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 company will be able to prepare a new drug application for its TX-001HR product candidate and, if prepared, whether the FDA will accept and approve the application; whether the FDA will approve the company’s new drug application for its TX-004HR product candidate and whether any such approval will occur by the PDUFA date; 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.

TX-004HR (Yuvvexy™), 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.
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

<table>
<thead>
<tr>
<th>Proposed Indication</th>
<th>TX-004HR (Yuvvexy™)</th>
<th>TX-001HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition Description</td>
<td>Moderate to Severe Dyspareunia, a Symptom of VVA, due to Menopause</td>
<td>Moderate to Severe Hot Flashes due to Menopause</td>
</tr>
<tr>
<td>Active Ingredients</td>
<td>Bio-Identical 17 β-Estradiol</td>
<td>Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone</td>
</tr>
<tr>
<td>Form</td>
<td>Vaginal softgel capsule</td>
<td>Oral softgel capsule</td>
</tr>
<tr>
<td>Key Value Proposition</td>
<td>Negligible systemic exposure, early onset of action, ease of use</td>
<td>Potential first and only bio-identical FDA-approved combination product</td>
</tr>
<tr>
<td>Affected US Population</td>
<td>32 million women¹,²</td>
<td>36 million women³</td>
</tr>
<tr>
<td>US TAM Opportunity</td>
<td>$20B⁵</td>
<td>$25B⁴,⁵</td>
</tr>
</tbody>
</table>

³) Derived from U.S. Census data
⁴) Based on pre-WHI annual scripts of FDA-approved HT products
⁵) Based on market pricing of current FDA-approved HT products
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

Angus Russell  
Board Member
- Former Chief Executive Officer and Chief Financial Officer of Shire PLC
- Former Vice President of Corporate Finance at AstraZeneca
- Holds multiple board memberships, including Chairman of Revance Therapeutics

J. Martin Carroll  
Board Member
- Former President and Chief Executive Officer of Boehringer Ingelheim (U.S.)
- Former EVP of Customer Marketing and Sales of U.S. Human Health at Merck
- Holds multiple board memberships, including Catalent

Robert Finizio  
CEO, Co-Founder, and Director
- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2006)
- 22 years of experience in early stage healthcare company development

Brian Bernick, MD  
Chief Clinical Officer, Co-Founder
- Co-founded vitaMedMD in 2008
- 25 years of experience in healthcare/women’s health
- Past OB/GYN Department Chair - Boca Raton Regional Hospital, and
- Past ACOG Committee Member
- OB/GYN - 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

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

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

Dawn Halkuff  
Chief Commercial Officer
- 20+ years of commercial and marketing experience
- SVP of the Pfizer Consumer Healthcare Wellness Organization
- Commercial lead for sales and marketing of the Pfizer Women’s Health Division
- Head of Global Innovation at Weight Watchers International

Yuli Bogatyrenko  
Executive VP, Corporate Development
- 20+ years of experience in biopharma and consumer businesses
- SVP of BD at Paratek Pharmaceuticals
- VP and GM at Teva Pharmaceuticals
- Senior women’s health positions at Bayer and Pfizer
TX-001HR | Combination Estrogen + Progesterone (E+P) Program
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 may spend, on average, more than one-third of their lives in a hypoestrogenic 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\(^2\)

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TX-001HR Product Development Rationale

- **July 2002** - Women’s Health Initiative (WHI) study showed that *synthetic* hormones in combination increased the risk of breast cancer, stroke, heart attack and blood clots.

- Since the WHI, both women and healthcare providers have chosen unapproved, bio-identical hormones that are now cash pay over FDA-approved, synthetic hormones that are covered by insurance.

- Today, patients have the choice between two second best therapies:
  - Unapproved, **compounded** bio-identical hormones that have not been proven safe and effective, or
  - FDA-approved, *synthetic* hormones

TherapeuticsMD’s goal is to deliver a best in class, bio-identical hormone therapy that is FDA-approved based on safety and efficacy and covered by insurance.
TX-001HR – Potential Best in Class VMS Therapy

**Potential first and only:**
1) Bio-identical combination
2) FDA-approved

**Dosing and Delivery**
- Once-a-day Oral Softgel Capsule

**Addresses Unmet Medical Need**
- First and only bio-identical combination of E2 and P4 product candidate
- Single dose option
- Positive Phase 3 Replenish trial safety and efficacy results
- Potential FDA-approval with insurance coverage

**Benefits to women, healthcare providers, and pharmacies**

1) NDA to be submitted
2) Reimbursement anticipated if FDA-approved
Medical Societies Discourage Prescribing of Compounded Bio-Identical Hormones

- ACOG and ASRM Committee Opinion states compounded hormones may pose additional risks compared to FDA-approved products¹
  - 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

¹) 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).
TX-001HR (if approved) - Healthcare Provider Benefits

- Provide clinically validated dose regimens
- Meet medical standards of care and society guidelines while reducing liability
- Eliminate risks of compounded hormone therapy
- Meet patient demands and reduce patient out-of-pocket costs via insurance coverage
TX-001HR (if approved) - Pharmacy Benefits

- **2014** - Majority of major payors eliminated reimbursement of compounded medications
- **2017** - Average pre-tax profit per script of compounded bio-identical hormones is **$3-$5**

**Pharmacy benefits if TX-001HR is approved:**

- Improve net margin per script vs compounded bio-identical hormones
- Meet patient and physician demand for bio-identical hormone therapy
- Drive top-line growth due to third-party reimbursement
- Lower legal and regulatory costs and risk
TX-001HR (if approved) - Patient Benefits

- Meet demand for bio-identical hormone therapy that is FDA-approved based on safety and efficacy
- Eliminate risks of compounded hormone therapy
- Reduce out-of-pocket costs via insurance coverage and a single co-pay
- Provide convenience of one combination product
- Be available at most pharmacies
TX-001HR | Replenish Trial Overview and Results
1. Healthy postmenopausal women aged 40 to 65 years with an intact uterus who were seeking relief from vasomotor symptoms (VMS) and who met all inclusion/exclusion criteria were eligible for 12 months of study treatment.

**Randomized Study Participants**

- Frequency and Severity of Hot Flash diary data was assessed during Screening

1. ≥ 7 moderate or severe hot flashes per day or ≥ 50 per week during Screening

2. < 7 moderate or severe hot flashes per day or < 50 per week during Screening

**12-Week VMS Efficacy Substudy**

- Placebo
- 1 mg/100 mg
- 0.5 mg/100 mg
- 0.25 mg/50 mg
- 0.5 mg/50 mg

**52-Week Endometrial Safety Study (No Placebo Arm)**

- 1 mg/100 mg
- 0.5 mg/100 mg
- 0.5 mg/100 mg
- 0.25 mg/50 mg

All four active arms continue on to 52-Week Endometrial Safety Study after 12-Week VMS Efficacy Substudy is completed.
# Replenish Trial Co-Primary Endpoints

### Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-mITT Population

<table>
<thead>
<tr>
<th>Estradiol/Progesterone</th>
<th>1 mg/100 mg (n = 141)</th>
<th>0.5 mg/100 mg (n = 149)</th>
<th>0.5 mg/50 mg (n = 147)</th>
<th>0.25 mg/50 mg (n = 154)</th>
<th>Placebo (n = 135)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4 P-value versus placebo</td>
<td>&lt;0.001</td>
<td>0.013</td>
<td>0.141</td>
<td>0.001</td>
<td>-</td>
</tr>
<tr>
<td>Week 12 P-value versus placebo</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.002</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td><strong>Severity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4 P-value versus placebo</td>
<td>0.031</td>
<td>0.005</td>
<td>0.401</td>
<td>0.1</td>
<td>-</td>
</tr>
<tr>
<td>Week 12 P-value versus placebo</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.018</td>
<td>0.096</td>
<td>-</td>
</tr>
</tbody>
</table>

### Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population

| Endometrial Hyperplasia | 0% (0/280) | 0% (0/303) | 0% (0/306) | 0% (0/274) | 0% (0/92) |

MITT = Modified intent to treat

*Per FDA, consensus hyperplasia refers to the concurrence of two of the three pathologists be accepted as the final diagnosis

P-value < 0.05 meets FDA guidance and supports evidence of efficacy

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**Primary Efficacy Analysis pre-specified with the FDA in the clinical protocol and Statistical Analysis Plan (SAP)**

- **P-value < 0.05 meets FDA guidance and supports evidence of efficacy**
Mean Change from Baseline in Weekly Frequency of Moderate to Severe Hot Flashes for Weeks 1 to 12

Study Week

Mean Weekly Frequency Reduction from Baseline

-60 -50 -40 -30 -20 -10 0 10 20 30 40 50 60

1 mg E/100 mg P
0.5 mg E/100 mg P
0.5 mg E/50 mg P
0.25 mg E/50 mg P
Placebo

Replenish Trial Topline Data
Mean Change from Baseline in Weekly Severity of Moderate to Severe Hot Flashes for Weeks 1 to 12

- Mean Weekly Reduction in Severity from Baseline
- Study Week
- 1 mg E/100 mg P
- 0.5 mg E/100 mg P
- 0.5 mg E/50 mg P
- 0.25 mg E/50 mg P
- Placebo

Replenish Trial Topline Data
TX-001HR | Market Opportunity
### Multi-Billion Dollar Total Substitutable Market Opportunity

<table>
<thead>
<tr>
<th>TX-001HR Potential Market</th>
<th>FDA-Approved</th>
<th>Compounded Combination Bio-Identical E+P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Separate Bio-Identical E &amp; P Pills</td>
<td>~3 million²</td>
<td>12 – 18 million</td>
</tr>
<tr>
<td>Combination Synthetic E+P¹</td>
<td>~3 million²</td>
<td>$2.4B-$4.5B³</td>
</tr>
<tr>
<td>TX-001HR Total Substitutable Market Opportunity</td>
<td>$600M-$750M³</td>
<td>$600M-$750M³</td>
</tr>
</tbody>
</table>

If approved, TX-001HR can provide a single pill solution for women and physicians who:

1. Demand an FDA-approved bio-identical combination hormone product
2. Do not trust compounded hormones

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1) Includes the following drugs: Activella®, FemHRT®, Angelica®, Generic 17β- Progestins, Prempro®, Premphase®, Duvoe®, Brisdelle®
2) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
3) Assume WAC pricing between $200-250

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Commercialization Strategy: BIO-IGNITE

BIO-IGNITE is an outreach program to quantify and qualify the interests of 3,000 independent and community based pharmacies that compound bio-identical E+P

**Goal:**
Understand and identify the high volume pharmacies and prescribers that have developed a specialty focus around women’s menopausal health

**Mission:**
Work with these specialists to transition patients from unapproved compounded therapies to an FDA-approved treatment
### BIO-IGNITE Progress and Results

**Partnerships with Large Pharmacy Networks**

<table>
<thead>
<tr>
<th>Pharmacy Network Partners</th>
<th>Network Size</th>
<th>Combination Bio-Identical E+P Scripts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Premier Value</strong></td>
<td>225 Pharmacies In Network</td>
<td>~1,000,000 prescriptions annually</td>
</tr>
<tr>
<td><strong>TCG</strong></td>
<td>104 Pharmacies In Network</td>
<td>~500,000 prescriptions annually</td>
</tr>
</tbody>
</table>

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Who Writes Compounded Bio-Identical E+P Prescriptions?

240,000 Total Eligible Physicians¹ (Includes OB/GYNs, PCPs, and Anti-Aging)

- 12,000 High Prescribers (5%)
- 30,000 Regular Prescribers (12.5%)
- 60,000 Low Prescribers (24.5%)
- 138,000 Never Prescribe (58%)

12M-18M Annual Compounded Bio-Identical E+P Prescriptions Breakout by Volume

- 5,000,000 (33%)
- 7,000,000 (47%)
- 3,000,000 (20%)
- 0

Adverse Reimbursement and Regulatory Environments Continue to Erode Independent Pharmacy Margins

**November 2013:** Congress enacts Drug Quality and Security Act (DQSA), which prohibits compounding of essential copies of an FDA-approved drug except in limited circumstances such as drug shortage.

**June 3, 2014:** ESI launches a “Compound Management Solution,” creating a list of excluded ingredients that eliminated almost 95% of all compound claims.

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

**July 2018:** USP-800 implementation will set 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
- Large fixed capital expenditure requirements, with some totaling >$150,000 per pharmacy to implement

5) [https://www.ascp.com/sites/default/files/Join%20USP%20letter%202015%20FINAL.pdf](https://www.ascp.com/sites/default/files/Join%20USP%20letter%202015%20FINAL.pdf)

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# Independent Pharmacy Net Income Per Compounded Script

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Co-Pay</td>
<td>50.00</td>
<td>50.00</td>
<td>50.00</td>
</tr>
<tr>
<td>Third-Party Reimbursement</td>
<td>115.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Net Revenue</strong></td>
<td>$165.00</td>
<td>$50.00</td>
<td>$50.00</td>
</tr>
<tr>
<td>Costs of Good Sold</td>
<td>7.50</td>
<td>7.50</td>
<td>7.50</td>
</tr>
<tr>
<td><strong>Gross Profit</strong></td>
<td>$157.50</td>
<td>$42.50</td>
<td>$42.50</td>
</tr>
<tr>
<td><strong>Gross margin</strong></td>
<td>95.5%</td>
<td>85.0%</td>
<td>85.0%</td>
</tr>
<tr>
<td><strong>Operating Expenses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G&amp;A</td>
<td>15.00</td>
<td>15.00</td>
<td>15.00</td>
</tr>
<tr>
<td>S&amp;M</td>
<td>7.50</td>
<td>7.50</td>
<td>7.50</td>
</tr>
<tr>
<td>Additional Compounding Costs¹</td>
<td>15.00</td>
<td>15.00</td>
<td>15.00</td>
</tr>
<tr>
<td><strong>Cost of USP-800 Requirements²</strong></td>
<td>-</td>
<td>-</td>
<td>10.00</td>
</tr>
<tr>
<td><strong>Total Operating Expenses</strong></td>
<td>$37.50</td>
<td>$37.50</td>
<td>$47.50</td>
</tr>
<tr>
<td><strong>Pre-Tax Profit</strong></td>
<td>$120.00</td>
<td>$5.00</td>
<td>$(5.00)</td>
</tr>
<tr>
<td><strong>Operating margin</strong></td>
<td>72.7%</td>
<td>10.0%</td>
<td>-10.0%</td>
</tr>
</tbody>
</table>

1) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses
2) July 2018 Implementation; includes >$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs
### Economic Incentives Provide Catalyst to Switch to TX-001HR

#### Independent Pharmacy Net Income Per Script with TX-001HR

<table>
<thead>
<tr>
<th></th>
<th>Compounded E+P Post USP-800</th>
<th>TX-001HR Launch 2H18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Co-Pay</td>
<td>50.00</td>
<td>50.00</td>
</tr>
<tr>
<td>Third-Party Reimbursement</td>
<td>-</td>
<td>200.00</td>
</tr>
<tr>
<td><strong>Total Net Revenue</strong></td>
<td>$50.00</td>
<td>$250.00¹</td>
</tr>
<tr>
<td>Costs of Good Sold</td>
<td>7.50</td>
<td>200.00²</td>
</tr>
<tr>
<td><strong>Gross Profit</strong></td>
<td>$42.50</td>
<td>$50.00</td>
</tr>
<tr>
<td><em>Gross margin</em></td>
<td>85.0%</td>
<td>20.0%</td>
</tr>
<tr>
<td><strong>Operating Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G&amp;A</td>
<td>15.00</td>
<td>15.00</td>
</tr>
<tr>
<td>S&amp;M</td>
<td>7.50</td>
<td>5.00</td>
</tr>
<tr>
<td>Additional Compounding Costs³</td>
<td>15.00</td>
<td>-</td>
</tr>
<tr>
<td>Cost of USP-800 Requirements⁴</td>
<td>10.00</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Operating Expenses</strong></td>
<td>$47.50</td>
<td>$20.00</td>
</tr>
<tr>
<td><strong>Pre-Tax Profit</strong></td>
<td>$ (5.00)</td>
<td>$30.00</td>
</tr>
<tr>
<td><em>Operating margin</em></td>
<td>-10.0%</td>
<td>12.0%</td>
</tr>
</tbody>
</table>

---

**Notes:**
1. Assume AWP-18% Third-Party Reimbursement
2. Assume $250 WAC less 20% distribution discount
3. Includes additional labor, pharmacists, technicians, regulatory, and legal expenses
4. July 2018 Implementation; includes >$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs.
FDA-Approved Separate Bio-Identical E & P Substitutable Market Opportunity

- Healthcare providers not comfortable with compounding will often prescribe two separate FDA-approved bio-identical products to treat menopausal symptoms.

<table>
<thead>
<tr>
<th>Product Use by Age</th>
<th>AGES 41-50</th>
<th>AGES 51-60</th>
<th>AGES 61-70</th>
<th>AGES 71+</th>
<th>TRx Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Progesterone</strong>*</td>
<td>528,325</td>
<td>1,326,618</td>
<td>1,060,666</td>
<td>678,775</td>
<td>3,594,3841</td>
</tr>
<tr>
<td><strong>Estradiol</strong></td>
<td>2,677,210</td>
<td>5,494,846</td>
<td>2,826,636</td>
<td>1,083,726</td>
<td>12,082,4181</td>
</tr>
</tbody>
</table>

*Menopausal use of progesterone directly substitutable to TX-001HR

~3M Potential Prescriptions for TX-001HR (if approved)
Market Opportunity = $600M-750M²

- This regimen carries significant risk of endometrial hyperplasia/cancer if the patient is non-compliant with regular progesterone use.
  - Progesterone’s side effects of nausea and somnolence can lead to a patient not taking the progesterone
  - Results in two separate co-pays for the patient

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2015
2) Assume WAC pricing between $200-250

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### FDA-Approved Combination Synthetic E+P Substitutable Market Opportunity

**FDA-Approved Combination Synthetic E+P Prescriptions by Age**

<table>
<thead>
<tr>
<th>AGES 31-40</th>
<th>AGES 41-50</th>
<th>AGES 51-60</th>
<th>AGES 61-70</th>
<th>AGES 71+</th>
<th>Unknown Ages</th>
<th>TRx Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>52,575</td>
<td>372,968</td>
<td>1,712,852</td>
<td>759,634</td>
<td>151,821</td>
<td>68,672</td>
<td>3,118,522</td>
</tr>
</tbody>
</table>

1) ~3M Potential Prescriptions for TX-001HR (if approved)

Market Opportunity = $600M-750M

---

1) Symphony Health Solutions PHAST Data powered by IQVIA; 12 months as of December 31, 2015
2) Includes the following drugs: Activella®, FemHRT®, Angelq®, Generic 17β + Progestins, Prempro®, Premphase®, Duvée®, Brisdelle®
3) Assume WAC pricing between $200-$250

*All trademarks are the property of their respective owners.*
Expect Robust Insurance Coverage For TX-001HR, If Approved, In-Line with Product Class

<table>
<thead>
<tr>
<th>4,315 Commercial Plans</th>
<th>% Unrestricted Access of Commercial Plans</th>
<th>Not Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrace® (Oral)</td>
<td>96%</td>
<td>1%</td>
</tr>
<tr>
<td>Prempro®</td>
<td>94%</td>
<td>5%</td>
</tr>
<tr>
<td>CombiPatch®</td>
<td>93%</td>
<td>4%</td>
</tr>
<tr>
<td>Climara Pro®</td>
<td>92%</td>
<td>4%</td>
</tr>
<tr>
<td>FemHRT®</td>
<td>87%</td>
<td>6%</td>
</tr>
<tr>
<td>Duavee®</td>
<td>86%</td>
<td>5%</td>
</tr>
<tr>
<td>Vivelle-Dot®</td>
<td>84%</td>
<td>5%</td>
</tr>
<tr>
<td>Activella®</td>
<td>83%</td>
<td>8%</td>
</tr>
<tr>
<td>Prometrium®</td>
<td>83%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Data Source MMIT August 17, 2016 – 4,300 commercial plans
All trademarks are the property of their respective owners.
TX-004HR (Yuvvexy™)
Vulvar and Vaginal Atrophy (VVA) Program
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**

**Superficial cells:** >15%

**Intermediate cells:** 80%

**Parabasal cells:** < 5%

**pH:** < 5

**Atrophic Vaginal Tissue**

**Superficial cells:** <5%

**Intermediate cells:** 60%

**Parabasal cells:** >30%

**pH:** > 5

---

### Current FDA-Approved VVA Competitive Landscape

- U.S. sales more than doubled since 2008
- Global market expected to be $2.1 billion in 2022
- 7% current market penetration

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Compound</th>
<th>2015 TRx (000)</th>
<th>2015 U.S. Sales ($M)</th>
<th>WAC Price ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premarin® Cream</td>
<td>Pfizer</td>
<td>Conjugated equine vaginal estrogen</td>
<td>1,615</td>
<td>$502</td>
<td>$288.40</td>
</tr>
<tr>
<td>Vagifem® Tablets</td>
<td>Novo Nordisk</td>
<td>Vaginal estradiol</td>
<td>1,620</td>
<td>$456</td>
<td>$382.86*</td>
</tr>
<tr>
<td>Yuvafem® Tablets (Vagifem AG)</td>
<td>Amneal</td>
<td>Vaginal estradiol</td>
<td>Launched October 2016</td>
<td></td>
<td>$349.17**</td>
</tr>
<tr>
<td>Estrace® Cream</td>
<td>Allergan</td>
<td>Vaginal estradiol</td>
<td>1,548</td>
<td>$420</td>
<td>$263.81</td>
</tr>
<tr>
<td>Estring® Ring</td>
<td>Pfizer</td>
<td>Vaginal estradiol ring</td>
<td>284</td>
<td>$91</td>
<td>$310.44</td>
</tr>
<tr>
<td>Osphena® Tablets</td>
<td>Shionogi</td>
<td>Oral SERM</td>
<td>263</td>
<td>$66</td>
<td>$530.07</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>5,330</td>
<td><strong>$1,535</strong></td>
<td></td>
</tr>
</tbody>
</table>

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) GlobalData July 2013 report GDHC54PIDR.
3) Medi-Span Price Rx Basic * for 18 tablets ($170.16 WAC for 8 tablets) ** for 18 tablets ($155.18 for 8 tablets)

All trademarks are the property of their respective owners.
Current VVA Market Overview

32M Women with VVA Symptoms\(^1,2\)

\(\sim 50\% \text{ of women seek treatment for VVA}\(^4\)

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

超出\textit{治疗总机会}\(^5\)

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.
# Current FDA-Approved VVA Product Use Falls Short

<table>
<thead>
<tr>
<th>Current HT Users</th>
<th>Past HT Users</th>
<th>OTC Product Users</th>
<th>Not Seeking Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3M Women (^2)</td>
<td>5.7M Women (^3)</td>
<td>8M Women (^3)</td>
<td>16M Women</td>
</tr>
<tr>
<td>7% of VVA Population</td>
<td>18% of VVA Population</td>
<td>25% of VVA Population</td>
<td>50% of VVA Population</td>
</tr>
</tbody>
</table>

### Market Size

<table>
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<td>18% of VVA Population</td>
<td>25% of VVA Population</td>
<td>50% of VVA Population</td>
</tr>
</tbody>
</table>

### Perceived Product Shortcomings

<table>
<thead>
<tr>
<th>Current HT Users</th>
<th>Past HT Users</th>
<th>OTC Product Users</th>
<th>Not Seeking Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not effectively treat the underlying pathological causes of VVA</td>
<td>Unsatisfied / unsuccessful with past treatments</td>
<td>Do not effectively treat the underlying pathological causes of VVA</td>
<td>Not aware that VVA is a treatable condition</td>
</tr>
<tr>
<td>Do not halt or reverse symptoms</td>
<td>Physical and clinical attributes of existing products</td>
<td>Do not halt or reverse symptoms</td>
<td>Estrogen exposure concerns</td>
</tr>
</tbody>
</table>

### VVA Market Opportunity

<table>
<thead>
<tr>
<th>Current HT Users</th>
<th>Past HT Users</th>
<th>OTC Product Users</th>
<th>Not Seeking Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(&gt;$1.5B)</td>
<td>(&gt;$3B)</td>
<td>(&gt;$5B)</td>
<td>(&gt;$10B)</td>
</tr>
</tbody>
</table>

---

2) IMS Health Plan Claims (April 2008-Mar 2011).
3) TherapeuticsMD "EMPOWER" Survey, 2016
TX-004HR (Yuvvexy™)

- 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**

**Prototype Starter Pack**

**Prototype Maintenance Pack**

0.69 x 0.3 inch

YUVVEXY™ is an investigational drug and is not approved for use by the FDA.
**TX-004HR – Potential Best In Class VVA Therapy**

<table>
<thead>
<tr>
<th>Products</th>
<th>Premarin®</th>
<th>Vagifem®</th>
<th>Estrace®</th>
<th>Osphena®</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method of Admin</th>
<th>Vaginal Cream</th>
<th>Vaginal Tablet</th>
<th>Vaginal Cream</th>
<th>Oral Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Reusable Vaginal Applicator</td>
<td>Vaginal Applicator</td>
<td>Reusable Vaginal Applicator</td>
<td>Oral Daily SERM</td>
</tr>
<tr>
<td>Active Ingredient</td>
<td>625 mcg/g CEEs</td>
<td>10 mcg Estradiol</td>
<td>100 mcg/g Estradiol</td>
<td>60,000 mcg ospemifene</td>
</tr>
<tr>
<td>Avg Maintenance Dose</td>
<td>312.5 mcg 2x/week</td>
<td>10 mcg 2x/week</td>
<td>100 mcg 2x/week</td>
<td>60,000 mcg daily</td>
</tr>
<tr>
<td>Onset of Action* Dyspareunia</td>
<td>Week 4+</td>
<td>Week 8</td>
<td>Approval Without Dyspareunia and Dryness Data</td>
<td>Week 12</td>
</tr>
<tr>
<td>Onset of Action* Dryness</td>
<td>Not Demonstrated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Onset of Action = First efficacy observation

**Based on Product Prescribing Information**

**Not Head-to-Head Comparative Studies**


All trademarks are the property of their respective owners.
TX-004HR - Designed for Long Term Compliance

Current Market

Vaginal Creams:

- Reasons Women Stop
  - Messiness
  - Reusable Applicator
  - Long-term Safety
  - Dose Preparation by User Required

Mean Duration of Use: 1.5 Months

Vaginal Tablets:

- Reasons Women Stop
  - Efficacy
  - Applicator
  - Long-term Safety
  - Systemic Absorption

Mean Duration of Use: 3.5 Months

Yuvvexy™

- Muco-adhesive, Dissolves Quickly and Completely
- No Applicator and No Dose Preparation
- Onset-of-Action (Efficacy observed at 2 weeks)
- Negligible Systemic Exposure

>75% Patient Satisfaction in a Market with Historically Low Compliance Rate

Potential Long Term Usage

- 0.69 x 0.3 inch

---

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

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

<table>
<thead>
<tr>
<th>Hours after capsule insertion Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>(° represents day 84)</td>
</tr>
</tbody>
</table>

LS Mean Change from Baseline to Week 12

<table>
<thead>
<tr>
<th>4 mcg</th>
<th>LS Mean Change from Baseline to Week 12</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 mcg</td>
<td>Placebo</td>
</tr>
<tr>
<td>Superficial Cells</td>
<td>17%</td>
<td>6%</td>
</tr>
<tr>
<td>Parabasal Cells</td>
<td>-41%</td>
<td>-7%</td>
</tr>
<tr>
<td>Vaginal pH</td>
<td>-1.3</td>
<td>-0.3</td>
</tr>
<tr>
<td>Severity of Dyspareunia</td>
<td>-1.5</td>
<td>-1.3</td>
</tr>
<tr>
<td>Severity of Vaginal Dryness</td>
<td>-1.27</td>
<td>-0.97</td>
</tr>
</tbody>
</table>

MMRM P-value vs placebo

AUC\(_{0-24}\) (pg.h/mL) | C\(_{avg(0-24)}\) (pg/mL)
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mcg</td>
<td>87.22 (42.77)</td>
</tr>
<tr>
<td>Placebo</td>
<td>104.16 (66.38)</td>
</tr>
<tr>
<td>P-value vs Placebo</td>
<td>0.3829</td>
</tr>
</tbody>
</table>

LS = Least Squares
REJOICE Trial Results
Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 10 mcg

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

![Mean Estradiol Serum Concentration Graph]

Hours after capsule insertion Day 14
( represents day 84)

<table>
<thead>
<tr>
<th></th>
<th>10 mcg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AUC(_{0-24}) (pg.h/mL)</strong></td>
<td>110.14 (54.57)</td>
<td>104.16 (66.38)</td>
</tr>
<tr>
<td><strong>C(_{avg(0-24)}) (pg/mL)</strong></td>
<td>4.58 (2.27)</td>
<td>4.34 (2.76)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>LS Mean Change from Baseline to Week 12</strong></th>
<th>10 mcg</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Superficial Cells</strong></td>
<td>17%</td>
<td>6%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Parabasal Cells</strong></td>
<td>-44%</td>
<td>-7%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Vaginal pH</strong></td>
<td>-1.4</td>
<td>-0.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Severity of Dyspareunia</strong></td>
<td>-1.7</td>
<td>-1.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Severity of Vaginal Dryness</strong></td>
<td>-1.47</td>
<td>-0.97</td>
<td>&lt;0.0001</td>
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MMRM P-value vs placebo

LS = Least Squares
REJOICE Trial Results
Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 25 mcg

Arithmetic Mean Estradiol Serum Concentrations - Unadjusted
TX-004HR 25 mcg (N=18)

<table>
<thead>
<tr>
<th></th>
<th>25 mcg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AUC</strong>_0-24 (pg.h/mL)</td>
<td>171.56 (80.13)</td>
<td>104.16 (66.38)</td>
</tr>
<tr>
<td><strong>C</strong>_avg(0-24) (pg/mL)</td>
<td>7.14 (3.33)</td>
<td>4.34 (2.76)</td>
</tr>
</tbody>
</table>

P-value vs Placebo

<table>
<thead>
<tr>
<th></th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Superficial Cells</strong></td>
<td>0.0108</td>
</tr>
<tr>
<td><strong>Parabasal Cells</strong></td>
<td>0.0108</td>
</tr>
<tr>
<td><strong>Vaginal pH</strong></td>
<td>&lt;0.0001</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Placebo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
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MMRM P-value vs placebo
Favorable Regulatory Dynamics Driven by Change in Treatment Paradigm

- 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

- 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
  - Healthcare practitioners may now consider topical estrogen therapy for patients with a history of estrogen-dependent breast cancer

- 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:
    - 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

---

Foundation Built for a Strong Launch

Operational leverage of OB/GYN relationships in key markets

Map Legend:
- Current TXMD Sales Presence
- Highest Prescribing Physicians for VVA

50 Sales Representatives; Planned Increase to 100-120 With Launch of Yuvvexy™
### Expect Robust Insurance Coverage For TX-004HR, If Approved, In-Line with Product Class

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<td>1%</td>
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</tbody>
</table>

Data Source: MMIT August 17, 2016 – 4,300 commercial plans
All trademarks are the property of their respective owners.
TXMD: Financial Snapshot

- Listing Exchange: TXMD
- Debt: $0MM
- Shares Outstanding: 196.6MM (as of October 31, 2016)
- Cash: $147.5MM (as of Sept 30, 2016)
Worldwide Patent Filings*

Strong IP Portfolio with 149 Patent Applications, including 82 international filings, and 17 issued U.S. patents

*Not all patent filings filed in all jurisdictions.
THANK YOU!
## Compounded Combination Bio-Identical E+P: Why Has It Been So Successful?

<table>
<thead>
<tr>
<th>Synthetic Progestins</th>
<th>Bio-identical Progesterone</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>No benefits on sleep properties</td>
<td><strong>Favorable CNS Profile</strong></td>
<td>Freeman, E, et al.¹</td>
</tr>
<tr>
<td>Increased risk of breast cancer</td>
<td><strong>Favorable breast profile</strong></td>
<td>E3N-EPIC²</td>
</tr>
<tr>
<td>Increased risk of MI, Stroke, VTE</td>
<td><strong>Favorable cardiovascular profile</strong></td>
<td>PEPI³, ELITE⁵</td>
</tr>
<tr>
<td>Less favorable lipid profile effects (cholesterol, LDL, triglycerides)</td>
<td><strong>Favorable lipid profile</strong></td>
<td>PEPI³</td>
</tr>
<tr>
<td>Adequate endometrial protection</td>
<td><strong>Adequate endometrial protection</strong></td>
<td>PEPI⁴</td>
</tr>
<tr>
<td>High incidence of bleeding</td>
<td><strong>Low incidence of bleeding</strong></td>
<td>Regidor, et al.⁶</td>
</tr>
</tbody>
</table>

Current FDA Guidance for VMS Drug Products*

• Co-primary efficacy endpoints (12 week VMS Efficacy Population)
  o Mean Change from Baseline to Weeks 4 and 12 in the frequency and severity of moderate and severe vasomotor symptoms versus placebo

• Primary safety endpoint (12 month Endometrial Safety Population)
  o Incidence rate of endometrial hyperplasia at 12 months (to demonstrate a hyperplasia rate that is ≤ 1% with an upper bound of the one-sided 95% confidence interval for that rate does not exceed 4%)

Study Analysis

• Clinically meaningful and statistically significant reduction within 4 weeks of initiation of treatment and maintained throughout 12 weeks of treatment

Study Considerations

• Single, 12-month study to demonstrate endometrial protection

Single Pivotal Phase 3 trial required unless:

• The drug to be studied is considered a new molecular entity
• The drug to be studied poses unique safety concerns

*2003 FDA Draft Guidance for Industry Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Recommendations for Clinical Evaluation