

**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): June 4, 2018

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(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 June 4, 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 June 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: June 4, 2018

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer



Investor Day

June 4, 2018

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THER-0086 1/17

Introduction

Robert Finizio
Co-founder &
Chief Executive Officer

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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 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; 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.

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

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Today's Agenda

11:30 am – 12:00 pm **Registration – Lunch**

12:00 – 12:10 pm **Introductions – Robert Finizio**
Overview – Brian Bernick, M.D.

12:10 – 1:25 pm **IMVEXXY™ (TX-004HR)**

- VVA & Impact – Sheryl Kingsberg, Ph.D
- Market Overview & Product Profile – Sharon Parish, M.D.
- Launch Strategy – Dawn Halkuff
- Payer Overview – Mike Steelman, Robert Lahman, and Robert Reid
- Treatment Compliance Program & Gross to Net Assumptions – Robert Finizio

1:25 – 1:50 pm **Q&A Panel**

1:50 – 2:25 pm

TX-001HR

- Market Opportunity – Brian Bernick, M.D.
- Bio-Ignite / Compounding Pharmacy Economics – Dedra Reiger Lyden, Richard Moon and John Walczyk

2:25 – 2:50 pm

Q&A Panel

2:50 – 3:00 pm

Closing Remarks - Life Cycle Management, Partnering & Financial Update – Robert Finizio

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TherapeuticsMD® (TXMD)

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

1 Worldwide commercial rights for multiple hormone therapy products

- Drug candidate portfolio is built on SYMBODA™ technology for the solubilization of bio-identical hormones
- Well-known chemical entities with established safety and efficacy thresholds
- Strong global intellectual property portfolio with 219 global patent applications and 19 issued US patents

2 Established US commercial business marketing prescription prenatal vitamins to established OB/GYN customer base

- Number 1 commercially covered prenatal vitamins

3 Experienced leadership team with proven development and commercial success in women's health

Reference: Data on file, TherapeuticsMD, Inc. calculated using market data from PHAST Symphony

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Seasoned Management Team with a Proven Track Record of Commercial Success



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



- 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



- 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



- Co-founded vitaMedMD in 2008
- Co-founded CareFusion (Sold to Cardinal Health in 2006)
- 22 years of experience in early stage healthcare company development: ESI, OmniCell, CareFusion



- 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



- 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



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



- 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



- 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®



- 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



- 20 years of industry experience
- Pfizer - Head of Government and Institutional Accounts
- Covered all the Pfizer franchises including Women's Health, Cardiovascular, Pain, Oncology, Specialty, and Generics.
- Global Pricing Head for Sanofi

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Overview

Brian Bernick, M.D.
Co-founder &
Chief Clinical Officer

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TherapeuticsMD Approach to Drug Development

- Drug development/discovery
- Designed with the patient and healthcare provider in mind
- Guiding principles
 - Better user experience
 - More comfortable
 - More convenient
 - Affordable
 - Safety and efficacy
 - Efficiency





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

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VVA and its Impact

Sheryl Kingsberg, Ph.D

Division Chief, OB/GYN Behavioral Medicine, UH Cleveland Medical Center

- Co-Director, Sexual Medicine and Vulvovaginal Health Program, UH Cleveland Medical Center
- Professor, Obstetrics and Gynecology, CWRU School of Medicine
- Professor, Psychiatry, CWRU School of Medicine
- President of the North American Menopause Society (NAMS)
- Past President of International Society for the Study of Women's Sexual Health (ISSWSH)
- Leading expert in sexual medicine and menopause
- Lead author for the pivotal peer reviewed publications on female sexual disorders and menopause
- Associate Editor for Sexual Medicine Reviews and editorial board of Menopause
- Principal investigator for multiple clinical trials of sexual disorders and menopause

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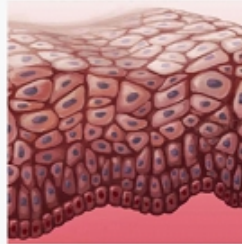
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Vulvar and Vaginal Atrophy (VVA)

- 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 women¹
- 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 Change) Survey." International Society for Sexual Medicine 2013, no. 10, 1790-1799.

Current US VVA Market Overview

32M with VVA symptoms (1 out of 2 menopausal women) in the United States^{1,2}

50% (16M)

seek treatment for VVA⁴

- 25% (8M) OTC products
- 18% (5.7M) past HT users
- 7% (2.3M) current HT users

Only 7% (2.3M) are current users of Rx hormone therapy³

- Only 7% of women (2.3M) with VVA symptoms, are currently being treated today with Rx hormone therapy (HT)³
 - Long-term safety concerns⁵
 - Efficacy⁵
 - Messiness⁵
 - Need for applicator⁵

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888-902.
2) Gass ML, Cochrane EB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160-1171.
3) IMS Health Plan Claims (April 2008-Mar 2011).
4) TherapeuticsMD "EMPOWER" Survey, 2016
5) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014;8:23-30 doi:10.4137/CMR9151449

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Market Overview and Product Profile

Sharon Parish, M.D.

Professor of Medicine in Clinical Psychiatry and Professor of Clinical Medicine at Weill Cornell Medical College

- Leading expert and clinician in sexual medicine and menopause
- Attending physician at New York Presbyterian Westchester Division
- Past President of International Society for the Study of Women's Sexual Health (ISSWSH)
- Board member of International Society for Sexual Medicine
- Lead author for the key peer reviewed publications and clinical practice guidelines on female sexual disorders and menopause
- Researcher and educational expert in sexual health communication and identification/management of sexual disorders in clinical practice
- Associate editor for Sexual Medicine Reviews and Current Sexual Health Reports
- Associate editor and editorial board for the Journal of Sexual Medicine (JSM)

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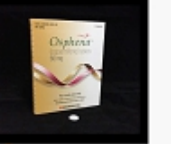







Women's Health Initiative Observational Study

Breast cancer, endometrial cancer, and cardiovascular events in participants who used vaginal estrogen in the Women's Health Initiative Observational Study

Carolyn J. Crandall, MD, MS,¹ Kathleen M. Hovey, MS,² Christopher A. Andrews, PhD,³ Rowan T. Chlebowski, MD, PhD,⁴ Marcia L. Stefanick, PhD,⁵ Dorothy S. Lane, MD, MPH,⁶ Jan Shifren, MD,⁷ Chu Chen, PhD,⁸ Andrew M. Kaunitz, MD,⁹ Jane A. Cauley, DrPH,¹⁰ and JoAnn E. Manson, MD, DrPH¹¹

- Long-term safety of women using only U.S. FDA-approved vaginal estrogen products
 - 45,663 users of vaginal estrogen
 - Median duration of use of 2-3 years and median duration of follow-up of 7.2 years
 - Representing over 300,000 patient years of data
 - Risks of breast cancer, endometrial cancer, colorectal cancer, stroke, and pulmonary embolism/deep vein thrombosis were not statistically different between vaginal estrogen users and nonusers
 - Risks of CHD, fracture, all-cause mortality, and GIE were lower in users than in nonusers

Current FDA-Approved VVA Products

Product	Estrace® Cream (estradiol vaginal cream, USP, 0.01%) ¹	Premarin Cream® (conjugated estrogens vaginal cream) 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
							
							
FDA approval	1984	1978	1996	1999	2018	2016	2013
TRx Dollars 2017 ⁹	\$583,612,698	\$533,386,029	\$120,499,734	\$525,321,410 ^a	-	\$4,187,571	\$75,683,654
Method of administration	Vaginal Cream	Vaginal Cream	Vaginal Ring	Vaginal Tablet	Vaginal Softgel	Vaginal Bullet	Oral Tablet
Application	Reusable vaginal applicator	Reusable vaginal applicator	90-day ring	Vaginal applicator	No applicator needed	Vaginal applicator	Oral daily SERM
Active ingredient	100 µg estradiol	625 µg/g conjugated equine estrogens	2,000 µg estradiol	10 µg estradiol	4 µg or 10 µg estradiol	6,500 µg prasterone	60,000 µg ospemifene
Average maintenance dose	100 µg 2x/week	312.5 µg 2x/week	7.5 µg daily	10 µg 2x/week	4 µg or 10 µg 2x/week	6,500 µg daily	60,000 µg daily
Onset of action* dyspareunia	Approved without dyspareunia and dryness data	Week 4+	Approved without dyspareunia and dryness data	Week 8	Week 2	Week 6	Week 12
Onset of action* dryness		Not demonstrated		Week 2	Week 12	Not demonstrated	
WAC 30-day supply (2018) ¹⁰	\$104.96	\$118.59	\$143.78	\$170.16	\$180.00	\$198.75	\$203.80

*Onset of action = first efficacy observation.

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: SERM, selective estrogen receptor modulator; 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]. B. Constantine GD, Simon JA, Pickar JH, et al. The RELIANCE 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 IQV; Annual 2017 [a. 2017 Vagifem, Yuzafem (authorized generic of Vagifem), and Teva generic]. 10. Price RX March 2018.

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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."



FDA³

"...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.

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- Small, digitally inserted, softgel capsule that dissolves completely
- Easy to use without the need for an applicator
- New lowest effective dose of estradiol 4 mcg and 10 mcg
- Used any-time of day with high patient satisfaction rates
- No label adverse drug reactions of vaginal discharge or abnormal pap smears
- Strong efficacy data for moderate to severe dyspareunia (evaluated as most bothersome symptom; 90% of women also reported moderate to severe vaginal dryness at baseline)
- Supports vaginal health and microbiome through improvements in pH and vaginal cytology
- Efficacy demonstrated at 12 weeks (primary endpoint), and as early as 2 week (secondary endpoint)
- pK data - doesn't increase systemic hormone levels beyond the normal postmenopausal range
- Mechanism of action and dosing that is familiar and comfortable
- No patient education required for dose preparation or applicators
- Two-times-a-week maintenance dosing
- Dose packaging to optimize compliance and convenience
- Strong patent estate with patent expirations starting 2032

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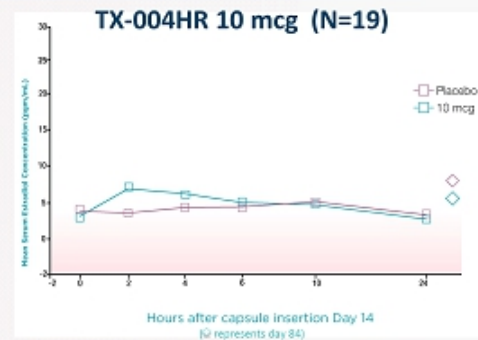
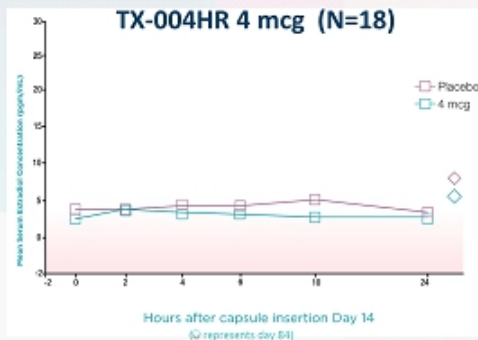
Co-Primary and Key Secondary Efficacy Endpoints



Co-Primary Endpoints		
	4 mcg	10 mcg
Superficial Cells	<0.0001	<0.0001
Parabasal Cells	<0.0001	<0.0001
Vaginal pH	<0.0001	<0.0001
Severity of Dyspareunia	0.0149	<0.0001
Key Secondary Endpoint		
Severity of Vaginal Dryness	0.0014	<0.0001

MMRM P-value vs placebo LS = Least Squares

Arithmetic Mean Estradiol Serum Concentrations – Unadjusted



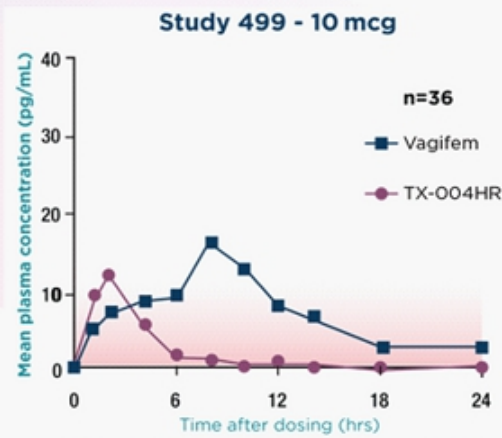
	AUC ₀₋₂₄ (pg.h/mL)	C _{avg(0-24)} (pg/mL)
4 mcg	87.22 (42.77)	3.634 (1.78)
Placebo (PI)	104.16 (66.38)	4.34 (2.76)
P-value vs PI	0.3829	0.3829

	AUC ₀₋₂₄ (pg.h/mL)	C _{avg(0-24)} (pg/mL)
10 mcg	110.14 (54.57)	4.58 (2.27)
Placebo (PI)	104.16 (66.38)	4.34 (2.76)
P-value vs PI	0.7724	0.7724

Phase 1 - Single Dose PK Studies¹

TX-004HR (IMVEXXY) vs. Vagifem[®]

Systemic absorption AUC (0-24 hours) and C_{ave} (0-24 hours) was 2- to 3-fold lower with TX-004HR relative to Vagifem



Baseline-Adjusted Mean*	TX-004HR 10 µg	Vagifem 10 µg
AUC ₀₋₂₄ , pg*h/mL	49.62	132.92 ^a
C _{max} , pg/mL	14.38	20.38 ^b

^aP < 0.0001; ^bP=0.0194 vs TX-004HR.

1) Pickar et al., *Climacteric* 2016;19(2):181-187

TX-004HR Qualitative Attributes



Ease of Use

	4 mcg (N=191)	10 mcg (N=191)	Placebo (N=192)
Easy to Use	171 (89.5%)	172 (90.1%)	164 (85.4%)

Patient Satisfaction

	4 mcg (N=191)	10 mcg (N=191)	Placebo (N=192)
Very Satisfied	74 (38.7%)	84 (44.0%)	41 (21.4%)
Satisfied	57 (29.8%)	55 (28.8%)	68 (35.4%)
Unsure	23 (12.0%)	28 (14.7%)	39 (20.3%)
Dissatisfied	19 (9.9%)	9 (4.7%)	20 (10.4%)
Very Dissatisfied	8 (4.2%)	5 (2.6%)	17 (8.9%)

Preferred vs Competition

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

IMVEXXY
**Commercialization
Launch Plans**
**Bringing the Vision to
Reality**

Dawn Halkuff
Chief Commercial Officer

Mitchell Krassan
Chief Strategy Officer

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Commercial Elements are in Place For Launch



Sales



Marketing



Data Analytics and Sales Operations

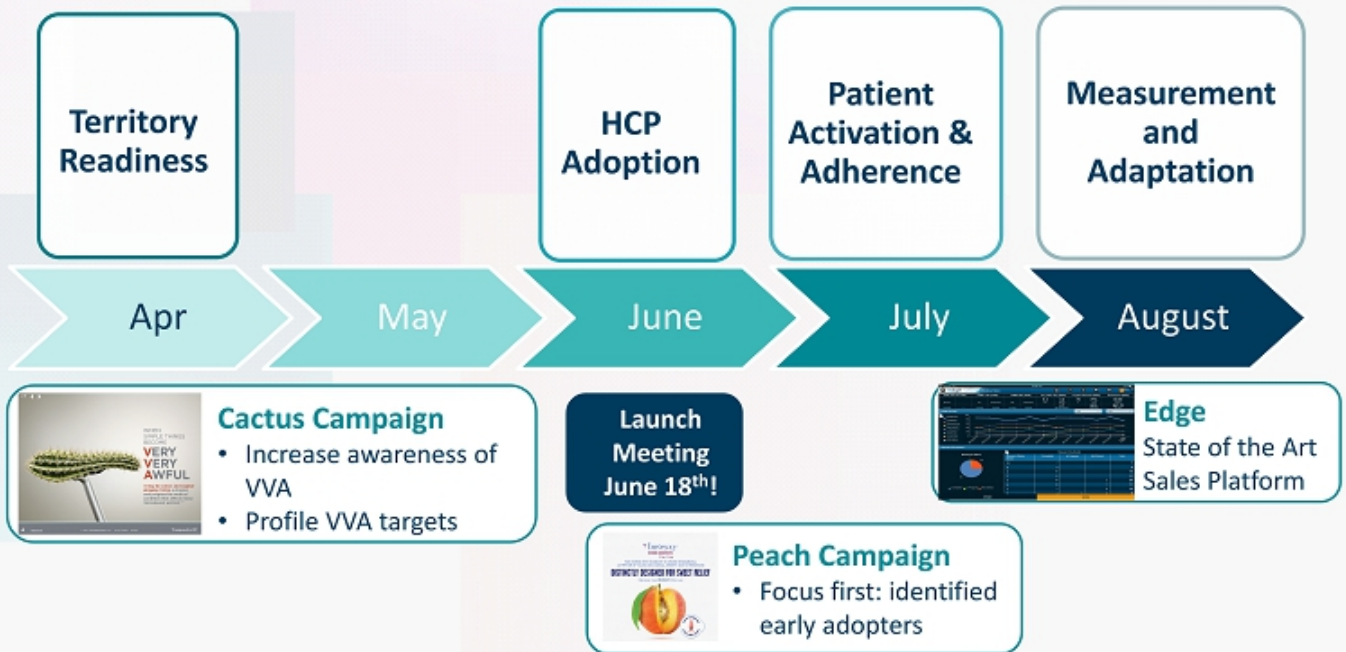


Market Access

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Building Invexxy Momentum



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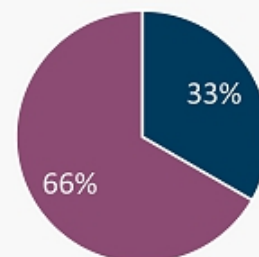
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150 Territory Sales Expansion Completed and Activated



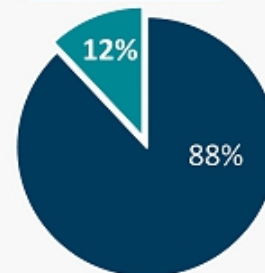
 =TXMD territories

Specialty



■ Womens Health ■ Other

Sales Experience



■ Pharma Sales ■ B2B Sales

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Salesforce Footprint Considers the Future Portfolio

Sales Team HCP Targeting



Further Targeting Details



Live coverage of all IMVEXXY decile HCPs



Alignment covers 85% of current PNV Volume



Of 150 territories will not change geographic footprint for TX-001HR expansion, if approved

TherapeuticsMD®

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State of the Art Sales Platform



- ❑ Maximizes the effectiveness of Sales Reps:
 - Deliver the right message to the right HCP at the right time
- ❑ Artificial Intelligence uses real time data to provide actionable insights to sales force



Results of Territory Readiness

We Took the Time to Know our Customers

- 16,000 + calls
- Understanding of office dynamics, treating preferences, barriers and opportunities

Our Learning Gives Us Confidence In Future Success

- Our Target Market Matches National Data
- Imvexxy label features align with treatment preferences

Targeted Messaging Training Based on Territory Readiness Results

- Drives momentum by starting with understanding vs. exploration

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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

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Introduction to Imvexxy

- HCP communication
- Focus on novel experience of Imvexxy
- Hints at differences in patient experience that is important to patients and HCP stakeholders

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

FOR WOMEN WITH MODERATE TO SEVERE DYSpareunia,
A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENOPAUSE

DISTINCTLY DESIGNED FOR SWEET RELIEF

Discover new **IMVEXXY** this July



* Electronic sales aid in development; pending MRL review and approval

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Imvexxy Differentiation Comes to Life

DISCOVER A TREATMENT EXPERIENCE WITH
SIMPLICITY AT ITS CORE¹

Contents

CONDITION	SCIENCE	EXPERIENCE	SUPPORT
GSM	Systemic Absorption	Applicator Free	Support Services
VVA	Safety Profile	Mess-Free Administration	Mission
Dyspareunia	Efficacy	Ease of Use	

INDICATION
IMVEXXY™ (estradiol vaginal inserts) is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

IMPORTANT SAFETY INFORMATION

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete details regarding **DRAFT** prescribing information.

Estrogen-Alone Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or

Imvexxy™ (estradiol vaginal inserts) 4 mg - 10 mg

PRESCRIBING INFORMATION
REFERENCES

* Electronic sales aid in development; pending MRL review and approval

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Fresh Approach to Deliver Imvexxy Messages



IMPORTANT SAFETY INFORMATION

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen-Only Therapy

- There is an increased risk of endometrial cancer with uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein

DRAFT



* Electronic sales aid in development; pending MRL review and approval

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Imvexxy Can Drive New Patients into the Category

2.4 mm Women Formerly on Therapy

67% less than satisfied with former product: Focus on physical characteristics

4.2 mm Using Lubricants/OTC

75% would consider an Rx if recommended: Efficacy and safety data underpinned by physical characteristics

4.7 mm Never Entered Therapy

72% never discussed symptoms with HCP: True impact combined with efficacy data

Focused Multichannel, Print and Digital Advertising

In Office at “tipping point” Communication

Patient Support Programs that Provide Access to HCPs and Education

Affordability Programs

Commercial Elements are in Place For Launch



Sales



Marketing



Data Analytics and Sales Operations



Market Access

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Payer Overview

Bob Lahman
Ret. Sr. VP OptumRx

Robert Reid
VP Market Access Operations Syneos Health

Mike Steelman
VP Market Access TherapeuticsMD

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What is Market Access?

Market access is the process to ensure that all appropriate patients who would benefit, get rapid and maintained access to the brand, at the right price

Access Objectives:

1. Reimbursed by health plans and PBMs
2. Easily prescribed by healthcare providers
(Unrestricted Access)
3. Reasonable copay amounts for patients
4. Available through a variety of supply chain sources

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IMVEXXY Market Access Dynamics

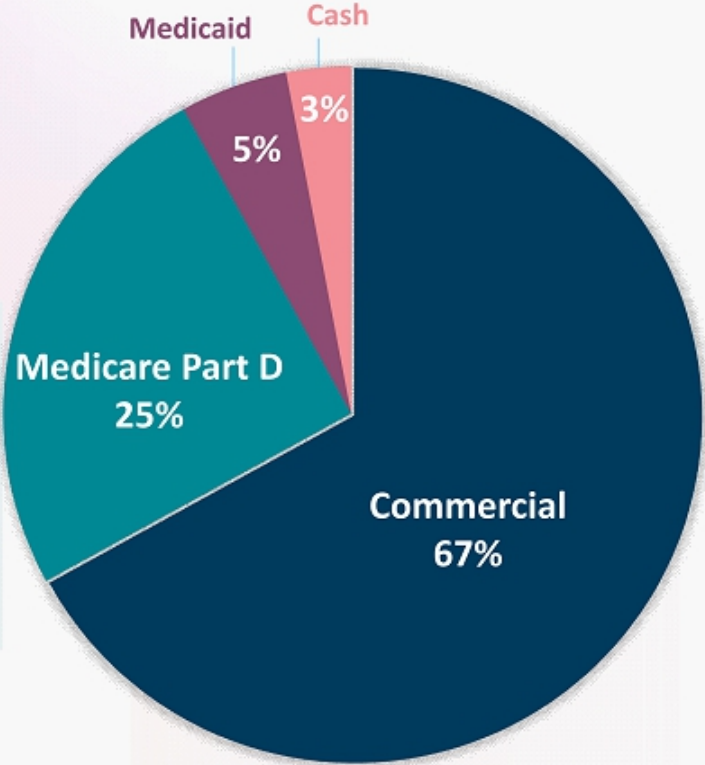
Unrestricted Access

- Majority of products in VVA category for majority of plans and PBMs currently have “Unrestricted Access”
- Remains a low cost category compared to other therapeutic areas
 - Managing this category is not a priority
- Importance of providing choice for women & prevent associated co-morbidities
- Lack of innovation in VVA category

Pricing and Contracting Dynamics

- Payers expect new products to be priced at parity to covered branded products at launch
- WAC price guidance for new category entrants ranged from \$150-\$180 a month
- Impact of generics have been confined to reference brands
- Contracting for new brands to secure access for a non-preferred brand tier position

Payer Breakdown of FDA-Approved VVA Products



VVA Class Commercial Coverage:¹

Top 25 payers represent ~87% of Commercial lives with a majority of access unrestricted

Vulvar and Vaginal Atrophy- 184,277,713 Commercial Lives			Estrace Cream	Intravosa	Ospheha	Premarin Cream	Vagifem	Yuvafem	Estring
Controlling Payer/PBM	Lives	% of Commercial lives							
Express Scripts PBM	28,507,971	15%	Covered	Covered	Covered	Preferred	Covered	Preferred	Preferred
CVS Caremark RX	27,256,869	15%	Preferred	Covered	Preferred	Preferred	Preferred	Covered	Preferred
Anthem, Inc.	14,385,833	8%	Covered	Covered (PA/ST)	Covered (PA/ST)	Preferred	Covered	Preferred	Covered
UnitedHealth Group, Inc.	13,571,816	7%	Covered	Covered	Covered	Covered	Covered	Preferred	Preferred
OptumRx	11,762,164	6%	Preferred	Covered	Covered	Preferred	Covered	Preferred	Covered
Aetna, Inc.	7,903,792	4%	Covered	Covered	Covered	Preferred	Covered	Preferred	Covered
Kaiser Foundation Health Plans, Inc.	7,453,024	4%	Preferred	Not Covered	Not Covered	Preferred	Not Covered	Not Covered	Preferred
CIGNA Health Plans, Inc.	7,408,428	4%	Covered	Covered	Covered	Preferred	Covered	Preferred	Preferred
Department of Defense - TRICARE	7,036,804	4%	Preferred	Preferred (PA/ST)	Preferred	Preferred	Preferred (PA/ST)	Preferred	Preferred
Blue Cross Blue Shield Association Corporation	5,410,238	3%	Preferred	Covered	Covered	Preferred	Covered	Covered	Covered
Health Care Service Corporation	5,290,357	3%	Preferred	Covered	Covered	Covered	Covered	Preferred	Covered
Department of Veterans Affairs (VHA)	4,777,557	3%	Covered (PA/ST)	Covered (PA/ST)	Covered (PA/ST)	Preferred	Covered (PA/ST)	Covered (PA/ST)	Covered (PA/ST)
Envision Pharmaceutical Services	3,125,237	2%	Covered	Covered	Covered	Preferred	Covered	Generic (Preferred)	Covered
Indian Health Service (IHS)	2,186,820	1%	Covered (PA/ST)	Covered (PA/ST)	Covered (PA/ST)	Preferred	Covered (PA/ST)	Covered (PA/ST)	Covered (PA/ST)
Blue Shield of California	1,840,474	1%	Covered	Covered (PA/ST)	Covered (PA/ST)	Preferred	Covered	Preferred	Preferred
CareFirst, Inc.	1,517,895	1%	Covered	Covered	Preferred	Preferred	Covered	Covered	Preferred
EmblemHealth, Inc.	1,477,204	1%	Covered	Covered	Covered	Preferred	Covered	Preferred	Preferred
Blue Cross Blue Shield of Michigan	1,399,562	1%	Covered	Covered	Covered	Preferred	Covered	Covered	Preferred
Humana, Inc.	1,212,751	1%	Covered	Not Covered	Not Covered	Not Covered	Not Covered	Not Covered	Covered
Blue Cross and Blue Shield of Florida, Inc.	1,207,374	1%	Covered	Covered	Covered	Preferred	Preferred	Preferred	Covered
Blue Cross Blue Shield of Minnesota	1,173,171	1%	Preferred	Covered	Covered	Covered	Covered	Preferred	Covered
State of New York	1,092,511	1%	Preferred	Not Covered	Preferred	Preferred	Covered	Covered	Covered
Blue Cross Blue Shield of North Carolina	1,061,152	1%	Covered	Covered	Covered	Preferred	Covered	Preferred	Covered
Centene Corporation	1,012,171	1%	Covered (PA/ST)	Not Covered	Covered	Preferred	Covered (PA/ST)	Covered	Covered
Blue Cross Blue Shield of Alabama	991,169	1%	Preferred	Covered	Covered	Covered	Preferred	Not Covered	Covered

References:
1. MMIT May 2018

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Prior Authorization Example in the VVA Class

- The majority of commercial payers do not require PA/ST for branded VVA treatments today¹
- However, select payers require written PA and stepping-through one or two preferred products in selected 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 Anthem²

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.

- | | | |
|------------------------------|-----------------------------|---|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Patient is female |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Patient has a diagnosis of moderate-to-severe dyspareunia due to vulvar and vaginal atrophy (VVA) associated with menopause |
| <input type="checkbox"/> Yes | <input type="checkbox"/> 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

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VVA Class Medicare Coverage:¹

Top 10 payers represent ~82% of lives with new favorable clarification from CMS

Vulvar and Vaginal Atrophy- 40,964,260 Medicare Lives		% of Medicare Lives	Estrace Cream	Intrarosa	Osphena	Premarin Cream	Vagifem	Yuvaferm	Estring
Controlling Payer/PBM	Lives								
UnitedHealth Group, Inc.	8,564,751	21%	Covered	Preferred	Not Covered	Preferred	Not Covered	Not Covered	Covered
Humana, Inc.	7,757,172	19%	Preferred	Not Covered	Not Covered	Preferred	Not Covered	Not Covered	Covered
CVS Caremark RX	6,031,720	15%	Preferred	Not Covered	Not Covered	Not Covered	Not Covered	Not Covered	Not Covered
Aetna, Inc.	3,052,533	7%	Covered	Not Covered	Not Covered	Covered	Preferred	Preferred	Covered
Express Scripts PBM	2,441,216	6%	Preferred	Not Covered	Not Covered	Covered	Covered	Preferred	Preferred
WellCare Corporation	1,545,245	4%	Covered	Not Covered	Not Covered	Not Covered	Not Covered	Preferred	Not Covered
Kaiser Foundation Health Plans, Inc.	1,493,836	4%	Not Covered	Not Covered	Not Covered	Preferred	Covered	Not Covered	Preferred
CIGNA Health Plans, Inc.	1,138,810	3%	Not Covered	Not Covered	Not Covered	Preferred	Not Covered	Covered	Preferred
Anthem, Inc.	1,023,317	2%	Covered	Not Covered	Not Covered	Preferred	Covered	Covered	Covered
Envision Pharmaceutical Services	493,727	1%	Preferred	Not Covered	Not Covered	Covered	Not Covered	Covered	Not Covered
Health Care Service Corporation	454,391	1%	Covered	Not Covered	Not Covered	Preferred	Not Covered	Preferred	Not Covered
Centene Corporation	293,532	1%	Not Covered	Not Covered	Not Covered	Preferred	Not Covered	Not Covered	Covered

In May 2018, CMS clarified that drugs used consistent with this labeling (the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause) are not excluded from Medicare Part D under §1860D-2(e)(2)(A) of the Social Security Act.²

References:

1. MMIT, May 2018
2. <http://www.menopause.org/docs/default-source/professional/nams-commends-cms.pdf>

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NAMS Recognizes and Commends CMS Clarification of GSM Drug Coverage

From JoAnn V Pinkerton, MD, NCMP, Executive Director

- The North American Menopause Society (NAMS) joins The International Society for the Study of Women's Sexual Health, the American College of Obstetricians and Gynecologists, and other major organizations in recognizing the Centers for Medicare and Medicaid Services (CMS) for acting on a major health concern for postmenopausal women by no longer excluding from Medicare Part D coverage drugs for the treatment of moderate to severe dyspareunia due to menopause when used consistent with this labeling under their "Prescription Drug Benefits" section 1860D-2(e)(2)(A) of the Social Security Act.
- Postmenopausal women can now receive access to newer, tested, and effective FDA-approved therapies to relieve symptoms and signs of vulvovaginal atrophy (VVA), a component of the genitourinary syndrome of menopause (GSM).

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Impact of Generics

- **Commercial plans-** impact of generics has been to move branded product to 3rd Tier and generic product to 1st Tier.¹
- **Medicare-** impact of generics has been to move brand to not covered and generic to generic/preferred/covered.¹

Commercial Coverage Tier	Vagifem	Yuvafem
Generic (Preferred)	<1%	6%
Preferred	14%	55%
Preferred (PA/ST)	4%	<1%
Covered	66%	28%
Covered (PA/ST)	6%	4%
Specialty		<1%
Not Covered	10%	5%
Total Unrestricted	80%	89%

Medicare Coverage Tier	Vagifem	Yuvafem
Generic (Preferred)		2%
Preferred	7%	34%
Preferred (PA/ST)	1%	
Covered	11%	23%
Covered (PA/ST)	6%	
Specialty	1%	
Not Covered	73%	41%
Total Unrestricted	19%	59%

References:
1. MMIT, May 2018

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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

Favorable Payer Dynamics: Limited Substitution Across Branded Products

Case Study: Estrace Cream Generics Launch

- Estrace Cream Generics launched in January 2018

	VVA TRx Market Share (%) Jan-Apr 2017	VVA TRx Market Share (%) Jan-Apr 2018	Gains (Losses)
Estrace Cream	33.5%	12.2%	-21.3%
Estrace Cream Generics	-	22.6%	22.6%
Total	33.5%	34.8%	1.3%

- Estrace Cream Generics continues to take market share from **mostly** Estrace Cream
- Limited substitution or cannibalization of other branded products
 - Premarin lost 1.94% Market Share during this time period
 - Intrarosa gained 2.16% during this time period















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), Ospheña (\$203.80)

Product	Estrace® Cream (estradiol vaginal cream, USP, 0.01%) ¹	Premarin Cream® (conjugated estrogens) ²	Estring® (estradiol vaginal inserts) ³	Vagifem® (estradiol vaginal inserts) ⁴	IMVEXXY (estradiol vaginal inserts) ^{5,6}	Intrarosa® (prasterone vaginal inserts) ⁷	Ospheña® (ospemifene) ⁸
							
							
FDA approval	1984	1978	1996	1999	2018	2016	2013
TRx Dollars 2017 ⁹	\$583,612,698	\$533,386,029	\$120,499,734	\$525,321,410 ⁹	-	\$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

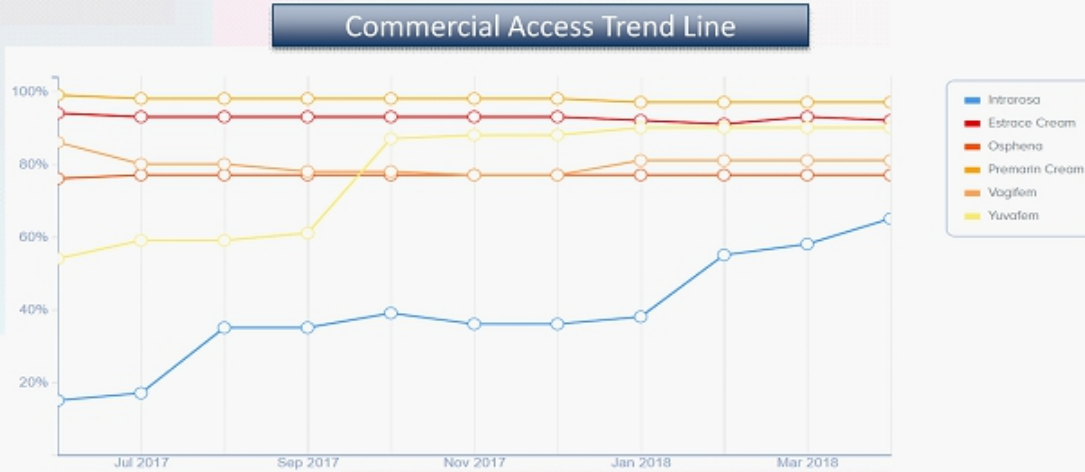
There have been no head-to-head trials between IMVEXXY and any of the products listed above. All trademarks are the property of their respective owners. Abbreviations: WAC, wholesale acquisition cost.

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. Ospheña [package insert]. Florham Park, NJ: Shionogi Inc.; 2015. 9. Symphony Health Solutions PHAST Data powered by IQVIA, Annual 2017 [a. 2017 Vagifem, Yuzafem (authorized generic of Vagifem), and Teva generic]. 10. Price RX March 2018.

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How Will Coverage Improve Over Time?

- Up to a six month formulary review process is standard for new products
- Market Access team is working hard to speed up the review process
- Historical trends show recent competitor launch getting to ~65% unrestricted Commercial access 9 months after field launch
- Medicare we will begin bids in September 2018 for the 2020 Medicare cycle and we will pursue opportunities for earlier access



References:
1. MMIT April 2018

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**Treatment
Compliance Program
& Gross-to-Net
Assumptions**

Robert Finizio
Co-founder &
Chief Executive Officer

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Developed for Imvexxy and TX-001HR Launch

- Prenatal line was developed ONLY as infrastructure to accelerate the launch of Imvexxy and TX-001HR
 - Compliance and Education program that effectively reduces out of pocket costs for patient 85% of the time
 - Applied and customized sales rep technology platform (Edge) that utilizes Artificial Intelligence and we believe is best in class
 - Very strong 9-year presence in top prescribing OB-GYN offices
 - Developed retail relationships, payer network and distribution channel

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 85% 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

Results of TXMD Prenatal Vitamin Adoption & Adherence Programs

Patient Adherence

Industry Avg: 2.5 of 9 months



TXMD Avg: 7 of 9 months

Prescriber Loyalty

Industry Avg: 30 prescriptions per physician per year



TXMD Avg: 76 prescriptions per physician per year

Data Insights

Industry Avg: 60 days



TXMD Avg: Real time Data

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Why this Applies to the VVA Market

Prenatal Vitamins vs. VVA Market Dynamics

Prenatal Vitamins Market

- Industry Average:
 - 2.5 fills per pregnancy
- Lower priced generics in the market
- OTC competition
- Little meaningful product differentiation / No drug claims



VVA Market

- Average fills per year:
 - 3.5 for Vagifem® and Osphena®
 - 1.5 Premarin® and Estrace® creams
- Lower priced generics in the market
- OTC competition
- Low satisfaction with existing products

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Patient Affordability & Adherence Programs Applied to Imvexxy

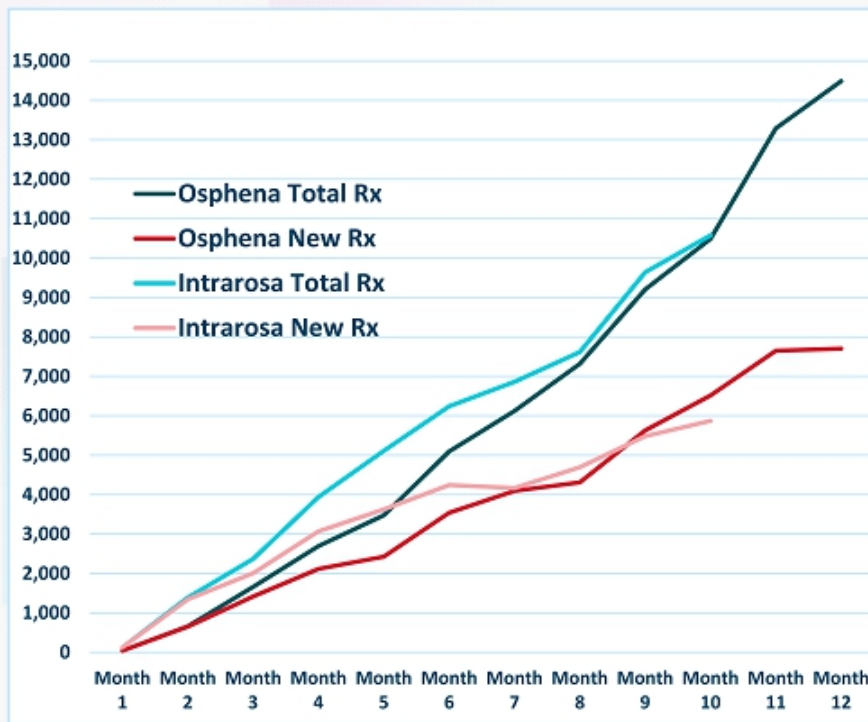
Why programs are applicable to Imvexxy:

- Eliminates educational shortcomings leading to improved adoption and compliance
- Manage patient out of pocket and coverage issues
- **Imvexxy was designed with the patient in mind**
 - Elegant design
 - New lowest effective dose
 - Blister dose packaging makes it easier for HCP to educate patient on use of product
 - Chronic progressive condition that requires periodic re-evaluation of treatment goals and risks for treatment life cycle of each woman

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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

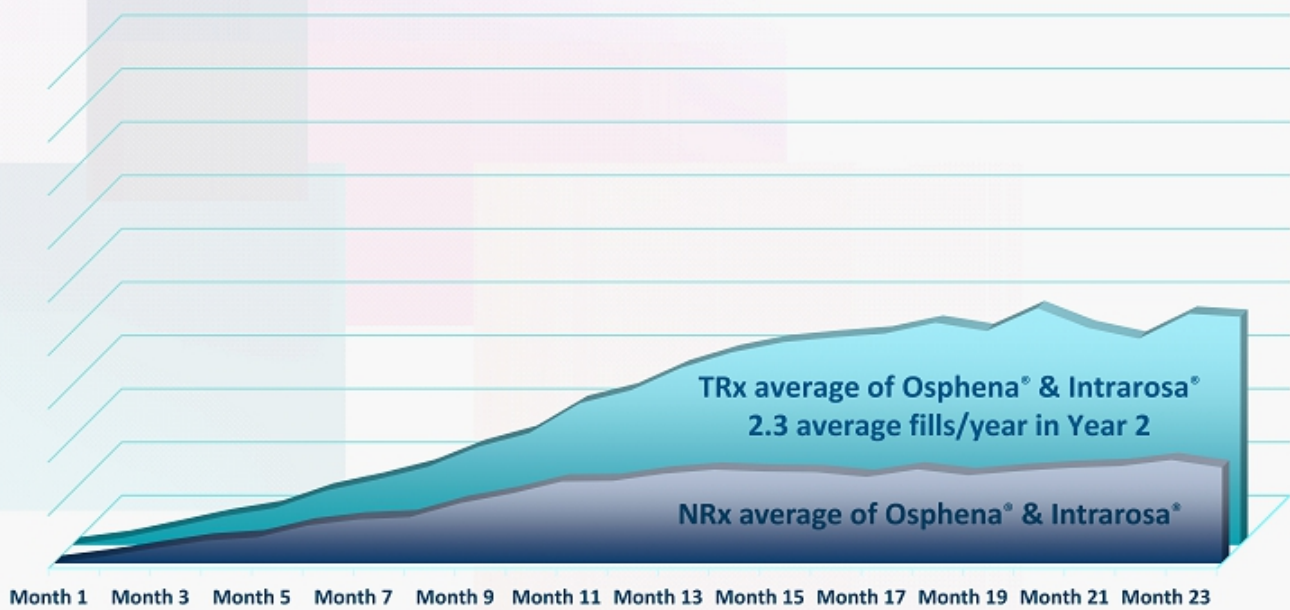
References:
1. PHAST Symphony

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Adherence Creates Increase Ramp Year 2 and Beyond

Assuming the same amount of new prescriptions as Osphena® and Intrarosa®

Average of Launch for Osphena® & Intrarosa®



AFPY – Average # of Fills per year per patient

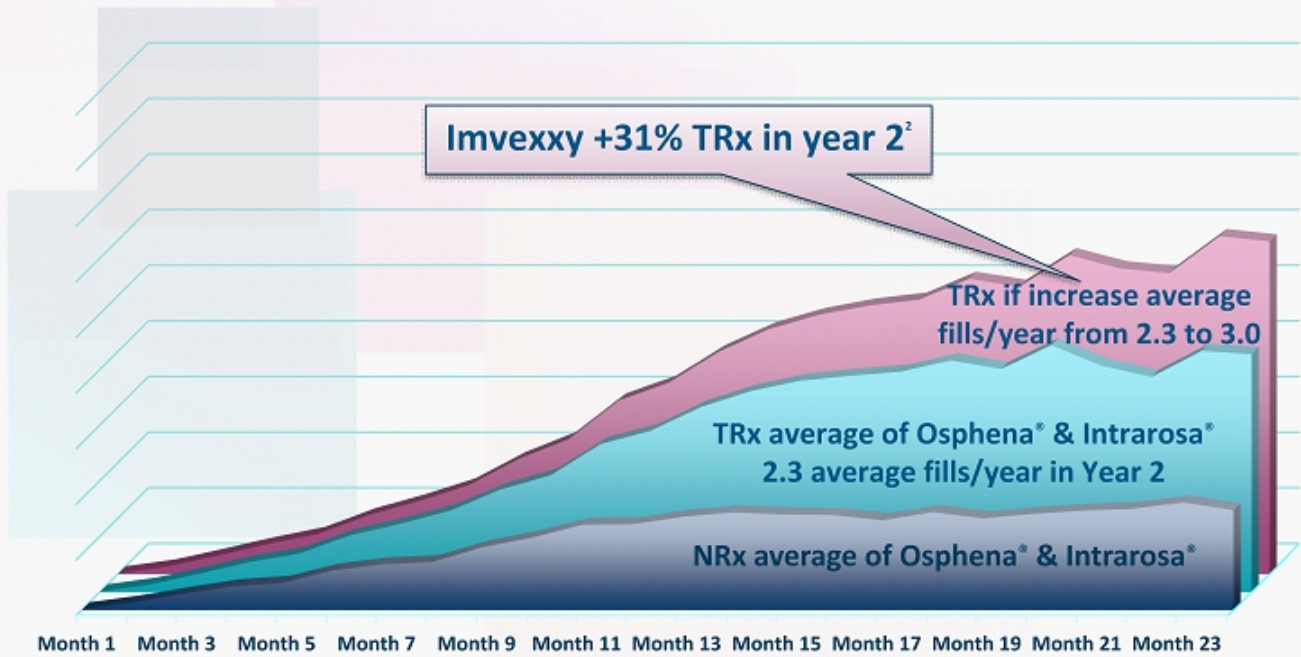
References:
1. PHAST Symphony

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Adherence Creates Increase Ramp Year 2 and Beyond

Assuming the same amount of new prescriptions as Osphena® and Intrarosa®



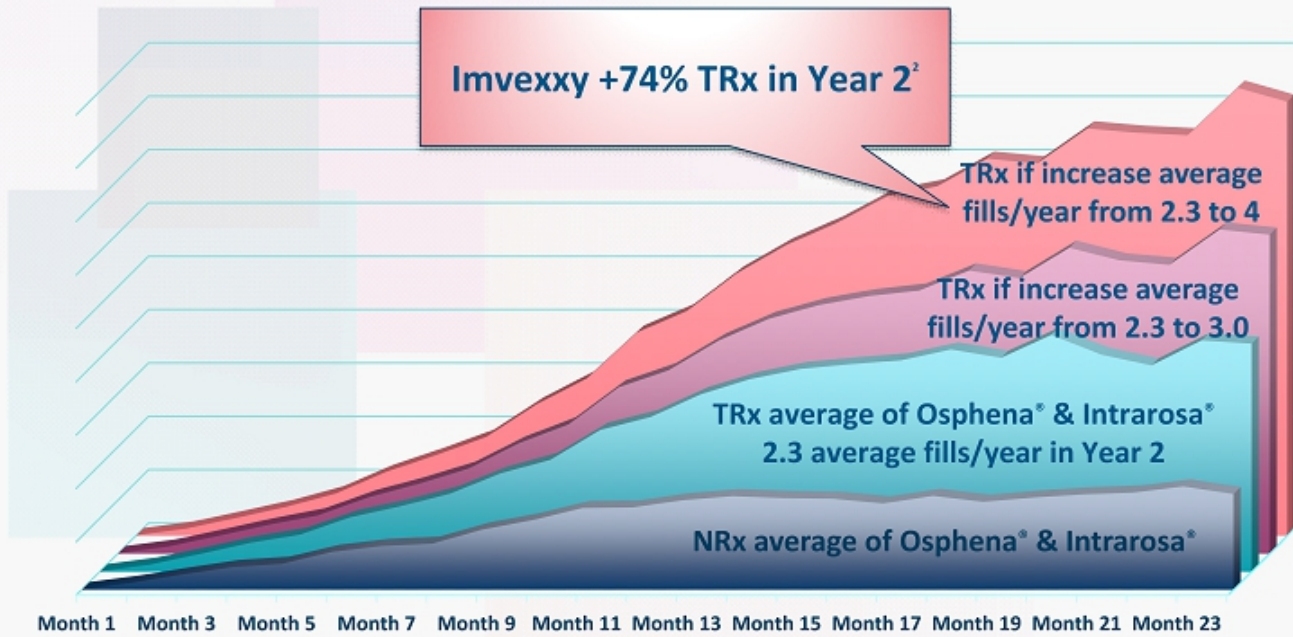
- References:
1. PHAST Symphony
2. Projected estimate

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Adherence Creates Increase Ramp Year 2 and Beyond

Assuming the same amount of new prescriptions as Osphena® and Intrarosa®



- References:
1. PHAST Symphony
 2. Projected estimate

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Market Potential of Imvexxy at Year 5

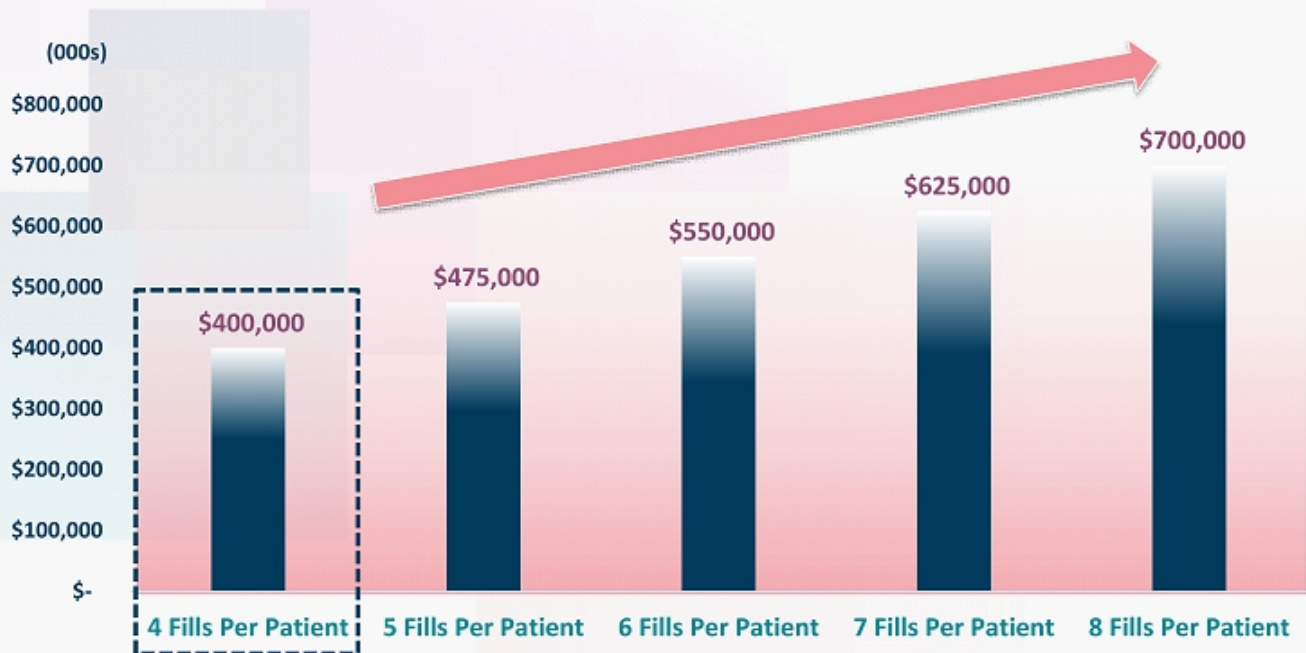
Year 5 Assumptions

- Total VVA Patients on HT¹ 2,300,000
 - Imvexxy Market Share 25 - 30%
 - Imvexxy Patients 665,000
 - WAC of Loading Dose \$405.00
 - WAC of Maintenance Dose \$180.00
 - Sum of Total Discounts per Rx 35%
-
- Assumes zero market growth
 - Assumes zero price increases

1) IQVIA Total Patient Tracker (2017 Data)

Incremental Fills Per Year Drives Significant Upside to Net Revenues

- Each incremental fill per year can add an estimated \$75M to Imvexxy net revenues



Trend of Payor Coverage Intrarosa®

Historical trends show recent competitor launch getting to ~65% unrestricted Commercial access 9 months after field launch



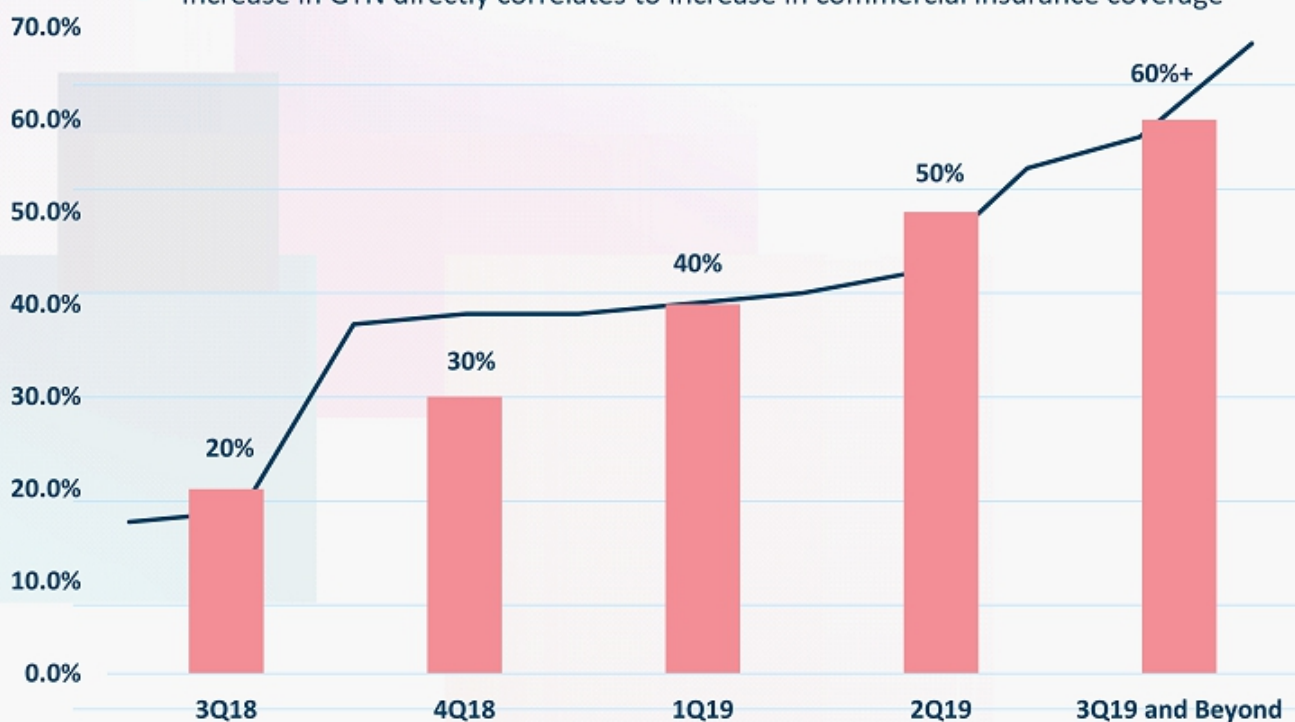
References:
1. MMIT

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Imvexxy Launch Quarterly Gross-to-Net Assumptions

- Long-term gross to net assumptions of 60%+ starting in second year of launch
- Increase in GTN directly correlates to increase in commercial insurance coverage



References:
1. MMIT

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How to Measure Progress

KPI's to Track

- ❑ **Number of new writers & total writers** - *indicates pace of trial and adoption by HCP*
- ❑ **New Rx** – *indicates market penetration against competition*
- ❑ **Total Rx** – *overall units sold*
- ❑ **Refill Rate** – *affordability and compliance programs taking hold*
- ❑ **Ramp of commercial insurance coverage** – *indicator of adoption by payors and precursor to increases in GTN*
- ❑ **Quarterly trend of gross to net**

Q&A

Panel

Sheryl Kingsberg

Sharon Parish

Bob Lahman

Robert Reid

Robert Finizio

Brian Bernick

Dawn Halkuff

Mitchell Krassan

Mike Steelman

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TX-001HR

Combination

Estrogen + Progesterone
(E+P) Program



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Market Opportunity

Brian Bernick, M.D.
Chief Clinical Officer

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TX-001HR Product Development Rationale

- 2002 Women's Health Initiative (WHI) study showed that *synthetic* hormones 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)
- 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*
 - 90M+ scripts of synthetic hormone therapy prescribed annually before 2002, declining to ~10M in 2015¹



➤ 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 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
- 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.

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TX-001HR – Potential Best in Class Therapy

	TX-001HR (If Approved)
Bio-Identical	✓
Single Dose Combination	✓
VMS Efficacy Data	✓
Endometrial Cancer Safety Data	✓
FDA-Approved	✓ ¹
Third-Party Reimbursement	✓ ²

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
- 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 to be submitted December 2017, pending FDA review and approval
2) Reimbursement anticipated if FDA-approved

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 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	3,802,925¹
	Estradiol	2,297,141	5,033,146	2,722,199	1,476,272	11,578,758¹

- **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 IQV; 12 months as of December 31, 2017
 2) Includes the following drugs: Activella®, FemHRT®, Argefka®, Generic 17β - Progesterin, Prempro®, Premphase®, Duavee®, Bristole®
 3) Assume WAC pricing between \$200-250

All trademarks are the property of their respective owners.

TX-001HR Could Fulfill Therapeutic Gap For All Participants

Patients

- Meet demand for bio-identical hormone therapy with a product approved by FDA on safety and efficacy
- safe and effective
- Reduce of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at all 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
- Significantly improve net margin per script with third-party reimbursement
- Lower legal and regulatory costs and risk

FDA/Regulatory Bodies

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

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Compounding Channel

Dedra Reiger Lyden
Strategic Partnerships &
Initiatives Lead

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Compounding Pharmacy Economics

Richard Moon, PharmD, R.Ph.

Principal, Premier Value Pharmacy Compounding Network (PVPCN)/Artiria

- Artiria - the largest compounding network representing 350 pharmacies

Additional owner of Pharmacy Innovations, a group of 7 specialty and compounding pharmacies throughout the United States:

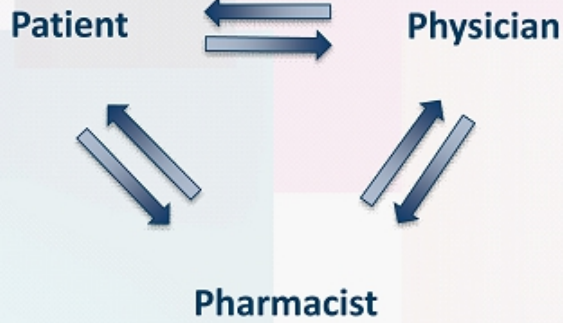
- 25 years in business
- Compounding 40% of revenue
- FDA-approved products 60% of revenue
- Licensed in all 50 states, Washington, DC and Puerto Rico
- Past International Academy of Compounding Pharmacists President (IACP), Treasurer, and Board Member

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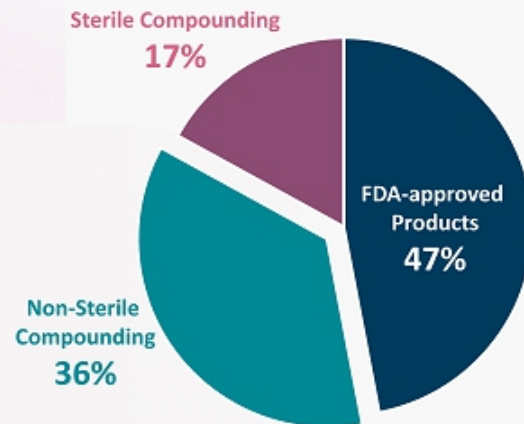
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Understanding the Compounding Pharmacy

Collaborative Relationship



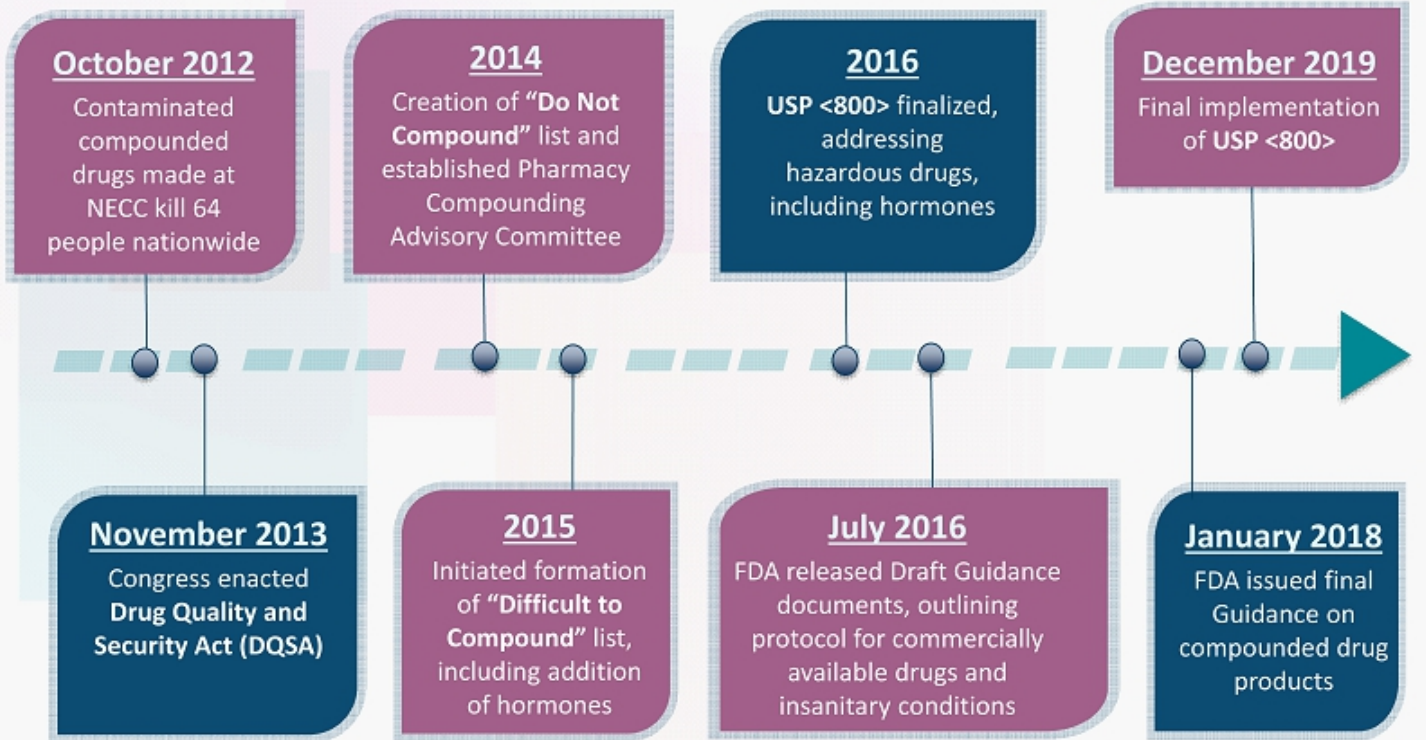
Compounding Pharmacies % of Business (by Prescription Units)



N = 3,000-3,500 Compounding Focused Pharmacies^{1,2,3}

(1) 2013 National Community Pharmacists Association Digest: Financial Benchmarks (Sponsored by Cardinal Health)
(2) NCPA Community Pharmacy Compounding Survey (November 2012)
(3) NPI Database: using taxonomy codes

Regulatory Environment Continues to Favor FDA-Approved Products



1) <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>
2) http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3) <https://www.ascp.com/sites/default/files/Join%20USP%20letter%200015%20FINAL.pdf>

Partnering Rationale

Increased Regulatory Pressures Facing Compounding Pharmacies

- Increased FDA and State enforcement of essential copies
- USP <800> now tied to USP <795> significantly increases cost for hormones
- OSHA, FDA, DEA, State, Accreditation Bodies (NAPB, JCAHO, PCAB and others) – All require documentation and compliance

Increased Financial Pressures

- Loss of reimbursement
- Cash pay market is limited once an FDA-approved drug is offered by other compounding pharmacies / coupon
- Increased cost of USP <800>
- Increased cost of regulatory compliance
- Already dispense FDA-approved drugs

Benefits of Partnering with TXMD

- Reduces or eliminates amount of regulatory pressure
- Reduces initial and ongoing costs of compliance
- Improved topline revenue
- Maintains and improves bottom line profit
- Redeploy internal staff to profitable areas
- Reduce patient out of pocket costs, keep patient happy
- Validates science behind existing B-HRT (vs the Bio-Ignite program– opportunity to increase the overall market like AndroGel® and several others)

Independent Pharmacy Net Income Per Compounded Script

Economic Support TXMD Partnership for Patient Care

	Insurance Coverage (before 2H14)	Present Day (2018)	Post USP <800> (Dec. 2019)	TX-001HR Launch 1Q2019
Revenue				
Patient Co-Pay	\$50.00	\$50.00	\$50.00	\$50.00
Third-Party Reimbursement	\$115.00	-	-	\$200.00
Total Net Revenue	\$165.00	\$50.00	\$50.00	\$250.00¹
Costs of Good Sold	\$7.50	\$7.50	\$7.50	\$200.00 ²
Gross Profit	\$157.50	\$42.50	\$42.50	\$50.00
<i>Gross margin</i>	<i>95.5%</i>	<i>85.0%</i>	<i>85.0%</i>	<i>20.0%</i>
Operating Expenses				
G&A	\$15.00	\$15.00	\$15.00	\$15.00
S&M	\$7.50	\$7.50	\$7.50	\$5.00
Additional Compounding Costs ¹	\$15.00	\$15.00	\$15.00	-
<i>Cost of USP <800> Requirements²</i>	-	-	\$10.00	-
Total Operating Expenses	\$37.50	\$37.50	\$47.50	\$20.00
Pre-Tax Profit	\$120.00	\$5.00	\$(5.00)	\$30.00

1) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses

2) December 2019 Implementation; includes >\$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs

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Small Compounding Pharmacy Economics

John Walczyk, PharmD, R.Ph.

Owner, Johnson's Compounding and Bird's Hill Pharmacy

- Owner of one of two sterile compounding pharmacies in Massachusetts
- Represents one of four USP<800> compliant compounding pharmacies in Massachusetts
- Board Member of American College of Apothecaries
- Massachusetts Board of Pharmacy, Advisory Council Member

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What USP <800> Really Means

Compounding Bioidentical
Hormone Therapy (BHRT) Today



Adolphe Pierre-Louis - Albuquerque Journal - 2/13/2017

Compounding BHRT
after December 2019



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USP <800> Expenses Create Large Barriers for Compounders

USP <800> Requirements	Cost	Implementation Time
Segregated Clean Room: <ul style="list-style-type: none">▪ USP <800> Design▪ Construction	\$60,000 - \$200,000	1 year – 1.5 years
Ventilation System	\$25,000 - \$50,000	
New Equipment for Hazardous Compounding	\$15,000 - \$50,000	-
Total	\$100,000 - \$300,000	1 year – 1.5 years

- High upfront capital expenditures required for compliance
- Long implementation time
- Increased ongoing operating expenses associated with capital expenditures

Increased Compounding Costs Support TX-001HR Partnership

Independent Pharmacy Net Income Per Script with TX-001HR

	Compounded E+P Post USP <800>	TX-001HR Launch 1Q2019
Revenue		
Patient Co-Pay	\$89.95	\$50.00
Third-Party Reimbursement	-	\$200.00
Total Net Revenue	\$89.95	\$250.00¹
Costs of Good Sold	\$9.95	\$200.00 ²
Gross Profit	\$80.00	\$50.00
<i>Gross margin</i>	<i>89.0%</i>	<i>20.0%</i>
Operating Expenses		
G&A	\$27.00	\$15.00
S&M	\$9.00	\$5.00
Additional Compounding Costs ³	\$7.50	-
Cost of USP <800> ⁴	\$15.00	-
Total Operating Expenses	\$58.50	\$20.00
Pre-Tax Profit	\$21.50	\$30.00

- Decreased volumes for bio-identical hormones
- Increased competition on price has resulted in loss of volumes



- FDA-Approved product provides ability to charge a more competitive price point

1) Assume AWP-18% Third-Party Reimbursement

2) Assume \$250/WAC less 20% distribution discount

3) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses

4) December 2019 Implementation; includes >\$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs

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Financial Effect of USP <800> Costs for Small Pharmacies

- Higher prices needed to recoup capital investment and pay for increased operating expenses
- Increased competition on price has resulted in loss of volumes
 - Current pricing unsustainable
- Patients continue to search for lowest cost options

	Pre-USP <800>	Post-USP <800>	TX-001HR Launch
Revenue			
Patient Co-Pay	\$59.95	\$89.95	\$50.00
Third-Party Reimbursement	-	-	200.00
Total Net Revenue	\$59.95	\$89.95	\$250.00 ¹

Key Takeaways

- FDA-approved products enable small pharmacies to compete on price
- Lower patient co-pays help retain existing customers and attract new business
- Implemented this model with Makena[®] - AndroGel[®]

1) Assume AWP-18% Third-Party Reimbursement

2) Assume \$250/WAC less 20% distribution discount

3) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses

4) December 2019 Implementation; includes >\$150,000 capital expenditure as well as new identification requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs

Bio-Ignite

Dedra Reiger Lyden
Strategic Partnerships &
Initiatives Lead

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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.



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BIO-IGNITE™

Implementation Plan

Limited Launch Goals

IMVEXXY

Operationalize – This new Segment

- ✓ Develop Case Studies for Marketing
- ✓ Build Trust with New Partners
- ✓ Utilization of Primary & Secondary Wholesalers
- ✓ Class of Trade Programs
- ✓ Develop pull through

Target Program Adoption

- ✓ 50-100 Pharmacy Partners First Year
- ✓ 12 Months
- ✓ Actively stocking & filling

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BIO-IGNITE™

Implementation Plan

National Rollout
TX-001HR

Complete Program Launch

- ✓ Activation of Invexxy Partners
- ✓ Peer-to-Peer Promotion
- ✓ Turn-key partner enrollment
- ✓ Product acquisition
- ✓ Account management programs

Target Program Adoption

- ✓ 900 pharmacies
- ✓ 24 Month Ramp

Target List

- ✓ Qualified: High-volume BHRT over 1,500
- ✓ Longtail: 3,000

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**Life Cycle
Management &
Financial Update**

Robert Finizio
Chief Executive Officer

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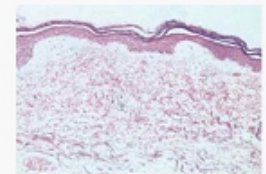
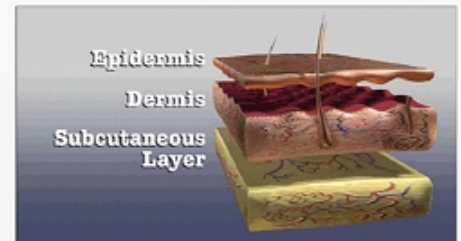
Life Cycle Management

- **To mitigate risks of competition and increase the overall value of Imvexxy and TX-001HR assuming we are taking significant market share**
 - New formulations / life cycle management for Imvexxy and TX-001HR goals
 - Improved bioavailability
 - Reduced variability
 - Reduced frequency of dosing
 - New lower effective doses
 - New delivery modalities (transdermal)
 - Label expansion and new indications
 - Symptoms of VVA in breast cancer survivors on aromatase inhibitors
 - Dermatologic indications for TX-001HR

- **Proof-of-concept studies to begin as early as second half of 2018**

TX-001HR: Skin Indication

- **Skin improvement often observed with compounded Bio-identical Hormone Therapy**
- **Numerous studies demonstrates that estrogen deprivation leads to:**
 - Skin dryness and atrophy
 - Decreased skin thickness and decreased collagen in the dermis
 - Decreased extensibility, consistency & elasticity
 - Diminished skin moisture and fine wrinkling
 - Altered ultrastructural skin organization
 - Poor wound healing
- **Business Rational**
 - If approved, only product for hot flashes to have an indication to improve skin quality
 - One of the top complaints for menopausal women
 - Financially bridge TX-001HR into the Aesthetic market domestically and cash pay market Ex-US
- **Anticipate meeting with FDA 1Q 2019 to evaluate**



Flexible, Non-Dilutive Term Loan Financing Secured

- Entered into a definitive loan agreement with MidCap Financial, managed by Apollo Capital Management, L.P., for \$200 million in non-dilutive term loan financing
- The term loan will be available to the company in three tranches following specific milestones through December 31, 2019:
 - \$75 million will be available upon the approval of Imvexxy and intend to draw down immediately
 - Anticipated to be funded on or about June 7, 2018
 - \$75 million will be available upon the approval and launch of TX-001HR
 - \$50 million will be available upon generating \$75 million of trailing twelve month net revenue attributable to Imvexxy and TX-001HR on or before December 31, 2019
- Upon drawing the capital, the term loan will accrue interest at 1-month LIBOR plus 7.75%, which equates to a **current interest rate of approximately 9.75%**
- No equity or warrants attached and a favorable prepayment fee schedule
- Maturity date: May 1, 2023

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Significant Insider and Institutional Share Ownership

- Board of directors and executive officers have long-term commitment to the company
 - Beneficially own approximately 23% of the company's shares
 - Three founding executives beneficially own approximately 19% of the company's shares ¹
- Large institutional holder support
 - Large institutional holders – many long-term – beneficially own more than 55% of the company's outstanding shares

1. 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.

Q&A

Panel

Rich Moon

John Walczyk

Robert Finizio

Brian Bernick

Dedra Reiger Lyden

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THANK YOU!

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Appendix

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Replenish Trial Co-Primary Endpoints

Primary Efficacy Endpoints: Mean Change in Frequency and Severity of Hot Flashes Per Week Versus Placebo at Weeks 4 and 12, VMS-mITT Population					
Estradiol/Progesterone	1 mg/100 mg (n = 141)	0.5 mg/100 mg (n = 149)	0.5 mg/50 mg (n = 147)	0.25 mg/50 mg (n = 154)	Placebo (n = 135)
Frequency					
Week 4 P-value versus placebo	<0.001	0.013	0.141	0.001	-
Week 12 P-value versus placebo	<0.001	<0.001	0.002	<0.001	-
Severity					
Week 4 P-value versus placebo	0.031	0.005	0.401	0.1	-
Week 12 P-value versus placebo	<0.001	<0.001	0.018	0.096	-
Primary Safety Endpoint: Incidence of Consensus Endometrial Hyperplasia or Malignancy up to 12 months, Endometrial Safety Population [†]					
Endometrial Hyperplasia	0% (0/280)	0% (0/303)	0% (0/306)	0% (0/274)	0% (0/92)

MITT = Modified intent to treat

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

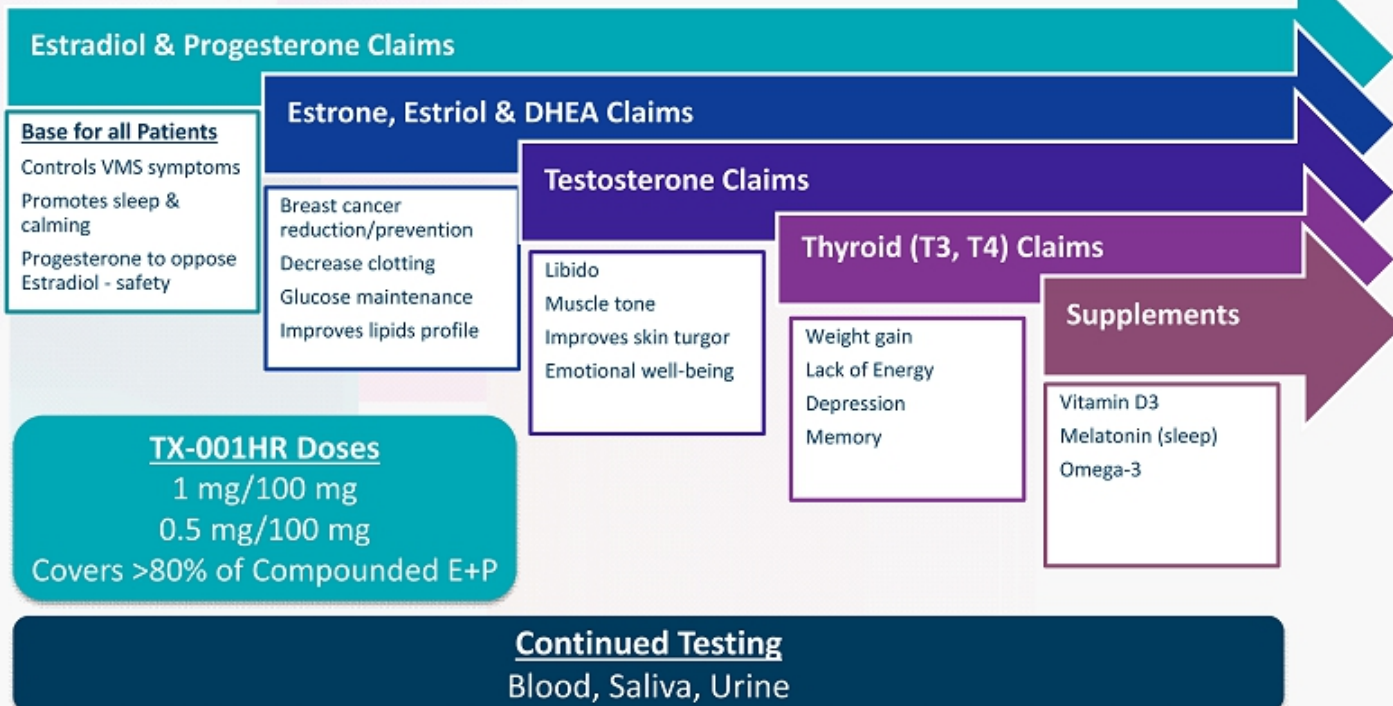
P-value < 0.05 meets FDA guidance and supports evidence of efficacy

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

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

Compounding Pharmacy Menopausal Treatment Paradigm

Customization is adding therapy...not tweaking dosages



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