UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 21, 2018

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

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

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230-405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on August 21, 2018 and at subsequent meetings with investors or analysts.

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

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Number	Description
99.1	TherapeuticsMD, Inc. presentation dated August 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 21, 2018

THERAPEUTICSMD, INC.

By: /s/ *Daniel A. Cartwright*
Name: Daniel A. Cartwright
Title: Chief Financial Officer

Exhibit 99.1


Investor
Presentation
August 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.

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: whether the FDA will approve the NDA for our TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; our ability to maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and one-year contraceptive vaginal system licensed product and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan agreement; the length, cost and uncertain results of our clinical trials; potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates or adversely affect the commercialization of our current or future approved products; the ability of our licensees to commercialize and distribute our product and product 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-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.

TherapeuticsMD, *A Premier Women's Health Company*

Annovera™ vitaMedMD Annovera™ TX-001HR* Imvexxy (estradiol vaginal inserts)

CONTRACEPTION → PRENATAL CARE → CONTRACEPTION/ FAMILY PLANNING - PERIMENOPAUSE → VASOMOTOR SYMPTOMS → DYSPAREUNIA (Vulvar & Vaginal Atrophy)

REPRODUCTIVE HEALTH

MENOPAUSE MANAGEMENT

*Investigational product, pending FDA approval

TherapeuticsMD®

For Her. For Life.

Seasoned Management Team with a Proven Track Record of Commercial Execution

Tommy Thompson
Chairman of the Board

- Former US 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 (US)
- Former EVP of Customer Marketing and Sales of US Human Health at Merck
- Holds multiple board memberships, including Catalent

Jane Barlow
Board Member

- 25 years of clinical and strategic healthcare experience
- Former Chief Medical Officer of CVS Health's Medicare and Government Services
- Former Vice President of Clinical Innovation at MEDCO Health Solutions

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
Co-Founder and Director

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

John Milligan
President

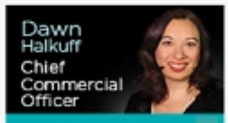
- Co-founded CareFusion
- Held executive sales and operation management positions at McKesson, Cardinal, and Omnicell
- 20+ years of operations experience

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

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



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

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®

Christian Bloomgren
VP, Sales

- 16+ years of experience in the pharmaceuticals and biotech
- Created a national sales channel, led the Specialty Diagnostics business at ViaCell, Inc.
- Product launch and sales management roles at Eli Lilly & Company and KV Pharmaceutical

Insiders own approximately ~21% of total outstanding shares

TherapeuticsMD®
For Her. For Life.

Women's Health Assets With Large Total Addressable Market Opportunities

	Annovera™	TX-001HR	Imvexxy™
Indication	Females to prevent pregnancy	Moderate to severe vasomotor symptoms (VMS) due to menopause*	Moderate to severe dyspareunia, a symptom of VVA, due to menopause
Condition Description	Contraception	VMS due to Menopause	VVA due to Menopause
Active Ingredients	Segesterone Acetate/ Ethinyl Estradiol	Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone	Bio-Identical 17 β-Estradiol
Form	Vaginal System	Oral softgel capsule	Vaginal softgel insert
Key Value Proposition	First and only patient-controlled, procedure-free, long-acting, reversible birth control product	Potential first and only bio-identical FDA-approved combination product	Easy to use, lowest effective dose, designed to support patient adherence
Affected US Population	43 million women[1]	36 million women[3]	32 million women[5,6]
US TAM Opportunity	$5B[2]	>$25B[4,7]	>$20B[7]
Status	Approved Aug. 10, 2018 Commercial Launch: Est. 4Q19-1Q20	PDUFA Target Action Date: Oct. 28, 2018	Approved May 29, 2018 Commercial Launch: August 2018

* Potential indication; pending FDA approval

1) Contraceptive Use in the United States, Guttmacher, July 2018. ICUTA Patient Tracker.
2) QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.
3) Derived from U.S. Census data on women in the age group who normally experience symptoms.
4) Based on pre-WHI annual scripts of FDA-approved HT products.
5) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.
6) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160-1171.
7) Based on market pricing of current FDA-approved HT products.

TherapeuticsMD®
For Her. For Life.


Annovera™
(Segesterone Acetate/Ethinyl Estradiol Vaginal System)
The first FDA-approved long-acting prescription birth control that is patient-controlled, procedure-free and reversible
TherapeuticsMD®
For Her. For Life.
6

Annovera - 1-Year Vaginal System

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

- Annovera approved on 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 long acting contraceptive products
  - **ParaGard®** and **Mirena®** IUDs**; Norplant®** and **Jadelle®** implants; and **Progering®**
- Benefits
  - Increase compliance over short acting products
  - Offer women a long-term birth control option without requiring a procedure for insertion and removal like IUDs or Implants
  - Allow women who haven't had a child (nulliparous) or are not in a monogamous relationship - who are often counseled against IUDs due to the potential risk of infertility - access to long-term reversible birth control

[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 Tsong, and Kalyan Sundaram. 2000. *"Nestorone: a Progestin with a Unique Pharmacological Profile,"* Steroids 65: 629-636

TherapeuticsMD®
For Her. For Life.

Annovera - 1-Year Vaginal System

Segesterone Acetate [Nestorone®]/Ethinyl Estradiol

- The vaginal system is composed of a "squishy" silicone elastomer
  - 21/7 days cyclical dosing regimen for one year (13 cycles)
  - 89% overall patient satisfaction in clinical trials[1]
- Average daily release over one year of use:
  - 0.15 mg/day segesterone acetate
  - 0.013 mg/day ethinyl estradiol
- Nestorone: progesterone derived unique progestin[2]
  - High progestational potency and anti-ovulatory activity
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Strong safety and efficacy data
- High patient satisfaction and acceptability

[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 Tsong, and Kalyan Sundaram. 2000. *"Nestorone: a Progestin with a Unique Pharmacological Profile,"* Steroids 65: 629-636

TherapeuticsMD®

For Her. For Life.

Clinical Trial Experience

Efficacy & Safety[1]

- **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**
  - Highly efficacious in preventing pregnancy when used as directed (97.3%)
    - Primary Endpoint Pearl Index was 2.98 per 100 woman-years
    - Consistent with all other combination hormone birth control pills, patches and 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
  - 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] http://annovera.com/pi.pdf

TherapeuticsMD®
For Her. For Life.

Phase 3 Acceptability Study

Demonstrated 1-Year Contraceptive Vaginal System High User Satisfaction

Acceptability Data[1]

- 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 (94.3%) and continuation (78%)

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)

[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.

TherapeuticsMD®

For Her. For Life.

Annovera Key Clinical Attributes

Clinical Attributes

- Only FDA approved long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
  - Empowers women to be in complete control of their fertility and menstruation
  - Annovera is the only user-directed single 12-month birth control product
- Highly effective in preventing pregnancy when used as directed (97.3%)
- High patient satisfaction in clinical trials[1] (89% overall satisfaction)
- Low daily release of ethinyl estradiol (13 mcg)
- Only product with new novel progestin - segesterone acetate[2]
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Favorable side effect profile including low rates of discontinuation related to irregular bleeding (1.7%)
- Safety profile generally consistent with other CHC products, including boxed warning

Physical Attributes

- Softer and more pliable than NuvaRing
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship[3]
- "Vaginal System" – the only product in a new class of contraception with potential for $0 co-pay
- Cost and convenience (pharmacy and doc visits)
- Does not require refrigeration by HCP

[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 Tsong, and Kalyan Sundaram. 2000. *"Nestorone: a Progestin with a Unique Pharmacological Profile,"* Steroids 65: 629-636
[3] Lohr, et al. Use of intrauterine devices in nulliparous women. Contraception 95 (2017); 529-537

TherapeuticsMD®
For Her. For Life.

U.S. Prescription Contraceptive Market

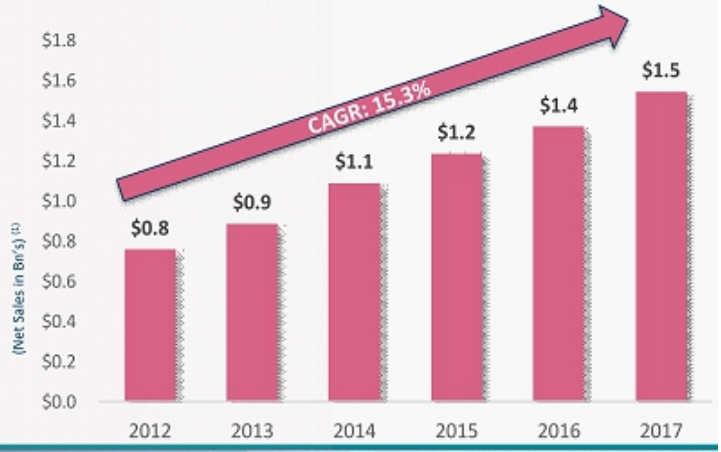
- One of the largest therapeutic categories by script count
- ~ > $5B U.S. net sales[1]

Daily Oral Contraceptives

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

Long Acting Reversible Contraceptives

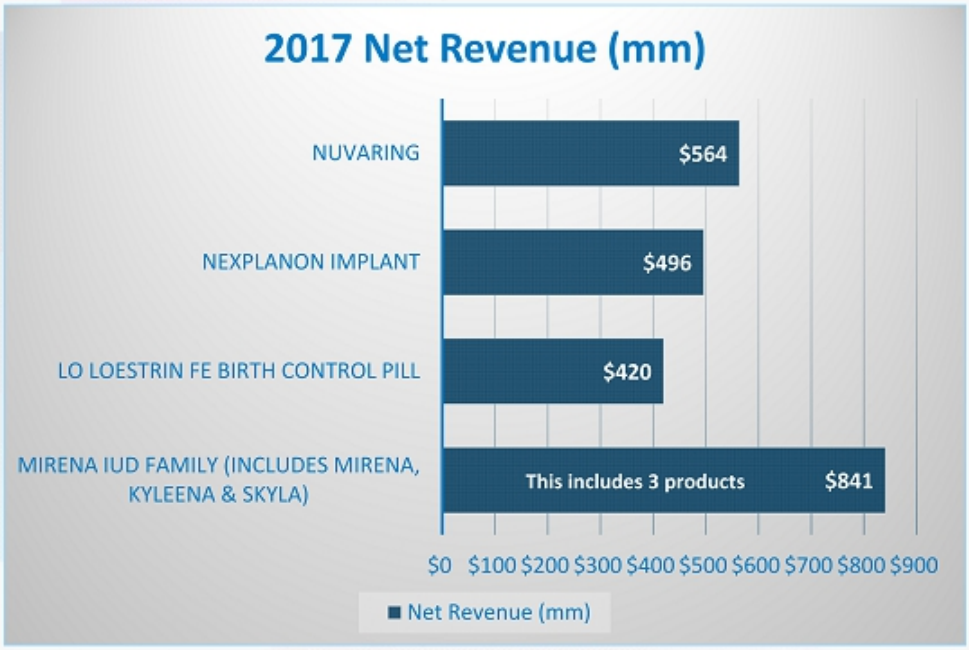
- *IUDs and Implants are experiencing significant growth as the market shifts towards long-acting solutions*



[1] IQVIA 2017, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family,Paragard and Liletta. Net sales as reported in company filings.

TherapeuticsMD®
For Her. For Life.

Top Contraceptive Products Based on Revenue



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

TherapeuticsMD®
For Her. For Life.

Large Established Ring Market

Annovera compared to existing NuvaRing and potential NuvaRing generic

- 1-year duration (vs. monthly)
- Soft, pliable, squishy (vs. semi-rigid ring body)
- 89% overall patient satisfaction in clinical trials[1]
- High rates of adherence (94.3%) and continuation (78%)[1]
- New/Lower hormones
  - New progestin segesterone acetate (vs. etonogestrel)
    - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses[2]
  - 13 mcg ethinyl estradiol (vs. 15 mcg)
- No monthly hormonal burst from each new NuvaRing placed
- No refrigeration required by HCP
- Low discontinuation rates[3]
  - Annovera: Irregular bleeding 1.7%, headache/migraine 1.3%, vaginal discharge/infections 1.3%, nausea/vomiting 1.2%
  - NuvaRing: Device-related events 2.7%, mood changes 1.7%, headache (including migraine) 1.5% and vaginal symptoms 1.2%
- Less expensive ~$1,400 for Annovera vs. $2,013 for NuvaRing based on annual WAC price
- "Vaginal System"- a new class of contraception with potential for $0 co-pay
- NuvaRing no longer actively promoted

[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(S): 514–521.
[2] Narender Kumar, Samuel S. Koide, Yun-Yen Tsong, and Kalyan Sundaram. 2000. *"Nestorone: a Progestin with a Unique Pharmacological Profile,"* Steroids 65: 629-636
[3] Based on product Prescribing Information; not a head to head comparison

TherapeuticsMD®
For Her. For Life.

Unique Product Characteristics Should Lead to Good Payor Coverage

- Anticipate parity or discount pricing level ~$1,400 annual WAC cost
  - 30% 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 per patient)
  - No repeat office visit or procedure fees (several hundred dollars per patient)
  - 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

1-Year Vaginal Contraceptive System Serves an Unmet Need in the U.S. Contraceptive Market

	Annovera™	NuvaRing®	IUD's	Oral Contraceptives
Duration of Action	✓ 1 year (21/7 regimen)	× 1 month (21/ 7 regimen)	✓ 3-10 years	× Daily pill intake
Patient Control	✓ Removable at any time	✓ Removable at any time	× Procedure required	✓ Stop at any time
Nulliparous Women	✓ Yes	✓ Yes	× Not universally acceptable	✓ Yes
Product Administration	✓ Patient administered pliable ring	✓ Patient administered Semi-rigid ring	× Physician in-office procedure	✓ Oral intake
Patient Convenience	✓ 1 doctor's visit, 1 pharmacy visit per year	× Monthly pharmacy visit	× Physician in-office procedure HCP stocking required	× Daily pill presents compliance/adherence risks; potential increase in unplanned pregnancies
Healthcare Provider Convenience	✓ Filled at pharmacy; No refrigeration; No inventory or capital outlay	✓ Filled at pharmacy; Refrigeration required prior to being dispensed	× HCP required to hold inventory	✓ Filled at pharmacy
Cost	✓ $1,400 WAC	× $154.89/28 days, or 1 year cost of $2013.57 (13 rings/year)	✓ $909 WAC + insertion and removal costs (good for 5 years)	× Lo Loestrin® Fe $128.51/28 days, or 1 year cost of $1,670.63 (13/year)
Contraceptive Class	Vaginal System	Vaginal Ring	IUD	Oral

- ✓ 89% overall patient satisfaction in clinical trials, 94% adherence rate, 78% continuation rate
- ✓ "Vaginal System"- potential for a new class of contraception with $0 co-pay
- ✓ Segesterone acetate component of Annovera expected to be classified as NCE with 5 year exclusivity

Chart comparisons for product characteristics only and are not intended to imply safety or efficacy comparisons

TherapeuticsMD®

For Her. For Life.

Commercialization Strategy

Launch Timing

- Estimated to be commercially available as early as Q3'19 with commercial launch as early as Q4'19 to Q1'20

Attractive Market Segments for Annovera

- NuvaRing users – leveraging the physical and clinical strengths of Annovera
  - No additional sales representatives needed
  - 81% of total prescribers within current 150 TXMD territories[1]
- Women who want long-acting reversible contraception but don't want a procedure
- Providers that that do not want to purchase and manage inventory of IUDs and Implants
- Women who haven't had a child (nulliparous) or are not in a monogamous relationship and want long-term contraceptive options

[1] IQUVIA Data

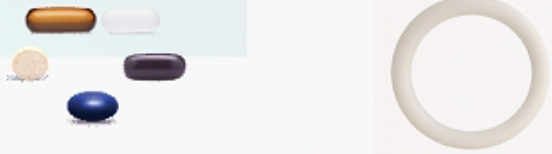
Complete Women's Healthcare Portfolio

vitaMedMD® | Annovera™ | TX-001HR* | Imvexxy® (estradiol vaginal inserts)

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

Vasomotor symptoms affect up to 75% of perimenopausal women[1]

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/

TherapeuticsMD®

For Her. For Life.

Contraceptive Pipeline

Exclusive rights to negotiate co-development and marketing rights[1]

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

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

TherapeuticsMD®
For Her. For Life.

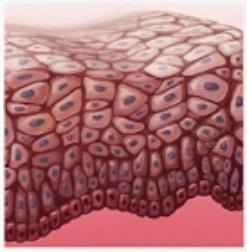

Imvexxy™
(estradiol vaginal inserts)
4 mcg • 10 mcg
Approved for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.
Vulvar and Vaginal Atrophy (VVA) Program
TherapeuticsMD®
For Her. For Life.
20

Vulvar and Vaginal Atrophy (VVA)

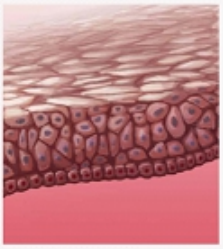
- A component of genitourinary syndrome of menopause (GSM)
- **Chronic** and **progressive** condition that results from decreased estrogen levels characterized by thinning of vaginal tissue
- Diagnosed in approximately **50%** of postmenopausal women[1]
- Primary symptom = dyspareunia (painful intercourse)
- Secondary symptoms include: vaginal dryness, itching, irritation, bleeding with sexual activity, dysuria, urgency, frequency, recurrent UTIs, and incontinence
- Current treatments include: prescription hormone creams, tablets, and rings in addition to over-the-counter lubricants

HEALTHY VAGINAL TISSUE

- **Thick**
- **Moist**
- **High estrogen level**
- **Low pH (<5)**
- **Increased superficial cells (>15%)**
- **Decreased parabasal cells (<5%)**



ATROPHIC VAGINAL TISSUE



- **Thin**
- **Dry**
- **Low estrogen level**
- **High pH (>5)**
- **Decreased superficial cells (<5%)**
- **Increased parabasal cells (>30%)**

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

TherapeuticsMD®
For Her. For Life.

Professional Societies and FDA Recommend the Lowest Effective Dose

American College of Obstetricians and Gynecologists (ACOG)[1]

"Low-dose and ultra-low systemic doses of estrogen may be associated with a better adverse effect profile than standard doses and may reduce vasomotor symptoms in some women."

North American Menopause Society (NAMS)[2]

"The lowest dose of HT should be used for the shortest duration needed to manage menopausal symptoms. Individualization is important in the decision to use HT and should incorporate the woman's personal risk factors and her quality-of-life priorities in this shared decision."

FDA[3]

"…this guidance encourages sponsors to develop the lowest doses and exposures for both estrogens and progestins for indications sought, even though specific relationships between dose, exposure, and risk of adverse events may not be known."

References: 1. ACOG Practice Bulletin No. 141: management of menopausal symptoms. *Obstet Gynecol.* 2014;123(1):202-216. **2.** The North American Menopause Society. Clinical care recommendations chapter 8: prescription therapies. http://www.menopause.org/publications/clinical-care-recommendations/chapter-8-prescription-therapies. Accessed March 8, 2018. **3.** Food and Drug Administration. Guidance for Industry – Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071643.pdf. Published January 2003. Accessed March 8, 2018.

TherapeuticsMD®
For Her. For Life.

Imvexxy is "Redefining Relief"

Owning clinical attributes with the underpinning of a highly effective patient experience

Key Clinical Attributes:

1	New lowest effective dose
2	Strong efficacy and safety data
3	Improvement seen at week 12 (primary) and as early as 2 weeks (secondary)
4	PK data where systemic hormone levels remain within normal postmenopausal range

Key Physical Attributes:

5	Ease of use and absence of applicator
6	Ability to be used any time of day
7	A mess-free way to administer
8	Dose packaging to optimize patient compliance and enhance provider and patient acceptance

TherapeuticsMD®
For Her. For Life.

Current FDA-Approved VVA Products

Local estrogen therapy currently represents over 95% market share in the VVA market

- Current standard of care per medical society guidelines
- Current poor compliance within the class
- Imvexxy is the new lowest effective dose with potential for improved compliance

30-day WAC Maintenance dose pricing $180 for IMVEXXY

- Near parity w/ Vagifem ($170.16) & less than newest entrants Intrarosa ($198.75), Osphena ($203.80)

Product	Estrace® Cream (estradiol vaginal cream, USP, 0.01%)[1]	Premarin Cream® (conjugated estrogens)[2]	Estring® (estradiol vaginal Ring)[3]	Vagifem® (estradiol vaginal inserts)[4]	IMVEXXY (estradiol vaginal inserts)[5,6]	Intrarosa® (prasterone vaginal inserts)[7]	Osphena® (ospemifene tablets)[8]
							
	Allergan	Pfizer	Pfizer		TherapeuticsMD	amag	DUCHESNAY USA
FDA approval	1984	1978	1996	1999	2018	2016	2013
Active Ingredient	100µg estradiol	625 µg conjugated equine estrogens	2,000 µg estradiol	10µg estradiol	4 µg or 10 µg estradiol	6,500 µg prasterone	60,000 µg ospemifene
TRx Dollars 2017[9]	$583,612,698	$533,386,029	$120,499,734	$525,321,410	-	$4,187,571	$75,683,654
Method of administration	Vaginal Cream	Vaginal Cream	Vaginal Ring	Tablet Vaginal Insert	Softgel Vaginal Insert	Vaginal Insert	Oral Tablet
WAC package price (2018)[10]	$314.87 (42.5-g tube)	$355.77 (30-g tube)	$431.34 (1 ring)	$170.16 (8 tablets)	$180.00 (8 inserts)	$185.50 (28 inserts)	$611.39 (90 tablets)
Calculated WAC 30-day supply (2018)[10]	$104.96	$118.59	$143.78	$170.16	$180.00	$198.75	$203.80

Local Vaginal Estrogen > 95% Market Share

There have been no head-to-head trials between IMVEXXY and any of the products listed above.
All trademarks are the property of their respective owners.
Abbreviations: WAC, wholesale acquisition cost.

References: 1. Estrace Vaginal Cream [package insert]. Irvine, CA: Allergan USA, Inc.; 2017. **2.** Premarin Vaginal Cream [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.; 2017. **3.** Estring [package insert]. New York, NY: Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc.; 2017. **4.** Vagifem [package insert] Plainsboro, NJ: Novo Nordisk Inc.; 2017. **5.** IMVEXXY [package insert] Boca Raton, FL: TherapeuticsMD, Inc.; 2018. **6.** Constantine GD, Simon JA, Pickar JH, et al. The REJOICE trial: a phase 3 randomized, controlled trial evaluating the safety and efficacy of a novel vaginal estradiol soft-gel capsule for symptomatic vulvar and vaginal atrophy. *Menopause*. 2017;24(4):409-416. **7.** Intrarosa [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2017. **8.** Osphena [package insert]. Florham Park, NJ: Shionogi Inc.; 2015. **9.** Symphony Health Solutions PHAST Data powered by IDV; Annual 2017 [a. 2017 Vagifem, Yuvafem (authorized generic of Vagifem), and Teva generic]. **10.** Price RX March 2018.

TherapeuticsMD®
For Her. For Life.

Favorable Payer Dynamics: No Substitution Across Branded Products

Case Study: Vagifem® Generics Launch

- Yuvafem launch in October 2016

	VVA TRx Market Share (%) Oct 2015-Sept 2016	VVA TRx Market Share (%) Oct 2016-April 2018	Gains (Losses)
Vagifem	29.7%	5.4%	-24.3%
Generic Estradiol Tablets (including Yuvafem and others)	-	24.4%	24.4%
Total	29.7%	29.8%	0.1%

- Yuvafem continues to take market share from **only** Vagifem
- No substitution or cannibalization of other branded products

Symphony Health Solutions PHAST Data powered by IDV
Vagifem and Yuvafem (authorized generic of Vagifem)

TherapeuticsMD®
For Her. For Life.

Prior Authorization Example in the VVA Class

- The majority of commercial payers do not require PA/ST for branded VVA treatments today[1]
- However, select payers require written PA and step-through one or two preferred products in select cases
  - Unlikely for Imvexxy to step-edit through a higher dose vaginal estrogen product
- Low dose vaginal estrogen remains frontline therapy

Example 1: PA Criteria for Osphena at Anthem[2]

8. APPROVAL CRITERIA: CHECK ALL BOXES THAT APPLY

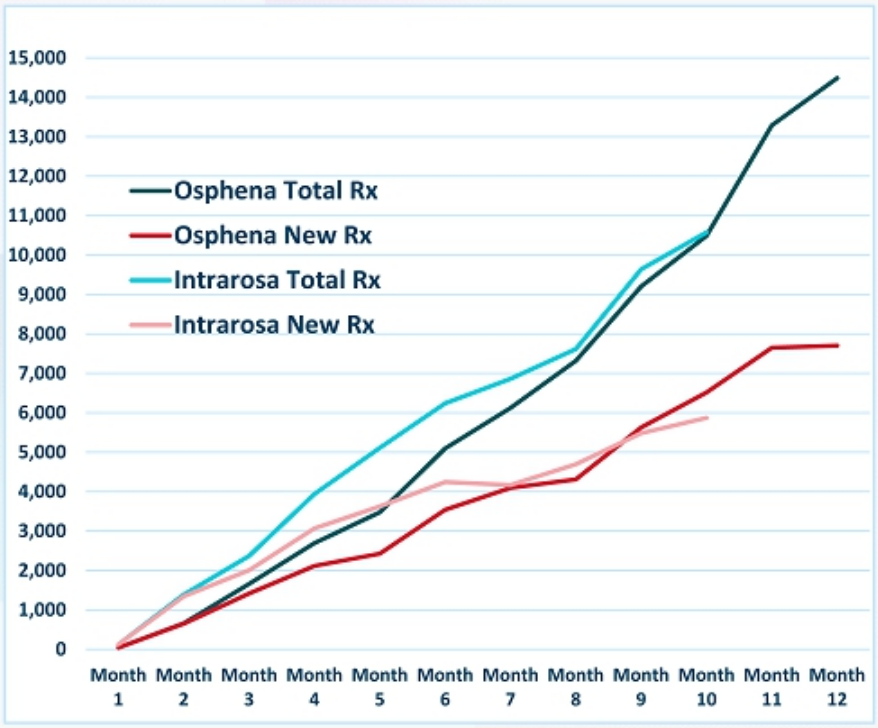
NOTE: Any areas not filled out are considered not applicable to your patient & MAY AFFECT THE OUTCOME of this request.

☐ Yes	☐ No	Patient is female
☐ Yes	☐ No	Patient has a diagnosis of moderate-to-severe dyspareunia due to vulvar and vaginal atrophy (VVA) associated with menopause
☐ Yes	☐ No	Patient has had a trial of, or insufficient response to one preferred vaginal estrogen product (that is, Premarin vaginal cream, Vagifem, or Femring)

References:
1. MMIT, May 2018
2. Anthem. https://www11.anthem.com/provider/noapplication/f0/s0/t0/pw_e213344.pdf?na=pharminfo

TherapeuticsMD®
For Her. For Life.

Recent VVA TRx Launch Trajectories Represent Reasonable Comparators for Imvexxy Launch in Year 1



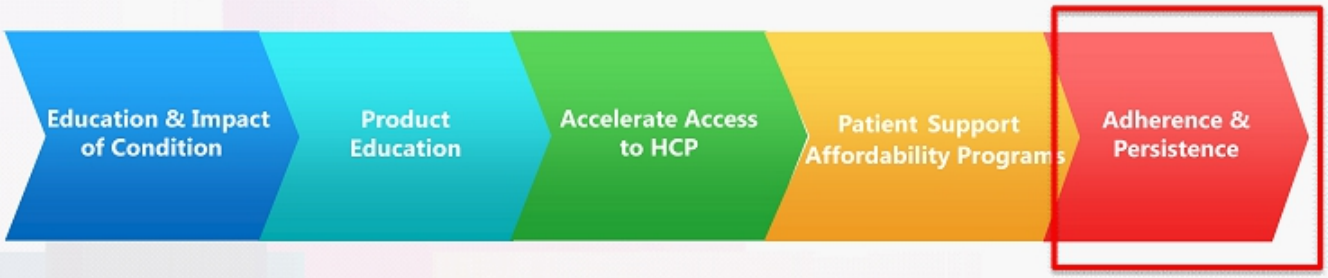
Rate Limited Factors in Year 1 that Impact Launch:

- ❑ Limited number of new women going onto therapy each year
- ❑ Number of women that switch to a new product year 1
- ❑ The impact of the above factors is reduced in years 2 and beyond

References:
1. PHAST Symphony

TherapeuticsMD®
For Her. For Life.

TXMD's Patient Engagement Programs for Adoption, Affordability & Adherence



- Developed over the past 6 years in an effort to improve the long term value of a patient through Education, Adherence and Co-Pay assistance
- TXMD utilizes standard pharmaceutical industry programs in a more coordinated and effective fashion – maximizing impact and results
- Program has achieved 78% utilization of the Co-Pay assistance program compared to an industry standard of 30%
- Created and piloted around the prenatal vitamin product line to enhance the launches of Imvexxy and TX-001HR (if approved)

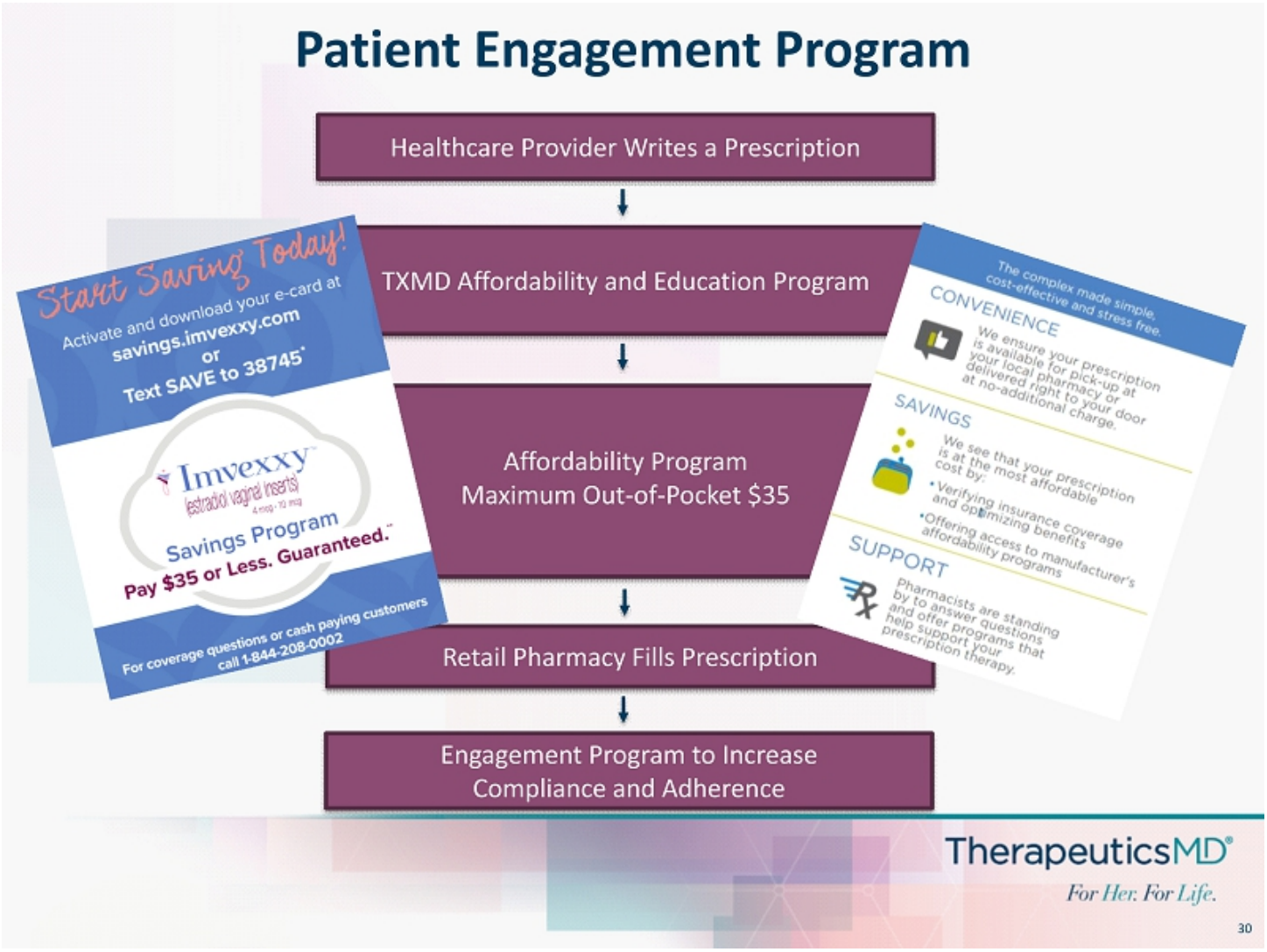
TherapeuticsMD®
For Her. For Life.

Results of TXMD Prenatal Vitamin Adoption & Adherence Programs

Patient Adherence	Prescriber Loyalty	Data Insights
Industry Avg: 2.5 of 9 months	Industry Avg: 30 prescriptions per physician per year	Industry Avg: 60 days
TXMD Avg: 7 of 9 months	TXMD Avg: 71 prescriptions per physician per year	TXMD Avg: Real time Data

TherapeuticsMD®
For Her. For Life.

Patient Engagement Program



TherapeuticsMD®

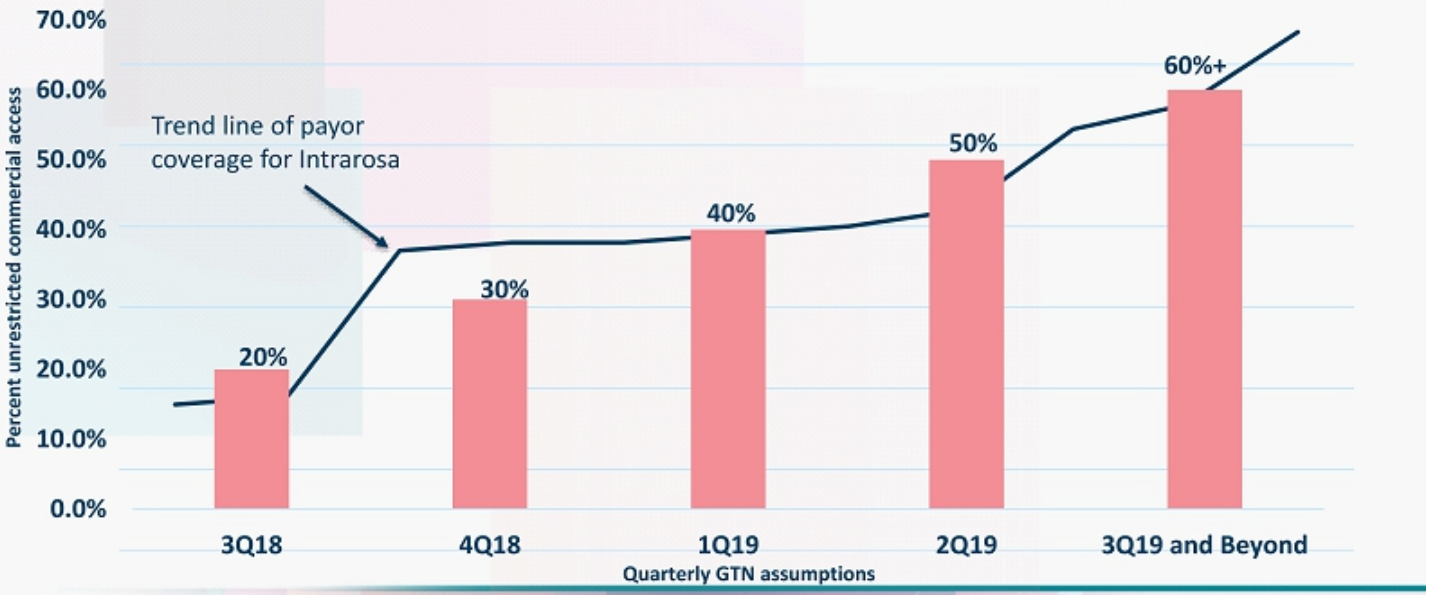
For Her. For Life.

Imvexxy Launch Quarterly Gross-to-Net Assumptions

- Already Achieved ~23% Unrestricted Commercial Coverage as of August 15, 2018
- Increase in GTN directly correlated to increase in commercial insurance coverage

Gross to Net Projections

3Q18	4Q18	1Q19	2Q19	3Q19 and beyond
20%	30%	40%	50%	60%+



References:
1. MMIT

TherapeuticsMD®
For Her. For Life.

Imvexxy Launch

- July 9, 2018 an early experience program with the 10 mcg dose of the Imvexxy monthly starter pack was sampled to a select group of healthcare providers (HCPs)
  - As of August 16, 2018
    - Over 1,700 HCPs started at least 1 patient on the sample starter pack and sent in a prescription for the maintenance pack
    - At least 2,400 patients have already received their first maintenance pack*
- Full national launch commenced August 6, 2018 for 10 mcg dose
- 4 mcg dose expected to be available September 10, 2018
- Bio-Ignite went live August 10, 2018 with 12 pharmacies ordering Imvexxy

*Based on utilization of our affordability programs

TherapeuticsMD®
For Her. For Life.


TX-001HR
Combination
Estrogen + Progesterone
(E+P) Program
TherapeuticsMD®
For Her. For Life.
33

TX-001HR Product Development Rationale

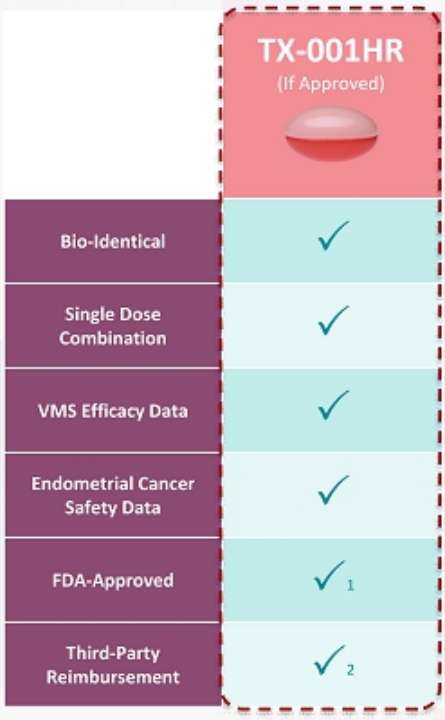
- **2002 Women's Health Initiative (WHI) study showed that the long-term use of certain *synthetic* hormones (a combination of medroxyprogesterone and conjugated equine estrogens) increased the risk of breast cancer, stroke, heart attack and blood clots** (all FDA-approved combination hormonal products contain a synthetic Progestin and not a bio-identical Progesterone)
- **2002 Post WHI, women and healthcare providers shifted to Bio-Identical Hormone Therapy (BHRT) containing bio-identical estradiol and bio-identical progesterone as an alternative despite being *unapproved* drugs that are *not covered by insurance***
  - Over 90M+ scripts of synthetic hormone therapy prescribed annually before 2002, declining to ~26M in 2015[1]
    - Today, patients have the choice between three therapies:
      - FDA-approved, **synthetic** combination hormones
      - FDA-approved, **separate** bio-identical hormone products
      - Unapproved, **compounded** bio-identical hormones that have not been proven safe and effective, or covered by insurance

- **Compounding filled the need for BHRT**
  - 30M scripts (3M women) of Compounded Bio-identical Hormone Therapy (CBHRT) prescribed annually in the U.S. currently[2,3]
- **All the major medical societies and the FDA discourage the prescribing of compounded hormones**
- **No FDA-approved BHRT bio-identical combination product of estradiol + progesterone**
- **If approved, TX-001HR would become the first and only FDA-approved bio-identical combination product to fill this unmet need**

1) Symphony Health Solutions PHAST Data powered by IDV; Annual 2015
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. Menopause, Vol.22, No.9, pp 0-11.

TherapeuticsMD®
For Her. For Life.

TX-001HR – Potential Best in Class Therapy



Potential first and only:

1) **Bio-identical combination estradiol & progesterone**
2) **FDA-approved**

Dosing and Delivery

- Once-a-day single oral softgel capsule

Addresses Unmet Medical Need

- First and only combination of bio-identical estradiol and bio-identical progesterone product candidate
- Single combination dose option
- Positive Phase 3 Replenish Trial safety and efficacy results
- Potential third-party reimbursement, if approved

PDUFA target action date October 28, 2018

- Strong patent estate with patent expirations starting 2032

Benefits to women, healthcare providers, and pharmacies

1) NDA submitted December 28, 2017; FDA PDUFA date October 28th, 2018
2) Reimbursement anticipated if FDA-approved

TherapeuticsMD®
For Her. For Life.

Multi-Billion Dollar Total Substitutable Market Opportunity

TX-001HR Substitutable Market (if approved)	FDA-Approved		Compounded Combination Bio-Identical E+P
	Separate Bio-Identical E & P Pills	Combination Synthetic E+P[1]	
TRx US:	~3.8 million[1]	~3 million[2]	12 – 18 million
TX-001HR Potential Substitutable Market	$760M-$950M[3]	$600M-$750M[3]	$2.4B-$4.5B[3]
TX-001HR Total Substitutable Market Opportunity	**$3.7B – $6.1B**		

Separate Bio-Identical E & P Pills

Product Use by Age	AGES 41-50	AGES 51-60	AGES 61-70	AGES 71+	TRx Totals
Progesterone	903,680	1,596,847	902,733	399,665	**3,802,925**[1]
Estradiol	2,297,141	5,033,146	2,772,199	1,476,272	11,578,758[1]

- **FDA-approved separate bio-identical estrogen and progesterone channel** alone represents up to $950M annually at a WAC price of $250
  - 2 separate copays
  - Not FDA approved to be used together for endometrial protection
- **Potential billion dollar opportunity with even only limited penetration into compounding channel**

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2017
2) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17β + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®
3) Assume WAC pricing between $200-250

TherapeuticsMD®
For Her. For Life.

TX-001HR Could Fulfill Therapeutic Gap For Stakeholders

Patients

- If approved, meet demand for bio-identical hormone therapy with a product approved by FDA on safety and efficacy
- Reduce of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at pharmacies and not just compounding pharmacies

Healthcare Providers

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

Pharmacies

- Meet patient and physician demand for bio-identical hormone therapy
- Assuming third-party reimbursement, significantly improve net margin per script
- Lower certain legal and regulatory costs and risks

FDA/Regulatory Bodies

- Reduce need for and use of compounded hormone products
- Full enforcement of regulations regarding compounded hormones

BIO-IGNITE™

Compounding Pharmacy Partnership Strategy

BIO-IGNITE™ started as an outreach program to quantify the number of compounded bio-identical estradiol and progesterone prescriptions currently dispensed by the 3,000 high-volume compounding pharmacies, and qualify their interests in distributing our hormone product candidates, if approved.

WHAT IT HAS BECOME:

A four-phase strategic initiative to activate all current stakeholders involved in the BHRT community. Ensuring that TX-001HR has the best national access and uptake possible.

TherapeuticsMD®
For Her. For Life.

BIO-IGNITE™ Progress and Results

Partnerships with Large Pharmacy Network and Individual Pharmacies

Pharmacy Network and Individual Pharmacy Partners	# of Pharmacies	Combination Bio-Identical E+P Scripts
Premier Value Pharmacy Compounding Network	>300 Pharmacies In Network	~1,500,000 prescriptions annually
TXMD Outreach to Individual Pharmacies	>400 Pharmacies with Prescription Data	>500,000 prescriptions annually

TherapeuticsMD®

For Her. For Life.

Committed to Become the Leading Women's Health Company

TherapeuticsMD®

For Her. For Life.

TherapeuticsMD, *A Premier Women's Health Company*

Annovera™ | vitaMedMD | Annovera™ | TX-001HR* | Imvexxy (estradiol vaginal inserts)

CONTRACEPTION → PRENATAL CARE → CONTRACEPTION/ FAMILY PLANNING - PERIMENOPAUSE → VASOMOTOR SYMPTOMS → DYSPAREUNIA (Vulvar & Vaginal Atrophy)

REPRODUCTIVE HEALTH

MENOPAUSE MANAGEMENT

*Investigational product, pending FDA approval

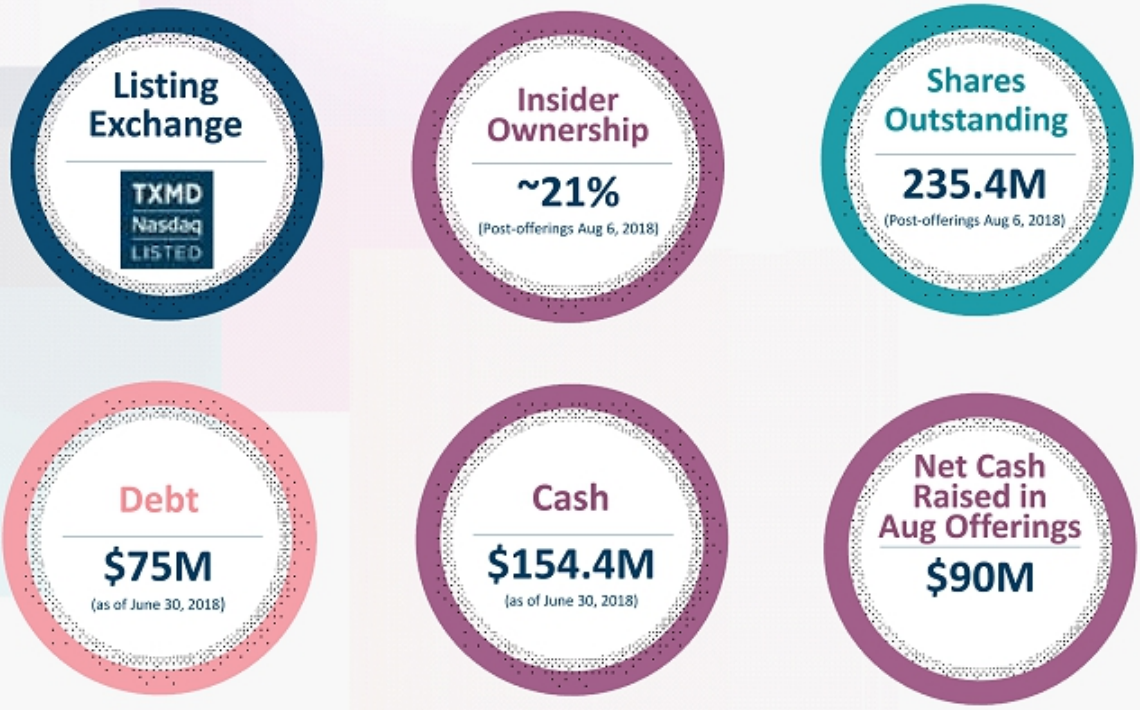
TherapeuticsMD®

For Her. For Life.

Significant Insider and Institutional Share Ownership

- Board of Directors and Executive Officers have long-term commitment to the company
  - Beneficially own approximately 21% of the company's shares
  - Three founding executives beneficially own approximately 17% of the company's shares
    - Includes vested options to acquire approximately 5 million shares of common stock (approximately 11% of such executives' current beneficial ownership) that were originally issued on January 1, 2009 and expire on January 1, 2019
- Large institutional holder support
  - Large institutional holders – many long-term – beneficially own more than 55% of the company's outstanding shares

TXMD: Financial Snapshot



TherapeuticsMD®

For Her. For Life.


Thank You
TherapeuticsMD®
For Her. For Life.
44