



# Investor Presentation

November 2018

**TherapeuticsMD<sup>®</sup>**

*For Her. For Life.*

TherapeuticsMD.com

# Forward-Looking Statements

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

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled “Risk Factors” in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: 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 agreement; 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 product and product candidates; 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.

# TherapeuticsMD, A Premier Women's Health Company

**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

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# Women's Health Assets With Large Total Addressable Market Opportunities

	 	 	 
<b>Indication</b>	Females of reproductive potential to prevent pregnancy	Moderate to severe vasomotor symptoms (VMS) due to menopause	Moderate to severe dyspareunia, a symptom of VVA, due to menopause
<b>Condition Description</b>	Contraception	VMS due to Menopause	VVA due to Menopause
<b>Active Ingredients</b>	Segesterone Acetate/ Ethinyl Estradiol	Bio-Identical 17 β-Estradiol + Bio-Identical Progesterone	Bio-Identical 17 β-Estradiol
<b>Form</b>	Vaginal System	Oral softgel capsule	Vaginal softgel insert
<b>Key Value Proposition</b>	First and only patient-controlled, procedure-free, long-acting, reversible birth control product	First and only FDA-approved bio-identical combination hormone therapy	Easy to use, lowest approved dose, designed to support patient adherence
<b>Affected US Population</b>	43 million women <sup>1</sup>	36 million women <sup>3</sup>	32 million women <sup>5,6</sup>
<b>US TAM Opportunity</b>	\$5B <sup>2</sup>	>\$25B <sup>4,7</sup>	>\$20B <sup>7</sup>
<b>Status</b>	Approved August 10, 2018 Commercial Launch: As early as 4Q19	Approved October 28, 2018 Commercial Launch: Est. 2Q19	Approved May 29, 2018 Commercial Launch: August 2018

1) Contraceptive Use in the United States, Guttmacher, July 2018. IQVIA Patient Tracker.

2) QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.

3) Derived from U.S. Census data on women in the age group who normally experience symptoms.

4) Based on pre-WHI annual scripts of FDA-approved HT products.

5) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):888–902.

6) Gass ML, Cochrane BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.

7) Based on market pricing of current FDA-approved HT products.

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# 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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# IMVEXXY Launch Update

as of November 16, 2018

- Total units since launch ~35,600 paid scripts<sup>1</sup> dispensed to ~14,000 patients
  - November (1<sup>st</sup> - 16<sup>th</sup>) total units of ~7,400 paid scripts<sup>1</sup>
  - Refills for November (1<sup>st</sup> - 16<sup>th</sup>) of ~5,000 paid scripts<sup>1</sup>
- New Rx for Nov (1<sup>st</sup> - 16<sup>th</sup>) of ~2,400 paid scripts<sup>1</sup>
- 58% month over month growth (September/October)
- Average refill rate ~75%
  - 2.2 IMVEXXY fills per patient in the first 4 months<sup>2</sup>
  - Previous two dyspareunia product launches during the first year of launch averaged 1.7 fills per patient<sup>3</sup>
- 38% commercial unrestricted coverage<sup>4</sup>
  - 14% adjudication rate



<sup>1</sup>Units are based on IQVIA and copay redemption data based on utilization of our affordability programs. Cash pay or covered by insurance.

<sup>2</sup>Imvexxy fill data is based on IQVIA and copay redemption data.

<sup>3</sup>Previous two launches is based on Symphony total script data divided by the patient count data from IQVIA total patient tracker info from the 12 months of launch.

<sup>4</sup>MMIT November 21, 2018

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# Expected Net Revenue Ramp for IMVEXXY

## Net Revenue Ramp for Commercially Insured Patient

### Starter Pack

- WAC \$405
- 60% net = \$243 average net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

### Maintenance Pack

- WAC \$180
- 60% net = \$108 average net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

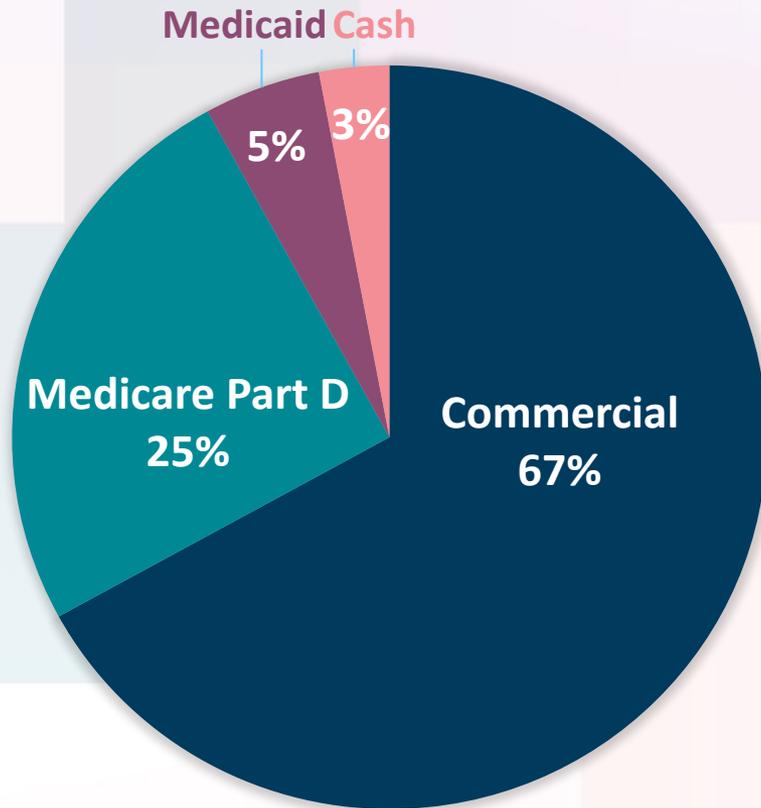
### Blended Starter/Maintenance

- Current average WAC \$225 (through October; will fluctuate based on mix and insurance coverage)
- 60% net = \$135 net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

## Net Revenue Ramp for Medicare Part D to be determined

# IMVEXXY Payer Update

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



## Commercial Coverage

- ~38% unrestricted **commercial lives coverage** (no step edits or PA)<sup>2</sup>
  - 90 days lag for each covered plan to operationalize before adjudication begins
  - Expect to sign major commercial payer contracts in 2018 with fully established coverage 4Q19
  - Anticipate strong commercial adjudication will start in 1Q19

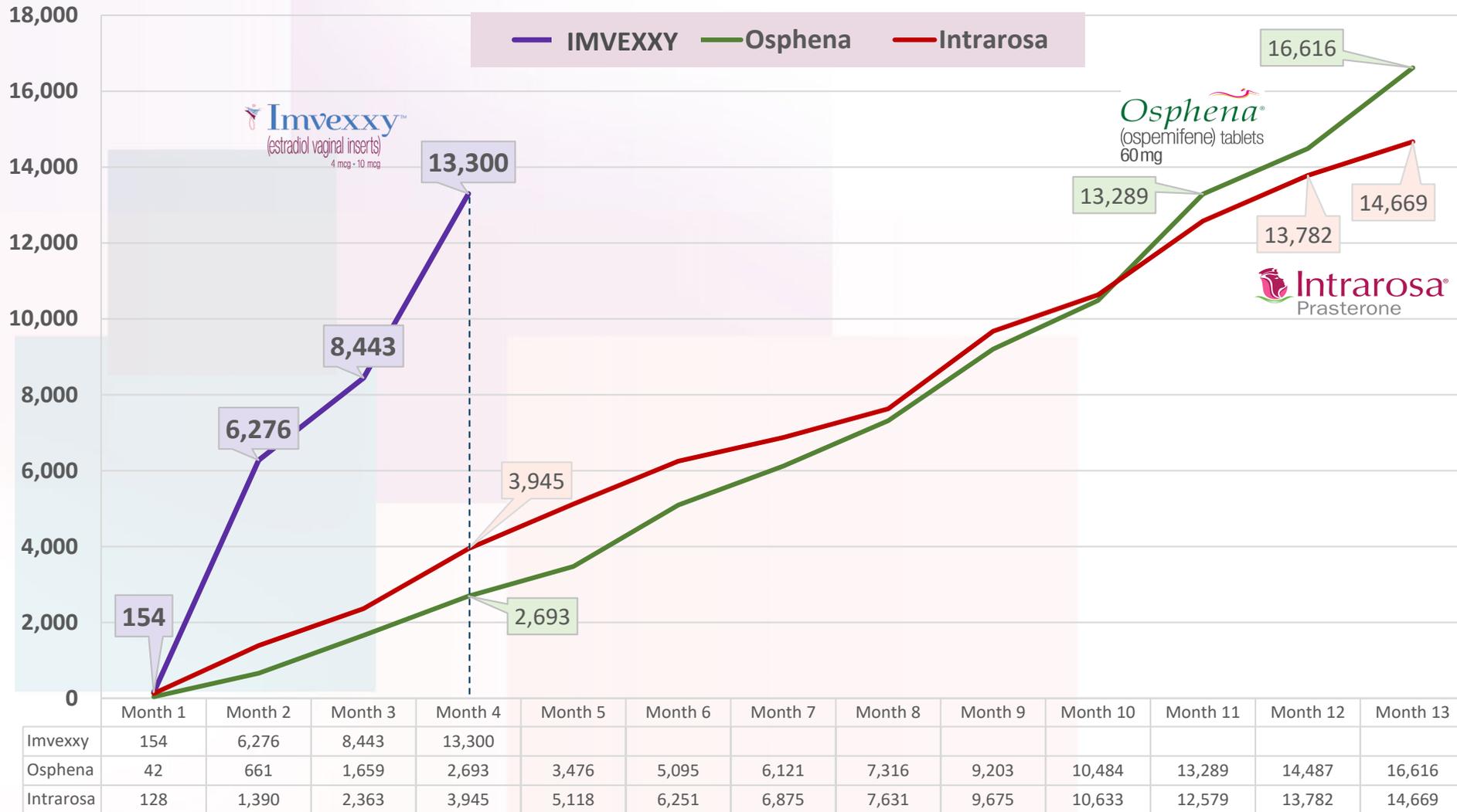
## Medicare Part D Coverage

- IMVEXXY currently stands at <1% of **Medicare Part D lives coverage** as expected with the next Medicare bid cycle for 2020
  - Expect Medicare Part D coverage October 1, 2019
    - Potential to be accelerated by some payors to April 1st, 2019

<sup>1</sup>Symphony as of November 8, 2018

<sup>2</sup>MMIT November 21, 2018

# Monthly VVA TRx Launch Comparison



## References:

Imvexxy is QVIA and copay redemption data.  
 Ospheña and Intrarosa is SHA PHAST data.  
 Vagifem is from IQVIA.

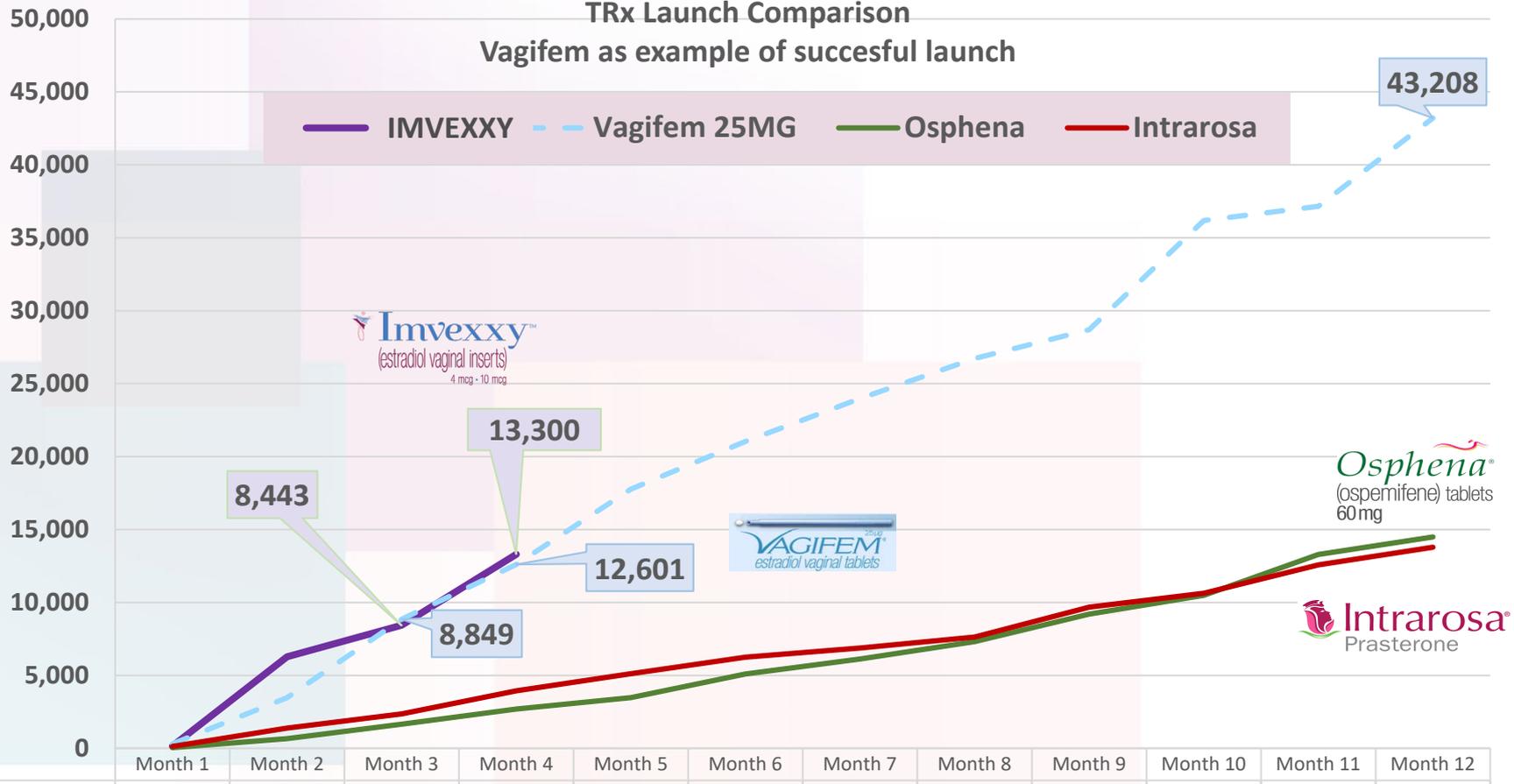
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# Monthly VVA TRx Launch Comparison

## TRx Launch Comparison

Vagifem as example of succesful launch



	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Imvexxy	154	6,276	8,443	13,300								
Vagifem 25MG	301	3,480	8,849	12,601	17,764	21,036	23,981	26,719	28,700	36,186	37,160	43,208
Ospheana	42	661	1,659	2,693	3,476	5,095	6,121	7,316	9,203	10,484	13,289	14,487
Intrarosa	128	1,390	2,363	3,945	5,118	6,251	6,875	7,631	9,675	10,633	12,579	13,782

### References:

Imvexxy is QVIA and copay redemption data.

Ospheana and Intrarosa is SHA PHAST data.

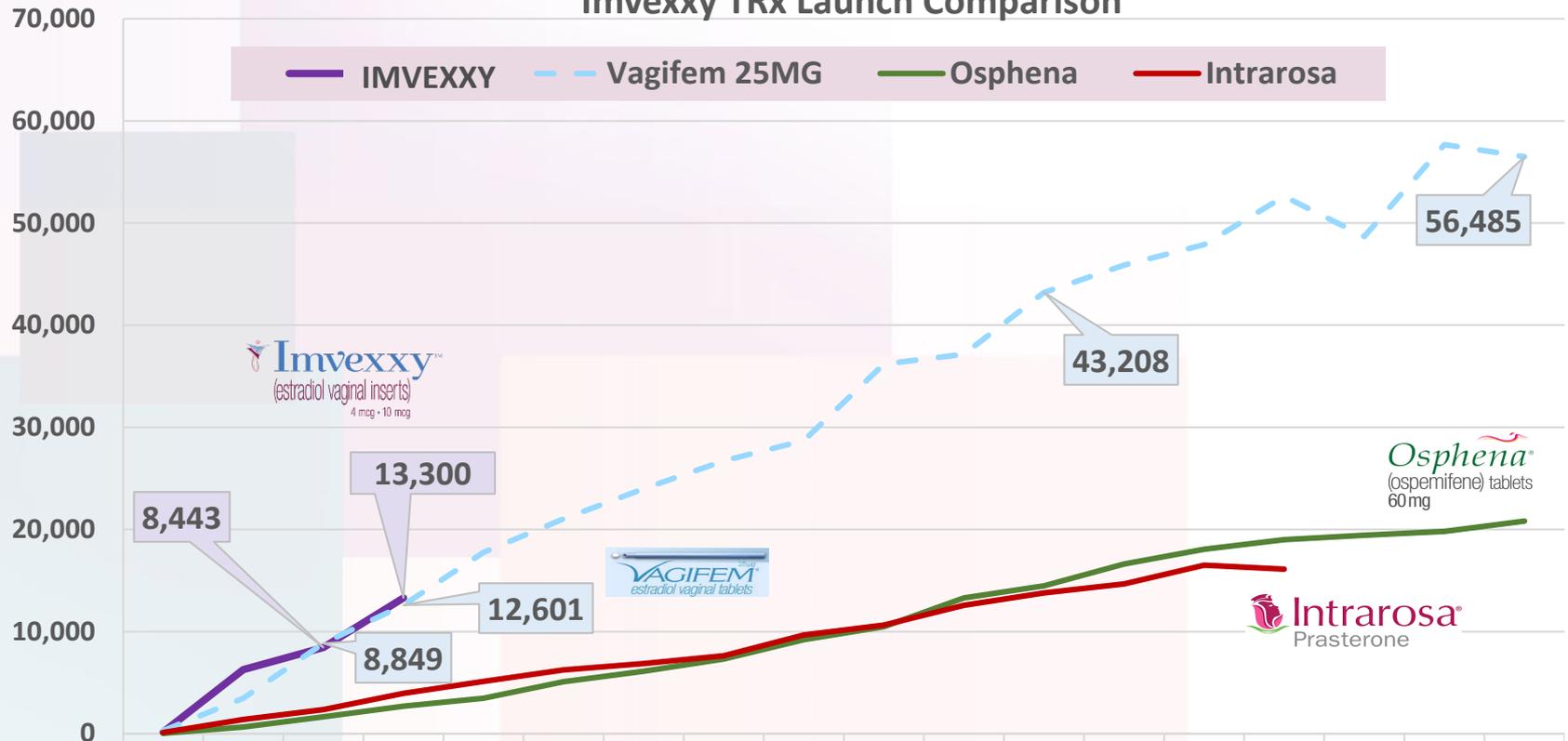
Vagifem is from IQVIA.

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# Monthly VVA TRx Launch Comparison

## Imvexxy TRx Launch Comparison



	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18
Imvexxy	154	6,276	8,443	13,300														
Vagifem 25MG	301	3,480	8,849	12,601	17,764	21,036	23,981	26,719	28,700	36,186	37,160	43,208	45,882	47,882	52,603	48,674	57,675	56,485
Ospheña	42	661	1,659	2,693	3,476	5,095	6,121	7,316	9,203	10,484	13,289	14,487	16,616	18,056	18,998	19,440	19,804	20,817
Intrarosa	128	1,390	2,363	3,945	5,118	6,251	6,875	7,631	9,675	10,633	12,579	13,782	14,669	16,508	16,119			

### References:

Imvexxy is QVIA and copay redemption data.  
 Ospheña and Intrarosa is SHA PHAST data.  
 Vagifem is from IQVIA.

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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 approved 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

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

DISCOVER A TREATMENT EXPERIENCE WITH

## SIMPLICITY AT ITS CORE<sup>1</sup>



COMFORTABLE, CONVENIENT, APPLICATOR-FREE ADMINISTRATION<sup>2</sup>

AN ELEGANT DESIGN THAT SIMPLY FITS INTO HER LIFE<sup>3</sup>

THE ONLY ULTRA-LOW-DOSE VAGINAL ESTRODIOL AVAILABLE IN BOTH 4-NG AND 10-NG DOSES<sup>4</sup>

**Imvexxy**  
(estradiol vaginal insert)  
4mg/10mg

**IMPORTANT SAFETY INFORMATION**

**WARNINGS: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA**  
See full prescribing information for complete boxed warning.

**Estrogen-Alone Therapy**

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone study reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

**Estrogen Plus Progestin Therapy**

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
- The WHI estrogen plus progestin study reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)
- The WHI estrogen plus progestin study reported increased risks of invasive breast cancer
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Please see additional Important Safety Information on the reverse side and the Full Prescribing Information, including the Boxed Warning, in packet.

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

Product	Estrogens			Non-estrogens		
	Estrace <sup>®</sup> Cream (estradiol vaginal cream, USP, 0.01%) <sup>1</sup>	Premarin <sup>®</sup> (conjugated estrogens) Vaginal Cream <sup>2</sup>	Vagifem <sup>®</sup> (estradiol vaginal inserts) <sup>4</sup>	IMVEXXY (estradiol vaginal inserts) <sup>5,6</sup>	Intrarosa <sup>®</sup> (prasterone) vaginal inserts <sup>7</sup>	Ospemifene <sup>®</sup> (ospemifene) tablets, for oral use <sup>8</sup>
						
						
FDA approval	1984	1978	1999	2018	2016	2013
TRx MSB Dollars 2017 <sup>9</sup>	\$504,804,770	\$463,264,428	\$446,044,670	-	\$3,597,519	\$66,904,883
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 capsule	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

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 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. Ospemifene [package insert]. Florham Park, NJ: Shionogi Inc.; 2015. 9. Symphony Health Solutions PHAST Data powered by IDV; Annual 2017 [a. 2017 Estrace and generics (Teva, Mylan, Impax & Alvogen) and 2017 Vagifem, Yuvafem (authorized generic of Vagifem), and Teva generic] 10. AnalySource. June 2018.

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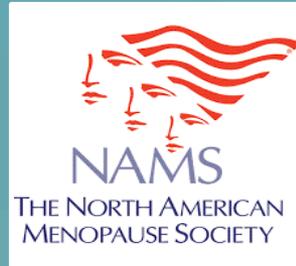
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# Professional Societies and FDA Recommend the Lowest Effective Dose



## American College of Obstetricians and Gynecologists (ACOG)<sup>1</sup>

“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)<sup>2</sup>

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



## FDA<sup>3</sup>

“...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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# Bijuva™

(estradiol and progesterone) capsules

1.0mg/100mg

The first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel capsule for the treatment of moderate to severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.

Bio-Identical Combination  
Estrogen + Progesterone  
(E+P) Program

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# BIJUVA Product Development Rationale

- 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, night sweats), mood changes and vaginal dryness
    - Prolonged lack of estrogen can affect the bones, cardiovascular system, and increases risks for osteoporosis
  - Estrogen to reduce symptoms and other long-term conditions
    - Increased risk for endometrial hyperplasia/endometrial cancer if estrogen unopposed<sup>2</sup>
  - Progesterone to prevent thickening of the uterine wall<sup>2</sup>
- 2002 Women's Health Initiative (WHI) study showed that the long-term use of certain *synthetic* hormones (a combination of medroxyprogesterone and conjugated equine estrogens) increased the risk of breast cancer, stroke, heart attack and blood clots (all FDA-approved combination hormonal products contain a synthetic Progestin and not a bio-identical Progesterone)



After WHI, women and healthcare providers shifted to Bio-Identical Hormone Therapy (BHRT as an alternative despite being *unapproved* drugs that are *not covered by insurance*

- Today, patients have the choice between three therapies:<sup>3</sup>
  - FDA-approved, synthetic combination hormones
  - FDA-approved, separate bio-identical hormone products
  - Unapproved, compounded bio-identical hormones that have not been proven safe and effective, or covered by insurance



- Compounding filled the need for BHRT
  - 30M scripts (3M women) of Compounded Bio-identical Hormone Therapy (CBHRT) prescribed annually in the U.S. currently<sup>4,5</sup>
- All the major medical societies and the FDA discourage the prescribing of compounded hormones

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) Symphony Health Solutions PHAST Data powered by IDV; Annual 2015  
4) 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)  
5) Pinkerton, J.V. 2015. Menopause, Vol.22, No.9, pp 0-11.



# Bijuva<sup>™</sup> 1mg/100mg

(estradiol and progesterone) capsules

**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
- Favorable lipid, coagulation and metabolic profiles, compared to the profiles separately established for synthetic progestins and synthetic estrogens
- Clinically meaningful improvements in quality of life and sleep disturbance data
- Low incidence of bleeding and somnolence
- The most common adverse reactions ( $\geq 3\%$ ) are breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%), and pelvic pain (3.1%)

## Key Physical Attributes

- Once-a-day single oral softgel capsule
- One prescription, one copay

\*“Bio-identical” refers to estradiol and progesterone that are molecularly identical to the hormones produced naturally in the woman’s body. There is no evidence that bio-identical hormones are safer or more effective than synthetic hormones.

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# BIJUVA Large Substitutable Market

	Column 1	Column 2	Column 3
 <b>BIJUVA</b> <u>Substitutable</u> <u>Market</u>	<b>FDA-Approved</b>		<b>Compounded Combination</b> <b>Bio-Identical E+P</b>  
	<b>Off Label</b> <b>Separate Bio-Identical</b> <b>E &amp; P Pills</b>  	<b>Combination Synthetic</b> <b>E+P<sup>1</sup></b>  	
<b>TRx US:</b>	<b>~3.8 million (each)<sup>1</sup></b>	<b>~3 million<sup>2</sup></b>	<b>12 – 18 million<sup>3</sup></b>
<b>BIJUVA Potential</b> <b>Substitutable Market</b>	<b>\$760M-\$950M<sup>4</sup></b>	<b>\$600M-\$750M<sup>4</sup></b>	<b>\$2.4B-\$4.5B<sup>4</sup></b>

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2017

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

3) Consensus estimate based on Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31, 2017 and Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market

4) Assume WAC pricing between \$200-250

# BIJUVA Advantages For Stakeholders

## Patients

- Satisfy demand for bio-identical hormone therapy with a product approved by FDA on safety and efficacy
- Reduce of out-of-pocket costs via insurance coverage
- Convenience of combined hormones in a single capsule
- Widely acceptable at pharmacies and not just compounding pharmacies

## Healthcare Providers

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

## Pharmacies

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

## FDA/Regulatory Bodies

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

# BIO-IGNITE™

## Compounding Pharmacy Partnership Strategy

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

### WHAT IT HAS BECOME:

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



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# BIO-IGNITE Progress and Results

## Partnerships with Large Pharmacy Network and Individual Pharmacies

Pharmacy Network and Individual Pharmacy Partners

# of Pharmacies

Combination Bio-Identical E+P Scripts

Artiria\*

>300 Pharmacies In Network

~1,500,000 prescriptions annually

TXMD Outreach to Individual Pharmacies

>400 Pharmacies with Prescription Data

>500,000 prescriptions annually

\*Formerly known as Premier Value Pharmacy Compounding Network

# ANNOVERA™

(Segesterone Acetate/Ethinyl Estradiol  
Vaginal System)

Approved for use by females of reproductive potential to prevent pregnancy. (Limitation of use: Not adequately evaluated in females with a body mass index of  $>29$  kg/m<sup>2</sup>).

TherapeuticsMD®

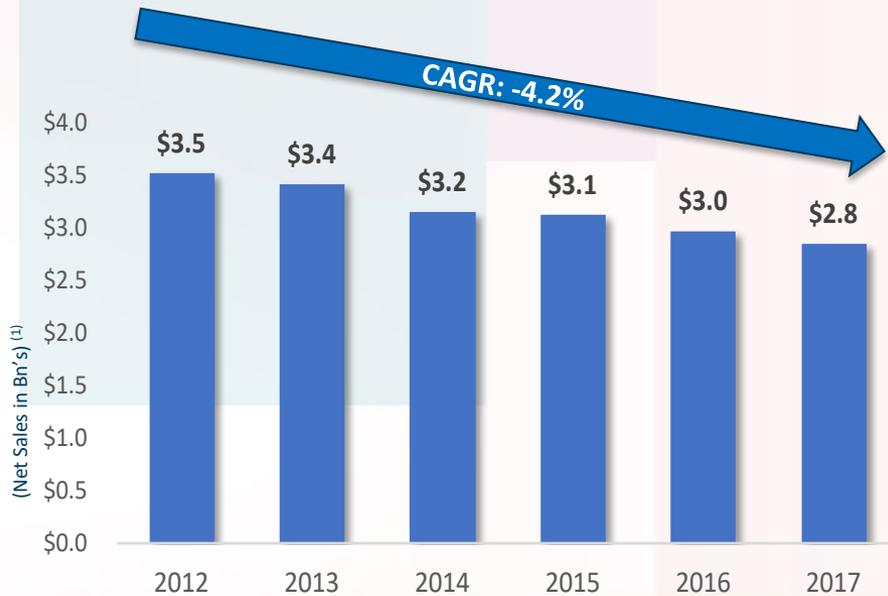
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# U.S. Prescription Contraceptive Market

- One of the largest therapeutic categories by script count
- ~ > \$5B U.S. net sales<sup>1</sup>

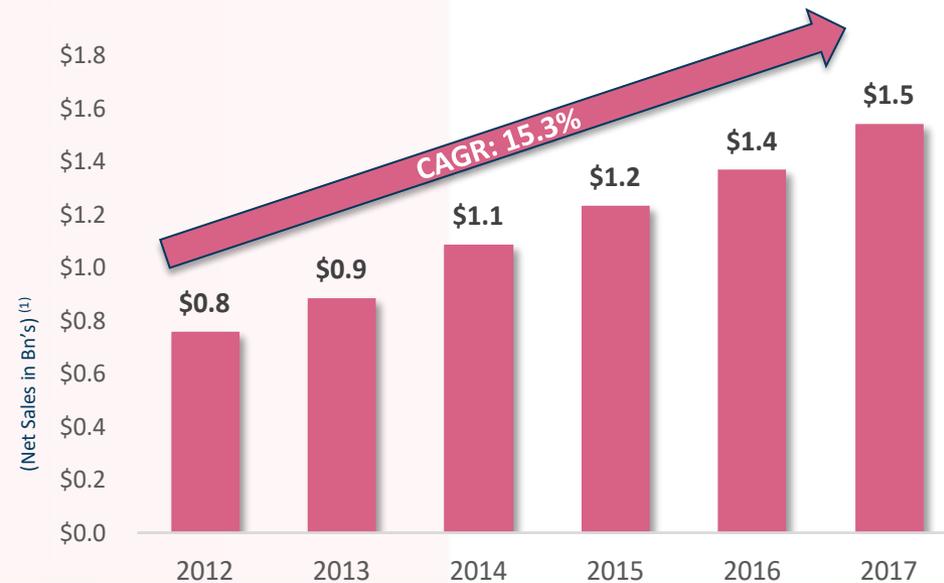
## Daily Oral Contraceptives

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



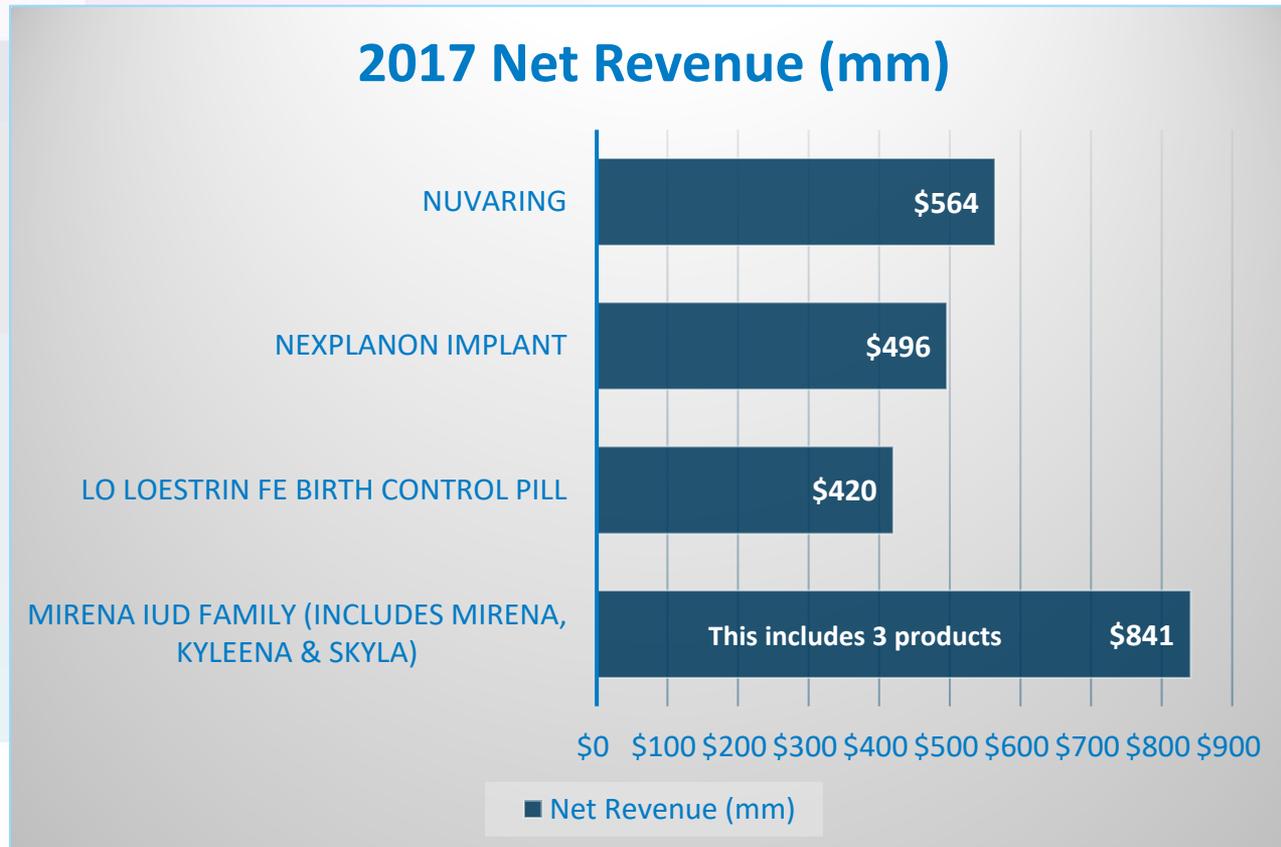
## Long Acting Reversible Contraceptives

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



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

# Top Contraceptive Products Based on Revenue



# ANNOVERA - 1-Year Vaginal System

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

- ANNOVERA approved on August 10, 2018
  - Segesterone acetate component of ANNOVERA classified as NCE with 5 year exclusivity
- Developed by the Population Council – developer of multi-billion dollar long acting contraceptive products
  - **ParaGard®** and **Mirena®** IUDs; **Norplant®** and **Jadelle®** implants; and **Progering®**
- Benefits
  - Increase compliance over short acting products
  - Offer women a long-term birth control option without requiring a procedure for insertion and removal like IUDs or implants
  - Allow women who haven't had a child (nulliparous) or are not in a monogamous relationship - who are often counseled against IUDs due to the potential risk of infertility - access to long-term reversible birth control

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

<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 Key Attributes

## Clinical Attributes

- Only FDA approved long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
  - Empowers women to be in 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<sup>1</sup> (89% overall satisfaction)
- Low daily release of ethinyl estradiol (13 mcg)
- Only product with new novel progestin - segesterone acetate<sup>2</sup>
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Favorable side effect profile including low rates of discontinuation related to irregular bleeding (1.7%)
- Safety profile generally consistent with other CHC products, including boxed warning

## Physical Attributes

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

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

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<sup>3</sup> Lohr, et al. Use of intrauterine devices in nulliparous women. *Contraception* 95 (2017); 529-537

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

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

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

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

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# ANNOVERA Commercialization Strategy

## Launch Timing

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

## Attractive Market Segments for Annovera

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

<sup>1</sup> IQUVIA Data

# Committed to Become the Leading Women's Health Company



TherapeuticsMD®

*For Her. For Life.*

# TherapeuticsMD, A Premier Women's Health Company

**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

TherapeuticsMD®

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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 20% of the company's shares\*
  - Three founding executives beneficially own approximately 17%\* of the company's shares
    - Includes vested options to acquire approximately 1.7 million shares\*\* of common stock that were originally issued on January 1, 2009 and expire on January 1, 2019
- Large institutional holder support
  - Large institutional holders – many long-term – beneficially own more than 55% of the company's outstanding shares

\*As of November 1, 2018

\*\*As of November 22, 2018

# TXMD: Financial Snapshot

**Listing  
Exchange**

**TXMD**  
Nasdaq  
LISTED

**Insider  
Ownership**

**~20%**

(Nov. 1, 2018)

**Shares  
Outstanding**

**237.9M**

(Nov. 1, 2018)

**Debt**

**\$75M**

(as of Sept. 30, 2018)

**Cash**

**\$190M**

(as of Sept. 30, 2018)

**TherapeuticsMD<sup>®</sup>**

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# Appendix



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# Current US VVA Market Overview

32M with VVA symptoms (1 out of 2 menopausal women) in the United States<sup>1,2</sup>

50% (16M)  
seek treatment for VVA<sup>4</sup>  
- 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  
therapy<sup>3</sup>

- Only 7% of women (2.3M) with VVA symptoms, are currently being treated today with Rx hormone therapy (HT)<sup>3</sup>
  - Long-term safety concerns<sup>5</sup>
  - Efficacy<sup>5</sup>
  - Messiness<sup>5</sup>
  - Need for applicator<sup>5</sup>

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 BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1160–1171.

3) Kingsberg SA, Krychman M, Graham S, Bernick B, Mirkin S. The Women's EMPOWER Survey: Identifying women's perceptions on vulvar and vaginal atrophy and its treatment. *J Sex Med*. 2017;14:413–424; IMS Health Plan Claims (April 2008–Mar 2011).

4) TherapeuticsMD "EMPOWER" Survey, 2016

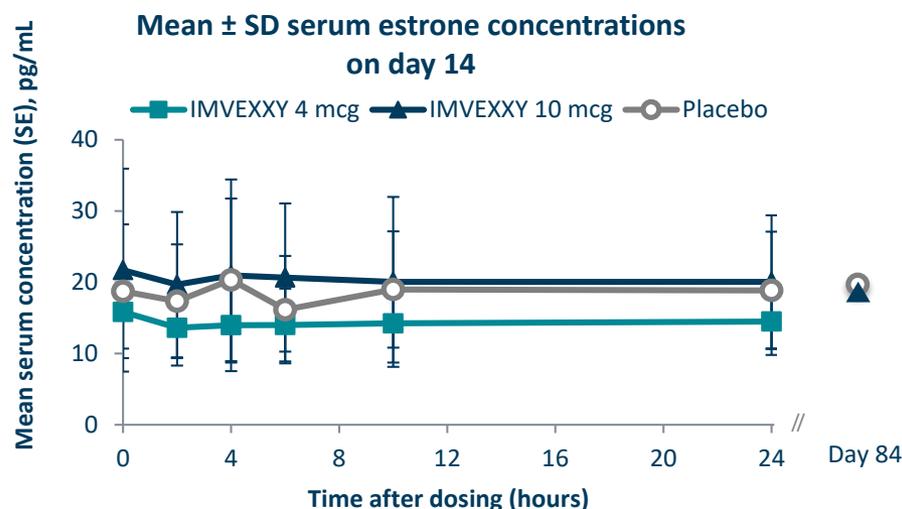
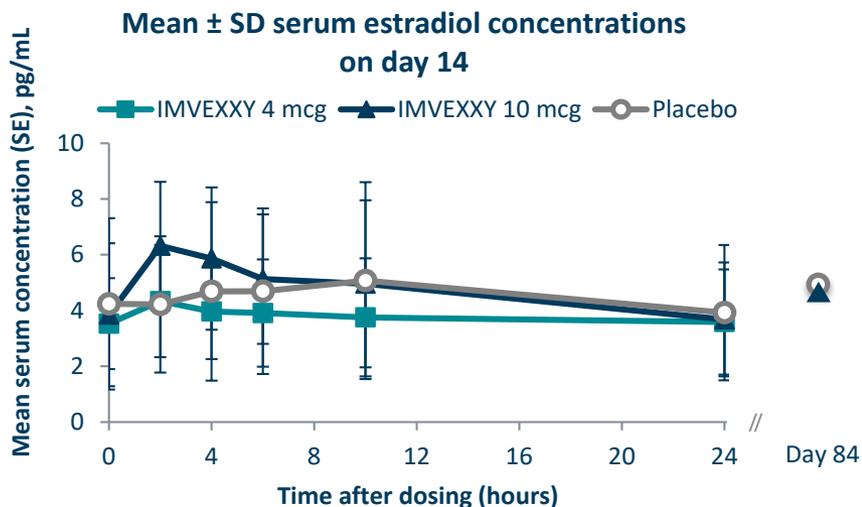
5) Wysocki, S et al, Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014;8 23-30 doi:10.4137/CMRH.S1449

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# IMVEXXY 4 and 10 mcg Resulted in Average Systemic Hormone Levels that were within the Normal Postmenopausal Range<sup>1,2</sup>

In a REJOICE substudy, 54 women received 1 IMVEXXY 4- or 10-mcg vaginal insert or placebo daily for 2 weeks followed by 1 insert twice weekly for 10 weeks with measurement of serum estradiol and estrone on days 1, 14, and 84.



Overall, there did not appear to be any estradiol accumulation with any doses of IMVEXXY as endogenous values were observed at day 84.

The clinical relevance of systemic absorption rates for all vaginal estrogen therapies is not known. Systemic absorption may occur with IMVEXXY; the risks associated with systemic estrogen-alone therapy should be considered.

References: 1. Test ID: EEST Estradiol, Serum. Mayo Clinic. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/81816>. Accessed on July 12, 2018.  
2. IMVEXXY [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2018.

# Patient Reported Outcomes with BIJUVA: CGI, MENQOL, and MOS-Sleep (Secondary Endpoints)

## Clinical Global Impression (CGI)

- Significantly more women rated their condition as very much or much improved with BIJUVA compared with placebo at Weeks 4 and 12

## Menopause-Specific Quality of Life Questionnaire (MENQOL)

- Statistically significant improvements in total score were observed at Week 12, Month 6, and Month 12 compared with placebo

## Medical Outcomes Study Sleep Scale (MOS-Sleep)

- Statistically significant improvements in total score were observed at Months 6 and 12 compared with placebo<sup>†</sup>

\* $P < 0.001$  vs placebo.

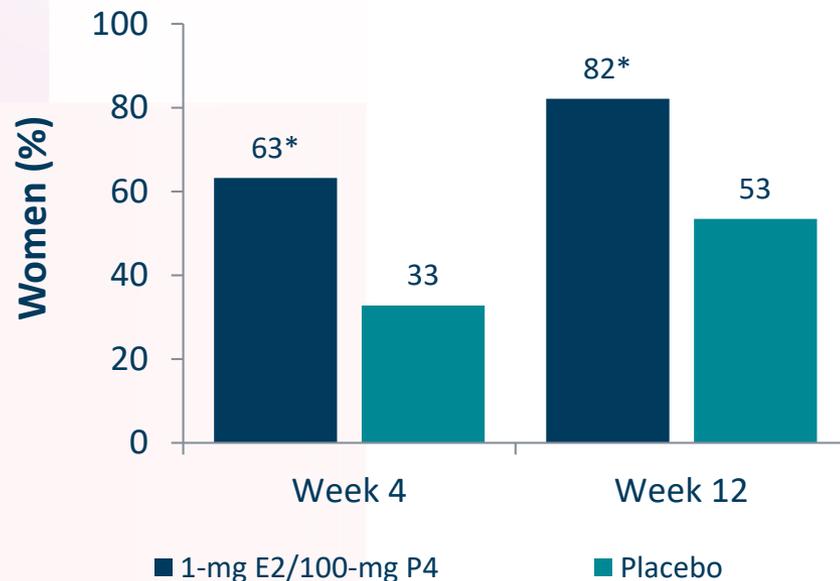
<sup>†</sup>Mean change from baseline at Month 12 was not significant.

E2=estradiol; P4=progesterone.

### Reference

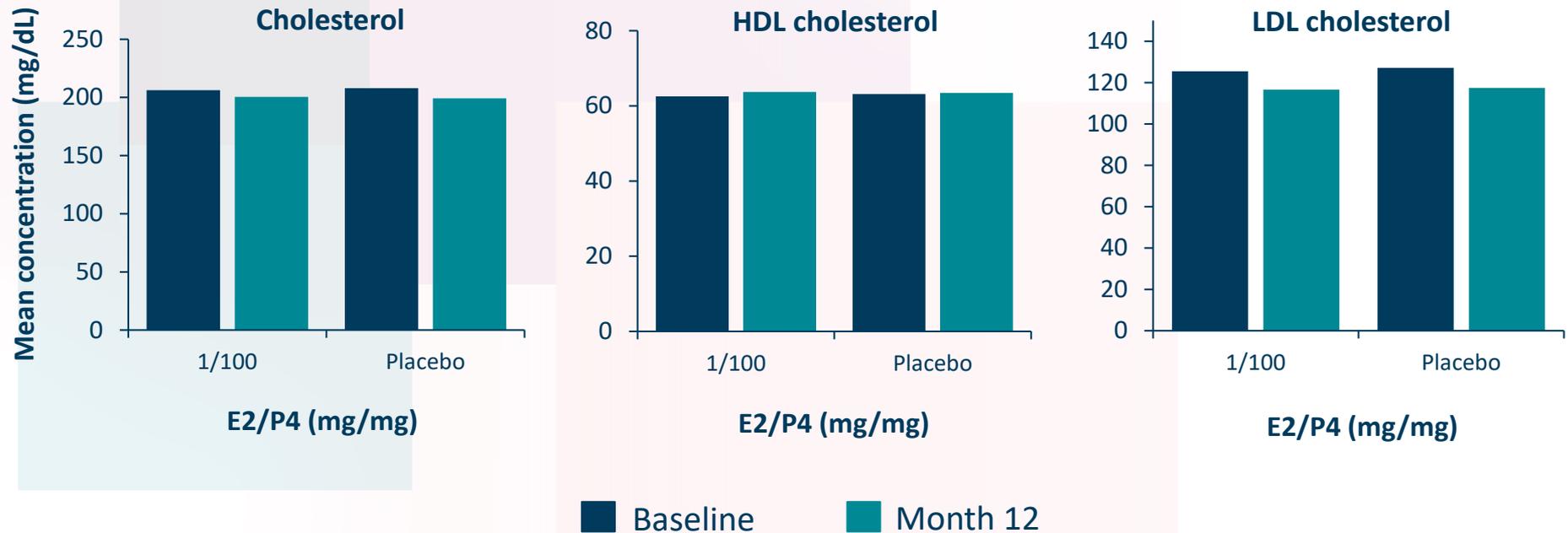
Data on file, TherapeuticsMD.

## CGI Response: Clinically meaningful improvement



# No Clinically Significant Changes in Cholesterol Levels were Observed

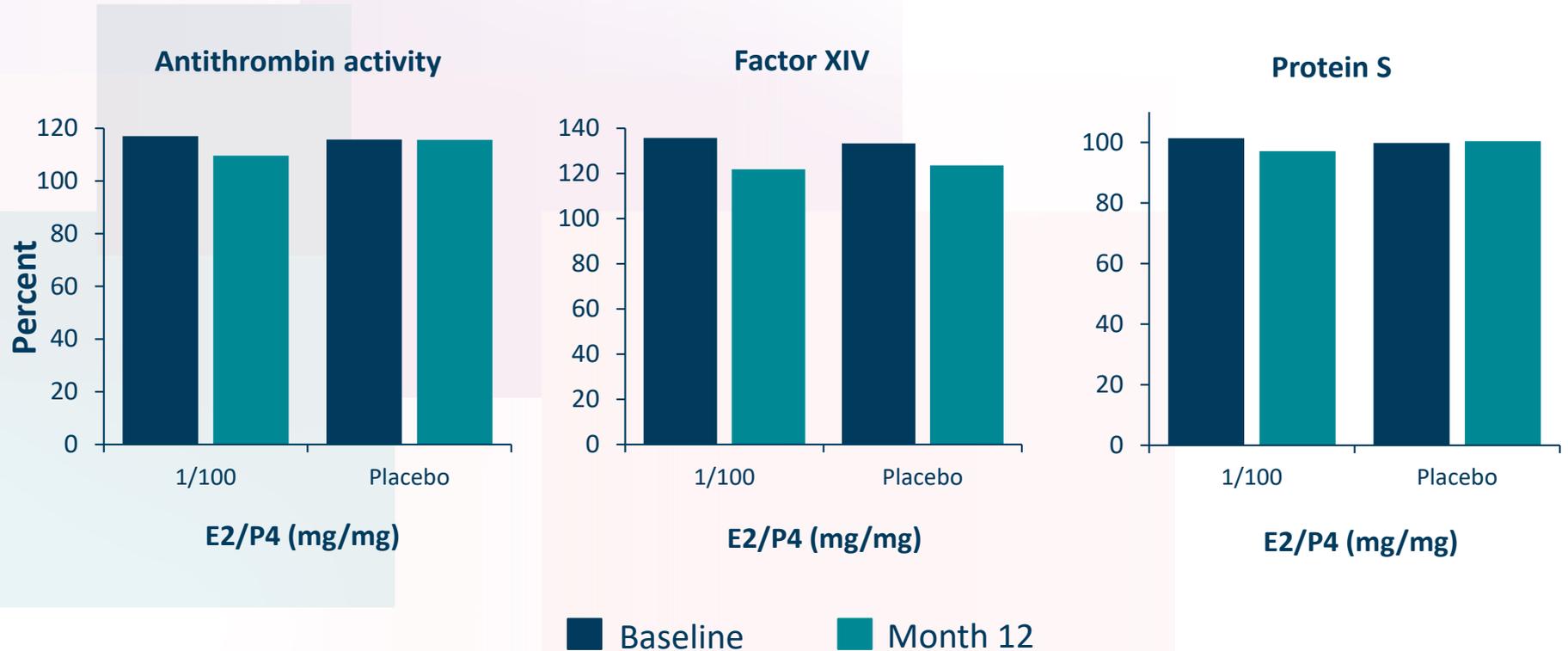
Few women had cholesterol increases ( $\geq 50$  mg/dL or above normal levels)  
at 12 months with BIJUVA vs placebo



E2=estradiol; P4=progesterone.

Reference  
Data on file, TherapeuticsMD.

# No Clinically Significant Changes in Coagulation Parameters were Observed with BIJUVA



E2=estradiol; P4=progesterone.

**Reference**  
Data on file, TherapeuticsMD.

# Bio-Identical Customization

Customization of therapy at compounding pharmacies refers to addressing the overall patient condition including menopausal symptoms, adrenal function, libido, energy levels, thyroid function and nutrition, rather than through micro-dose changes in estrogen/progesterone amounts based on blood levels

## Estradiol & Progesterone Claims

### Base for all Patients

- Controls VMS symptoms
- Promotes sleep & calming
- Progesterone to oppose Estradiol - safety

## Estrone, Estriol & DHEA Claims

- Breast cancer reduction/prevention
- Decrease clotting
- Glucose maintenance
- Improves lipids profile

## Testosterone Claims

- Libido
- Muscle tone
- Improves skin turgor
- Emotional well-being

## Thyroid (T3, T4) Claims

- Weight gain
- Lack of Energy
- Depression
- Memory

## Supplements

- Vitamin D3
- Melatonin (sleep)
- Omega-3

Continued Testing  
Blood, Saliva, Urine

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# Example of Economic Incentives Provide Catalyst to Switch to BIJUVA

## Economic Support TXMD Partnership for Patient Care

	Insurance Coverage (before 2H14)	Present Day (2018)	Post USP <800> (Dec. 2019)	BIJUVA Est. Launch 2Q2019
<b>Revenue</b>				
Patient Co-Pay	\$50.00	\$50.00	\$50.00	\$50.00
Third-Party Reimbursement	\$115.00	-	-	\$200.00
<b>Total Net Revenue</b>	<b>\$165.00</b>	<b>\$50.00</b>	<b>\$50.00</b>	<b>\$250.00<sup>1</sup></b>
Costs of Good Sold	\$7.50	\$7.50	\$7.50	\$200.00
<b>Gross Profit</b>	<b>\$157.50</b>	<b>\$42.50</b>	<b>\$42.50</b>	<b>\$50.00</b>
<i>Gross margin</i>	<i>95.5%</i>	<i>85.0%</i>	<i>85.0%</i>	<i>20.0%</i>
<b>Operating Expenses</b>				
G&A	\$15.00	\$15.00	\$15.00	\$15.00
S&M	\$7.50	\$7.50	\$7.50	\$5.00
Additional Compounding Costs <sup>1</sup>	\$15.00	\$15.00	\$15.00	-
<i>Cost of USP &lt;800&gt; Requirements<sup>2</sup></i>	-	-	<b>\$10.00</b>	-
<b>Total Operating Expenses</b>	<b>\$37.50</b>	<b>\$37.50</b>	<b>\$47.50</b>	<b>\$20.00</b>
<b>Pre-Tax Profit</b>	<b>\$120.00</b>	<b>\$5.00</b>	<b>\$(5.00)</b>	<b>\$30.00</b>

1) Includes additional labor, pharmacists, technicians, regulatory, and legal expenses. WAC expected to be \$200 to \$250.

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