

# INVESTOR DAY

## June 10, 2019

**TXMD**  
Nasdaq Listed

**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

**Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

**ANNOVERA™**  
(segesterone acetate  
and ethinyl estradiol  
vaginal system)



# Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as “we” and “our”) may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as “believe,” “hope,” “may,” “anticipate,” “should,” “intend,” “plan,” “will,” “expect,” “estimate,” “project,” “positioned,” “strategy” and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled “Risk Factors” in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop and commercialize IMVEXXY®, ANNOVERA™, BIJUVA™ and 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 facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our products; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; 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.

This non-promotional presentation is intended for investor audiences only.



# WELCOME

**Robert Finizio**

*Chief Executive Officer*

**TXMD**  
Nasdaq Listed

**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

**Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

**ANNOVERA™**  
(segesterone acetate  
and ethinyl estradiol  
vaginal system)



# TXMD Investor Day Agenda

11:00-11:10 AM

## OVERVIEW AND INTRODUCTIONS

Welcome – Robert Finizio  
Introductions – Brian Bernick, M.D.

11:10-11:50 AM

## KEY OPINION LEADERS – IMVEXXY, BIJUVA AND ANNOVERA

IMVEXXY – Risa Kagan, M.D.  
BIJUVA – James Simon, M.D.  
ANNOVERA – James Liu, M.D.  
Portfolio View – Jay Cohen, M.D.

11:50-12:00 PM

## Q&A PANEL

12:00-1:00 PM

## PORTFOLIO COMMERCIAL LAUNCH STRATEGY

IMVEXXY Launch Strategy & Performance Metrics – Dawn Halkuff  
BIJUVA Launch Strategy & Performance Metrics – Dawn Halkuff  
ANNOVERA Launch Strategy - Dawn Halkuff  
BIO-IGNITE Update - Dedra Lyden  
Compounding Pharmacist Perspective - Donnie Calhoun  
Compounding Pharmacist Perspective - Scott Mazza

1:00-1:10 PM

## Q&A PANEL

1:10-1:40 PM

## PAYER OVERVIEW

Payer Environment – Robert Lahman  
Payer Update – Mike Steelman  
ANNOVERA – Ambrose Carrejo

1:40-2:15 PM

## CLOSING – PORTFOLIO OF 3 PRODUCTS AND FINANCIAL GUIDANCE

How strategy, plan and model come together – Mitch Krassan  
Financial Guidance - Rob Finizio

2:15-2:30 PM

## Q&A PANEL



# CLINICAL INTRODUCTION

**Brian Bernick, M.D.**

*Co-founder and Director*



**Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

**ANNOVERA™**  
(segesterone acetate  
and ethinyl estradiol  
vaginal system)

**TXMD**  
Nasdaq Listed



# Portfolio Approach to Women's Health

## Sum of the Parts

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

 **vitaMedMD®**  
Prenatal Vitamins

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

  
**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

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



### Focused on lifespan of the patient and healthcare provider's needs

- Innovative products, chronic conditions, large markets
- Single call point
- Products transition from one to the next through the various stages of life
  - contraception → prenatal vitamins → contraception → vasomotor symptoms → vulvar and vaginal atrophy
- Patient cost conscious portfolio
  - Products with patient out-of-pocket costs of \$35 or less with copay programs
  - Possibility of no out-of-pocket costs for Annovera

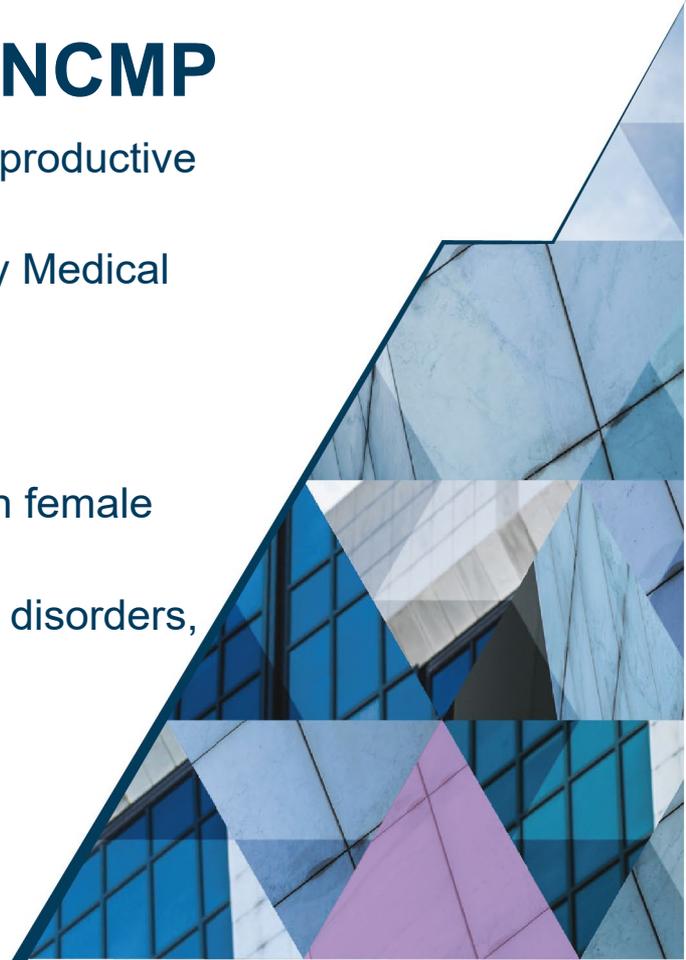




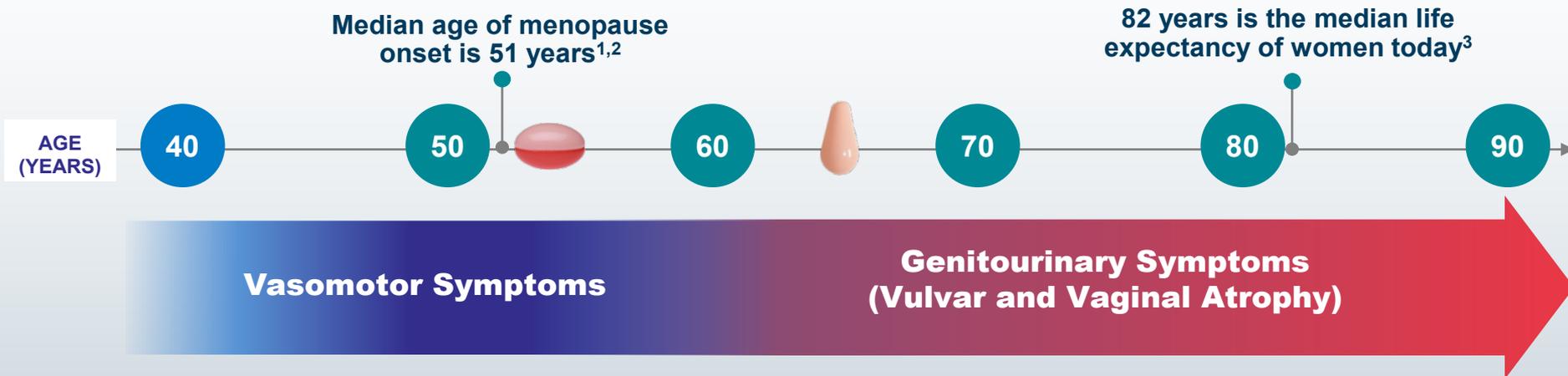
## Risa Kagan, MD, FACOG, CCD, NCMP

- Clinical Professor in the Department of OB/GYN and Reproductive Sciences at UCSF
- Gynecologist and Clinical Research with Sutter East Bay Medical Foundation
- Past Trustee of NAMS
- Leading expert in sexual medicine and menopause
- Lead author for the pivotal peer reviewed publications on female sexual disorders, menopause and bone health
- Principal investigator for over 100 clinical trials of sexual disorders, menopause and bone health

**TXMD**  
Nasdaq Listed



# Women are Menopausal More Than One-third of Their Lives<sup>1</sup>



**Vulvar and Vaginal Atrophy (VVA)** is a chronic and progressive condition and is unlikely to resolve without medical intervention<sup>4,5</sup>

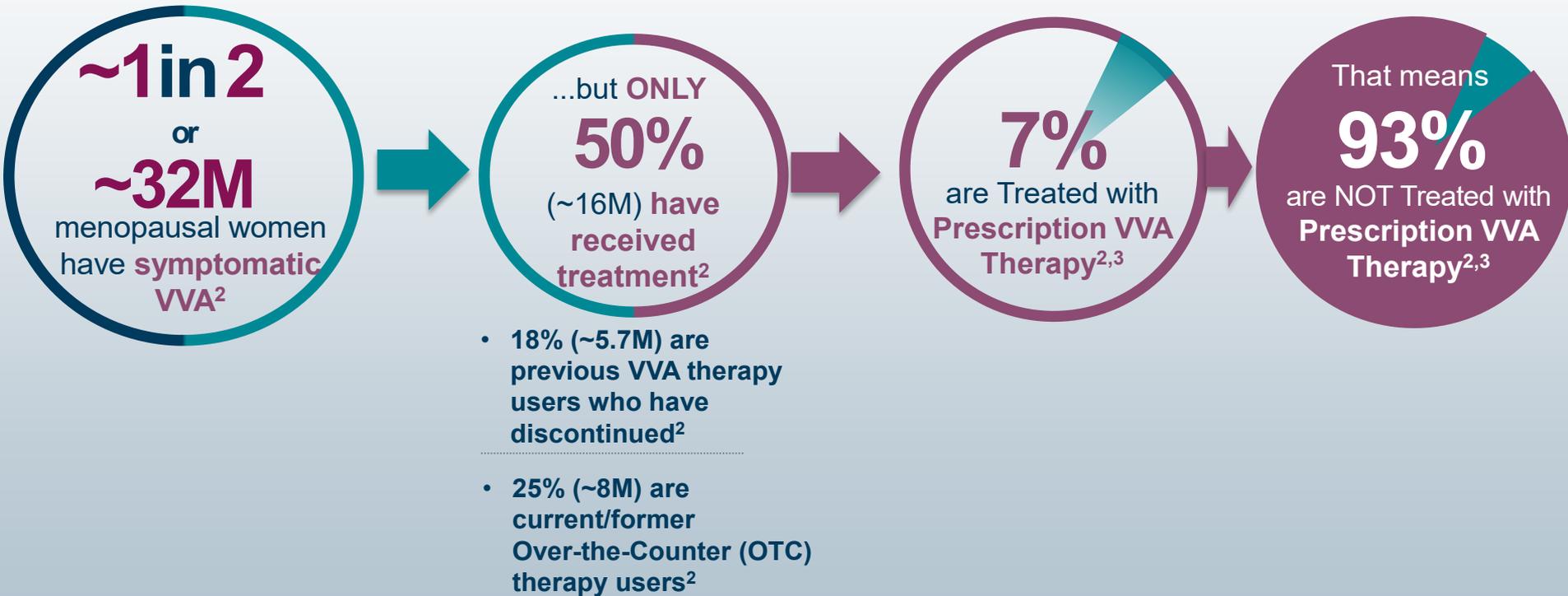
Symptoms of VVA may include:<sup>6,7</sup>

- Dyspareunia (vaginal pain associated with sexual activity)
- Vaginal dryness
- Vaginal and/or vulvar irritation/itching/burning
- Bleeding with sexual activity
- Dysuria (pain when urinating)

1. Parish SJ, et al. *Menopause*. 2018;25(8):937-941. 2. North American Menopause Society. *Menopause* 101. [www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal](http://www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal). Accessed March 25, 2019. 3. US Census Bureau. <http://worldpopulationreview.com/countries/united-states-population/>. Accessed April 23, 2019. 4. North American Menopause Society. *Menopause*. 2013;20(9):888-902. 5. Wysocki S et al. *Clin Med Insights Reprod Health*. 2014;8:23-30. 6. Kingsberg SA et al. *J Sex Med*. 2013;10(7):1790-1799. 7. North American Menopause Society. *Menopause*. 2013;20(9):888-902.

# The Scope of VVA in the US

## 64 Million Menopausal Women in the US<sup>1</sup>



1. Wysocki S et al. *Clin Med Insights Reprod Health*. 2014;8:23-30.

2. Kingsberg SA et al. *J Sex Med*. 2017;14:413-424.

3. IMS Health Plan Claims (April 2008-Mar 2011).

# IMVEXXY is “Redefining Relief”

A highly effective patient experience supported by strong clinical attributes

 **Imvexxy**<sup>®</sup>  
(estradiol vaginal inserts)



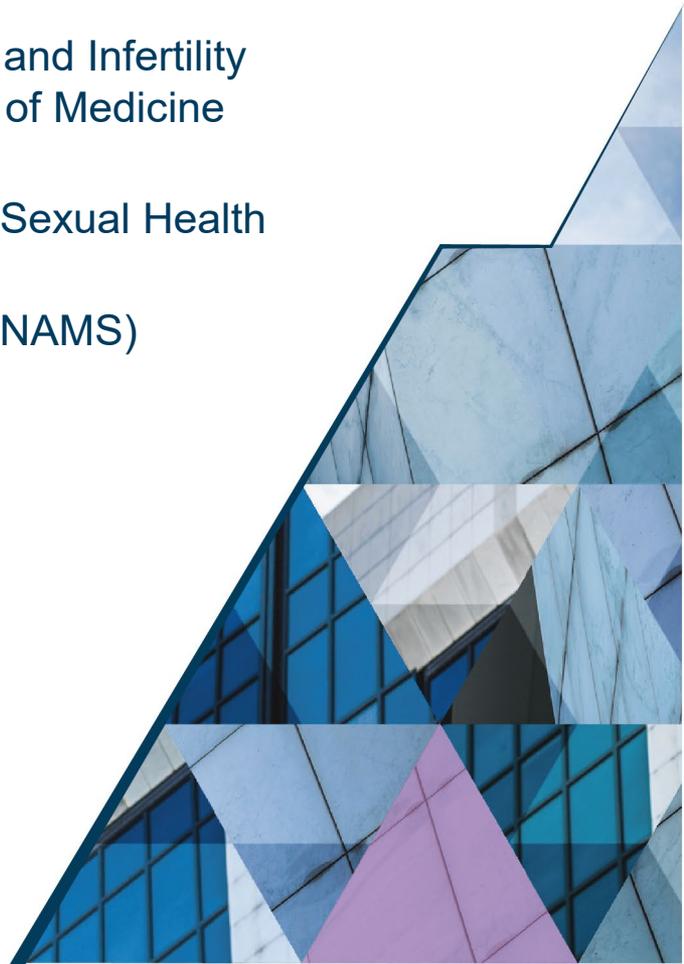
- Small, digitally inserted, vaginal softgel insert that dissolves completely
  - **Easy to use without the need for an applicator**
  - **Mess-free** administration
  - Use **any-time of day**
  - **New lowest approved doses** of estradiol 4 mcg and 10 mcg
  - **Efficacy demonstrated as early as 2 weeks** (secondary endpoint) and maintained through week 12
  - PK data - **No increase in systemic hormone levels** beyond the normal postmenopausal range\*
  - Mechanism of action and dosing that are familiar and comfortable
  - No patient education required for dose preparation or applicators
  - **Dose packaging to optimize compliance and convenience**
- ➔ **High patient satisfaction resulting in high refill rates**



\*The clinical relevance of systemic absorption rates for vaginal estrogen therapies is not known.

## James A. Simon, MD, CCD, NCMP, IF

- Clinical Professor Division of Reproductive Endocrinology and Infertility  
Department of The George Washington University School of Medicine  
Washington, D.C.
- President, International Society for the Study of Women's Sexual Health  
(ISSWSH)
- Past President, The North American Menopause Society (NAMS)
- Leading expert in sexual medicine and menopause
- Lead author for the pivotal peer reviewed publications on  
female sexual disorders and menopause
- Over 400 publications
- Principal investigator for more than 350 clinical trials



# Menopause Overview



Menopause represents the natural life-stage transition when women stop having periods as the production of estrogen and progesterone decreases

- May result in physical and emotional symptoms<sup>1</sup>
  - Symptoms include vasomotor symptoms (hot flashes and night sweats), mood changes and vaginal dryness
  - Prolonged lack of estrogen can affect the bones and cardiovascular system
- Estrogen is given to reduce symptoms and other long-term conditions
  - Increased risk for endometrial hyperplasia/endometrial cancer if estrogen unopposed<sup>2</sup>
- Progesterone is given to prevent thickening of the uterine wall when estrogen is used<sup>2</sup>



Vasomotor symptoms are experienced by the majority of women during the menopausal transition<sup>3</sup>

- As many as 74% of menopausal women<sup>4</sup>
- Up to 88% of perimenopausal women<sup>4</sup>



Vasomotor symptoms typically continue for 4 to 5 years following menopause and may last more than 10 years after final menstrual period in some women<sup>5,6</sup>

## References

1. National Institutes of Health, National Institute on Aging, <https://www.nia.nih.gov/health/publication/menopause>, last accessed November 3, 2015. 2. International Journal on Women's Health, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3897322/> 3. Thurston RC et al. *Obstet Gynecol Clin North Am.* 2011;38(3):489-5014. Rapkin AJ. *Am J Obstet Gynecol.* 2007;196(2):97-106... 5. Freeman EW et al. *Menopause.* 2014;21(9):924-932. 6. Kleinman NL et al. *JOEM.* 2013;55(4):465-470.

# BIJUVA Product Development Rationale

- **2002 Women's Health Initiative (WHI)** study showed that the long-term use of certain ***synthetic* hormones** (a combination of medroxyprogesterone acetate and conjugated equine estrogens) **increased the risk of breast cancer, stroke, heart attack and blood clots**
  - **Prior to BIJUVA**, all FDA-approved combination hormonal products contain a synthetic progestin and not a bio-identical progesterone
- **After WHI**, women and healthcare providers shifted to bio-identical hormone therapy as an alternative despite estradiol and progesterone combinations being *unapproved* drugs for use together
- **Compounding filled the need for bio-identical hormone therapy**
- **All the major medical societies and the FDA discourage the prescribing of compounded hormones**

➤ **NEED FOR AN FDA-APPROVED COMBINATION BIO-IDENTICAL HORMONE THERAPY**

# Current Hormone Therapy Options for Vasomotor Symptoms

After WHI (2002), a majority of women and clinicians shifted to bio-identical hormone therapy<sup>1,2</sup>

FDA-APPROVED		NOT FDA-APPROVED
<b>Combination <u>Synthetic</u> Estrogens + Progestins*</b> 	<b>Separate <u>Bio-identical</u> Estradiol &amp; Progesterone</b> 	<b>Compounded <u>Bio-identical</u> Estradiol + Progesterone</b> 
~ 2.5 million total annual prescriptions <sup>1</sup>	~ 3.9 million total annual prescriptions (each) <sup>2</sup>	12 - 18 million total annual prescriptions <sup>3</sup>
Prempro®, Activella®, Angeliq®, Femhrt®, Climara Pro®, Combipatch®	Oral or transdermal estradiol & Prometrium®	Compounded estradiol + progesterone
FDA-approved	Not FDA-approved to be used together	Not FDA-approved
1 copay	2 copays	Often not covered by insurance
Insurance coverage	Insurance coverage	Almost 100% out of pocket

## ➤ NEED FOR AN FDA-APPROVED COMBINATION BIO-IDENTICAL HORMONE THERAPY

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2018

2) Includes the following drugs: Activella®, FemHRT®, Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Bristelle®

3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications

All trademarks are the property of their respective owners.



**BIJUVA is indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause**

## KEY CLINICAL ATTRIBUTES

- First and only bio-identical combination of estradiol to reduce moderate to severe hot flashes combined with progesterone to help reduce the risk to the endometrium
- Strong efficacy and safety data
- Sustained steady state of estradiol
- No clinically meaningful changes in weight or blood pressure
- No clinically meaningful changes in coagulation or lipid parameters
- No clinically meaningful changes in mammograms
- Clinically meaningful improvements in quality of life and sleep disturbance data
- High desired amenorrhea rates (no bleeding)

## OTHER KEY ATTRIBUTES

- Once-a-day single oral softgel capsule – only approved continuous combined progesterone product
- No peanut allergen (as in other FDA-approved progesterone products)
- One prescription, one copay
- BIJUVA is available in blister packages containing 30 capsules

**Bijuva**<sup>™</sup> 1mg/100mg  
(estradiol and progesterone) capsules

References:

BIJUVA [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2019. Lobo RA, et al. *Obstet Gynecol.* 2018;132(1):161-170. Lobo RA, et al. North American Menopause Society Annual Meeting, October 3 – 6, 2018, San Diego, CA, USA, abstract number S-2.

**TherapeuticsMD**<sup>®</sup>  
For Her. For Life.

**TXMD**  
Nasdaq Listed

# ANNOVERA™

(segesterone acetate and ethinyl  
estradiol vaginal system)

TherapeuticsMD®

*For Her. For Life.*

## James Liu, MD

- President, North American Menopause Society (NAMS)
- Chairman, Department of Obstetrics and Gynecology, University Hospitals Health System, MacDonald Women's Hospital, Cleveland, Ohio
- Chair, Department of Reproductive Biology, Case Western Reserve University
- Obstetrician-Gynecologist in Chief, University Hospitals Health System
- Leading expert in fertility, contraception, sexual medicine and menopause
- Lead author for over 114 pivotal peer reviewed publications on women's health
- Principal investigator for multiple clinical trials including NIH Contraceptive Clinical Trials Network
- Holds five patents on vaginal drug delivery

**TXMD**  
Nasdaq Listed



# ANNOVERA - 1-Year Vaginal System

Segesterone Acetate [Nestorone®]/Ethinyl Estradiol

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



- ANNOVERA approved on August 10, 2018
  - Segesterone acetate component of ANNOVERA classified as NCE with 5 year exclusivity
- Developed by the Population Council – creator of the best selling long- acting contraceptive products
  - **ParaGard®** and **Mirena®** IUDs; **Norplant®** and **Jadelle®** implants®
- Motivation was for a long-acting product that doesn't require a procedure for insertion or removal

All trademarks are the property of their respective owners.

# U.S. Contraceptive Market

- Contraception is most notably used for family planning, but also to control symptoms associated with menstruation, endometriosis, fibroids, acne and perimenopause
  - Nearly all women (99%) have used contraceptives at some point in their lives<sup>1</sup>
  - Long-acting methods of contraception (IUDs and Implants) are experiencing the greatest growth (CAGR 15.3% from 2012 to 2017), while daily oral contraceptive use has declined (CAGR -4.2% from 2012 to 2017)<sup>2</sup>
  - Yet, these long-acting methods are not offered routinely by a large segment of women's health providers
    - According to research, only 56% of office-based obstetricians/gynecologists, family practitioners, and adolescent medicine specialists offered on-site IUDs; only 32% offered implants<sup>3</sup>
      - ~45% of preventive care visits among reproductive-age women are made to family practitioners, nurse practitioners, or internists<sup>3</sup>
        - Less than a quarter of family practitioners report providing any form of long-acting reversible contraception<sup>4</sup>
- **Women and healthcare providers want a long-lasting, reversible, patient controlled and procedure-free birth control**



1. CDC. Current Contraceptive Status Among Women Aged 15–49: United States, 2015–2017, <https://www.cdc.gov/nchs/products/databriefs/db327.htm> 2. QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. 3. Pace, Lydia E. et al., Incorporating Long-acting Reversible Contraception Into Primary Care: A Training and Practice Innovation. Women's Health Issues, Volume 26, Issue 2, 131 – 134 4. Chelvakumar, M, et al, Long-acting Reversible Contraception (LARC) Provision by Family Physicians: Low But on the Rise, The Journal of the American Board of Family Medicine January 2019, 32 (1) 10-12 LARC market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.

# ANNOVERA Key Attributes

## ACCESS ATTRIBUTES

- Market shift to long-acting
- Offer women a long-term birth control option without requiring a procedure for insertion and removal like IUDs or Implants
- Available to all prescribers – no special training, equipment, or inventory
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship<sup>1</sup>
- “Vaginal System” – the only product in a potential new category of contraception with potential for \$0 co-pay
- Does not require refrigeration

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

# ANNOVERA Key Attributes

## CLINICAL ATTRIBUTES

- Only FDA-approved long-lasting reversible birth control that doesn't require a procedure or repeat visit
  - Empowers women to be in control of their fertility and menstruation
  - ANNOVERA is the only user-directed single 12-month birth control product (used in repeated 4-week cycles for 13 cycles)
- Highly effective in preventing pregnancy when used as directed (97.3%)
- High patient satisfaction in clinical trials (phase 3 acceptability study of 905 women)<sup>1</sup>
  - 89% overall satisfaction, adherence (94.3%) and continuation (78%)
- Softer and more pliable than NuvaRing<sup>®</sup>
- Only product with new novel progestin - segesterone acetate<sup>2</sup>
  - No androgenic or glucocorticoid effects at contraceptive doses\*
- Low rates of discontinuation related to irregular bleeding (1.7%)

<sup>1</sup> Merkatz, Ruth B., Marlana 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.

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

# ANNOVERA Patient Types

- Broad-based product – a single contraceptive product for most patient and prescriber types
- Supports patient preference
- Amenable to women of all reproductive ages and demographics
- Highly effective
- Self-administered, long-lasting product that is reversible
- Nulliparous women (never had a child before)
- Between children – birth spacing
- Women not in monogamous relationships
- Ideal for adolescents of reproductive age who don't want to take a product everyday, but don't want a procedure or nulliparous or non-monogamous
- College women – no need for monthly refills
- Women in the military – control fertility for 1 year



# Jay Cohen, MD

- Medical Director of all Women's Healthcare of West Broward, Clinical Research, and Discovery Clinical Research, divisions of Envision Women's Healthcare
- Board certified OB/GYN at all Women's Healthcare of West Broward, a division of Envision Women's Healthcare
- Author for multiple peer reviewed publications on women's health
- Past of Board Member with the William Little OB/GYN Society, American Cancer Society (Breast Task Force), West Broward Unit of the American Cancer Society
- Principal Investigator of over 110 clinical trials on women's healthcare



# What Impact of TXMD Portfolio has on Typical Practice

- TXMD portfolio is important when covers critical stages of a woman's life cycle
  - Leads to trust with Women
  - Very much like Wyeth, Ortho, Warner Chilcott – market is wide open
- Women are more apt to discuss sexual health with their doctors today
  - Women are staying healthier and active longer
  - Often question products and safety more
- Modern products supported by strong clinical data that enable a provider to meet patient demands for bio-identical therapy
- Cost point is the most important
  - Consumer focused company
  - Menopause products have \$35 commercial co-pay with card; ~\$40 for preferred Medicare Part D co-pay
  - ANNOVERA potential for no-copay due to potential new method of contraceptive



# Why Do IMVEXXY and BIJUVA Matter to Typical Clinicians

- Addresses the real life discussions between patients and physicians
- IMVEXXY is a unique product with the lowest approved dose
  - Key issue today systemic vs local estrogen
- BIJUVA is the only FDA-approved systemic therapy that is bio-identical, meets demand of patients
  - Do not need to compound
  - Can replace use of two separate FDA-approved products, which are not approved in combination and are not supported by endometrial safety data
- One co-pay per product – affordability is key and creates compliance



# How Can ANNOVERA Change Things

- Only one visit to the doctor and pharmacy
- Addresses important reasons women discontinue daily and/or monthly contraceptives
  - Access, insurance coverage
  - Adverse events such as bleeding, weight gain, and nausea
- Long lasting ring (cyclical dosing for 13 cycles)
- State mandated coverage and potential 19<sup>th</sup> contraceptive method





# COMMERCIAL UPDATE

*Building a Premier  
Women's Health Portfolio*

**Dawn Halkuff**

*Chief Commercial Officer*

  
**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

  
**Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

**TXMD**  
Nasdaq Listed



# The Power of a Women's Health Portfolio

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

 **vitaMedMD®**  
Prenatal Vitamins

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

 **Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

 **Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg



**CONTRACEPTION**

**PRENATAL CARE**

**CONTRACEPTION/  
FAMILY PLANNING -  
PERIMENOPAUSE**

**VASOMOTOR  
SYMPTOMS**

**DYSPAREUNIA  
(Vulvar & Vaginal  
Atrophy)**



**REPRODUCTIVE HEALTH**

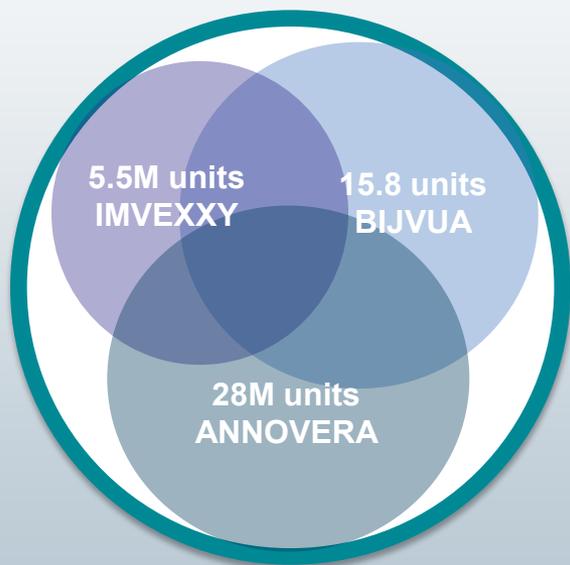


**MENOPAUSE MANAGEMENT**



# The Power of A Women's Health Portfolio

## Market Opportunity<sup>1</sup>



## Overlapping Prescribers & Patients

REPRODUCTIVE PORTFOLIO

MENOPAUSE PORTFOLIO

## The Power of 3



Even though there are over 400,000 total writers for these products<sup>2</sup>

~25,000 targets we call on represent over 60% of market opportunity for each product<sup>2</sup>

1) Symphony Health Integrated Dataverse.  
2) IQVIA National Prescriber Level Data.

# Launch Approach Developed to Shift Entrenched Behavior



## Remove Barriers

- No new Estrogen product launched since 2000
- Affordability a challenge for patients while insurance builds
- Prescribers typically slow writing during this phase because of lack of access



## Drive Early Experience for a Differentiated Product

- Open access approach only works for a product that delivers a good patient experience
- \$ spent went toward copay program, removed barrier to HCP writing and less expensive than pushing early through DTC
- IMVEXXY cost does not change for patient as insurance builds



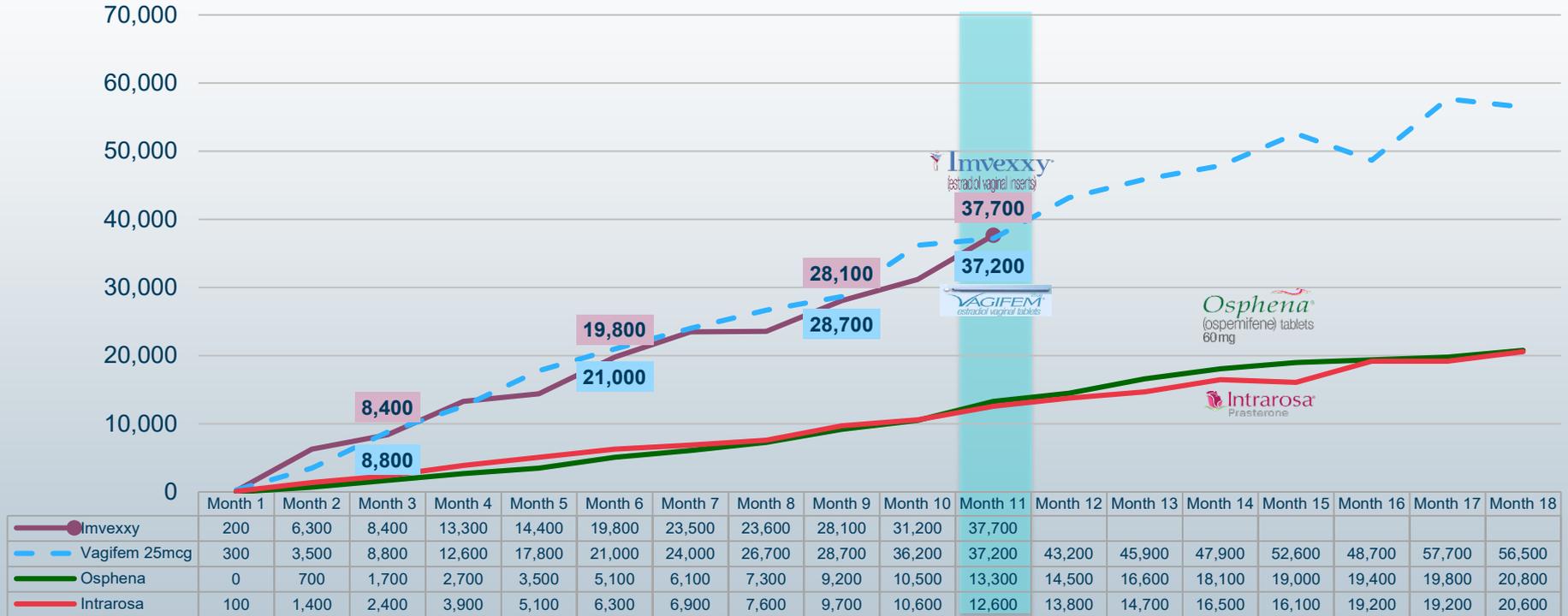
## Drive Share Momentum Through New Writers and Share of Existing Writers

- Continuous unlocking of new levers as insurance adjudication normalizes



# Launch Results Remain Strong and On-Track: Strategy is Working

## Imvexxy TRx Launch Comparison



\*Month 11 for IMVEXXY is May 2019

- IMVEXXY continues to grow both weekly average volume and daily average volume for May (31 day month) vs April (30 day month)
- Average daily volume for 31 days in May 2019 increased to ~1,200 from ~1,000 for the 30 days in April 2019

### References:

- Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. This includes a one week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
  - Ospheana and Intrarosa data sourced from Symphony Health Integrated Dataverse.
  - Vagifem data sourced from IQVIA National Prescriber Level Data.
- All trademarks are the property of their respective owners.

# Strong Patient Adherence = Women are Staying on IMVEXXY

## IMVEXXY Patient Adherence<sup>1,2</sup>

Month Initial Prescription Filled	Average # Fills for those Patients	Maximum Allowable Fills Given the Month of Initial Fill
May 2019	1 Fills	1 Fills
Apr 2019	1.8 Fills	2 Fills
Mar 2019	2.4 Fills	3 Fills
Feb 2019	3.0 Fills	4 Fills
Jan 2019	3.6 Fills	5 Fills
Dec 2018	4.0 Fills	6 Fills
Nov 2018	4.7 Fills	7 Fills
Oct 2018	5.0 Fills	8 Fills
Sep 2018	5.6 Fills	9 Fills
Aug 2018	7.0 Fills	10 Fills

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 4.7 fills from November 2018 through May 2019

**Average fills for all patients through May 31, 2019 = 3.34<sup>3</sup>**

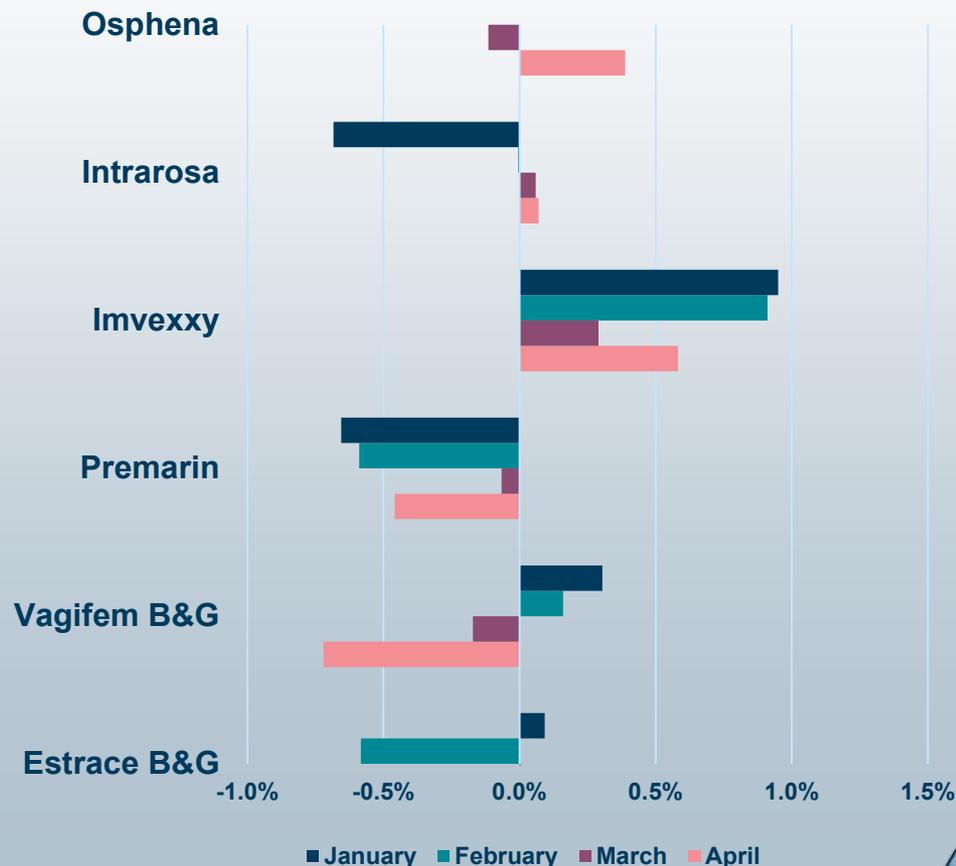


- 1) Average number of fills per patient is the average number of fills per patient grouped by their initial month on therapy.
- 2) Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.
- 3) Average number of fills for all patients is calculated as Total Rx / Total Patients.

# IMVEXXY Momentum Driven by Increased Experience With the Product

- 61% aided awareness among prescribers
- Growing number of high volume writers every month
- Highest association with lowest approved dose vs. competitors
- Highest score on ease of Use vs. other estrogen competitors: *no applicator, high patient satisfaction, mess-free administration, easy to use packaging*<sup>1</sup>
- IMVEXXY has ~7% market share of TRx for the month of May 2019

2019 Month Over Month Change in Market Share<sup>2</sup>



1) Claims used in promotion to support a positive patient experience  
2) Symphony Health Integrated Dataverse.

# The Next Lever to Unlock to Support IMVEXXY Growth is Consumer in Q3

## Introducing: “No Interruptions”

**USE**  
IMVEXXY® is a prescription medicine that contains an estrogen hormone in a vaginal insert. It is used after menopause to treat moderate to severe painful intercourse, a symptom of changes in and around your vagina, due to menopause.

**IMPORTANT RISK INFORMATION**  
MOST IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT IMVEXXY (an estrogen hormone)  

- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Report any unusual vaginal bleeding right away while you are using IMVEXXY. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- Do not use estrogen-alone or with

**Without vaginal discomfort, you can have moments in the**

**Don't let vaginal pain and discomfort interrupt your life**

**USE**  
IMVEXXY® is a prescription medicine that contains an estrogen hormone in a vaginal insert. It is used after menopause to treat moderate to severe painful intercourse, a symptom of changes in and around your vagina, due to menopause.

**IMPORTANT RISK INFORMATION**  
MOST IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT IMVEXXY (an estrogen hormone)  

- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Report any unusual vaginal bleeding right away while you are using IMVEXXY. Vaginal bleeding after menopause may be a warning sign of

**EASY TO INSERT. EASY TO LIVE WITH.**

In a patient survey, 88% of women said IMVEXXY is easy to use and 60% found it easy to insert.\*

**EASY TO USE**    **INSERT ANY TIME OF DAY**    **NO DOWNTIME AFTER USE**    **AVOID INTERRUPTIONS**

\*A patient survey evaluated the acceptability of the product administration experience and was completed at the end of the study by women in 4-mg, 10-mg, and matching softgel placebo arms (N=324).

## Research Findings Demonstrate Strong Engagement\*

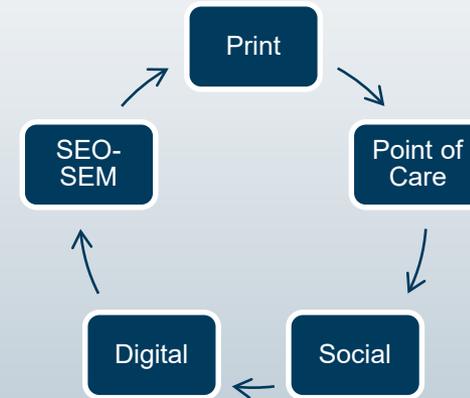
Strong Communication Calls out functional and emotional benefits

Relatable And Aspirational

70% of women found the ad to be appealing, leading to strong desire to talk to HCP

Persuasive Call To Action aligned with the top reason Patients and HCPs discuss VVA “Impact to Relationship”

## Media Plan Across Multiple Platforms



\* Market research data on file (May 2019).



# BIJUVA UPDATE



# A Large Target Market For BIJUVA

**Q2** → **Launched April 17, 2019**  **Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

**Q2** →  **Target FDA-approved separate bio-identical E&P pills segment**  
~3.9M TRx (each)<sup>1</sup> | \$836M<sup>2</sup> TAM

**Q4** →  **Once payer coverage achieved, expand BIO-IGNITE partnerships to access the compounding channel**  
 **12M – 18M TRx<sup>3</sup> | \$2.5B-3.8B<sup>2</sup> TAM**

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2018

2) Based on WAC pricing of \$214.50

3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications

# Launch Plan Mirrors IMVEXXY

## Focused on Driving Early Behavior Change that Leads to Long Term Adoption



- Pay No More Than \$35 from Day 1 of launch

- \$35 or less out-of-pocket cost\*
- Addresses the cost and coverage concerns which are often barriers to early adoption
- “Keep Cool” Early Experience Program drives appropriate patient and prescriber education
- Positive early clinical experience has the potential to drive momentum

\*For commercial patients

# Early BIJUVA Uptake Insights

- Opportunity to reinvigorate category given little to no promotion by competitor
- Initial focus on those prescribers writing 2-Pill regimen
  - ~10 targets per sales representatives at start
- Since launch, ~1,100 writers and ~2,000 scripts
- ~80+% are also IMVEXXY writers

## Core HCP Marketing Campaign





# ANNOVERA



# U.S. Contraceptive Market

\$5B U.S. net sales<sup>1</sup>

~ 90mm annual scripts to ~20 million women<sup>2</sup>

**SHORT-ACTING**  
CONTRACEPTIVES

Complete control but  
no long acting benefits



**ORAL MARKET SIZE:**  
55% of sales in 2017<sup>1</sup>

**ANNOVERA™**

Long-acting benefits  
without a procedure  
and complete control  
over fertility and  
menstruation



Oral contraceptive's continue to lose  
market share (CAGR -4.2% 2012 to  
2017) to long acting methods<sup>1</sup>

**LONG-ACTING**  
CONTRACEPTIVES

Long-acting  
benefits but requires  
a procedure and  
does not offer  
complete control



**LARC MARKET SIZE:**  
15.3% 2012 to 2017<sup>1</sup>

1. QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings.  
2. Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2017

# Prescribers and Consumers are Open to ANNOVERA

- High level of acceptance from prescribers with 89% of prescribers very or somewhat likely to prescribe<sup>1</sup>
- Providers report that they would expect to use ANNOVERA for 18% of their patients using birth control<sup>2</sup>
- 2 consumer segments accounting for almost 50% of the population have a high openness to ANNOVERA and openness to switching their current birth control product<sup>3</sup>
- Features that resonate for both prescribers and patients around long-acting/ long-lasting and “patient-controlled”<sup>4</sup>

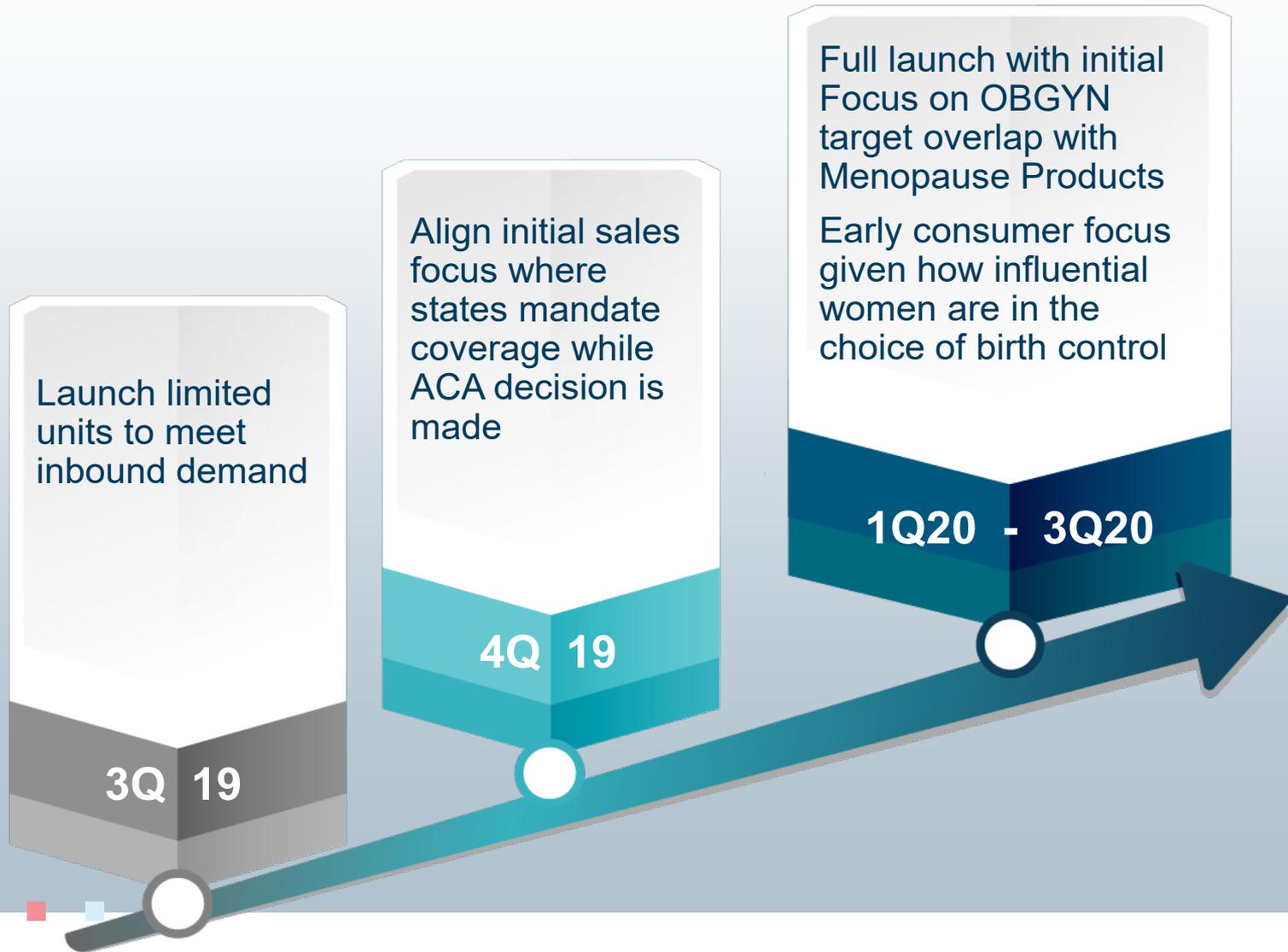
1) Internal Concept Evaluation, n=100 HCPs, SurveyGizmo, Nov, 2018

2) Annovera HCP Concept/Positioning Study, n=300 HCPs, Phoenix, June 2019

3) Women in their Reproductive Years Segmentation, n=1000, SMI Alcott/Brado, May, 2019

4) Internal Concept Evaluation, n=100 HCPs, n=300 women, SurveyGizmo, Nov, 2018. Annovera HCP and Consumer positioning Study, n=300 HCPs, n= 450 consumers, Phoenix, June 2019.

# ANNOVERA Launch Approach



# The Power of a Women's Health Portfolio

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

 **vitaMedMD®**  
Prenatal Vitamins

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

  
**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

 **Imvexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg



CONTRACEPTION

PRENATAL  
CARE

CONTRACEPTION/  
FAMILY PLANNING -  
PERIMENOPAUSE

VASOMOTOR  
SYMPTOMS

DYSPAREUNIA  
(Vulvar & Vaginal  
Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT



# BIO-IGNITE Introduction

**Dedra Reiger Lyden**

*Vice President, Strategic Partnerships & Initiatives*

**TXMD**  
Nasdaq Listed



# Bio-Ignite = Innovative Collaborative Approach

## Large, Untapped Market

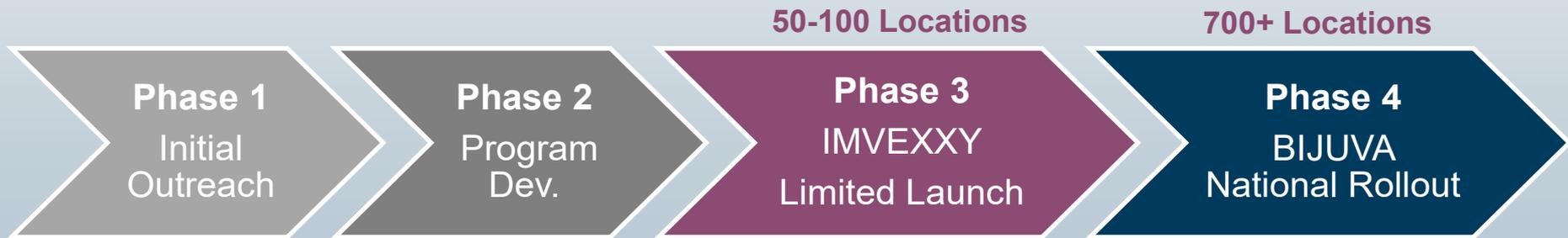
- Over 3,000 physicians are currently writing high volumes of bio-identical hormones
- Over 700 pharmacies are currently dispensing high volumes of bio-identical hormones
  - With marketing reps
- HYBRID pharmacy model (filling FDA approved and compounded products)
- Changing commercial and regulatory dynamics ultimately driving change in this market
- Compounding channel opportunity is ignored by pharmaceutical companies
- **We want to be where our competition is not**

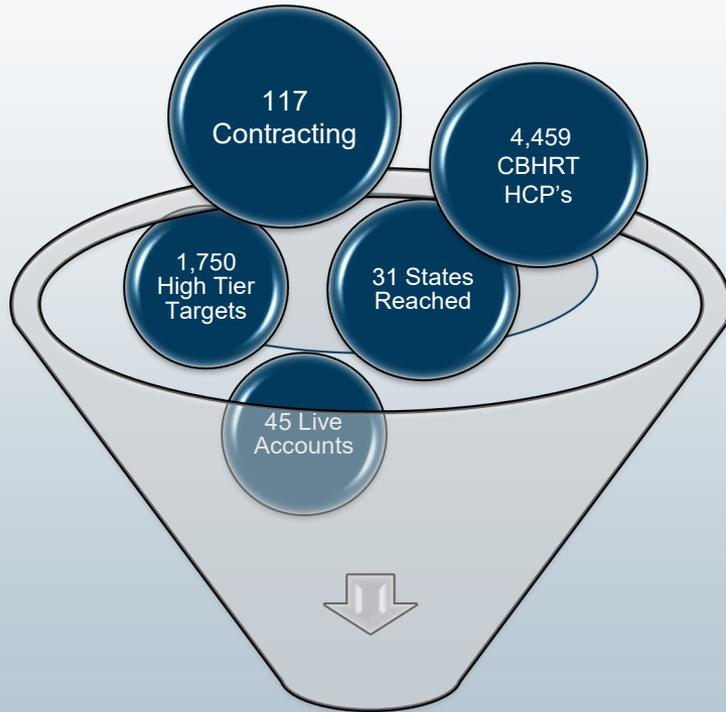
## Regulatory Environment

- Drug Quality and Security Act
- Loss of Third-Party Reimbursement
- USP <800> – Hazardous Drugs

## A Four-Phase Strategic Initiative

Goal to activate all current stakeholders involved in the Bio-identical Hormone Replacement Therapy (BHRT) community, ensuring that TherapeuticsMD's portfolio has the best national access and uptake possible





## Pharmacy Targeting:

- Over 1,750 are high tier targets
  - These locations produce the highest volume of compounded bio-identical hormone replacement therapy (CBHRT) scripts

## Program Stats:

- Live Accounts: 45
- States Reached: 31
- In Vetting Process: 89
- In Contracting Process: 117
- Unique CBHRT Prescribers Identified not in IMS: 4,459
  - *1,202 are identified as high-value CBHRT HCP's targeted by KAM's*

## Donnie Calhoun, BPharm, RPh.

- Licensed pharmacist in Alabama and owner of Calhoun Compounding Pharmacy in Anniston, Alabama
- Past President of the National Community Pharmacists Association, Past President of the Alabama Board of Pharmacy, Past Executive Director of the Specialty Sterile Pharmaceutical Society
- Has held many positions with the Alabama Pharmacy Association
- Former CEO/Executive Vice President for the American College of Apothecaries, CEO/Executive Vice President for the American College of Veterinary Pharmacists and CEO/Executive Vice President for the American College of Apothecaries Research and Education Foundation
- Elected to the Pharmacist Mutual Board of Directors in 2005



## Scott Mazza PharmD, MS, R.Ph.

- Over 30 years of clinical pharmacy experience in a variety of practice settings
- Currently oversees the Therapeutic Interchange Program for Polaris Pharmacy Services
- Served as Pharmacy Manager for a regional specialty and compounding pharmacy specializing in oncology and women's health compounding services
- Former National Director of Regulatory Compliance and Professional Practice for CVS Caremark
- Served on both national and state Medicaid Pharmacy & Therapeutics Committees and currently maintains 27 pharmacist licenses

# USP <800> Compliance Deadline December 2019

The practice of pharmacy as we know  
it today will be changing

The U.S. Pharmacopeial Convention (USP) has issued [USP General Chapter <800> Hazardous Drug Handling in Healthcare Settings](#) describing practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection

## Key Points:

- To protect patients, personnel, and the environment from hazardous drug contamination
- Estradiol and progesterone are considered hazardous drugs
- Upgrades to be compliant are timely and costly
- OSHA has adopted the standards for enforcement

Community compounding pharmacies had hoped this would go away, but it did not

- Deadline for compliance now very close



## Pharmacy Profiles

1. Will not be USP <800> Compliant
  - No longer plans to compound BHRT
    - ✓ Bio-Ignite provides access to the greatest subset of BHRT patients and prescribing HCPs
2. Will be USP 800 Compliant
  - Will still be capable of compounding forms of BHRT
    - ✓ Bio-Ignite provides another option for their location to fill all patient and prescriber needs (not just a compounder)

## Pharmacy Size and Reach

- Single pharmacy location (with/without wholesaler purchasing requirements)
- Multi pharmacy location, multi state, not self-distributing model
- Self-distributing pharmacy, 10-100's of pharmacy locations



# What is the opportunity for IMVEXXY and BIJUVA and why

## Headwinds

- Community Pharmacies that compound are going through a significant market shift
  - Loss of reimbursement for many areas for compounded drugs including hormones
  - Significant increase in cost and regulation associated with compounding hormones and other “hazardous” drugs (USP800)

## Solutions

- Pharmacy can continue to provide BHRT through FDA-approved product without increasing costs
- Decrease patient out-of-pocket through patient support program
- Respond to patient and provider requests for commercially available BHRT product
- Expand the tool chest with FDA-approved products
- Encourage pharmacy engagement with the medical community and patient community



# Why are Community Pharmacies Right for this Opportunity

- Compounding pharmacies offer a concierge experience with patients
  - Available 24/7 and offer cell phone contact
  - Pharmacy business model has changed significantly over the past few years and will continue to change
  - Lower reimbursement, increasing costs of compliance
  - Need to find innovative solutions
- Compounding pharmacies opportunities
  - Increased prescriber access/relationships with HCPs who are not listed as prescribers in IMS
  - Large female patient demographic
  - Separate sales force to promote pharmacy offerings
  - Meet patient demands for FDA-approved BHRT products



# Hybrid Pharmacy Based Rx Model

- The “Hybrid” pharmacy- compounding, specialty care and traditional Rx
- Compounders are local community pharmacy providers and have key relationships with physicians and other community based health care providers
- Engage regularly with the prescriber community
- Pharmacies with a large female demographic
- Patient-centric approach establishes patient trust with their pharmacist
- Offer services not available with other delivery systems, such as charge accounts, free delivery, consultation services, and a host of others
- Ability to readily obtain refills for their patients, perform prior authorizations and other insurance services for their patients
- Medication Therapy Management Approach





# PAYER OVERVIEW

**Bob Lahman**

*Ret. SR VP Optum Rx*

**Mike Steelman**

*TXMD Vice President, Market Access*

**Ambrose Carrejo**

*Ret. Pharmaceutical Contracting Lead  
Kaiser Permanente*



# 2019 US Payer Environment is Rapidly Evolving

## Acquisitions



## New Pricing Pressures

- Authorized generics and lower WAC strategies are impacting rebate guarantees
- Rebate and Admin Fee pass through (transparency) tightening profitability
- HHS Proposed Rule may reshape prescription drug prices
- FDA approves Novartis' \$2.1 million gene therapy – making it the world's most expensive drug
-  **PillPack**  
an  company

# Commercial Payer Update

- **Commercial Average Non Preferred Copay is \$59**
- **IMVEXXY co-pay card offering can bring this down to \$35**

**Among Covered Workers With Prescription Drug Coverage, Average Copayments and Coinsurance, 2018**

	Average Copayment	Average Coinsurance
<b>Plans With Three or More Tiers</b>		
First Tier	\$11	19%
Second Tier	\$33	26%
Third Tier	\$59	36%
Fourth Tier	\$105	31%
<b>Plans With Two Tiers</b>		
First Tier	\$11	NSD
Second Tier	\$31	28%
<b>Plans With the Same Cost Sharing For All Covered Drugs</b>		
First Tier	NSD	20%

NOTE: Number of tiers refers to the number of tiers excluding those specifically for specialty drugs.  
NSD: Not Sufficient Data

SOURCE: KFF Employer Health Benefits Survey, 2018

Source: 2018 Employer Health Benefits Survey, Section 9: Prescription Drug Benefits (KFF, Oct. 3, 2018), <https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-9-prescription-drug-benefits/> (accessed June 5, 2019).

# Medicare Part D Payer Update

## Medicare Part D Median Preferred Copay is \$40

**Table 4: Median Cost Sharing (Copayments or Coinsurance Rates) for all Medicare Part D Stand-alone Prescription Drug Plans and Top 10 PDPs with the Highest Enrollment, 2018 and 2019**

Name of PDP	Preferred generics		Generics		Preferred brands*		Non-preferred drugs		Specialty drugs	
	2018	2019	2018	2019	2018	2019	2018	2019	2018	2019
<b>Median for all PDPs</b>	\$1	\$1	\$6	\$5	\$37/21%	\$40/20%	40%	40%	26%	26%
<b>Top 10 PDPs</b>										
SilverScript Choice	\$3	\$3	\$14	\$13	\$42	\$42	46%	45%	33%	33%
AARP MedicareRx Preferred	\$5	\$5	\$12	\$10	\$37	\$40	40%	40%	33%	33%
Humana Walmart Rx	\$1	\$1	\$4	\$4	23%	20%	35%	35%	25%	25%
Humana Preferred Rx	\$0	\$0	\$1	\$1	20%	25%	35%	37%	25%	25%
AARP MedicareRx Saver Plus	\$1	\$1	\$3	\$6	\$33	\$25	30%	33%	25%	25%
Aetna Medicare Rx Saver	\$1	\$1	\$2	\$2	\$30	\$30	35%	35%	26%	27%
WellCare Classic	\$0	\$0	\$1	\$2	\$35	\$37	42%	41%	25%	25%
Humana Enhanced	\$3	\$5	\$7	\$10	\$42	\$47	44%	50%	33%	33%
AARP MedicareRx Walgreens	\$0	\$0	\$6	\$5	\$31	\$30	32%	32%	25%	25%
Aetna Medicare Rx Value Plus	\$1	\$1	\$2	\$2	\$47	\$47	50%	47%	33%	33%

NOTE: PDP is prescription drug plan. Estimates are weighted medians for those plans that vary cost sharing by region (weighted by September 2018 enrollment). \*Approximately 77% of September 2018 enrollees are in plans with a preferred brand copay and 23% are in plans with a preferred brand coinsurance.

SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2018-2019 Part D plan files.

**Source:** Juliette Cubanski, Anthony Damico, and Tricia Neuman, Medicare Part D: A First Look at Prescription Drug Plans in 2019 (Kff, Oct. 16, 2018), <https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019-tables/> (accessed June 5, 2019).

# The Power of 3 in the Payer World

Expected widespread insurance coverage across the portfolio in 1<sup>st</sup> Half, 2020

## Target Timeline for Insurance Coverage from Launch

### **ANNOVERA™**

(segesterone acetate and ethinyl estradiol vaginal system)

- Establishes TXMD as a Women's Health company with products across the life stages
- Back again with the same payer contacts
- Largest Women's Health Category with no Medicare Part D
- ACA and State mandates exist in birth control category

- 1-3 Quarters from launch.
- ACA / 19<sup>th</sup> Category Designation decision by FDA will impact

  
**Bijuva™** 1mg/100mg  
(estradiol and progesterone) capsules

- Establishes TXMD as key Women's Health product leader
- Back negotiating with the same Women's Health contacts at the payers
- Contract amendments in larger category with little Medicare Part D overall

- 3-4 Quarters Commercial
- Part D not viewed as material at this point

  
**Invexxy®**  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

- Introduced TXMD to the Women's Health contacts in the payer community
- Started base contracts from scratch in Commercial and Medicare
- Smallest category of the portfolio with highest Medicare Part D patient population and longest time lag to access

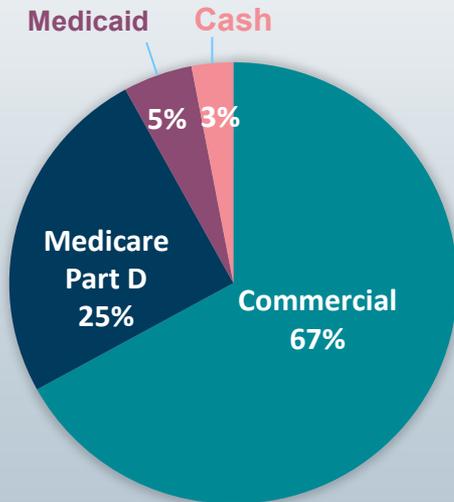
- 4 Quarters Commercial
- 6 Quarters for Part D



# IMVEXXY Payer Update

## ~102M Commercial Lives are Unrestricted<sup>2</sup>

TRx Payer Breakdown of FDA-Approved VVA Products<sup>1</sup>



### Commercial Payer Update<sup>2, 3</sup>

- **Strategy: Continue to seek unrestricted access in a fiscally responsible manner**
- ~102 million lives are unrestricted with the majority being adjudicated at a Non Preferred copay\*
- 21 states have greater than 60% unrestricted Commercial access
- IMVEXXY has secured access with the majority of the largest Commercial payers
- CVS and Aetna continue to not cover for the majority of their plan designs
  - Access available with a Non Preferred copay on open plan designs which is ~12% of CVS (~3.5M lives) and ~24% of Aetna (~1.8M lives)
  - Negotiations for all other plans with CVS / Aetna are ongoing seeking financially responsible opportunities to increase access

<sup>1</sup>IMS Data April 2018

<sup>2</sup>Plan numbers as of May 2019 from MMIT

<sup>3</sup>MMIT May 2019 and Account Insights

\*Adjudication of claim by payer: IMVEXXY is on payer formulary as covered product and is being submitted to insurance company for payment by payer to pharmacy.

# IMVEXXY Payer Update

## ~12M Medicare Lives are Unrestricted<sup>2</sup>

### Medicare Part D Update<sup>1, 2</sup>

- **Strategy: Continue to seek Preferred unrestricted access in a fiscally responsible manner**
- IMVEXXY launched in July 2018, after the 2019 bid cycle was completed.
- ~12 million lives are unrestricted with a majority adjudicating at a Preferred copay (~\$40)\*
  - Pull through underway with key United Healthcare HCP targets
- 2020 bids submitted for other Medicare Part D plans
  - Plan to finalize these contracts in Q4, 2019 for adjudication in Q1, 2020

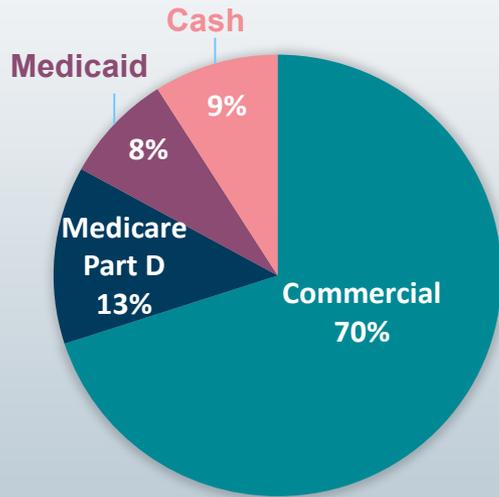
<sup>1</sup>Plan numbers as of May 2019 from MMIT  
<sup>2</sup>MMIT May 2019 and Account Insights

\*Adjudication of claim by payer: IMVEXXY is on payer formulary as covered product and is being submitted to insurance company for payment by payer to pharmacy.

# BIJUVA Payer Update

## ~77M Commercial Lives are Unrestricted<sup>2</sup>

TRx Payer Breakdown of  
FDA-Approved VMS Products<sup>1</sup>



### Commercial Payer Update<sup>2,3</sup>

- **Strategy: Seek unrestricted access in a fiscally responsible manner**
- BIJUVA clinical and financial reviews are underway with payers
- ~77 million Commercial lives are unrestricted with the majority adjudicating at a Non Preferred copay
- 2 of the top 10 already adjudicating\*
- Most additional commercial plans will make a decision in Q3-Q4, 2019 with coverage the following quarter. Any plan we miss could take an additional 6-12 months to secure coverage

<sup>1</sup>IMS Data April 2018

<sup>2</sup>Plan numbers as of May 2019 from MMIT

<sup>3</sup>MMIT May 2019 and Account Insights

\*Adjudication of claim by payer: BIJUVA is on payer formulary as covered product and is being submitted to insurance company for payment by payer to pharmacy.

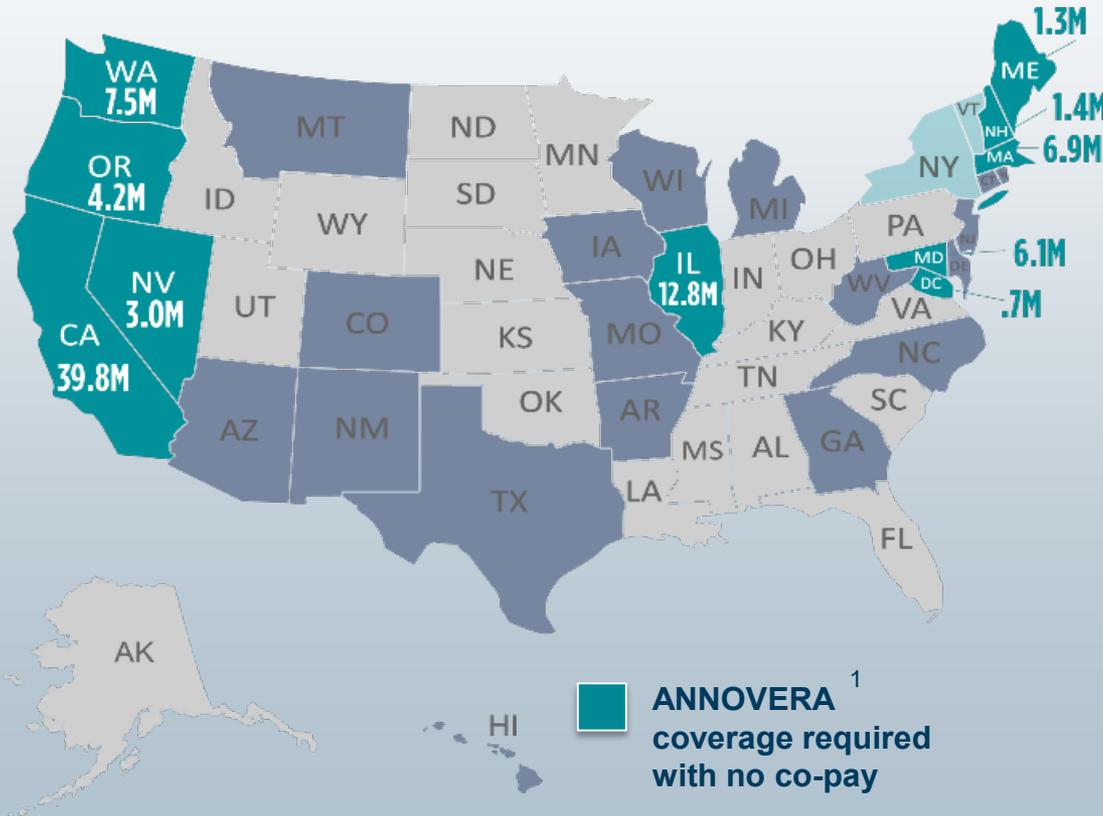
# Access to Contraception

- **In 2012, the Affordable Care Act (ACA) required all health insurances to cover, without cost-sharing, the full range of contraceptive methods and services approved by the FDA as prescribed for women**
  - 18 methods of birth control – at least one product in each method must be covered with no patient out-of-pocket costs
  - If a provider recommends a specific option or product, plans must cover it at no cost as well
  - Expectation that ANNOVERA would become the 19<sup>th</sup> method – 1-year contraceptive vaginal system
- **Irrespective of ACA mandate, 19 states require insurance plans to cover all contraceptives without a generic equivalent**



# BIRTH CONTROL STATE LAWS REGARDLESS OF ACA MANDATES

**10 STATES REQUIRE COVERAGE WITH NO COPAY REGARDLESS OF ACA DECISION  
(~42 Million women in these states)**



**Washington State Office of the Insurance Commissioner**  
December 4, 2018

Starting in 2019, health plans in Washington state must cover all forms of birth control at no cost to you! It includes over-the-counter birth control, prescription birth control and vasectomies. Learn more about the changes to coverage: <http://bit.ly/ReproHealthWA>  
If you need coverage, you can sign up through Washington Healthplanfinder until Dec. 15 for coverage starting Jan. 1: <https://www.wahealthplanfinder.org>

**Don't pay for birth control!**  
All birth control is now covered at no out-of-pocket cost to you.  
Find out more: <http://bit.ly/ReproHealthWA>

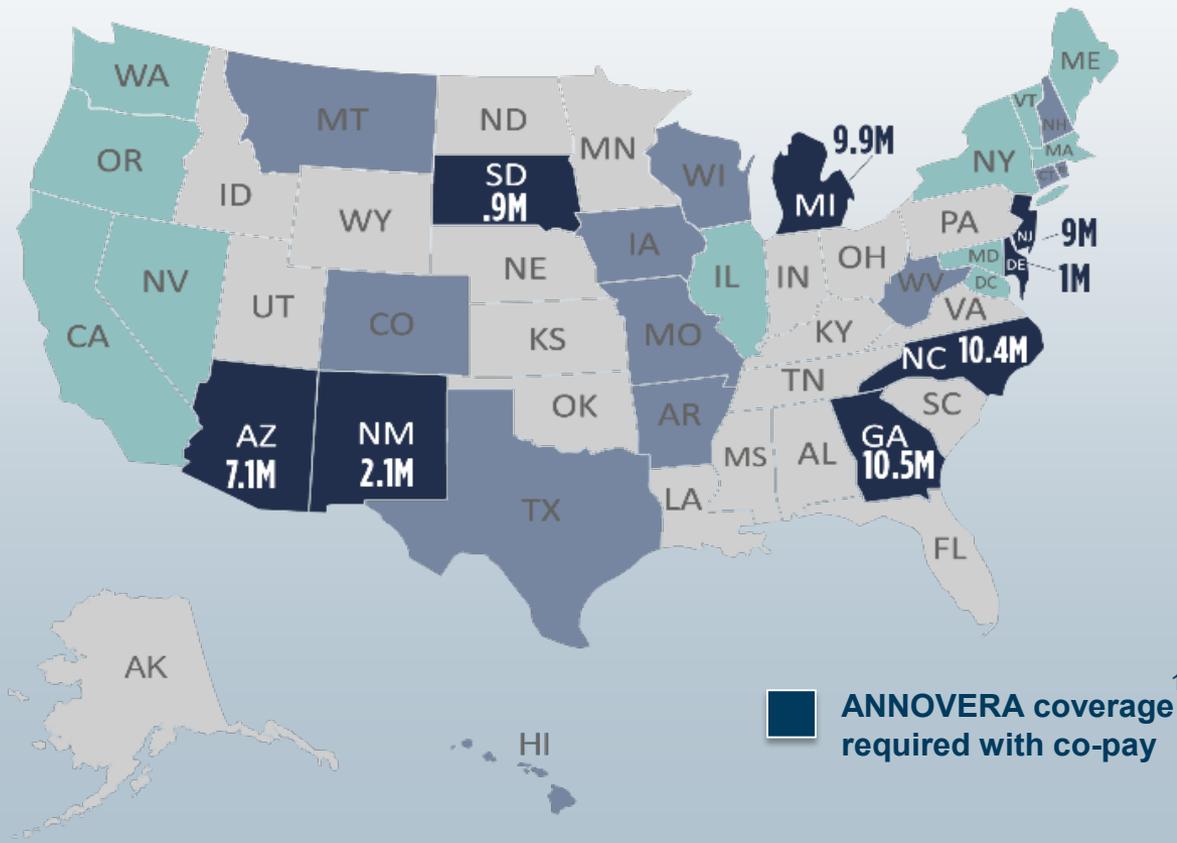
<sup>1</sup> Data on file (May 2019).

<sup>2</sup> Washington State Office of the Insurance Commissioner

<https://www.facebook.com/WSOIC/photos/starting-in-2019-health-plans-in-washington-state-must-cover-all-forms-of-birth-2485878528095084/> (accessed July 5, 2019).

# BIRTH CONTROL STATE LAWS REGARDLESS OF ACA MANDATES

**9 STATES REQUIRE COVERAGE WITH COPAY REGARDLESS OF ACA DECISION**  
(~25 Million women in these states)



<sup>1</sup> Data on file (May 2019).

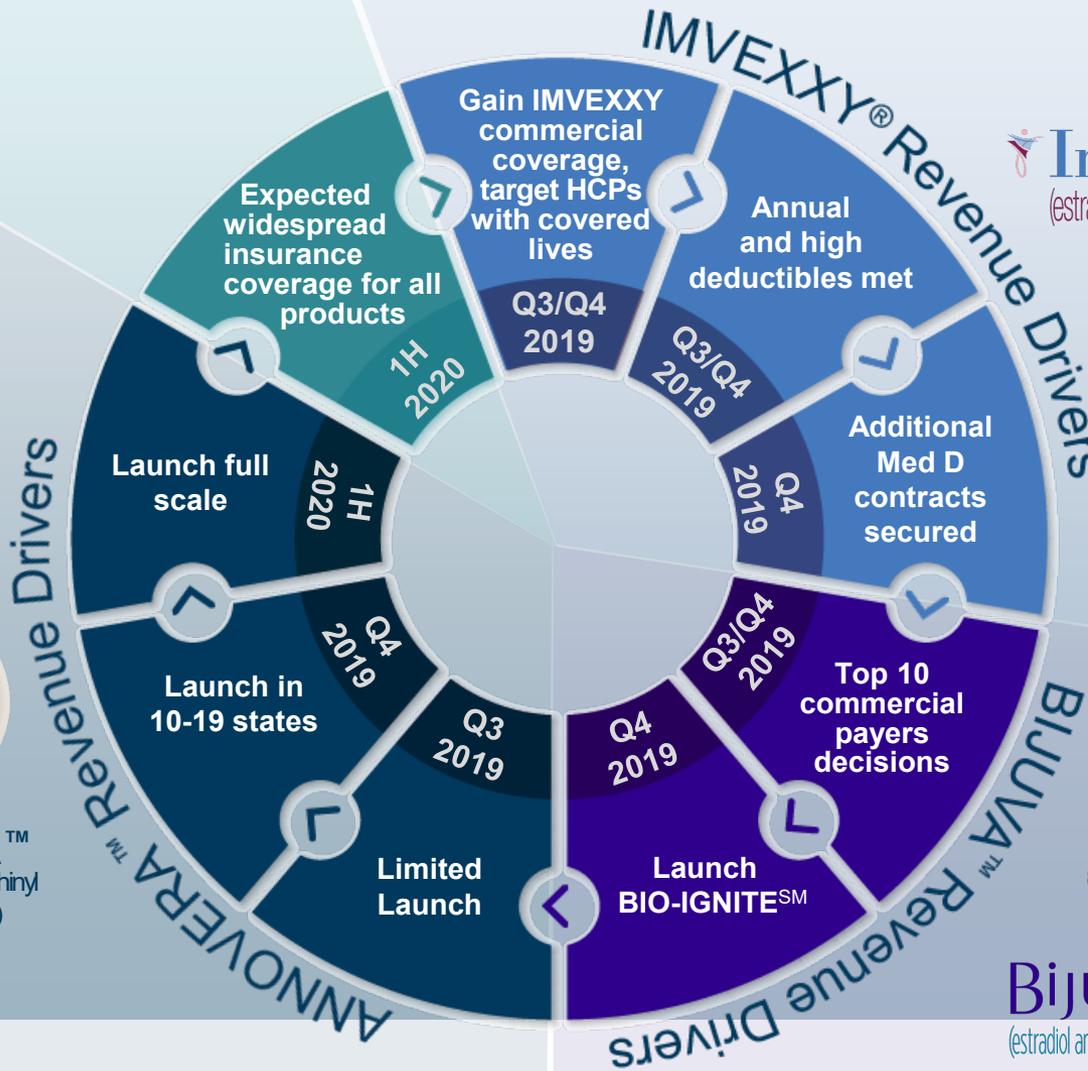
# PAYER INSIGHT ON BIRTH CONTROL COVERAGE

## Select Quotes from Market Research<sup>1</sup>

- *Flat open, covered. There is one thing that scares the living hell out of me and it's a female millennial with a smartphone and a Twitter and Facebook account. The last thing I want to do is set one of them off. The quickest way I could think of doing it would be to go out and mess with her birth control.*
- *I can't think of another category that we just leave broad open, don't even think about...We're mandated to cover it at zero co-pay...None of us was going to be the guy that said – oh, you can't have your birth control. And so they're just not managed.*
- *The ACA mandate really drives a lot of the decision making within the process. And then pricing.*
- *I think the point in the contraceptive class is to provide a number of different options for patients and providers.*

<sup>1</sup> Milliman Pricing Research on ANNOVERA May 2019

# TXMD Power of the Portfolio

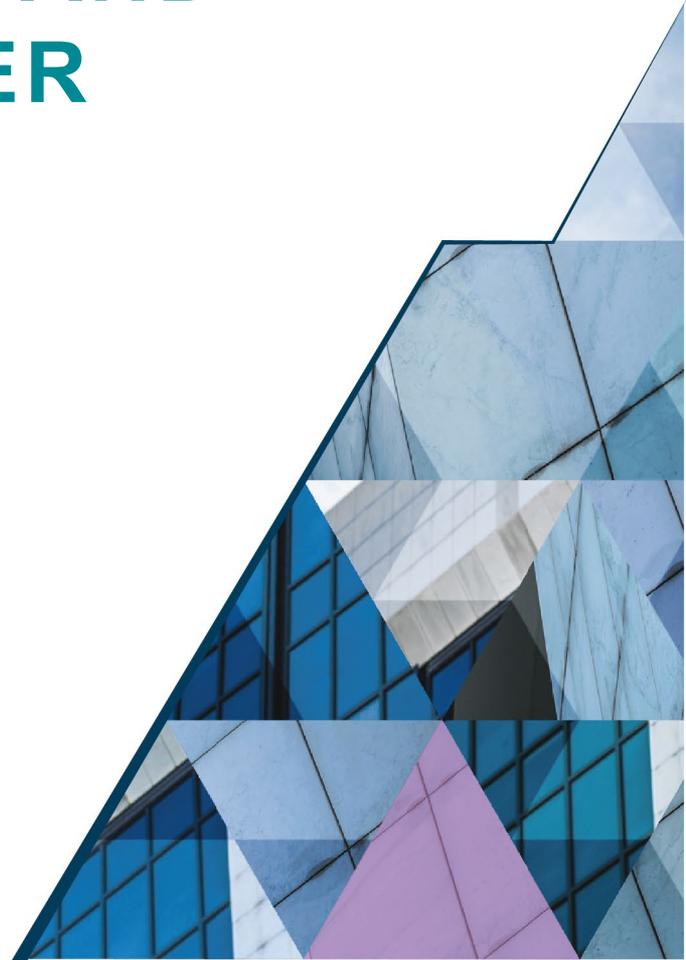


# HOW STRATEGY, PLAN, AND MODEL COME TOGETHER

**Mitch Krassan**

*Chief Strategy and Performance Officer*

**TXMD**  
Nasdaq Listed

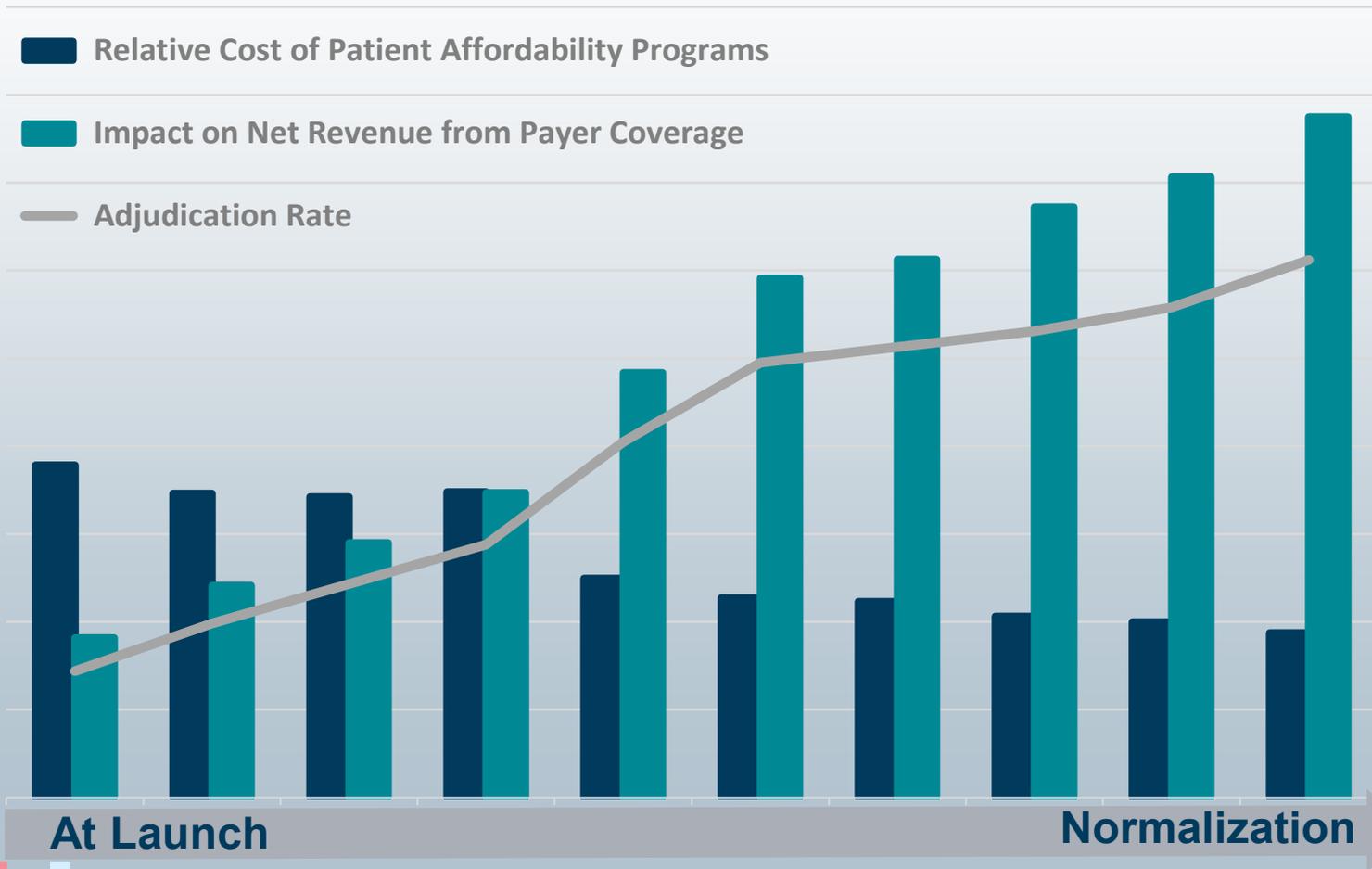


# IMVEXXY Model Different Than Typical Pharmaceutical Launch

<b>Gross Revenue</b>	
<b>Patient Copay Assistance</b>	<b>← Where We Focused</b>
Wholesale Costs	
Pharmacy Discounts	
<b>Payer Rebates</b>	
Returns, Allowances & Other Accruals	
<b>Net Revenue</b>	
Cost of Sales	
<b>Gross Margin</b>	
<b>Sales &amp; Marketing Cost</b>	<b>← Copay Assistance substituted for Marketing Cost</b>



# Example: Relationship of Cost of Copay Card vs Net Revenue Driven by Insurance Adjudication



# Example: How a Prescription is Paid & the Impact on Manufacturer

	Column A Patient's Insurance Doesn't Cover Product Yet	Column B Commercial Insurance Used w/ Patient Deductible Not Yet Met & High Deductible Plans	Column C Commercial Insurance Used w/ Average Copay	Column D Medicare Part D Insurance Used w/ Average Copay
Payment from Copay Card <small>(cost to Manufacturer)</small>	<b>\$200</b>	<b>\$215</b>	<b>\$40</b>	<b>\$0</b>
Payment from Insurance Company	\$0	\$0	\$175	\$205
Payment from Patient	<u>\$ 35</u>	<u>\$ 35</u>	<u>\$ 35</u>	<u>\$ 40</u>
Total Amount Received by Pharmacy	\$235	\$250	\$250	\$245

- For columns A and B, the copay card covers most of the cost of the product for the patient
- For columns C and D, the insurance company pays most of the cost of the product for the patient



# How Adjudication Rate Will Change Over Time: NOW

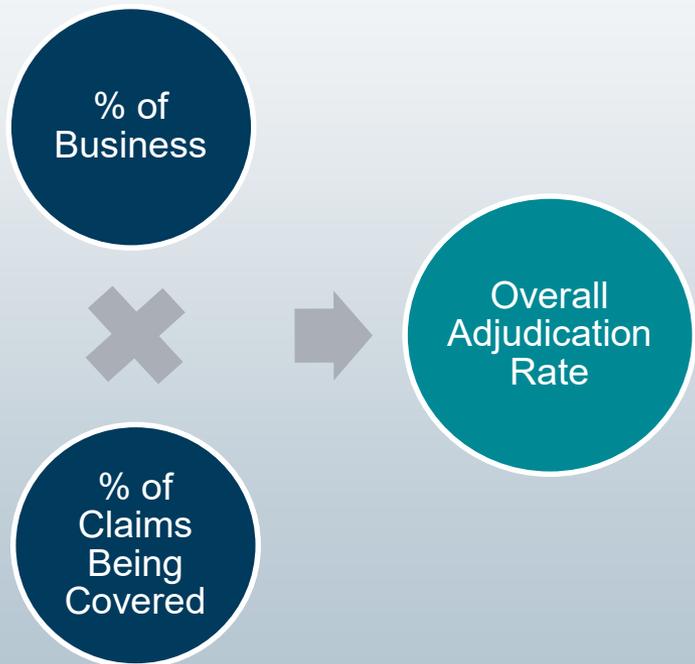


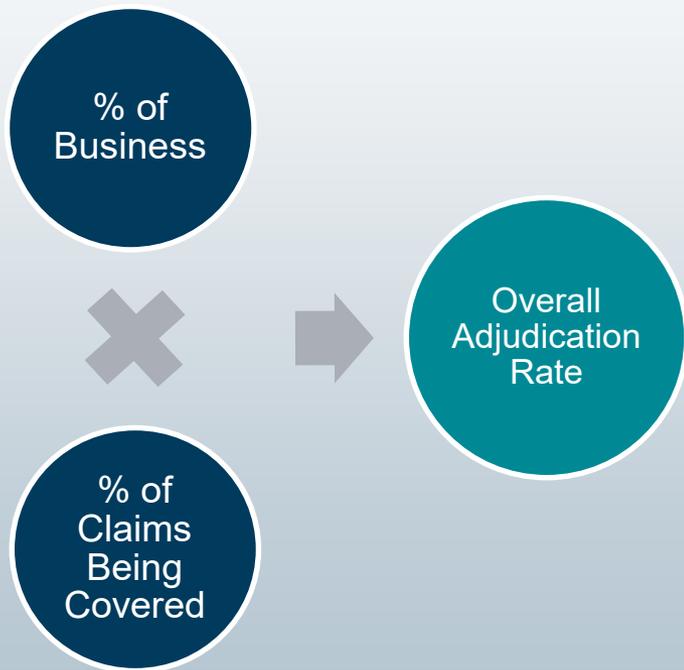
Chart are based on May Actuals

	Column A	Column B	Column C
<b>IMVEXXY</b>	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	5%	61%	35%
% Adjudicated	0%	47%	7%
Contribution to Overall Adjudication Rate	0%	29%	2%
Overall Adjudication Rate	31%		

	Column A	Column B	Column C
<b>BIJUVA</b>	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	8%	82%	9%
% Adjudicated	0%	30%	0%
Contribution to Overall Adjudication Rate	0%	25%	0%
Overall Adjudication Rate	25%		



# Target Adjudication Rate at Fully Established Insurance Coverage



	Column A	Column B	Column C
<b>IMVEXXY</b>	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	8%	68%	24%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	51%	17%
Overall Adjudication Rate	68%		

	Column A	Column B	Column C
<b>BIJUVA</b>	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	8%	82%	10%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	62%	7%
Overall Adjudication Rate	69%		



# Financial Update

**Robert Finizio**

*Chief Executive Officer*

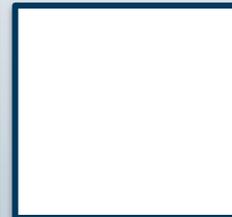
**TXMD**  
Nasdaq Listed



# \$300M Non-Dilutive Term Loan Financing Secured

\$200M accessed to date with up to additional \$100M through Specific Company Milestones

	Amount (\$)	TXMD Company Milestone <sup>1</sup>	Anticipated Timing
Tranche 1	\$200 million	Closing of the facility	Completed in April 2019
Tranche 2	\$50 million	Designation of ANNOVERA as a new category of birth control by the U.S. Food and Drug Administration on or prior to December 31, 2019	Second Half of 2019
Tranche 3	\$50 million	Achieving \$11 million in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019	First Quarter of 2020



1. TXMD Company Milestones are draw triggers for additional tranches of funding only and are not affirmative covenants that the company must otherwise meet. Ability to draw additional tranches is also subject to satisfaction (or waiver) of other customary conditions precedent.

# The Power of the Portfolio at Peak Sales \$1B

Percent of Market Based on Patient Count of 2.3M and 4 fills per year				
Average Net Revenue / Unit	20%	30%	40%	50%
\$ 60	\$ 110,400,000	\$ 165,600,000	\$ 220,800,000	\$ 276,000,000
\$ 80	\$ 147,200,000	\$ 220,800,000	\$ 294,400,000	\$ 368,000,000
\$ 100	\$ 184,000,000	\$ 276,000,000	\$ 368,000,000	\$ 460,000,000

Total Addressable FDA Market		3,800,000		
Total Addressable Compounding Market		12,000,000		
Percent of Addressable Market				
Average Net Revenue / Unit	20%	25%	35%	40%
\$ 60	\$ 189,600,000	\$ 237,000,000	\$ 331,800,000	\$ 379,200,000
\$ 80	\$ 252,800,000	\$ 316,000,000	\$ 442,400,000	\$ 505,600,000
\$ 100	\$ 316,000,000	\$ 395,000,000	\$ 553,000,000	\$ 632,000,000

Addressable Birth Control Market NRx		28,000,000		
Addressable NuvaRing Market NRx		1,200,000		
Percent of Overall Market for Birth Control / Percent of NuvaRing Market of NRx				
Average Net Revenue / Unit	1.0% / 23%	1.5% / 35%	2.0% / 47%	2.5% / 58%
\$ 1,000	\$ 280,000,000	\$ 420,000,000	\$ 560,000,000	\$ 700,000,000
\$ 1,500	\$ 420,000,000	\$ 630,000,000	\$ 840,000,000	\$ 1,050,000,000
\$ 1,750	\$ 490,000,000	\$ 735,000,000	\$ 980,000,000	\$ 1,225,000,000



# Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as “we” and “our”) may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as “believe,” “hope,” “may,” “anticipate,” “should,” “intend,” “plan,” “will,” “expect,” “estimate,” “project,” “positioned,” “strategy” and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled “Risk Factors” in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop and commercialize IMVEXXY®, ANNOVERA™, BIJUVA™ and 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 facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our products; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; 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.

This non-promotional presentation is intended for investor audiences only.



# TXMD Financial Guidance Overview

 **Imvexxy**<sup>®</sup>  
(estradiol vaginal inserts)

 **Bijuva**<sup>™</sup> 1mg/100mg  
(estradiol and progesterone) capsules

**ANNOVERA**<sup>™</sup>  
(segesterone acetate and ethinyl estradiol vaginal system)

**FDA-Approved Drugs  
Net Revenue**



**Prenatal Vitamins  
Net Revenue**

 **vitaMedMD**<sup>®</sup>

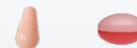


**TherapeuticsMD**<sup>®</sup>  
*For Her. For Life.*

**TXMD**  
Nasdaq Listed

# 2019 TXMD Quarterly Financial Guidance

	1Q2019 Actual	2Q2019 Expectation	3Q2019 Expectation	4Q2019 Expectation	FY2019 Expectation
--	------------------	-----------------------	-----------------------	-----------------------	-----------------------



**FDA-Approved Drugs  
Net Revenue**

\$2.0M

\$2.5-3.0M

\$4.5-6.5M

\$11-13M

\$20-24.5M

**Prenatal Vitamins  
Net Revenue**

\$1.9M

\$2.0-2.5M

\$1.75-2.25M

\$1.5-2.0M

\$7.15-8.65M

**Total TXMD  
Net Revenue**

\$3.9M

\$4.5-5.5M

\$6.25-8.75M

\$12.5-15M

\$27.1-33.1M



# 2019 TXMD Annual Financial Guidance

	FY2018 Actual	FY2019 Expectation	y/y growth <sup>1</sup>
FDA-Approved Drugs Net Revenue	\$1.0M	\$20-24.5M	2,125%
Prenatal Vitamins Net Revenue	\$15M	\$7.15-8.65M	(47%)
<b>Total TXMD Net Revenue</b>	<b>\$16M</b>	<b>\$27.1-33.1M</b>	<b>~88%</b>

- **Important Guidance Notes:**

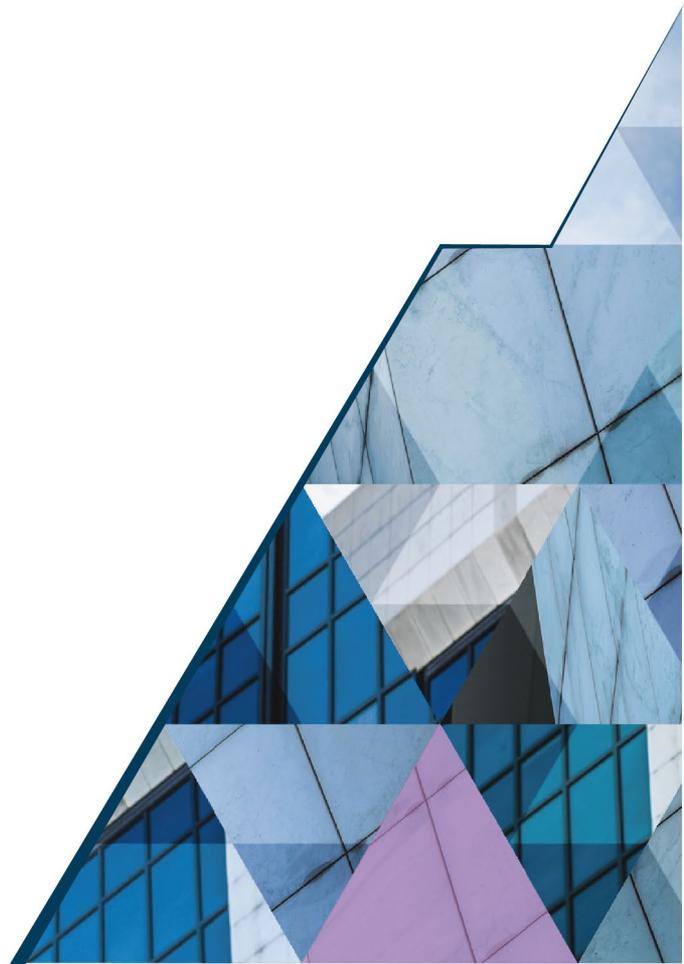
- As our sales force focus shifts to our FDA-approved drugs and payer headwinds continue to increase for prenatal vitamins, we anticipate prenatal vitamins will continue to become a smaller percentage of overall company revenues

1. y/y growth calculated at midpoint of guidance



# Appendix

**TXMD**  
Nasdaq Listed



# Strong IMVEXXY Launch

IMVEXXY Launch Metrics		
Total paid scripts dispensed to patients <sup>1</sup> (since launch through May 31, 2019)		~206,500
Total paid scripts (May 1-31, 2019)		~37,700
Total patients (since launch through May 31, 2019)		~61,800
Total prescribers <sup>2</sup> (since launch through May 31, 2019)		~12,000
Comparison of Average Weekly & Daily Script Volume (Average Weekly Volume: TRx for month / # days in month * 7 days)		
	For 30 Days in Apr. 2019	For 31 Days in May. 2019
Average weekly volume	~7,300	~8,500
Average daily volume	~1,040	~1,200

<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a two week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

<sup>2</sup> Total Unique Prescribers that have sent a prescription to a pharmacy for at least 1 patient for IMVEXXY.

# Model To Change Behavior Is Working

Scripts are accelerating while adjudication is increasing and adherence (staying on therapy) is growing

IMVEXXY Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through May 31, 2019)	~206,500
Total paid scripts (May 1-31, 2019)	~37,700
Total patients (since launch through May 31, 2019)	~61,800
Total prescribers <sup>2</sup> (since launch through May 31, 2019)	~12,000

<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a one week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

<sup>2</sup> Total Unique Prescribers that have sent a prescription to a pharmacy for at least 1 patient for IMVEXXY.

# IMVEXXY Product Characteristics Compare Favorably<sup>1-9</sup>

	Estrogens				Non-estrogens	
Product	Estrace® Cream (estradiol vaginal cream, USP, 0.01%) <sup>1</sup>	Premarin® (conjugated estrogens) Vaginal Cream <sup>2</sup>	Vagifem® (estradiol vaginal inserts) <sup>4</sup>	IMVEXXY® (estradiol vaginal inserts) <sup>5</sup>	Intrarosa® (prasterone) vaginal inserts <sup>7</sup>	Osphena® (ospemifene) tablets, for oral use <sup>8</sup>
						
						
FDA approval	1984	1978	1999	2018	2016	2013
TRx MSB Dollars of Brand & Generic 2018 <sup>9</sup>	\$540,000,000	\$462,226,000	\$420,030,000	\$44,000,000	\$35,001,000	\$73,908,000
2018 Total Units <sup>9</sup>	1,902,000	1,220,000	1,500,000	205,500 (10 months)	169,000	218,000
Method of administration	Vaginal cream	Vaginal cream	Vaginal insert	Vaginal insert	Vaginal insert	Oral tablet
Application	Reusable vaginal applicator-cream	Reusable vaginal applicator-cream	Disposable vaginal applicator-tablet	No applicator needed- softgel vaginal insert	Disposable vaginal applicator- bullet insert	Oral daily tablet
Active ingredient	100 mcg estradiol	625 mcg/g conjugated equine estrogens	10 mcg estradiol	4 mcg or 10 mcg estradiol	6,500 mcg prasterone	60,000 mcg ospemifene
Average maintenance dose	100 mcg 2x/week	312.5 mcg 2x/week	10 mcg 2x/week	4 mcg or 10 mcg 2x/week	6,500 mcg daily	60,000 mcg daily
WAC package price (2018) <sup>10</sup>	\$314.87 (42.5-g tube)	\$355.77 (30-g tube)	\$170.16 (8 tablets)	\$180.00 (8 softgel capsules)	\$185.50 (28 inserts)	\$611.39 (90 tablets)
WAC 30-day supply (2018) <sup>10</sup>	\$104.96	\$118.59	\$170.16	\$180.00	\$198.75	\$203.80

**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; 2019. 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 2018 and Imvexxy is 10 months data through May 2019 [a. [2017 Estrace and generics (Teva, Mylan, Impax & Alvogen) and 2017 Vagifem, Yuvafem (authorized generic of Vagifem), and Teva generic] 10. AnalySource. June 2018.

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.

**TherapeuticsMD®**  
For Her. For Life.

**TXMD**  
Nasdaq Listed

# BIJUVA Launch Metrics

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through May 31, 2019)	~2,000
Total paid scripts (May 1-31, 2019)	~1,600
Total patients (since launch through May 31, 2019)	~1,500
Total prescribers <sup>2</sup> (since launch through May 31, 2019)	~1,100

<sup>1</sup>Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a two week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

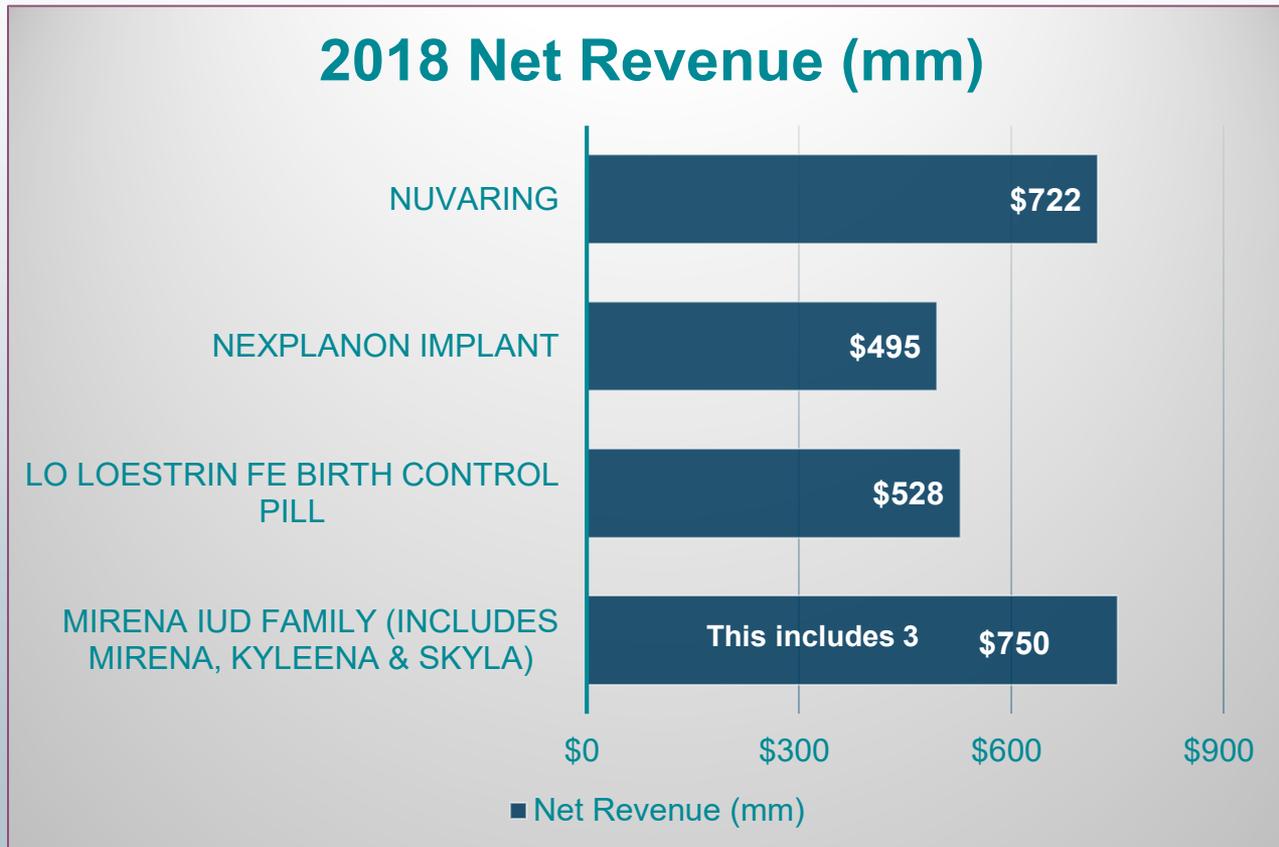
<sup>2</sup>Total Unique Prescribers that have sent a prescription to a pharmacy for at least 1 patient for BIJUVA.

# ANNOVERA Key Attributes

	Oral Contraceptives	Vaginal Ring NuvaRing®	Contraceptive Injection	Vaginal System ANNOVERA™	IUDs
<b>Duration of Action</b>	Daily pill intake	1 month (21/7 regimen)	3 months	1 year (21/7 regimen)	3-10 years
<b>Patient Control</b>	Stop at any time	Removable at any time	Stop at any time, but residual effects for 3 months	Removable at any time	Procedure required
<b>Nulliparous Women</b>	Yes	Yes	Yes	Yes	Not universally acceptable
<b>Product Administration</b>	Oral intake	Patient administered flexible ring	Physician in-office injection every 3 months	Patient administered Soft and pliable vaginal system	Physician in-office procedure for insertion and removal
<b>Patient Convenience</b>	Daily pill presents compliance and adherence risks; potential increase in unplanned pregnancies	Monthly pharmacy visit	Physician in-office injection, prescriber stocking required	1 doctor's visit, 1 pharmacy visit per year	Physician in-office procedure, prescriber stocking required
<b>Healthcare Provider Convenience</b>	Filled at pharmacy	Filled at pharmacy; Refrigeration required prior to being dispensed	Prescriber required to hold inventory	Filled at pharmacy; No refrigeration; No inventory or capital outlay	Prescriber required to hold inventory
<b>Yearly WAC</b>	Lo Loestrin® Fe: \$1,829.36	NuvaRing® \$2,114.19	Depo-Provera® \$799.12	\$1,800-\$2,100	Liletta® \$749.40 + \$425.25 for insertion/removal Plus office visits and screenings

All trademarks are the property of their respective owners.

# Top Contraceptive Products Based on Revenue

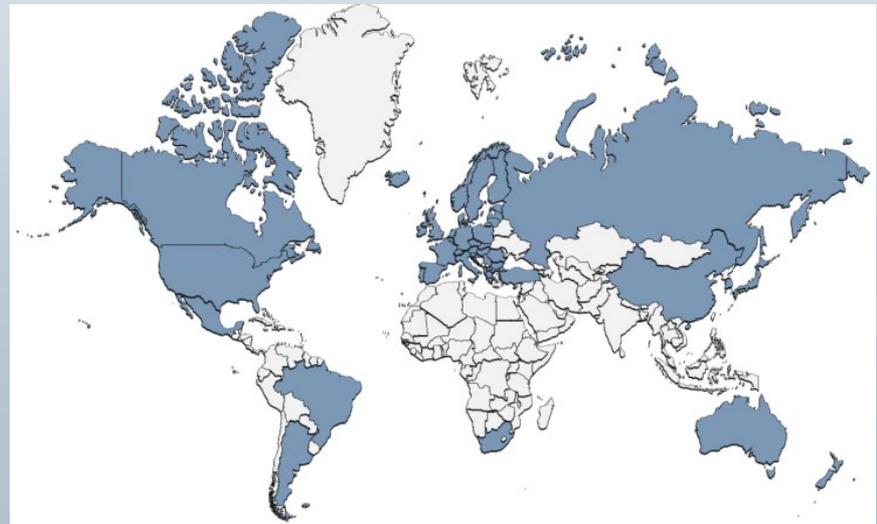


Company filings; Net sales as reported in 2018 company filings.

# Overview of TXMD's Patents

- As of June 7, 2019, TherapeuticsMD's patent portfolio includes:
  - 293 patent applications:
    - 24 issued U.S. patents
      - 12 U.S. patents have been listed in the Orange Book for BIJUVA
      - 3 U.S. patents have been listed in the Orange Book for IMVEXXY
    - 27 issued international patents
- TXMD currently has international patents or patent applications in:

- Argentina
- Australia
- Brazil
- Canada
- China
- Europe
- Hong Kong
- Israel
- Japan
- Mexico
- New Zealand
- Russia
- South Africa
- South Korea



# Overview of TXMD's Patents for BIJUVA and IMVEXXY

BIJUVA Patent Summary	
Formulation and Method Claims	
US Issued / Allowed	12* / 0
Expiration	2032
US Patents Pending	8
International Patents Granted	5
International Patents Pending	52
International Coverage	AR, AU, BR, CA, CN, EU, IL, MX, NZ, JP, KR, RU, ZA
Expiration	No earlier than 2032

IMVEXXY Patent Summary	
Formulation and Method Claims; Design Patent	
US Issued / Allowed	4 / 3
Expiration	No earlier than 2032
US Patents Pending	11
International Patents Granted	13
International Patents Pending	33
International Coverage	AR, AU, BR, CA, EU, HK, IL, MX, NZ, JP, KR, RU, ZA
Expiration	No earlier than 2033

\* This number does not include the 3 issued U.S. patents that cover the 0.25/50, 0.5/50, and 0.5/100 E+P dosage strengths