-24}$ (pg.h/mL) | $C_{avg(0-24)}$ (pg/mL) |
|---|---|---|
| 25 mcg | 171.56 (80.13) | 7.14 (3.33) |
| Placebo | 104.16 (66.38) | 4.34 (2.76) |
| P-value vs Placebo | 0.0108 | 0.0108 |

## LS Mean Change from Baseline to Week 12

| 25mcg | LS Mean Change from Baseline to Week 12 | | P-value |
|---|---|---|---|
| | 25 mcg | Placebo | |
| Superficial Cells | 23% | 6% | <0.0001 |
| Parabasal Cells | -46% | -7% | <0.0001 |
| Vaginal pH | -1.3 | -0.3 | <0.0001 |
| Severity of Dyspareunia | -1.7 | -1.3 | <0.0001 |
| Severity of Vaginal Dryness | -1.47 | -0.97 | <0.0001 |

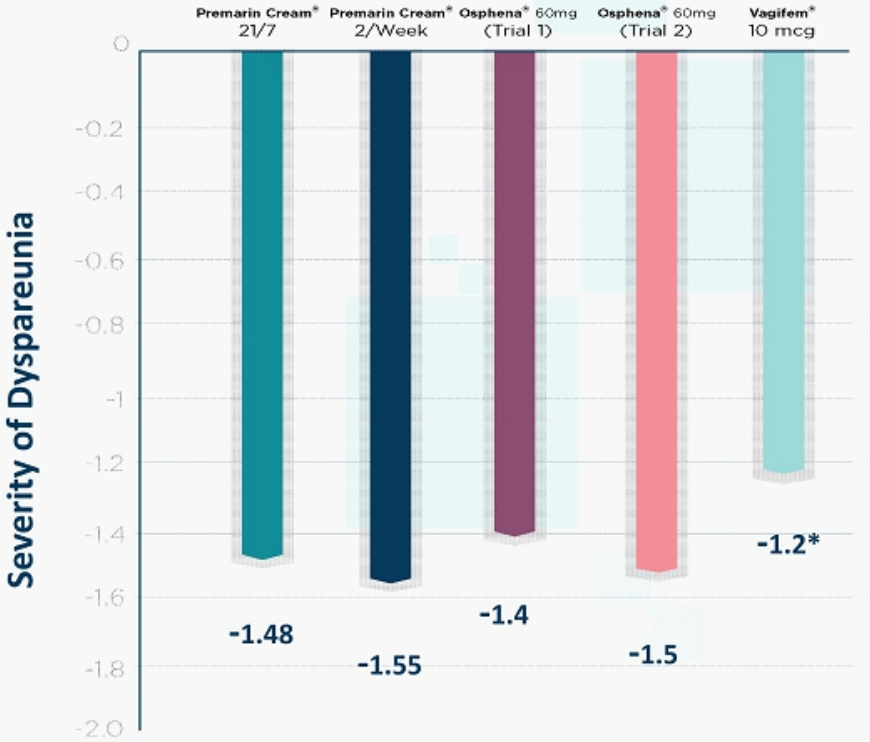
MMRM P-value vs placebo

LS = Least Squares

REJOICE Trial Results

# Unadjusted Change From Baseline Severity Score Dyspareunia

## Based on Pivotal Clinical Data - Not Head-to-Head Comparative Studies




*Composite score of most bothersome symptoms, including dyspareunia


Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf?400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567



TherapeuticsMD®

# Dyspareunia and Vaginal Dryness By Study Visit

**Statistical Significance of Severity of Dyspareunia**
**LS Mean Change from Baseline (by Study Visit)**

| | 4 mcg | 10 mcg | 25 mcg |
|---|---|---|---|
| Week 2 | 0.026 | 0.0019 | 0.0105 |
| Week 6 | 0.0069 | 0.0009 | < 0.0001 |
| Week 8 | 0.0003 | < 0.0001 | < 0.0001 |
| Week 12 | 0.0149 | < 0.0001 | < 0.0001 |

**Statistical Significance of Severity of Vaginal Dryness**
**LS Mean Change from Baseline (by Study Visit)**

| | 4 mcg | 10 mcg | 25 mcg |
|---|---|---|---|
| Week 2 | 0.1269 | 0.0019 | 0.0082 |
| Week 6 | 0.0094 | 0.0001 | 0.0005 |
| Week 8 | 0.0128 | < 0.0001 | 0.0008 |
| Week 12 | 0.0014 | < 0.0001 | < 0.0001 |

LS = Least Squares
REJOICE Trial Results

# Efficacy and Onset of Action
## Not Head-to-Head Comparative Studies

| | Premarin® | Vagifem® | Estrace® | Osphena® | Estring® |
|---|---|---|---|---|---|
| Onset of Action* Dyspareunia | Week 4+ | Week 8 (composite score) | Approval without dyspareunia and dryness data | Week 12 | Approval without dyspareunia and dryness data |
| Onset of Action* Dryness | Not demonstrated | | | Not demonstrated | |

*Onset of Action = First efficacy observation

Vagifem [package label] http://www.novo-pi.com/vagifem.pdf
Premarin Vaginal Cream [package label] http://labeling.pfizer.com/showlabeling.aspx?id=132
Estrace Vaginal Cream [package label] http://pi.actavis.com/data_stream.asp?product_group=1880&p=pi&language=E
Osphena [package label] http://www.shionogi.com/pdf/pi/osphena.pdf7400706572
Estring [package label] http://labeling.pfizer.com/ShowLabeling.aspx?id=567

# Yuvvexy™ Qualitative Attributes

## Ease of Use

| | 4 mcg (N=181) | 10 mcg (N=181) | 25 mcg (N=184) | Placebo (N=185) |
|---|---|---|---|---|
| Easy to Use | 171 (94.5%) | 172 (95.0%) | 175 (95.1%) | 164 (88.9%) |

Overall p-value = 0.035

## Patient Satisfaction

| | 4 mcg (N=181) | 10 mcg (N=181) | 25 mcg (N=184) | Placebo (N=185) |
|---|---|---|---|---|
| Very Satisfied | 74 (40.1%) | 84 (46.4%) | 83 (45.1%) | 41 (22.2%) |
| Satisfied | 57 (31.5%) | 55 (30.4%) | 62 (33.7%) | 68 (36.8%) |
| Unsure | 23 (12.7%) | 28 (15.5%) | 21 (11.4%) | 39 (21.1%) |
| Dissatisfied | 19 (10.5%) | 9 (5.0%) | 12 (6.5%) | 20 (10.8%) |
| Very Dissatisfied | 8 (4.4%) | 5 (2.8%) | 6 (3.3%) | 17 (9.2%) |

Overall p-value <0.0001

## Preferred vs Competition

| | 4 mcg (N=119) | 10 mcg (N=113) | 25 mcg (N=128) |
|---|---|---|---|
| TX-004HR over previously used VVA therapies | 73.9% | 67.3% | 74.2% |
| P-value vs. Placebo | 0.0010 | 0.0212 | 0.0003 |

LS = Least Squares

REJOICE Trial Results

# Physical and Clinical Attributes Enable Market Expansion

| | Yuvvexy™ Attributes Could Address Perceived Shortcomings of Current Products | Yuvvexy™ Market Opportunity |
|---|---|---|
| Current HT Users | ▪ Negligible systemic profile may give comfort for long term use<br>▪ REJOICE data: first efficacy observation for dyspareunia and dryness at two weeks<br>▪ No applicator<br>▪ No mess | Market Share Gain |
| Past HT Users | ▪ REJOICE data: 70%-95% patient satisfaction<br>▪ Ease of use could lead to less discontinuation<br>▪ Negligible systemic profile may give comfort for long term use<br>▪ Two week efficacy may increase refill rates past month 1 | Reintroduce HT |
| OTC Product Users | ▪ Negligible systemic profile may alleviate fear of HT<br>▪ Dose pack helpful to physicians likely to prescribe HT<br>▪ Could eliminate need to see a specialist<br>▪ Ease of use profile | New HT Users |
| Not Seeking Treatment | ▪ Dose pack may reduce time for patient education on product use, making physicians more likely to initiate VVA conversation<br>▪ Could eliminate need to see a specialist<br>▪ Negligible systemic profile may enable access to a new demographic | New HT Users |

# Favorable Regulatory Dynamics Driven by Change in Treatment Paradigm

**Removal of Black Box Warning**

- Citizen's Petition, spearheaded by NAMS, for modification of black box warnings
- Nov. 2015 – FDA "boxed warnings" workshop provided an opportunity for FDA to obtain input related to prescribing information of lower-dose estrogen alone products[1]

**Citizen's Petition Supporters:**

Academy of Women's Health; Endocrine Society; NAMS The North American Menopause Society; NPWH Nurse Practitioners in Women's Health; ISSWSH; The American Society for Reproductive Medicine; AMWA; ACOG

**Estrogen use in Breast Cancer Survivors**

- ACOG released opinion stating it is safe for breast cancer survivors to use vaginal estrogen as data showed no increased risk[2]
- Health practitioners may now consider topical estrogen therapy for patients with a history of estrogen-dependent breast cancer

ACOG

**Changing Perception on Use of Estrogen**

- Women's Health Initiative's Hormone Trials follow up concluded that the risk/benefit profile for estrogen use is positive[3]:
  - 63% lower risk of dying of breast cancer
  - 16% reduced risk of illness and death
  - Preventative for heart disease, diabetes, and other illnesses if started early

Harvard Medical School; NIH National Heart, Lung, and Blood Institute; International Menopause Society; Women's Health Initiative; Yale University School of Medicine; NAMS The North American Menopause Society

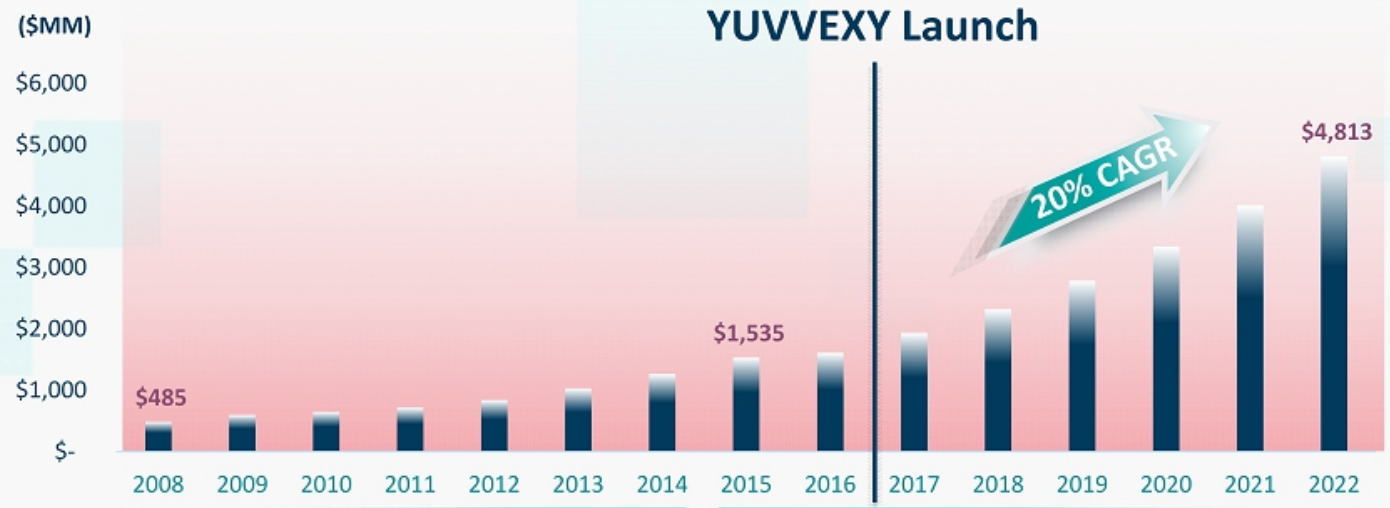
1) Scientific Workshop on Labeling "Lower" Dose Estrogen-Alone Products for Symptoms of Vulvar and Vaginal Atrophy (VVA) http://www.fda.gov/Drugs/NewsEvents/ucm459690.htm
2) ACOG Supports the Use of Estrogen for Breast Cancer Survivors http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/ACOG-Supports-the-Use-of-Estrogen-for-BreastCancer-Survivors
3) Manson JE, Chlebowski RT, Stefanick ML, et al. "Menopausal Hormone Therapy and Health Outcomes During the Intervention and Extended Poststopping Phases of the Women's Health Initiative Randomized Trials." JAMA. 2013;310(13):1353-1368.

# Future VVA HT Market

**TherapeuticsMD VVA Market Goals**

- Potential launch of Yuvvexy
- Increase market awareness for VVA and the associated symptoms
- Convert unsatisfied past users of HT therapy to satisfied patients on drug
- Increase market penetration among OTC product users
- Increase duration of use and patient compliance

**Increase in market penetration and duration of use could lead to market size increase of >100% by 2022**




1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) GlobalData July 2013 report GDHC54PIDR.

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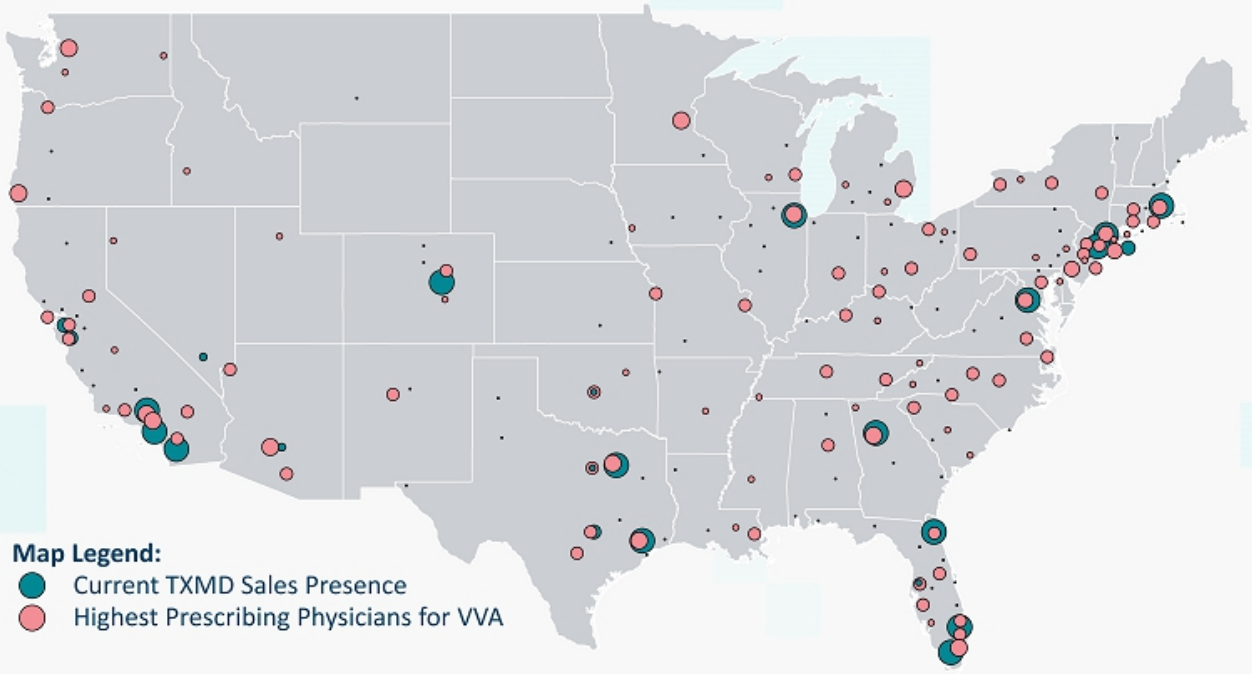
# Foundation Built for a Strong Launch

## Operational leverage of OB/GYN relationships in key markets




***50 Sales Representatives; Planned Increase to 150 With Launch of Yuvvexy™***

# Expect Robust Insurance Coverage For Yuvvexy™, If Approved, In-line with Product Class

| 4,312 Commercial Plans | % Unrestricted Access of Commercial Plans | Not Covered |
|---|---|---|
| Premarin Cream® | 94% | 2% |
| Estrace Cream® | 96% | 2% |
| Vagifem® | 90% | 2% |
| Estring® | 93% | 1% |

Data Source MMIT August 17, 2016 – 4,300 commercial plans


TX-001HR | Combination
Estrogen + Progesterone
(E+P) Program
TherapeuticsMD®

# Menopause Overview

## Menopause represents the natural life-stage transition when women stop having periods as the production of Estrogen (E) and Progesterone (P) decreases

- Average age of menopause 51 years[1]
- Women will spend approximately half of their lives in this state

## May result in physical and emotional symptoms[1]

- Symptoms include hot flashes, night sweats, mood changes and vaginal dryness
- Prolonged lack of estrogen can affect the bones, cardiovascular system, and increases risks for osteoporosis

## Long history of Estrogen (E) and Progesterone (P) use

- Estrogen and Progesterone have been used for over 50 years as treatment
- Estrogen to reduce symptoms and other long-term conditions
- Progesterone to prevent thickening of the uterine wall[2]
  - Increased risk for endometrial hyperplasia/endometrial cancer if estrogen unopposed[2]

1) National Institutes of Health, National Institute on Aging, https://www.nia.nih.gov/health/publication/menopause, last accessed November 3, 2015.
2) International Journal on Women's Health, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3897322/

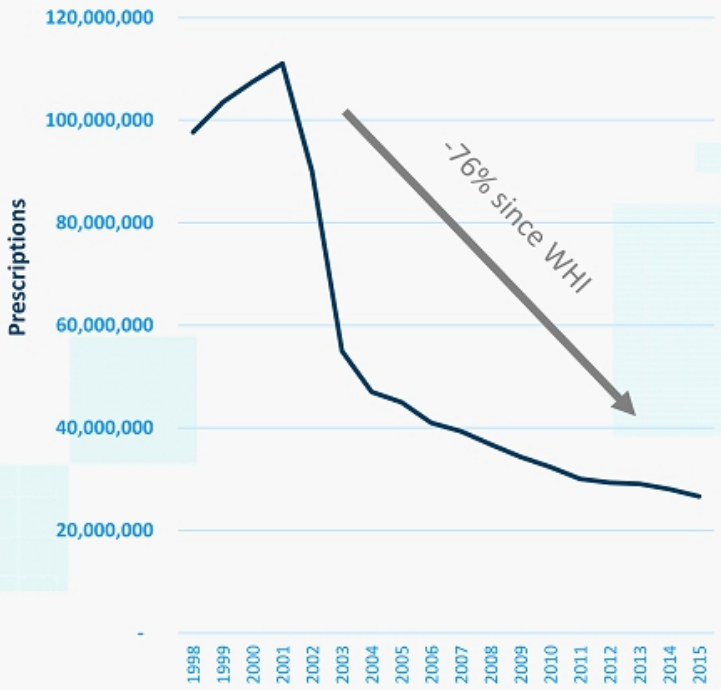
# Evolution of U.S. HT Market Post WHI Study

- **July 2002 - Women's Health Initiative (WHI) study showed that synthetic hormones increased the risk of breast cancer, stroke, heart attack and blood clots**
- **Post WHI, women shifted to Bio-Identical Hormone Therapy (BHT) containing Natural Estradiol (E2) and Natural Progesterone (P4) as a safer alternative**
  - All FDA-approved combination hormone products contain a synthetic progestin and not a natural progesterone
  - 110MM+ scripts of FDA-approved HT prescribed annually before 2002, declining to ~25MM in 2015[1]
- **Compounding filled the need and demand for BHT**
  - 30MM scripts (1-2.5MM women) of Compounded BHT prescribed annually in the U.S. currently[2,3]
- **No FDA-approved BHT combination product of E2 + P4**

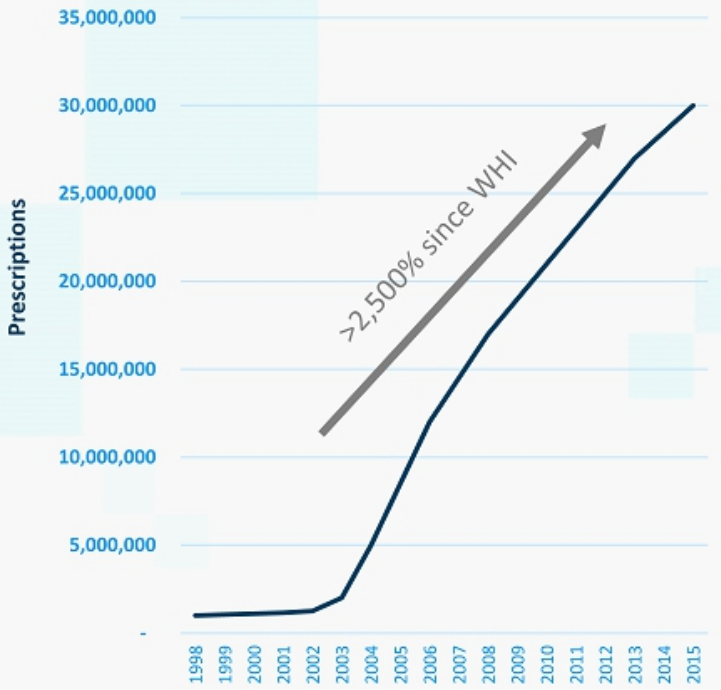
1] Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2] The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3] Pinkerton, J.V. 2015. *Menopause*, Vol.22, No.9, pp 0-11.
WHI = Women's Health Initiative, DQSA = Drug Quality and Security Act, BHRT = Bio-identical Hormone Replacement Therapy

# Bio-Identical Hormones Are What Women and Doctors Want

## FDA-Approved Synthetic and Separate E&P Market[1]




## Compounded Bio-identical Hormone Therapy Market[2,3]




1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. *Menopause*, Vol.22, No.9, pp 0-11.
WHI = Women's Health Initiative, DQSA = Drug Quality and Security Act, BHRT = Bio-identical Hormone Replacement Therapy

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# Compounded Bio-Identical HT: Why Has It Been So Successful?

| Synthetic Progestins | Bio-identical Progesterone | References |
|---|---|---|
| No benefits on sleep properties | Favorable CNS Profile | Freeman, E, et al.[1] |
| Increased risk of breast cancer | Favorable breast profile | E3N-EPIC[2] |
| Increased risk of MI, Stroke, VTE | Favorable cardiovascular profile | PEPI[3], ELITE[5] |
| Less favorable lipid profile effects (cholesterol, LDL, triglycerides) | Favorable lipid profile | PEPI[3] |
| Adequate endometrial protection | Adequate endometrial protection | PEPI[4] |
| High incidence of bleeding | Low incidence of bleeding | Regidor, et al.[6] |


1) Freeman E, Rickels K, Sondheimer S J. et al. A double-blind trial of oral progesterone, alprazolam and placebo in treatment of severe premenstrual syndrome. *JAMA*. 1995;274:51-57.
2) Fournier A, Berrino F, Clavel-Chapelon F. Unequal risks for breast cancer associated with different hormone replacement therapies: results from the E3N cohort study. Breast Cancer Res Treat. 2008;107:103–111.
3) Writing Group for the PEPI Trial . Effects of estrogen or estrogen/progestin regimes on heart disease. Risks factors in postmenopausal women. *JAMA*. 1995;273:199–208.
4) The Writing Group for the PEPI Trial . Effects of hormone replacement therapy on endometrial histology in postmenopausal woman. The postmenopausal estrogen/progestin interventions (PEPI) trial. *JAMA*. 1996;275:370–375.
5) Hodis HN, et al. "Testing the menopausal hormone therapy timing hypothesis: The early versus late intervention trial with estradiol" AHA 2014; Abstract 13283.
6) Regidor, P-A, et al. Progesterone in Peri- and Postmenopausal: A Review. *Geburtshilfe Frauenheilkd*. 2014 Nov; 74 (11): 995-1002.


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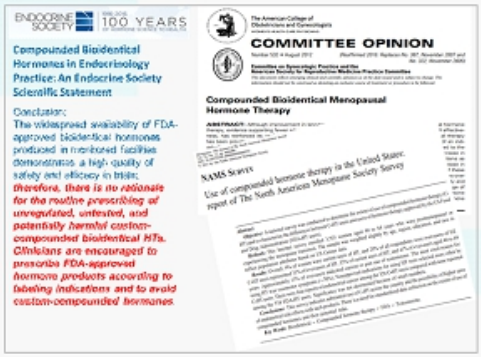
# But…..Compounded Products Pose Significant Risks

- **Medical Societies' global consensus statement declares that the use of Custom-Compounded HT is not recommended[1]**
- **ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products[2]**
  - Lack of efficacy and safety data
  - Lack of Good Manufacturing Practices (GMP)
  - Variable purity
  - Variable content uniformity
  - Variable potency (under/over dose)
  - Lack of stability
  - Unopposed E / Ineffective P leads to increased risk of endometrial hyperplasia / cancer


ENDOCRINE SOCIETY 100 YEARS

Compounded Bioidentical Hormones in Endocrinology Practice: An Endocrine Society Scientific Statement

Conclusion:
The widespread availability of FDA-approved bioidentical hormones produced in monitored facilities demonstrates a high quality of safety and efficacy in trials; *therefore, there is no rationale for the routine prescribing of unregulated, untested, and potentially harmful custom-compounded bioidentical HTs. Clinicians are encouraged to prescribe FDA-approved hormone products according to labeling instructions and to avoid custom-compounded hormones.*

COMMITTEE OPINION

Compounded Bioidentical Menopausal Hormone Therapy

NAMS Survey

Use of compounded hormone therapy in the United States: report of The North American Menopause Society Survey

ACOG THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

ENDOCRINE SOCIETY

NAMS THE NORTH AMERICAN MENOPAUSE SOCIETY

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE 1944

INTERNATIONAL MENOPAUSE SOCIETY

1) Villiers, T.J. et al. Global Consensus Statement on Menopausal Hormone Therapy, *Climacteric*, June 2013, Vol. 16, No. 3 : Pages 316-337.
2) Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee, Number 532, August 2012 (Reaffirmed 2014, Replaces No. 387, November 2007 and No. 322, November 2005).

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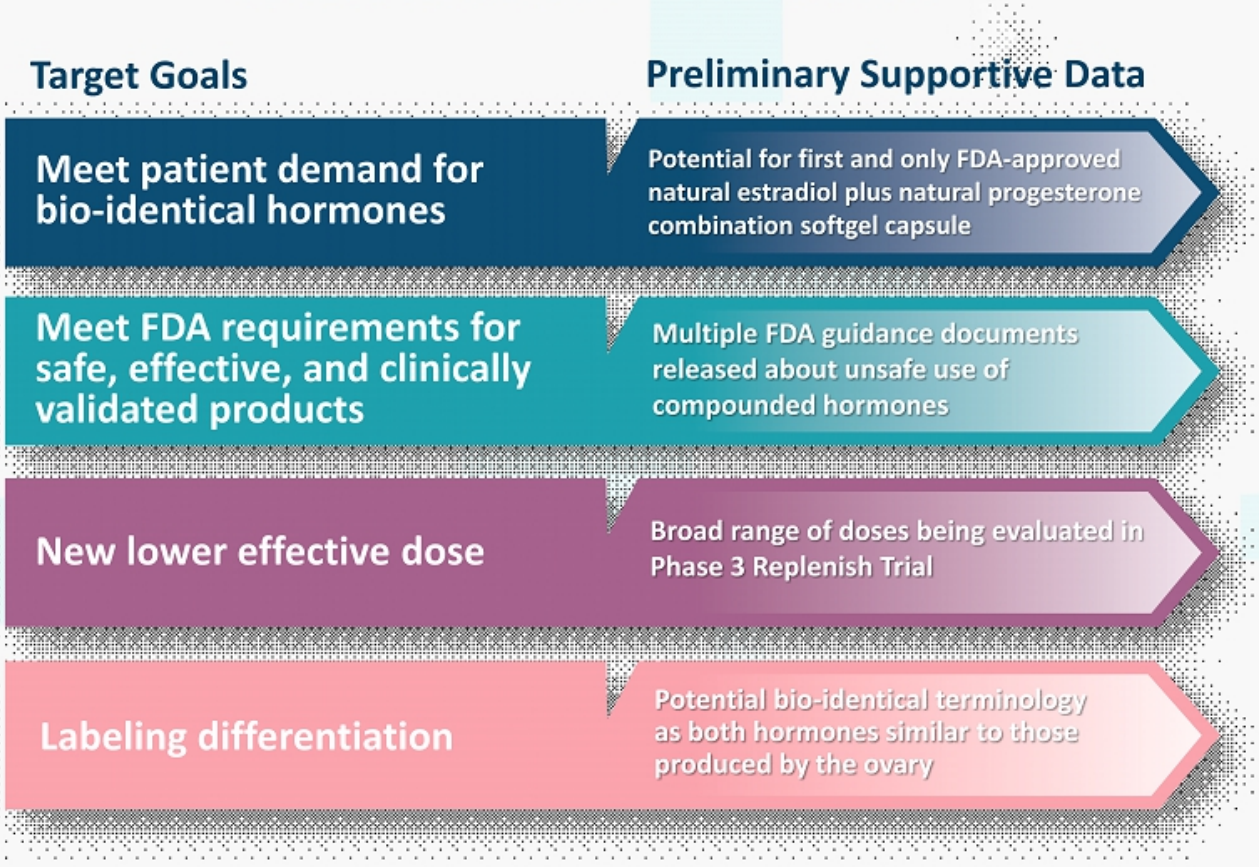
# Rationale for TX-001HR



# TX-001HR Estradiol + Progesterone U.S. Development Timeline

Q1 '15 | Q2 '15 | Q3 '15 | Q4 '15 | Q1 '16 | Q2 '16 | Q3 '16 | Q4 '16 | Q1 '17 | Q2 '17 | Q3 '17 | Q4 '17 | Q1 '18

Phase 3 Vasomotor & Endometrial Safety

NDA Prep/Filing/PDUFA

- **Phase 3 Trial[1]: ~100 U.S. sites**
- **Subjects: ~1750 fully enrolled as of October 2015**
  - Four active arms (N=400/arm)
    - Estradiol 1 mg/Progesterone 100 mg
    - Estradiol 0.5 mg/Progesterone 100 mg
    - Estradiol 0.5 mg/Progesterone 50 mg
    - Estradiol 0.25 mg/Progesterone 50 mg
  - Control arm: Placebo (N=150)
- **12-month study with 12-week VMS substudy endpoints:**
  - Vasomotor substudy: number and severity of hot flashes (4 weeks and 12 weeks)
  - Endometrial safety: incidence of endometrial hyperplasia (12 months)
- **As of August 4, 2016, approximately 1,642 subjects have exited the trial and the incidence of endometrial hyperplasia is less than 1%**

Replenish TRIAL

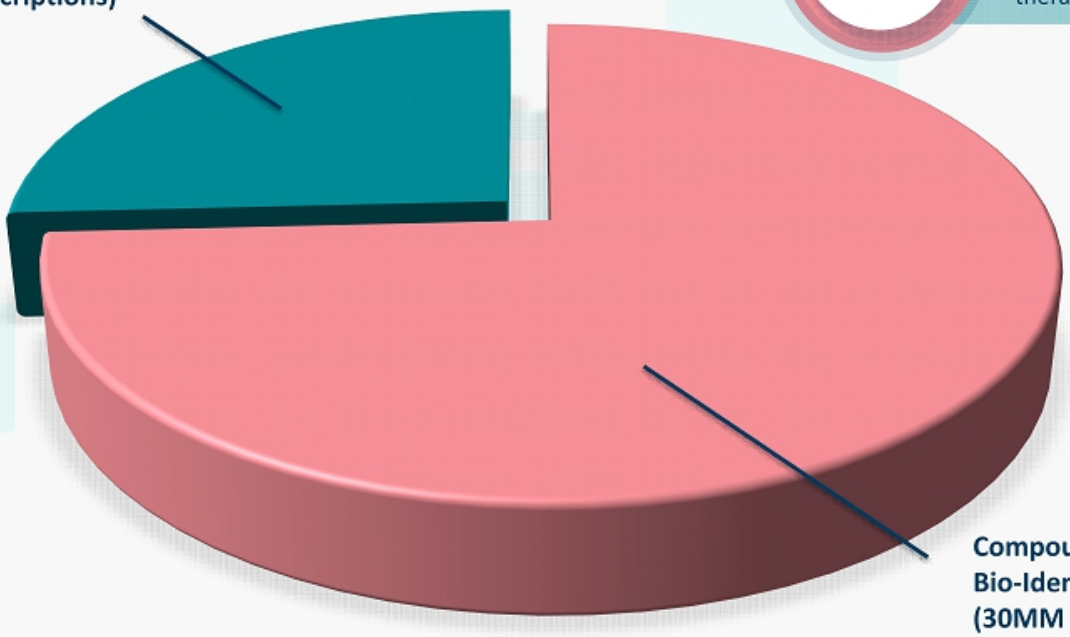
**Topline results expected in the fourth quarter of 2016**

1) https://clinicaltrials.gov/ct2/show/NCT01942668?term=replenish+trial&rank=1, last accessed November 3, 2015.

# Total HT Market = 38+MM Prescriptions

**FDA-approved Combinations of Estradiol, Estrogens, Progesterones & Progestins (8.1MM prescriptions)[1]**

**1-2.5MM[3]** U.S. women using custom-compounded menopausal hormone therapy



**Compounded Bio-Identical Hormones (30MM prescriptions)[2,3]**

1] Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
Includes Single Pill Combination of E+P and Estradiol, Estrogen, Progesterone and Progestins taken in combination (oral and transdermal)
2] The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3] Pinkerton, J.V. 2015. *Menopause*, Vol.22, No.9, pp 0-11.

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# Potential First and Only FDA-Approved Bio-Identical Combination Product

| Products | FDA Approved | | | | | | Compounded E+P | If Approved |
|---|---|---|---|---|---|---|---|---|
| | Separate E+P | Activella® FemHRT® Angeliq® | Generic 17β + Progestins | Prempro® Premphase® | Duavee® | Brisdelle® | | TX – 001HR |
| | | Allergan, novo nordisk, Bayer | Teva | Pfizer | Pfizer | noven PHARMACEUTICALS, INC. | 25,000 compounding pharmacies | TherapeuticsMD |
| Bio-Identical | ✓ | ✗ | ✗ | ✗ | ✗ | ✗ | ✓ | ✓ |
| Safety Data with Endometrial Cancer Data | ✗ | ✓ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓ |
| Combination | ✗ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓ | ✓ |
| FDA-Approved | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓[3] |
| Reimbursement | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓[4] |
| Market Size | $520MM | $28MM | $218MM | $302MM | $30MM | $38MM | $4.5B[2] | --- |

1) 2015 US Sales, per IMS Health Plan Claims (April 2008-Mar 2011)
2) $150 average net monthly cost based on WAC, net of rebates/discounts, of existing FDA-approved hormone therapy combination products
3) NDA to be submitted assuming successful results of Replenish trial
4) Reimbursement anticipated if FDA-approved

# Adverse Reimbursement Changes for Compounded Drugs

**May 30, 2014:** *CVS/Caremark forces compounding pharmacies to include NDC numbers for each ingredient used and two scientifically valid studies in peer-reviewed journals supporting clinical efficacy of the additional ingredients*[1]

**June 3, 2014:** *ESI launches a "Compound Management Solution," creating a list of excluded ingredients that eliminated almost 95% of all compound claims*[1]

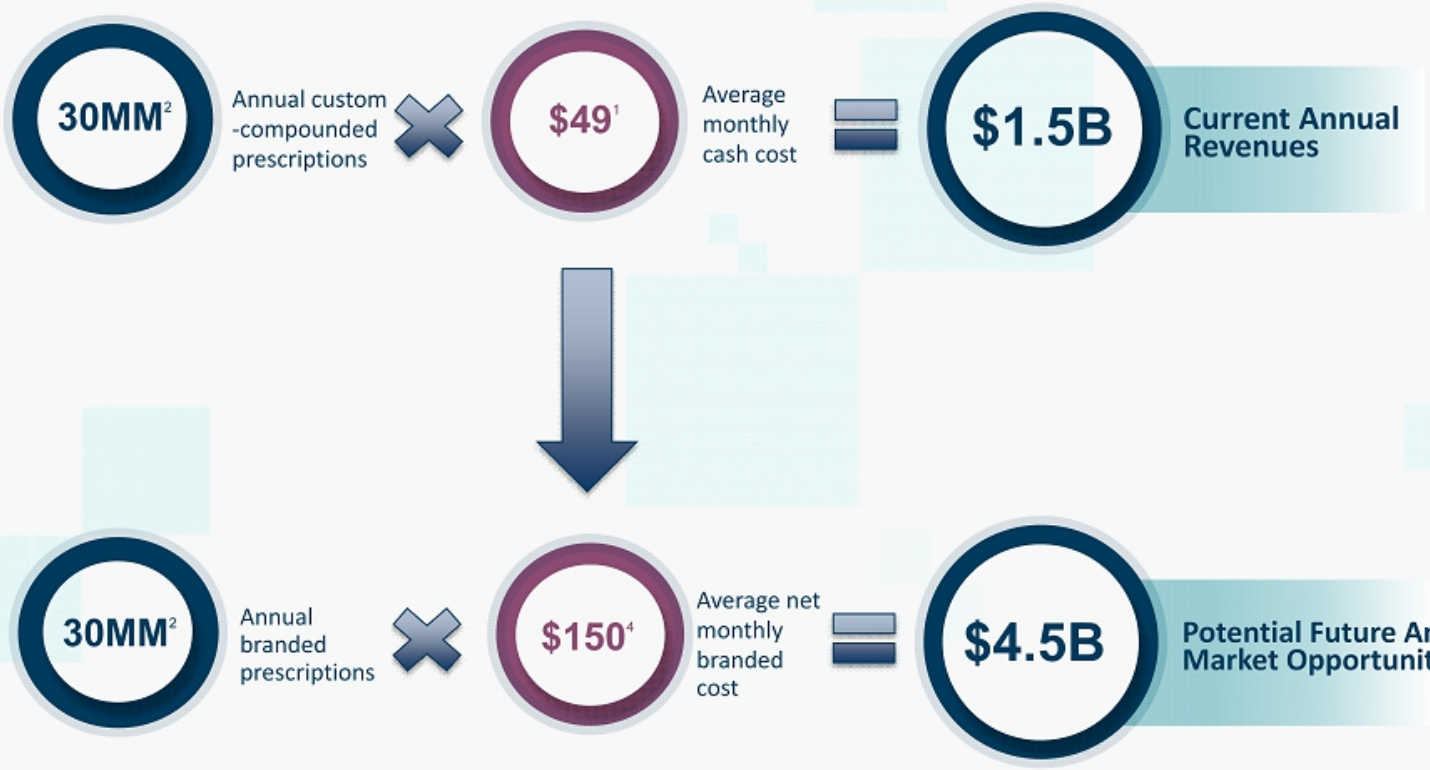
**July 2014:** *Optum initiates a comprehensive compound management program, including prior authorizations and step therapy for all compounded prescriptions*[2]

**May 1, 2015:** *Tricare initiates changes to their compounded medication coverage policy, effectively utilizing Express Scripts' compounded screening process and slashed costs by 74% within one month*[3]

**June 2016:** *Report released that Medicare Part D spending on compounded drugs rose 625% in the past decade. Beginning in February 2017, CMS is adding new screening requirements, blocking any reimbursement for prescriptions from unapproved providers*[4]

1. http://www.iacprx.org/general/custom.asp?page=CCIns161314
2. http://www.optum.com.br/content/optum/en/optumrx/pharmacy-insights/restoring-trust-compound-medications.html
3. http://www.militarytimes.com/story/military/benefits/health-care/2015/06/18/tricare-compounded-medications-update-defense-health-agency-dha-prescription-express-scripts/28914815/?from=global&sessionKey=&autologin=
4. https://www.statnews.com/pharmalot/2016/06/22/medicare-compounded-drugs-fraud/

# Compounded BHT Market Represents Significant Opportunity for First FDA-Approved Product




1. Pinkerton, J.V. Compounded bio-identical hormone therapy: identifying use trends and knowledge gaps among U.S. women. *Menopause*, Vol.22, No.9, 2015
2. Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA Approved MHT Has Increased http://press.endocrine.org/doi/abs/10.1210/endo-meetings.2015.RE.5.FRI-124#sthash.PySEhZ9P.dpuf
3. *Obstetrics & Gynecology* 2015;Vol 125, No. 5, p. 98S (Supplement), May 2015
4. $150 average net monthly cost based on WAC, net of rebates/discounts, of existing FDA-approved hormone therapy combination products

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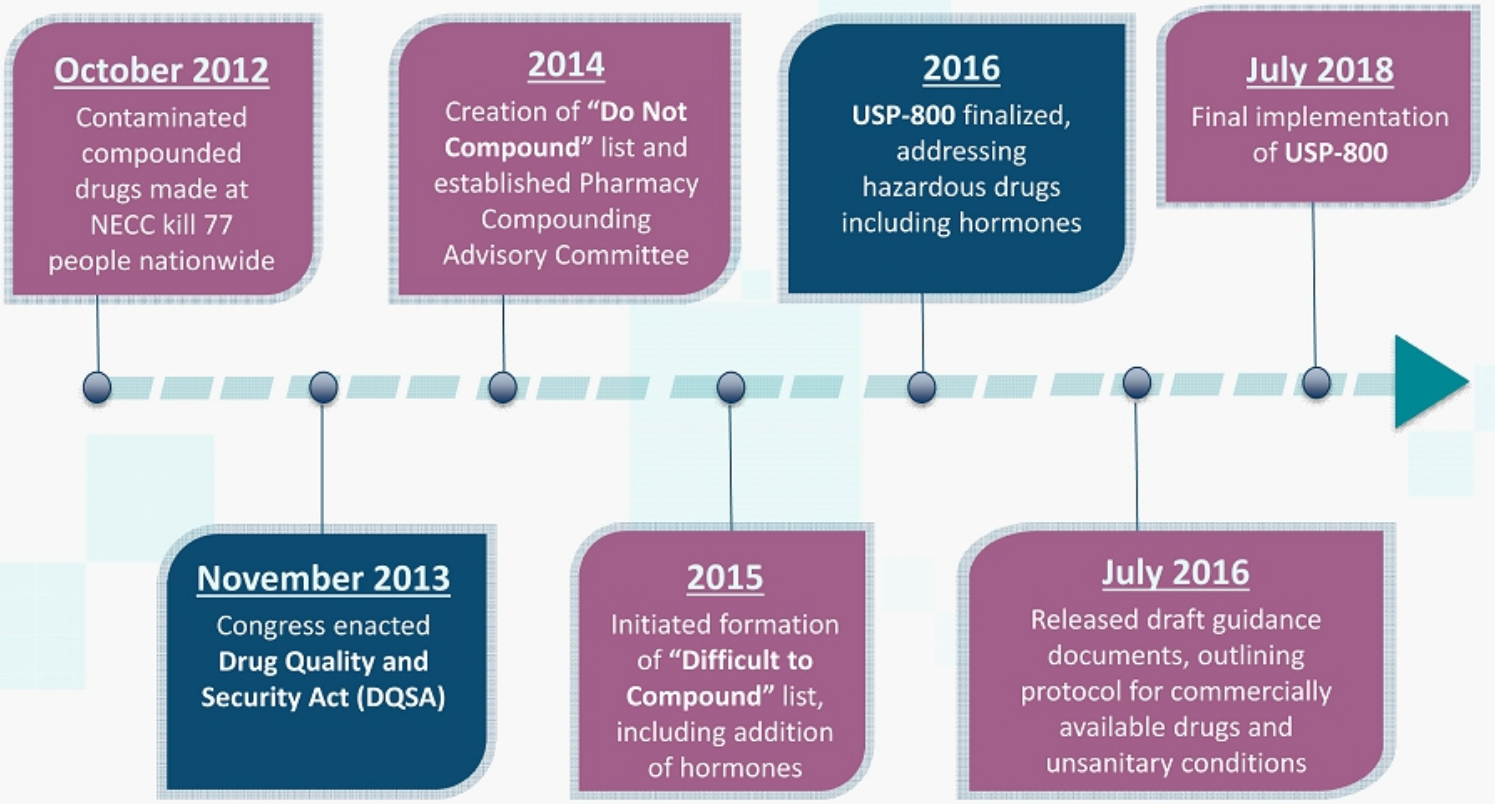
# Regulatory Environment Continues to Favor FDA-Approved Products




1] http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2] http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3] https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf

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# Regulatory Tailwinds for FDA-Approved Products

## Drug Quality and Security Act (DQSA)[1]

- Prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortages
- Requires collaboration between the FDA and state boards of pharmacy to inspect, enforce, and take action against compound pharmacies
- Anticipate significant impact on compounding upon FDA approval of first bio-identical combination hormone therapy product


## USP 800 – Hazardous Drugs[2,3]

- New identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs
- Considered "prohibitively expensive" requiring major pharmacy upgrades and renovations to be compliant

1) http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
2) http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf

# Compounding Pharmacies Need An FDA-Approved Product

| | Compounded BHT  | TX-001HR (if approved)  |
|---|---|---|
| Third-Party Reimbursement | No | Yes |
| Required Capital Expenditure to Dispense | Yes | No |
| Manufacturing and Compliance Investment | Yes | No |
| Legal & Regulatory Risk | Yes | No |

**If approved, compounding pharmacies who dispense TX-001HR achieve:**

Higher Revenues → Lower Costs → Increased Profits

# TX-001HR Could Fulfill Therapeutic Gap For All Participants

## Patients

- Meet demand for natural bio-identical hormone therapy
- Assurance of safety and efficacy
- Reduction of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at all pharmacies and not just compounding pharmacies

## Physicians

- First and only FDA-approved bio-identical combination hormone therapy
- Clinically validated dose regimens
- Eliminates risks of compounded hormone therapy
- Meet patient demands and reduce patient out-of-pocket costs via insurance coverage
- Follow medical standards of care and society guidelines while reducing liability

## Pharmacies

- Meet patient and physician demand for bio-identical hormone therapy
- Significantly improve net margin per script
- Lower legal and regulatory costs and risk

## FDA/Regulatory Bodies

- Reduces need of compounded hormone products
- Full enforcement of regulations regarding compounded hormones
- Reduces false claims and misleading advertising statements about compounded HT products

# Expect Robust Insurance Coverage For TX-001HR, If Approved, In-line with Product Class

| 4,315 Commercial Plans | % Unrestricted Access of Commercial Plans | Not Covered |
|---|---|---|
| Estrace (Oral) ® | 96% | 1% |
| Prempro® | 94% | 5% |
| CombiPatch® | 93% | 4% |
| Climara Pro® | 92% | 4% |
| FemHRT® | 87% | 6% |
| Duavee® | 86% | 5% |
| Vivelle-Dot® | 84% | 5% |
| Activella® | 83% | 8% |
| Prometrium® | 83% | 6% |

Data Source MMIT August 17, 2016 – 4,300 commercial plans



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# TXMD: Financial Snapshot

**Listing Exchange**

TXMD
LISTED
NYSE MKT

**Debt**

$0MM

**Shares Outstanding**

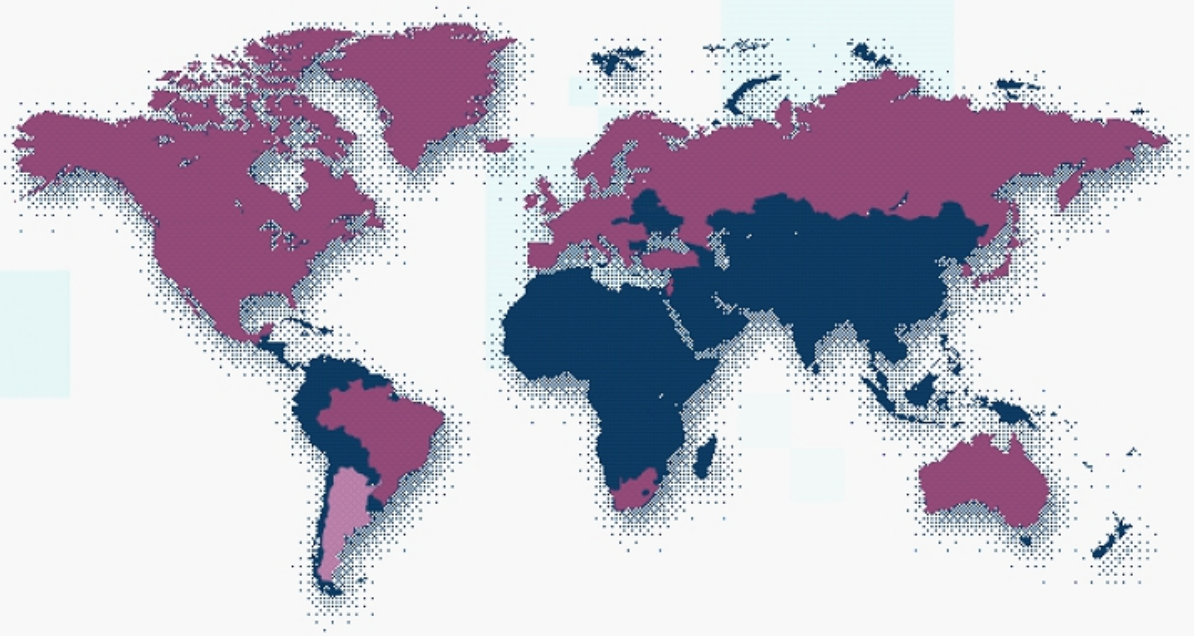
196.5MM
(as of August 1, 2016)

**Cash**

$166.5MM
(as of June 30, 2016)

# Worldwide Patent Filings*

## Strong IP Portfolio with 135 Patent Applications, including 72 international filings, and 17 issued U.S. patents



*Not all patent filings filed in all jurisdictions.

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# THANK YOU!

# Appendix

# Seasoned Management Team with a Proven Track Record of Commercial Execution

**Tommy Thompson**
Chairman of the Board

- Former U.S. Secretary of Health and Human Services (2001-2005)
- Holds multiple board memberships, including Centene and United Therapeutics
- 40-year public health career

**Robert Finizio**
CEO, Co-Founder, and Director

- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2006)
- 16 years of experience in early stage healthcare company development

**John Milligan**
President

- Co-founded CareFusion
- Held executive sales and operation management positions at McKesson, Cardinal and Omnicell
- 20+ years of operations experience

**Dan Cartwright**
Chief Financial Officer

- Former CFO of American Wireless, Telegeography, and WEB Corp
- Participated in American Wireless/Arush Entertainment merger
- Former KPMG and PricewaterhouseCoopers accountant

**Brian Bernick, MD**
Chief Clinical Officer, Co-Founder

- Co-founded vitaMedMD in 2008
- 25 years of experience in healthcare/women's health
- ACOG Committee Member
- Past OBGYN Department Chair - Boca Raton Regional Hospital
- Practicing OBGYN - trained University of Pennsylvania

**Sebastian Mirkin, M.D.**
Chief Medical Officer

- Former Clinical Lead of Women's Health at Pfizer
- 15+ years of experience developing women's health products
- Reproductive endocrinologist & infertility specialist

**Julia Amadio**
Chief Product Officer

- 25+ years of women's health pharmaceutical experience
- Product development leader for J&J, Wyeth, Aventis, and others
- Worked on development of Prempro®, Premphase®, and Estalis®

**Jason Spitz**
VP, Marketing

- 25+ years of pharmaceutical marketing, sales, and operations experience
- Led commercialization of anti-estrogens/estradiol, breast cancer, and ovarian cancer drugs

**Christine Miller, PharmD.**
VP, Regulatory Affairs, Quality Assurance, & Technical Operations

- Led the Regulatory Affairs NDA practice for Lachman Consultants
- Vice President of Regulatory Affairs and Quality Assurance for Santarus and Bausch and Lomb
- Submitted and obtained approval for numerous 505(b)(1) and 505(b)(2) new drug applications

**Jennifer Wilson**
VP, Business Development

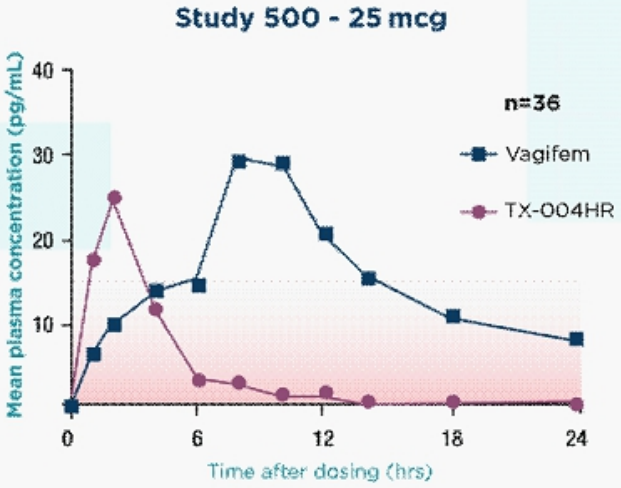
- Former Director of Corporate Development at Anthem
- Lead the Cigna and Amerigroup transactions
- Investment banker in healthcare coverage at Bank of America Merrill Lynch
- Executed over $60bn in deal value

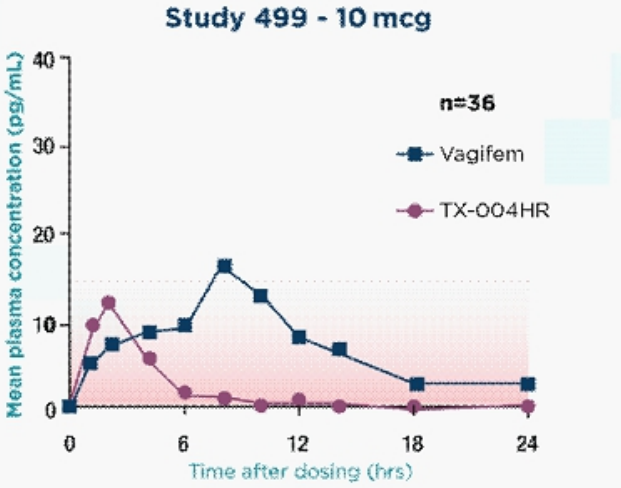
**Supported by a team of regulatory consultants with decades of FDA experience**

# TX-004HR vs. Vagifem®
# Phase 1 Single Dose PK Studies

## Key Findings

- Tmax ~2 hours with TX-004HR and ~8 hours with Vagifem
- Systemic absorption of estradiol AUC (0-24 hours) is 2- to 3-fold lower with TX-004HR relative to Vagifem




Vagifem is a registered trademark of Novo Nordisk A/S Corp.
Pickar, et al. *Climacteric* 2016

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