

Annovera™

FDA Approval Conference Call

August 13, 2018



TherapeuticsMD®

For Her. For Life.

TherapeuticsMD.com

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.

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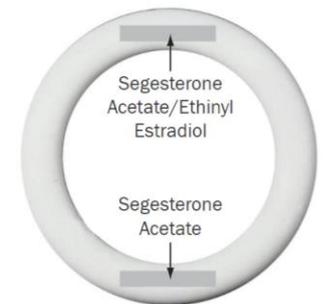
TX-001HR, TX-005HR, and TX-006HR are investigational drugs and are not approved by the FDA. This non-promotional presentation is intended for investor audiences only.

Annovera - 1-Year Vaginal System

Segesterone Acetate [Nestorone[®] (NES)]/Ethinyl Estradiol (EE)

First and only **patient-controlled, procedure-free, long-acting, reversible** birth control

- Product fits into existing TXMD infrastructure
 - **Approved: August 10, 2018**
 - **Segesterone acetate component of Annovera expected to be classified as NCE with 5 year exclusivity**
- Developed by the Population Council – developer of multi-billion dollar products
 - ParaGard[®] and Mirena[®] IUDs; Norplant[®] and Jadelle[®] implants; and Progering[®]
 - Funded by several organizations, including: Bill & Melinda Gates Foundation, US National Institutes of Health, USAID and The Population Council
- The ring system is composed of a “squishy” silicone elastomer
 - 21/7 days cyclical dosing regimen
 - 89% overall patient satisfaction in clinical trials¹
- Average daily release over one year of use:
 - 0.15 mg/day segesterone acetate
 - 0.013 mg/day ethinyl estradiol
- Nestorone: progesterone derived unique progestin²
 - High progestational potency and antiovolatory activity
 - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses



¹ Merkatz, Ruth B., Marlena Plagianos, Elena Hoskin, Michael Cooney, Paul C. Hewett, and Barbara S. Mensch. 2014. "Acceptability of the Nestorone[®]/ethinyl estradiol contraceptive vaginal ring: Development of a model; implications for introduction," *Contraception* 90(5): 514–521.

² Narender Kumar, Samuel S. Koide, Yun-Yen Tsoong, and Kalyan Sundaram. 2000. "Nestorone: a Progestin with a Unique Pharmacological Profile," *Steroids* 65: 629-636

Clinical Trial Experience

Efficacy & Safety^{1,2}

- **Based on two pivotal Phase 3 clinical trials with 2,308 women**
 - Efficacy and safety consistent with other birth control pills, patches and hormonal rings
- **Efficacy**
 - 97.3% effective in preventing pregnancy when used as directed
 - Primary Endpoint Pearl Index was 2.98 per 100 woman-years
 - Consistent with all other combination hormone birth control pills, patches and other rings
- **Safety**
 - Class labeling for combination hormonal contraceptives (CHCs)
 - All CHCs carry the boxed warning about cigarette smoking and serious cardiovascular events, particularly for women over age 35
 - The risk profile is consistent with other CHCs
 - The most common adverse reactions include headache, nausea/vomiting, vulvovaginal mycotic infections, abdominal pain, dysmenorrhea, vaginal discharge, UTIs, among others
 - Consistent with other CHC products the most common adverse reactions leading to discontinuation were:
 - Irregular bleeding (1.7%), headache (1.3%), vaginal discharge (1.3%), and nausea/vomiting (1.2%)

¹ www.annovera.pi.pdf

²Data with respect to the Phase 3 clinical trials

Phase 3 Acceptability Study

Demonstrated 1-Year Contraceptive Vaginal System High User Satisfaction

Acceptability Data¹

- Phase 3 acceptability study (n=905 subjects)
- Overall satisfaction 89% related to ease of use, side effects, expulsions/feeling the product, and physical effect during sexual activity
- High rates of adherence and continuation

Ease of inserting (N=905)	Ease of removing (N=905)	Ease of remembering CVR insertion (N=905)	Ease of remembering CVR removal (N=905)	No side effects reported on questionnaire (N=905)
90.8% (n=823)	88.2% (n=798)	87.6% (n=793)	85.2% (n=771)	81.8% (n=740)

¹Merkatz, Ruth B., Marlena Plagianos, Elena Hoskin, Michael Cooney, Paul C. Hewett, and Barbara S. Mensch. 2014. "Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: Development of a model; implications for introduction," *Contraception* 90(5): 514–521.

³http://www.merck.com/product/usa/pi_circulars/n/nuvaring/nuvaring_ppi.pdf

Annovera Deal Terms

Milestone Payments

- Upon FDA approval: \$20mm
- First commercial batch release: \$20mm
- \$200mm in cumulative net sales: \$40mm
- \$400mm in cumulative net sales: \$40mm
- \$1b in cumulative net sales: \$40mm

Royalty %

Step structure:

- Annual net sales \leq \$50mm: 5%
- Annual net sales $>$ \$50mm and \leq \$150mm: 10%
- Annual net sales $>$ \$150mm: 15%

Additional Cost Considerations

- TXMD and Population Council jointly responsible for one observational PMR study*

*Costs exceeding \$20mm to be shared with Population Council

NuvaRing – Large Established Ring Market

- NuvaRing Owner: Merck
- **\$500mm+ net sales in US ring market with no other branded products in the space***
- NuvaRing monthly contraceptive ring (vs. Annovera 1-year ring)
 - Annual WAC Price of \$2,013 (vs. \$1,400)
 - Semi-rigid ring body (vs. pliable/squishy)
 - Monthly visit to pharmacy (vs. one annual visit)
- 2 NuvaRing generics expected in 2019

(Dollars in Millions)

	Year End December 31,				
	2013A	2014A	2015A	2016A	2017A
NuvaRing Net Revenue*	\$426	\$461	\$515	\$576	\$564
<i>market growth</i>		8.2%	11.7%	11.8%	-2.1%
NuvaRing Scripts*	4.7	4.6	4.4	4.5	4.3
<i>script growth</i>		-1.4%	-4.8%	1.1%	-3.6%

*Symphony Health Solutions PHAST Data powered by IDV. Net sales as reported in company filings.

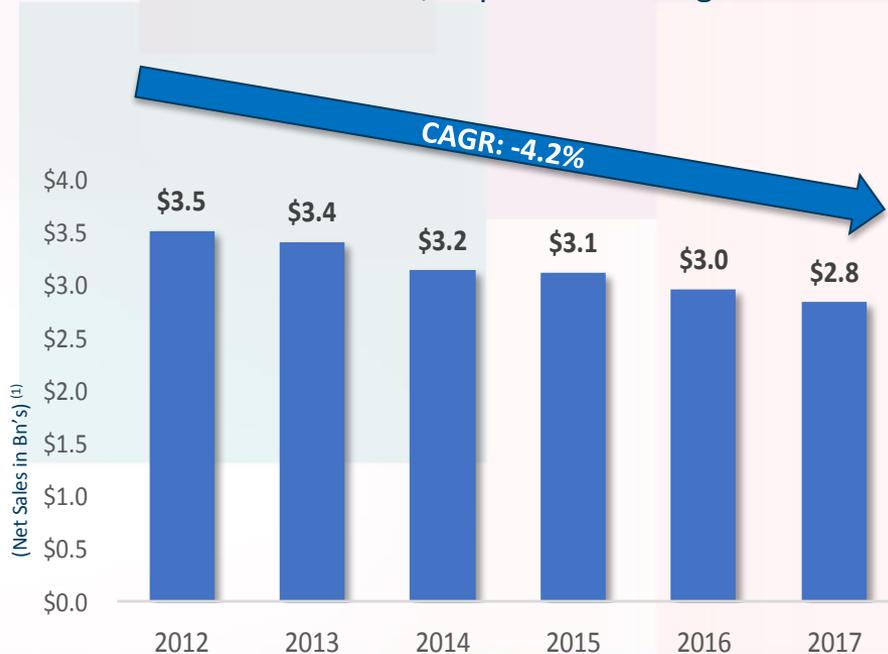
U.S. Prescription Contraceptive Market

U.S. Contraceptive Market

- One of the largest therapeutic categories by script count
- ~ 90mm scripts¹
- ~ > \$5B U.S. net sales²
- ~ 43 million women are at risk of unintended pregnancy of which ~ 18 million want to avoid pregnancy³

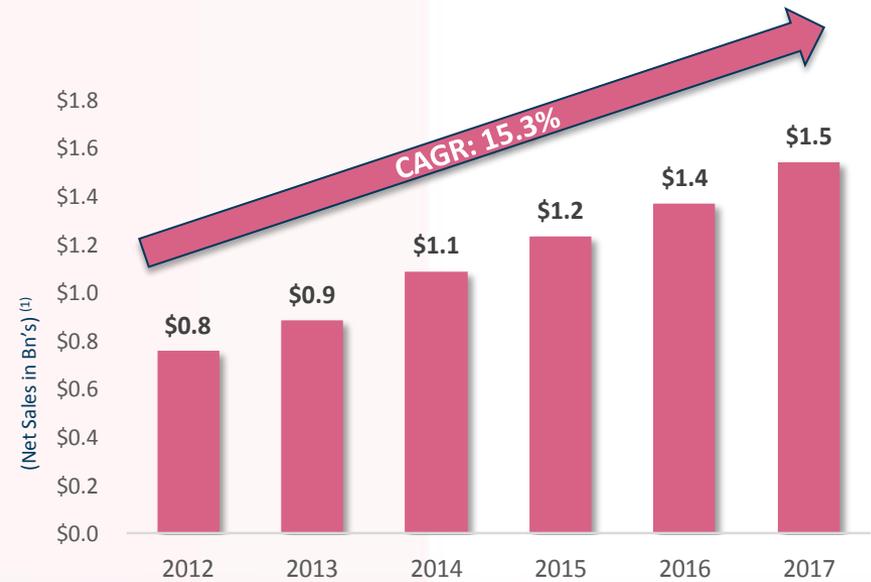
Daily Oral Contraceptives

- OC's continue to lose market share to longer acting solutions such as IUDs, Implants and Rings



Long Acting Reversible Contraceptives

- IUDs and Implants are experiencing significant growth as the market shifts towards long-acting solutions



¹ IQVIA Total Patient Tracker database; Annual 2017

² IQVIA 2017, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family, reported in company filings.

³ Contraceptive Use in the United States, Guttmacher, July 2018.

Expected Benefits of 1-Year Vaginal Contraceptive System

Patients

- Long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
- Softer and more pliable than NuvaRing and doesn't require refrigeration
- "Vaginal System"- a new class of contraception with potential for \$0 co-pay
- Acceptable for all indicated women including nulliparous women and women who are not in a monogamous relationship*
- Empowers women to be in complete control of their fertility and menstruation
- Available with a single annual pharmacy visit

Healthcare Providers

- A long-acting reversible birth control option that doesn't require a procedure
- No requirement to buy, hold and manage inventory
- Acceptable for nulliparous women and women not in a monogamous relationship*
- Satisfies patients' desire to be in control of their fertility and menstruation

Unique Product Characteristics Should Lead to Good Payor Coverage

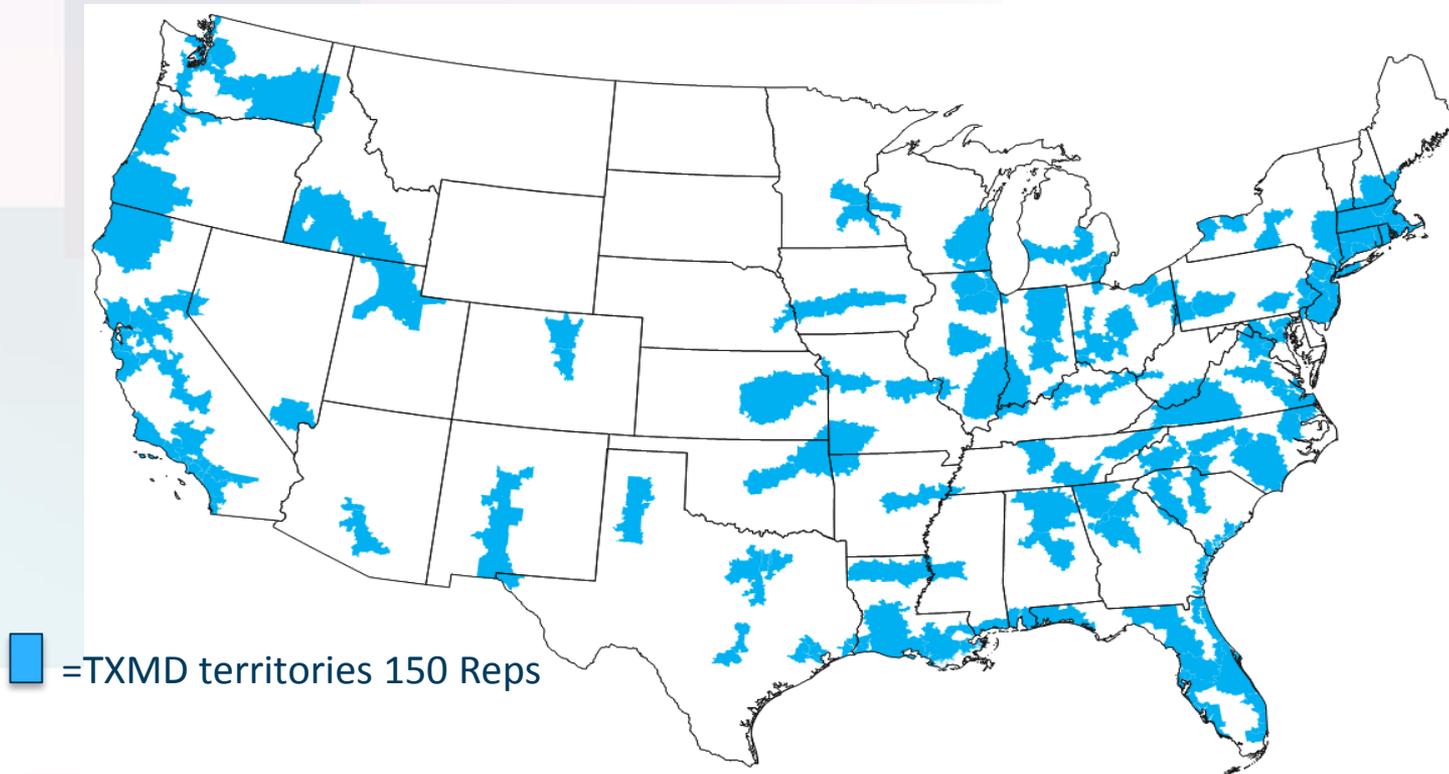
- Anticipate parity or discount pricing level ~\$1400 annual WAC cost
 - 40% decrease to annual WAC of NuvaRing, reflects TXMD's responsible brand pricing
 - Allows for improved patient adherence and a potential decrease in unplanned pregnancies
 - Only one pharmacy fill fee per year (estimated savings of \$33 annually)
 - No repeat office visit or procedure fees (several hundred dollars)
 - Contains ethinyl estradiol and Nestorone[®], a new and unique progestin
 - "Vaginal System"- a new class of contraception with potential for \$0 co-pay

The Affordable Care Act (ACA) mandates that private health plans provide coverage for one treatment per class of contraception used by women with no patient out-of-pocket costs

TXMD Sales Force Has Strong Overlap With NuvaRing Prescribers

NuvaRing Prescribers Overlap with TXMD Sales Force¹

- 81% of total prescribers within current 150 TXMD territories
- No additional sales representatives needed



Commercialization Strategy & Timing

Focused Launch Strategy - Base Case Market Opportunity

- NuvaRing customers – monthly ring replaced by annual ring
- ~60K annual vitaMedMD prenatal customers who may proceed to contraception
- Patients who prefer long acting reversible contraception but fear procedures
- Healthcare providers who prefer long acting reversible contraception but forgo due to procedures and cost of procurement
- Nulliparous women and those who are not in a monogamous relationship who desire long acting reversible contraception but discouraged from IUDs¹

Commercialization & Launch Timing

- Estimated to be commercially available as early as Q3'19 with commercial launch as early as Q4'19 to Q1'20
- Additional marketing team exclusively focused on Anovera anticipated
- TXMD to be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages, and any additional desired clinical studies (subject to oversight by the Joint Product Committee)

1. Lohr, et al. Use of intrauterine devices in nulliparous women. *Contraception* 95 (2017); 529-537

Contraceptive Pipeline



Exclusive rights to negotiate co-development and marketing rights¹

- 3 month ring using NES plus bio-identical Estradiol (E2) (Phase 2)
- 1 Year ring (NES/EE) life cycle management

1. TXMD has the option to co-develop and market in the US, if approved

Complete Women's Healthcare Portfolio



Anovera™

TX-001HR*

Imvexxy™
(estradiol vaginal inserts)
4 mcg • 10 mcg



**~60,000
New Prenatal
Patients**
*Many will go on
contraception after
breastfeeding*



**Vasomotor
symptoms affect
up to 75% of
perimenopausal
women¹**



PRENATAL CARE

**CONTRACEPTION/ FAMILY
PLANNING -PERIMENOPAUSE**

VASOMOTOR SYMPTOMS

**DYSPAREUNIA
(Vulvar & Vaginal Atrophy)**



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

*Investigational product, pending FDA approval

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4539866/>

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Q&A



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