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.
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>Yuvvexy™</th>
<th>TX-001HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate to Severe Dyspareunia, a Symptom of VVA, due to Menopause</td>
<td>Moderate to Severe Hot Flashes due to Menopause</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition Description</th>
<th>VVA due to Menopause</th>
<th>Menopause</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Bio-Identical 17 β-Estradiol</th>
<th>Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form</th>
<th>Vaginal softgel capsule</th>
<th>Oral softgel capsule</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Key Value Proposition</th>
<th>Negligible systemic exposure, early onset of action, ease of use</th>
<th>Potential first and only bio-identical FDA-approved combination product</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Affected US Population</th>
<th>32 million women&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>36 million women&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>US TAM Opportunity</th>
<th>&gt;$20B&lt;sup&gt;5&lt;/sup&gt;</th>
<th>&gt;$25B&lt;sup&gt;4,5&lt;/sup&gt;</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Status</th>
<th>NDA submitted July 7, 2016 PDUFA target action date: May 7, 2017</th>
<th>Pivotal Phase 3 topline data expected 4Q 2016</th>
</tr>
</thead>
</table>

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<sup>3</sup> Derived from U.S. Census data.

<sup>4</sup> Based on pre-WHI annual scripts of FDA-approved HT.

<sup>5</sup> Based on current FDA-approved market pricing.
# Investigational Pipeline

<table>
<thead>
<tr>
<th>Pre-Clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>PDUFA Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuvvexy™ (17β-estradiol Vaginal Softgel Capsule)</td>
<td>TX-004HR</td>
<td></td>
<td></td>
<td>05/07/2017</td>
</tr>
<tr>
<td>Oral Combination: 17β-estradiol + Progesterone</td>
<td>TX-001HR</td>
<td></td>
<td></td>
<td>Q4 2016</td>
</tr>
<tr>
<td>Transdermal Progesterone</td>
<td>TX-005HR</td>
<td></td>
<td></td>
<td>Q4 2016</td>
</tr>
<tr>
<td>Transdermal 17β-estradiol + Progesterone</td>
<td>TX-006HR</td>
<td></td>
<td></td>
<td>Q4 2016</td>
</tr>
</tbody>
</table>
Key Accomplishments and Anticipated Milestones

- Submitted New Drug Application for Yuvvexy™ (TX-004HR) for all three doses (4 mcg, 10mcg, 25mcg)
- Yuvvexy™ PDUFA target action date of May 7, 2017
- Expected NDA submission for TX-001HR

- Expected to report phase 3 Replenish Trial topline results (TX-001HR)
- Projected transdermal E+P and progesterone alone phase 1 results

1) NDA to be submitted assuming successful results of Replenish trial
Yuvvexy™
TX-004HR | 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
- 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 vs. Atrophic Vaginal Tissue

<table>
<thead>
<tr>
<th>Component</th>
<th>Healthy</th>
<th>Atrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Superficial cells</strong></td>
<td>&gt;15%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td><strong>Intermediate cells</strong></td>
<td>80%</td>
<td>60%</td>
</tr>
<tr>
<td><strong>Parabasal cells</strong></td>
<td>&lt;5%</td>
<td>&gt;30%</td>
</tr>
<tr>
<td>pH</td>
<td>&lt;5</td>
<td>&gt;5</td>
</tr>
</tbody>
</table>

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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

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Compound</th>
<th>2015 TRx (000)(^1)</th>
<th>2015 U.S. Sales ($MM)(^1)</th>
<th>WAC Price(^3)</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>Estrace® Cream</td>
<td>Allergan</td>
<td>Vaginal estradiol</td>
<td>1,548</td>
<td>$420</td>
<td>$263.81</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>Estring® Ring</td>
<td>Pfizer</td>
<td>Vaginal estradiol ring</td>
<td>284</td>
<td>$91</td>
<td>$310.44</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>5,330</strong></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) 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) Global Data July 2013 report GD/HCP/MNDR.
All trademarks are the property of their respective owners.
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\(^4\)

Not Seeking Treatment
50%

OTC Product Users
25%

Past HT Users
18%

Current HT Users
7%

Not Seeking Treatment
50%

** 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.

4) TherapeuticsMD “EMPOWER” Survey, 2016.
5) Based on current FDA-approved market pricing.
Current FDA-Approved VVA Product Use Falls Short

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

2) IMS Health Plan Claims (April 2008-Mar 2011).  
3) TherapeuticsMD "EMPOWER" Survey, 2016
Yuuvexy™ – 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**

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Yuuvexy™ is an investigational drug and is not approved for use by the FDA.
# Yuvvexy™ – 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>
<tbody>
<tr>
<td>Method of Admin</td>
<td>Vaginal Cream</td>
<td>Vaginal Tablet</td>
<td>Vaginal Cream</td>
<td>Oral Tablet</td>
</tr>
<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>Not Demonstrated</td>
<td></td>
</tr>
</tbody>
</table>

*Onset of Action = First efficacy observation

**Based on Product Prescribing Information**

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

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Yuvvexy® (if approved)

TherapeuticsMD™


All trademarks are the property of their respective owners
## Yuvvexy™ - Designed for Long Term Compliance

### Current Market

**Vaginal Creams:**

**Mean Duration of Use:** 1.5 Months

**Reasons Women Stop**

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

**Vaginal Tablets:**

**Mean Duration of Use:** 3.5 Months

**Reasons Women Stop**

- Efficacy
- Applicator
- Long-term Safety
- Systemic Absorption

### 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

**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

### Sources

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 Endpoints
### LS Mean Change from Baseline to Week 12 Compared to Placebo

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>4 mcg</th>
<th>10 mcg</th>
<th>25 mcg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial Cells</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Parabasal Cells</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Vaginal pH</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severity of Dyspareunia</td>
<td>0.0149</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severity of Vaginal Dryness</td>
<td>0.0014</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**MMRM P-value vs placebo**
Co-Primary and Key Secondary Efficacy Endpoints
TX-004HR 4 mcg

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

Hours after capsule insertion Day 14
(\(\bigtriangledown\) represents day 84)

<table>
<thead>
<tr>
<th></th>
<th>(\text{AUC}_{0-24}) (pg.h/mL)</th>
<th>(\text{C}_{\text{avg}(0-24)}) (pg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mcg</td>
<td>87.22 (42.77)</td>
<td>3.634 (1.78)</td>
</tr>
<tr>
<td>Placebo</td>
<td>104.16 (66.38)</td>
<td>4.34 (2.76)</td>
</tr>
<tr>
<td>(\text{P-value vs Placebo})</td>
<td>0.3829</td>
<td>0.3829</td>
</tr>
</tbody>
</table>

\[\text{LS Mean Change from Baseline to Week 12}\]

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>4 mcg</th>
<th>(\text{P-value})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial Cells</td>
<td>6%</td>
<td>17%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Parabasal Cells</td>
<td>-7%</td>
<td>-41%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Vaginal pH</td>
<td>-0.3</td>
<td>-1.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severity of Dyspareunia</td>
<td>-1.3</td>
<td>-1.5</td>
<td>0.0149</td>
</tr>
<tr>
<td>Severity of Vaginal Dryness</td>
<td>-0.97</td>
<td>-1.27</td>
<td>0.0014</td>
</tr>
</tbody>
</table>

\(\text{MMRM P-value vs placebo}\)

\(\text{LS = Least Squares}\)
\(\text{REJOICE Trial Results}\)
## Co-Primary and Key Secondary Efficacy Endpoints

**TX-004HR 10 mcg**

### Arithmetic Mean Estradiol Serum Concentrations - Unadjusted

**TX-004HR 10 mcg (N=19)**

<table>
<thead>
<tr>
<th></th>
<th>Mean Serum Estradiol Concentration (pg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AUC$_{0-24}$</td>
</tr>
<tr>
<td>10 mcg</td>
<td>110.14 (54.57)</td>
</tr>
<tr>
<td>Placebo</td>
<td>104.16 (66.38)</td>
</tr>
<tr>
<td>P-value vs Placebo</td>
<td>0.7724 0.7724</td>
</tr>
</tbody>
</table>

### LS Mean Change from Baseline to Week 12

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

**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>TX-004HR 25 mcg</th>
<th>25 mcg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>LS Mean Change from Baseline to Week 12</td>
<td>25 mcg</td>
<td>Placebo</td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Superficial Cells</td>
<td>23%</td>
<td>6%</td>
</tr>
<tr>
<td>Parabasal Cells</td>
<td>-46%</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>-1.7</td>
<td>-1.3</td>
</tr>
<tr>
<td>Severity of Vaginal Dryness</td>
<td>-1.47</td>
<td>-0.97</td>
</tr>
</tbody>
</table>

LS = Least Squares
REJOICE Trial Results

---

**Table:**

<table>
<thead>
<tr>
<th>Group</th>
<th>(\text{AUC}_{0-24} \text{ (pg.h/mL)})</th>
<th>(\text{C}_{\text{avg}}[0-24] \text{ (pg/mL)})</th>
<th>P-value vs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mcg</td>
<td>171.56 (80.13)</td>
<td>7.14 (3.33)</td>
<td>0.0108</td>
</tr>
<tr>
<td>Placebo</td>
<td>104.16 (66.38)</td>
<td>4.34 (2.76)</td>
<td>0.0108</td>
</tr>
<tr>
<td>P-value vs Placebo</td>
<td>0.0108</td>
<td>0.0108</td>
<td></td>
</tr>
</tbody>
</table>
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
## Dyspareunia and Vaginal Dryness By Study Visit

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

<table>
<thead>
<tr>
<th></th>
<th>4 mcg</th>
<th>10 mcg</th>
<th>25 mcg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 2</td>
<td>0.026</td>
<td>0.0019</td>
<td>0.0105</td>
</tr>
<tr>
<td>Week 6</td>
<td>0.0069</td>
<td>0.0009</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Week 8</td>
<td>0.0003</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Week 12</td>
<td>0.0149</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>4 mcg</th>
<th>10 mcg</th>
<th>25 mcg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 2</td>
<td>0.1269</td>
<td>0.0019</td>
<td>0.0082</td>
</tr>
<tr>
<td>Week 6</td>
<td>0.0094</td>
<td>0.0001</td>
<td>0.0005</td>
</tr>
<tr>
<td>Week 8</td>
<td>0.0128</td>
<td>&lt; 0.0001</td>
<td>0.0008</td>
</tr>
<tr>
<td>Week 12</td>
<td>0.0014</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

LS = Least Squares
REJOICE Trial Results
Efficacy and Onset of Action
Not Head-to-Head Comparative Studies

<table>
<thead>
<tr>
<th>Onset of Action*</th>
<th>Premarin®</th>
<th>Vagifem®</th>
<th>Estrace®</th>
<th>Osphena®</th>
<th>Estring®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspareunia</td>
<td>Week 4+</td>
<td>Week 8 (composite score)</td>
<td>Approval without dyspareunia and dryness data</td>
<td>Approval without dyspareunia and dryness data</td>
<td>Not demonstrated</td>
</tr>
<tr>
<td>Dryness</td>
<td>Not demonstrated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Onset of Action = First efficacy observation
## Yuvvexy™ Qualitative Attributes

### Ease of Use

<table>
<thead>
<tr>
<th></th>
<th>4 mcg (N=181)</th>
<th>10 mcg (N=181)</th>
<th>25 mcg (N=184)</th>
<th>Placebo (N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to Use</td>
<td>171 (94.5%)</td>
<td>172 (95.0%)</td>
<td>175 (95.1%)</td>
<td>164 (88.9%)</td>
</tr>
</tbody>
</table>

### Patient Satisfaction

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

Overall p-value = 0.035

### Preferred vs Competition

<table>
<thead>
<tr>
<th></th>
<th>4 mcg (N=119)</th>
<th>10 mcg (N=113)</th>
<th>25 mcg (N=128)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX-004HR over previously used VVA therapies</td>
<td>73.9%</td>
<td>67.3%</td>
<td>74.2%</td>
</tr>
<tr>
<td>P-value vs. Placebo</td>
<td>0.0010</td>
<td>0.0212</td>
<td>0.0003</td>
</tr>
</tbody>
</table>

Overall p-value <0.0001

---

LS = Least Squares
REJOICE Trial Results
## Yuvvexy™ Attributes Could Address Perceived Shortcomings of Current Products

### Current HT Users
- Negligible systemic profile may give comfort for long term use
- REJOICE data: first efficacy observation for dyspareunia and dryness at two weeks
- No applicator
- No mess

### Past HT Users
- REJOICE data: 70%-95% patient satisfaction
- Ease of use could lead to less discontinuation
- Negligible systemic profile may give comfort for long term use
- Two week efficacy may increase refill rates past month 1

### OTC Product Users
- Negligible systemic profile may alleviate fear of HT
- Dose pack helpful to physicians likely to prescribe HT
- Could eliminate need to see a specialist
- Ease of use profile

### Not Seeking Treatment
- Dose pack may reduce time for patient education on product use, making physicians more likely to initiate VVA conversation
- Could eliminate need to see a specialist
- Negligible systemic profile may enable access to a new demographic

### Yuvvexy™ Market Opportunity
- **Market Share Gain**
- **Reintroduce HT**
- **New HT Users**

---

**REJOICE Trial Results**

---

**TherapeuticsMD**
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

**Removal of Black Box Warning**

**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
- Health 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

---


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

YUVVEXY Launch

($MM)


$485  $500  $1,000  $2,000  $3,000  $4,000  $5,000  $6,000

20% CAGR

$4,813

1) Symphony Health Solutions PHAST Prescription Monthly Powered by IDV, 12 months as of December 31, 2015.
2) GlobalData July 2013 report GDHC54PDR.
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 150 With Launch of Yuvvexy™
## Expect Robust Insurance Coverage For Yuvvexy™, If Approved, In-line with Product Class

<table>
<thead>
<tr>
<th>4,312 Commercial Plans</th>
<th>% Unrestricted Access of Commercial Plans</th>
<th>Not Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Premarin Cream®</strong></td>
<td>94%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Estrace Cream®</strong></td>
<td>96%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Vagifem®</strong></td>
<td>90%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Estring®</strong></td>
<td>93%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Data Source MMIT August 17, 2016 – 4,300 commercial plans
All trademarks are the property of their respective owners.
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 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\(^2\)

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

Compounding filled the need and demand for BHT

- 30MM scripts (1-2.5MM women) of Compounded BHT prescribed annually in the U.S. currently

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)

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) 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)

**Compounded Bio-identical Hormone Therapy Market**

**TherapeuticsMD**

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)

WHI = Women’s Health Initiative, DQSA = Drug Quality and Security Act, BHRT = Bio-identical Hormone Replacement Therapy
## Compounded Bio-Identical HT: 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>Favorable CNS Profile</td>
<td>Freeman, E, et al. ¹</td>
</tr>
<tr>
<td>Increased risk of breast cancer</td>
<td>Favorable breast profile</td>
<td>E3N-EPIC²</td>
</tr>
<tr>
<td>Increased risk of MI, Stroke, VTE</td>
<td>Favorable cardiovascular profile</td>
<td>PEPI³, ELITE⁵</td>
</tr>
<tr>
<td>Less favorable lipid profile effects (cholesterol, LDL, triglycerides)</td>
<td>Favorable lipid profile</td>
<td>PEPI³</td>
</tr>
<tr>
<td>Adequate endometrial protection</td>
<td>Adequate endometrial protection</td>
<td>PEPI⁴</td>
</tr>
<tr>
<td>High incidence of bleeding</td>
<td>Low incidence of bleeding</td>
<td>Regidor, et al.⁶</td>
</tr>
</tbody>
</table>


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

---

\(^1\) 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).
Rationale for TX-001HR

**Target Goals**

- Meet patient demand for bio-identical hormones
- Meet FDA requirements for safe, effective, and clinically validated products
- New lower effective dose
- Labeling differentiation

**Preliminary Supportive Data**

- Potential for first and only FDA-approved natural estradiol plus natural progesterone combination softgel capsule
- Multiple FDA guidance documents released about unsafe use of compounded hormones
- Broad range of doses being evaluated in Phase 3 Replenish Trial
- Potential bio-identical terminology as both hormones similar to those produced by the ovary
TX-001HR Estradiol + Progesterone U.S. Development Timeline

- **Phase 3 Trial**: ~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%

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

---

Total HT Market = 38+MM Prescriptions

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

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)

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

<table>
<thead>
<tr>
<th>Products</th>
<th>Separate E+P</th>
<th>Activella® FemHRT® + Progestins</th>
<th>Generic 17β Progestins</th>
<th>Prempro® Premphase®</th>
<th>Duavee®</th>
<th>Brisdelle®</th>
<th>Compounded E+P</th>
<th>TX – 001HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio-Identical</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Safety Data with Endometrial Cancer Data</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Combination</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>FDA-Approved</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Market Size</td>
<td>$520MM</td>
<td>$28MM</td>
<td>$218MM</td>
<td>$302MM</td>
<td>$30MM</td>
<td>$38MM</td>
<td>$4.5B²</td>
<td>---</td>
</tr>
</tbody>
</table>

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.

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.

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.

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.


All symbols trademarks of CVS/Caremark, Express Scripts, Optum, Tricare, and CMS
Compounded BHT Market Represents Significant Opportunity for First FDA-Approved Product

30MM^2
Annual custom-compounded prescriptions

$49\textsuperscript{1}
Average monthly cash cost

$1.5B
Current Annual Revenues

30MM^2
Annual branded prescriptions

$150\textsuperscript{4}
Average net monthly branded cost

$4.5B
Potential Future Annual Market Opportunity

2. Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA Approved MHT Has Increased
4. $150 average net monthly cost based on WAC, net of rebates/discounts, of existing FDA-approved hormone therapy combination products
Regulatory Environment Continues to Favor FDA-Approved Products

October 2012
Contaminated compounded drugs made at NECC kill 77 people nationwide

2014
Creation of “Do Not Compound” list and established Pharmacy Compounding Advisory Committee

2016
USP-800 finalized, addressing hazardous drugs including hormones

July 2018
Final implementation of USP-800

November 2013
Congress enacted Drug Quality and Security Act (DQSA)

2015
Initiated formation of “Difficult to Compound” list, including addition of hormones

July 2016
Released draft guidance documents, outlining protocol for commercially available drugs and unsanitary conditions

3) https://www.ascp.com/sites/default/files/Joint%20USP%20letter%202015%20FINAL.pdf
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 Drugs²,³
- 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

³) https://www.ascp.com/sites/default/files/JoinUSPLetter%202015%20FINAL.pdf
Compounding Pharmacies Need An FDA-Approved Product

<table>
<thead>
<tr>
<th>Compounded BHT</th>
<th>TX-001HR (if approved)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Third-Party Reimbursement</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Required Capital Expenditure to Dispense</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Manufacturing and Compliance Investment</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Legal &amp; Regulatory Risk</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

- Higher Revenues
- Lower Costs
- Increased Profits
**TX-001HR Could Fulfill Therapeutic Gap For All Participants**

<table>
<thead>
<tr>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Meet demand for natural bio-identical hormone therapy</td>
</tr>
<tr>
<td>• Assurance of safety and efficacy</td>
</tr>
<tr>
<td>• Reduction of out-of-pocket costs via insurance coverage</td>
</tr>
<tr>
<td>• Convenience of one combination product</td>
</tr>
<tr>
<td>• Widely acceptable at all pharmacies and not just compounding pharmacies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>• First and only FDA-approved bio-identical combination hormone therapy</td>
</tr>
<tr>
<td>• Clinically validated dose regimens</td>
</tr>
<tr>
<td>• Eliminates risks of compounded hormone therapy</td>
</tr>
<tr>
<td>• Meet patient demands and reduce patient out-of-pocket costs via insurance coverage</td>
</tr>
<tr>
<td>• Follow medical standards of care and society guidelines while reducing liability</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Meet patient and physician demand for bio-identical hormone therapy</td>
</tr>
<tr>
<td>• Significantly improve net margin per script</td>
</tr>
<tr>
<td>• Lower legal and regulatory costs and risk</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FDA/Regulatory Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reduces need of compounded hormone products</td>
</tr>
<tr>
<td>• Full enforcement of regulations regarding compounded hormones</td>
</tr>
<tr>
<td>• Reduces false claims and misleading advertising statements about compounded HT products</td>
</tr>
</tbody>
</table>
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.
TXMD: Financial Snapshot

- **Listing Exchange**: TXMD
- **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.
THANK YOU!
Appendix
Seasoned Management Team with a Proven Track Record of Commercial Execution

- 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

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

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

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

- 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

- 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®

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

- 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

- 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
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