

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

FORM 8-K  
CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): July 9, 2019

**TherapeuticsMD, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Nevada**

(State or Other  
Jurisdiction of Incorporation)

**001-00100**

(Commission File Number)

**87-0233535**

(IRS Employer  
Identification No.)

6800 Broken Sound Parkway NW, Third Floor  
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of Each Class</b>	<b>Trading Symbol</b>	<b>Name of Each Exchange on Which Registered</b>
Common Stock, par value \$0.001 per share	TXMD	The Nasdaq Stock Market LLC

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

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

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

Emerging growth company

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

**Item 7.01. Regulation FD Disclosure.**

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on July 9, 2019 and at subsequent meetings with investors or analysts.

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

**Item 9.01. Financial Statements and Exhibits.**

(d) *Exhibits*

Exhibit  
Number

Description

[99.1](#)

TherapeuticsMD, Inc. presentation dated July 9, 2019.

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**SIGNATURES**

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

Date: July 9, 2019

THERAPEUTICSMD, INC.

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

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**INVESTOR  
UPDATE**

**July 9, 2019**

*Building a Premier  
Women's Health Portfolio*

TherapeuticsMD®  
*For Her. For Life.*

# 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<sup>®</sup>, ANNOVERA<sup>™</sup>, BIJUVA<sup>™</sup> 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.

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# Seasoned Management Team with a Proven Track Record of Commercial Execution



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



- Former Chief Executive Officer and Chief Financial Officer of Shire PLC
- Former Vice President of Corporate Finance at AstraZeneca
- Holds multiple board memberships, including Chairman of Revance Therapeutics



- Former President and Chief Executive Officer of Boehringer Ingelheim (US)
- Former EVP of Customer Marketing and Sales of US Human Health at Merck
- Holds multiple board memberships, including Catalent



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



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



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



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



- Former CFO of American Wireless, Telegeography, and WEB Corp
- Participated in American Wireless/Arush Entertainment merger
- Former KPMG and PricewaterhouseCoopers accountant



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



- 20+ years of commercial and marketing experience
- SVP of the Pfizer Consumer Healthcare Wellness Organization
- Commercial lead for sales and marketing of the Pfizer Women's Health Division



- 25+ years of women's health pharmaceutical experience
- Product development leader for J&J, Wyeth, Aventis, and others
- Worked on development of Prempro®, Premphase®, and Estalis®



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

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# TherapeuticsMD® (TXMD)

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



**DYSPAREUNIA**  
(a symptom of VVA due to Menopause)

**VASOMOTOR SYMPTOMS**  
(Hot Flashes due to Menopause)

**PREGNANCY PREVENTION**



Easy to use, lowest approved dose, designed to support patient adherence

First and only FDA-approved bio-identical combination hormone therapy

First and only long-lasting (one year/13 cycles), procedure-free, patient-controlled, reversible birth control product

32 million women affected<sup>1,2</sup>

36 million women affected<sup>3</sup>

43 million women affected<sup>4</sup>

Launched

Launched

Limited launch expected 3Q19

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20(9):988-992.  
2) Gass ML, Cochran HS, 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) Derived from U.S. Census data on women in the age group who normally experience symptoms.  
4) Contraceptive Use in the United States, Guttmacher, July 2008. IQVIA Patient Tracker.

# Portfolio Approach to Women's Health

## Sum of the Parts



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

- Innovative products, chronic conditions, large markets
- 200 sales representatives focused on 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

\* \$35 or less copay with commercial coverage. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state health care programs (including any state pharmaceutical assistance programs). Program Terms, Conditions, and Eligibility Criteria apply.

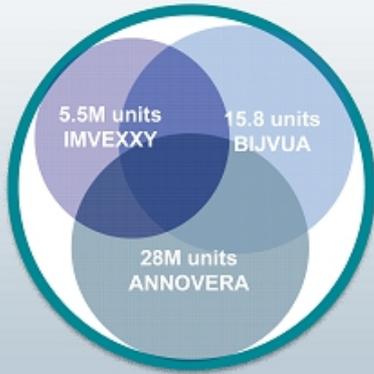
**TherapeuticsMD**

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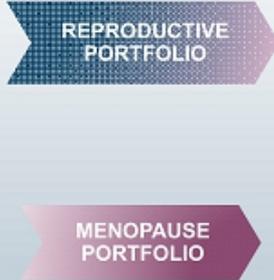
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# The Power of A Women's Health Portfolio

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



## Overlapping Prescribers & Patients



## The Power of 3

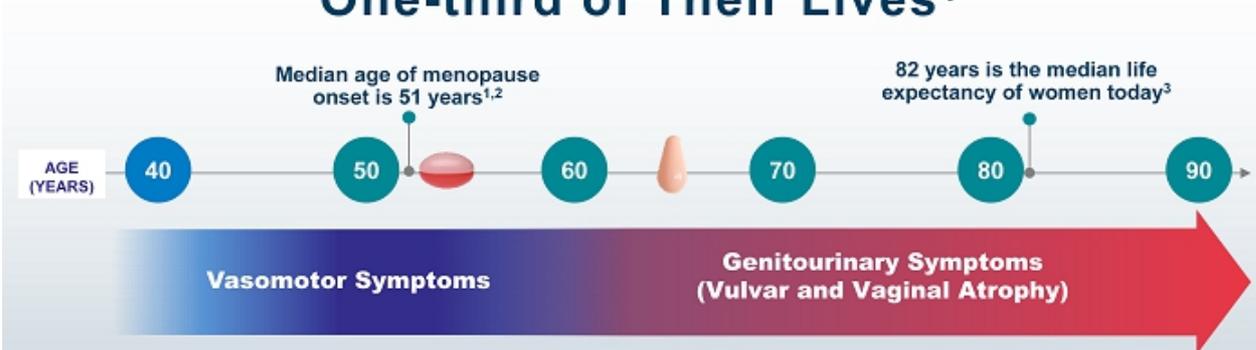


Even though there are over 400,000 total writers for these products<sup>2</sup>

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

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

# 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>

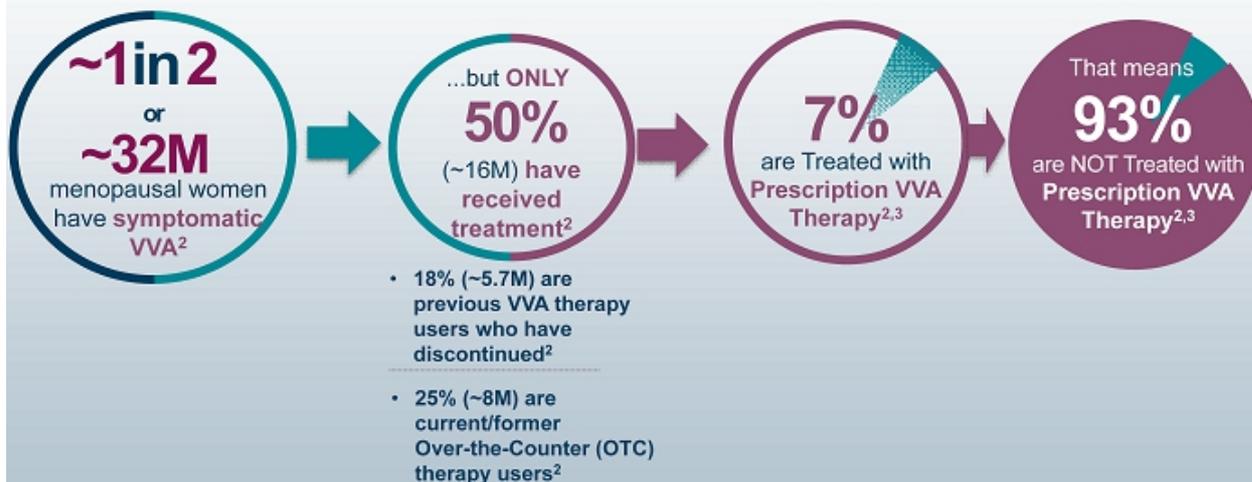
Symptoms of VVA may include:<sup>6,7</sup>

- 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(8):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**  
(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**
- **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.

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## Launch Approach Developed to Shift Entrenched Behavior



Remove Barriers



Drive Early Experience for a Differentiated Product



Drive Share Momentum Through New Writers and Share of Existing Writers

- 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
- 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
- Continuous unlocking of new levers as insurance adjudication normalizes



## Strong IMVEXXY Launch

IMVEXXY Launch Metrics		
Total paid scripts dispensed to patients <sup>1</sup> (since launch through June 30, 2019)	~244,000	
Total paid scripts (June 1-30, 2019)	~37,500	
Total patients (since launch through June 30, 2019)	~69,700	
Total prescribers <sup>2</sup> (since launch through June 30, 2019)	~12,900	
Comparison of Average Weekly & Daily Script Volume (Average Weekly Volume: TRx for month / # days in month * 7 days)		
	For 31 Days in May 2019	For 30 Days in June 2019
Average weekly volume	~8,500	~8,750
Average daily volume	~1,200	~1,250

<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.

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

Imvexxy TRx Launch Comparison



\*Month 12 for IMVEXXY is June 2019

- IMVEXXY continues to grow both weekly average volume and daily average volume for June (30 day month) vs May (31 day month)
- Average daily volume for 30 days in June 2019 increased to ~1,250 from ~1,200 for the 31 days in May 2019

**References:**

1. Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. This includes two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
  2. Ospheina and Intrarosa data sourced from Symphony Health Integrated Database.
  3. 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
Jun 2019	1 Fill	1 Fill
May 2019	1.7 Fills	2 Fills
Apr 2019	2.4 Fills	3 Fills
Mar 2019	2.9 Fills	4 Fills
Feb 2019	3.5 Fills	5 Fills
Jan 2019	4.0 Fills	6 Fills
Dec 2018	4.5 Fills	7 Fills
Nov 2018	5.1 Fills	8 Fills
Oct 2018	5.4 Fills	9 Fills
Sep 2018	6.0 Fills	10 Fills
Aug 2018	7.5 Fills	11 Fills

**Average fills for all patients through June 30, 2019 = 3.5<sup>3</sup>**

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 5.1 fills from November 2018 through June 2019

- 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.

## TXMD VVA Market Share



**References:**

1. Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program.

# Commercial Payer Update

- Commercial Average Non Preferred Copay is \$59
- IMVEXXY co-pay card offer 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).

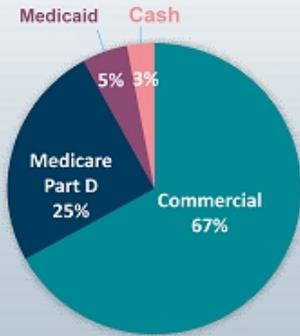
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# IMVEXXY Payer Update

## ~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**



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# 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. *JGEM*. 2013;55(4):465-470.

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# 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**

1) Symphony Health Solutions PHAST Data powered by IDV; Annual 2015

 **Bijuva**<sup>®</sup>  
estradiol and progesterone capsules

**TherapeuticsMD**<sup>®</sup>  
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# 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 unlike other FDA-approved progesterone products
- One prescription, one copay
- BIJUVA is available in blister packages containing 30 capsules



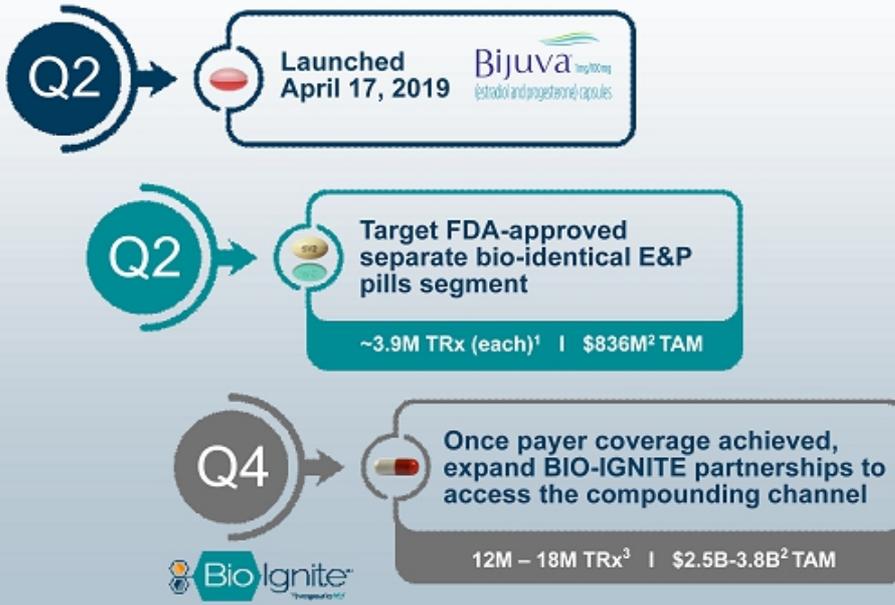
References:

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.

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# A Large Target Market For BIJUVA



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

\* Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state health care programs (including any state pharmaceutical assistance programs). Program Terms, Conditions, and Eligibility Criteria apply.

## BIJUVA Launch Metrics

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through June 30, 2019)	~4,600
Total paid scripts (June 1-30, 2019)	~2,600
Total patients (since launch through June 30, 2019)	~2,900
Total prescribers <sup>2</sup> (since launch through June 30, 2019)	~1,700

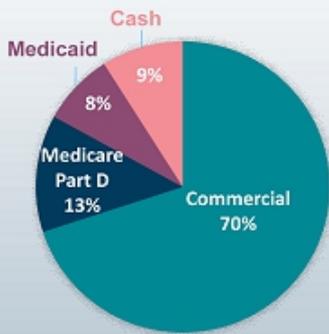
<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a two week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

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

# 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.

# 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



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## 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

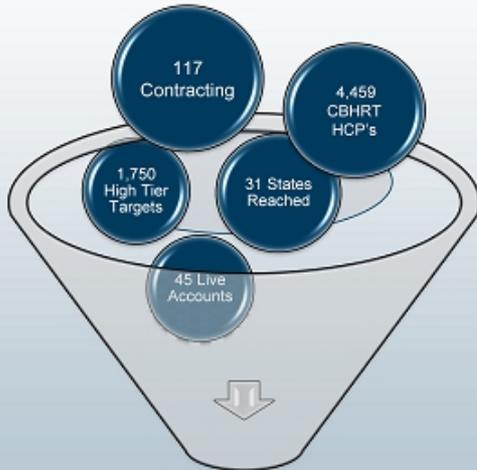


## Pharmacy Targeting:

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

## Program Stats as of June 7, 2019:

- 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*



# 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

## 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 Rxs
- 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



# ANNOVERA



# 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

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# ANNOVERA Key Attributes

## ACCESS ATTRIBUTES

- Market shift to long-acting reversible contraceptives
- 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®
- 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., 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

\*Based on pharmacological studies in animals and in vitro receptor binding studies.

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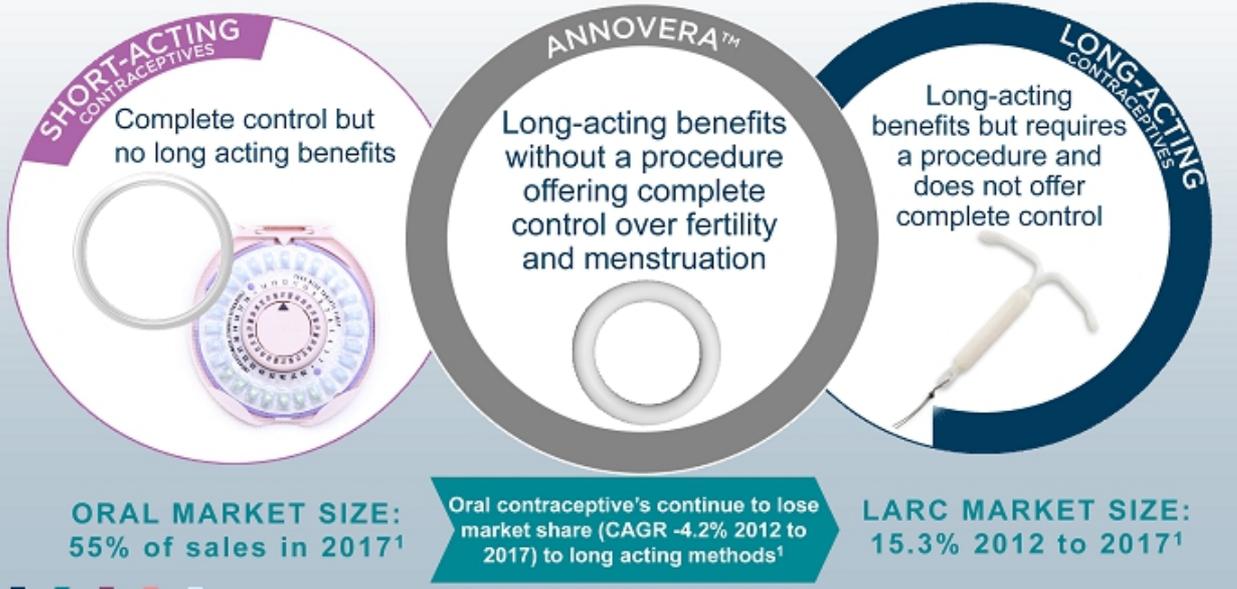
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# U.S. Contraceptive Market

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

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



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

# 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



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# ANNOVERA Launch Approach

Launch limited units to meet inbound demand

3Q 19

Align initial sales focus where states mandate coverage while ACA decision is made

4Q 19

Full launch with initial focus on OBGYN target overlap with Menopause Products  
Early consumer focus given how influential women are in the choice of birth control

1Q20 - 3Q20

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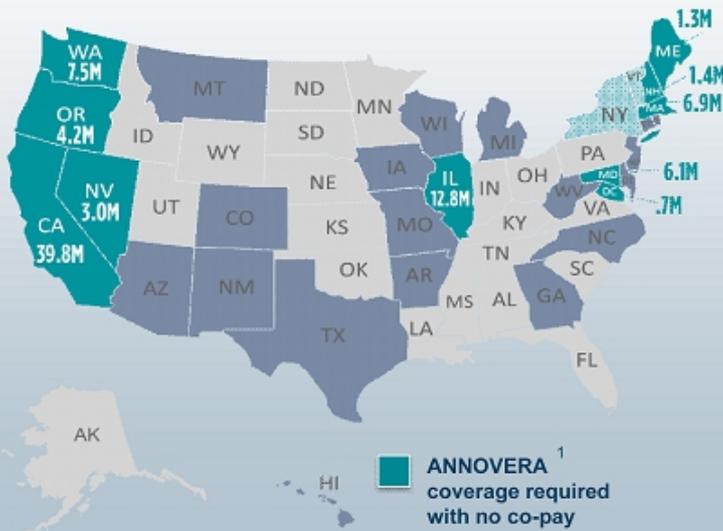
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# Access to Contraception

- **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)

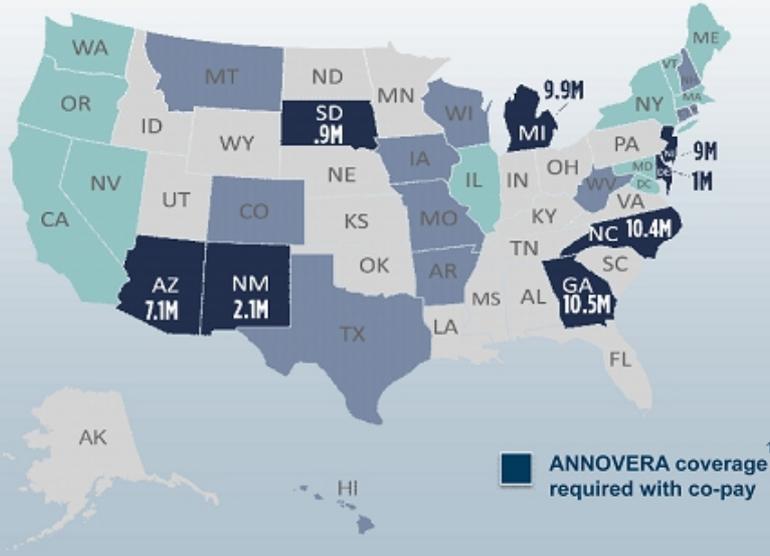


<sup>1</sup> Data on file (May 2019).

<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-12485878528095084/> (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).

# 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 amazon company

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# 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™

(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 mg • 10 mg

- 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

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# HOW STRATEGY, PLAN, AND MODEL COME TOGETHER



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# 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	
<hr/>	
<b>Gross Margin</b>	
<b>Sales &amp; Marketing Cost</b>	← <b>Copay Assistance substituted for Marketing Cost</b>



## 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>	\$200	\$200	\$40	\$0
Payment from Insurance Company	\$0	\$0	\$160	\$195
Payment from Patient	\$35	\$35	\$35	\$40
Total Amount Received by Pharmacy	\$235	\$235	\$235	\$235

- 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

Charts 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%		

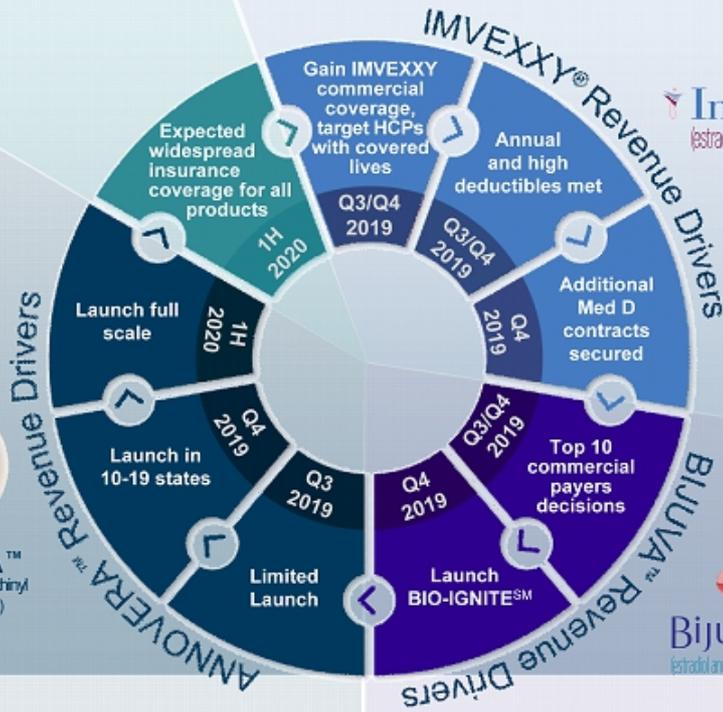
# Target Adjudication Rate at Fully Established Insurance Coverage



	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%		

# TXMD Power of the Portfolio



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

**Imvexxy**  
(estradiol vaginal inserts)

**Bijuva** (1mg/0.02mg)  
(estradiol and progesterone) capsules

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# Financial Update

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# \$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



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# 2019 TXMD Quarterly Financial Guidance

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



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# 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

# TXMD: Financial Snapshot



\* \$300 million non-dilutive term loan facility with TPG Sixth Street Partners (TSSP) entered into on April 24, 2019. The initial tranche of \$200 million was drawn on April 24, 2019, with additional tranches of \$50 million available to the company upon the designation of ANNOVERA as a new category of contraception by the U.S. Food and Drug Administration on or prior to December 31, 2019 and another \$50 million available to the company upon achieving \$11 million in net revenues from IMVEXXY, ANNOVERA and BIJUVA for the fourth quarter of 2019. A portion of the proceeds (\$81M) from the initial tranche of the TSSP facility was used to repay all amounts outstanding under the company's prior credit facility.

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# 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™**  
(estradiol and progesterone) capsules

**Imvexxy™**  
(estradiol vaginal inserts)  
4 mg · 0 mg



CONTRACEPTION

PRENATAL  
CARE

CONTRACEPTION/  
FAMILY PLANNING -  
PERIMENOPAUSE

VASOMOTOR  
SYMPTOMS

DYSPAREUNIA  
(Vulvar & Vaginal  
Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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## Appendix

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## Model To Change Behavior Is Working

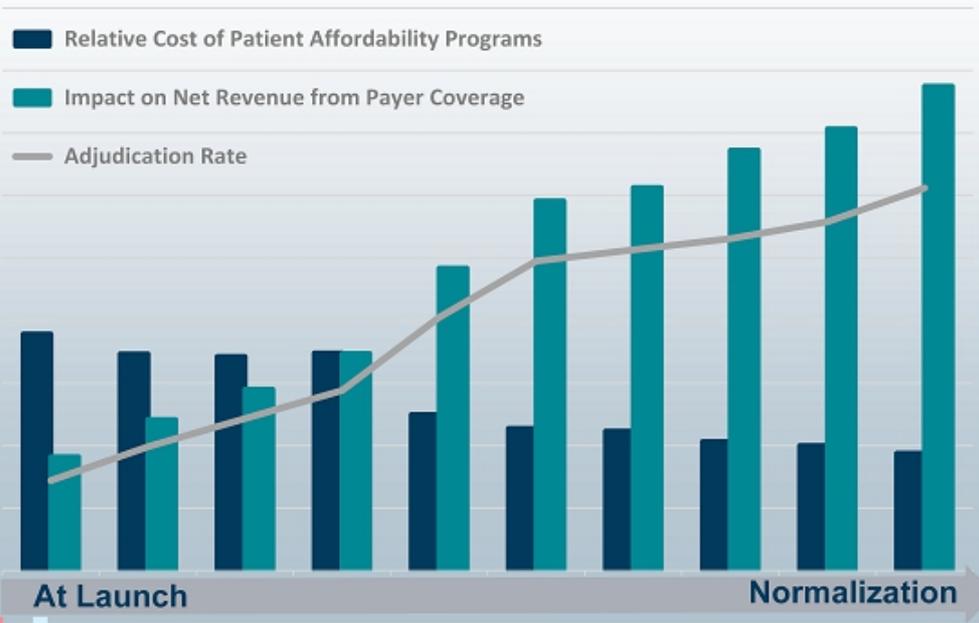
Scripts are accelerating while adjudication is increasing and adherence (staying on therapy) is growing

IMVEXXY Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through June 30, 2019)	~244,000
Total paid scripts (June 1 - 30, 2019)	~37,500
Total patients (since launch through June 30, 2019)	~69,700
Total prescribers <sup>2</sup> (since launch through June 30, 2019)	~12,900

<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.

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



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

Product	Estrogens				Non-estrogens	
	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. Estrin [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 2018. [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.

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# ANNOVERA Key Attributes

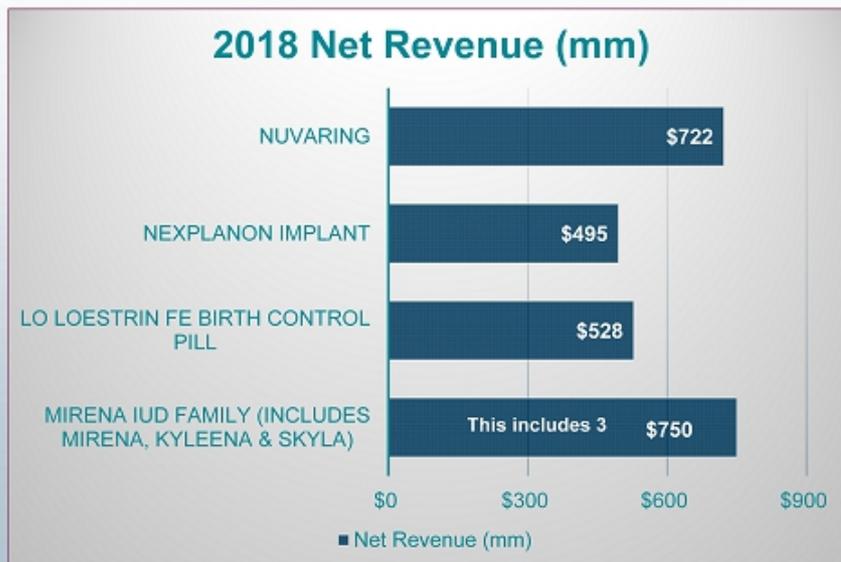
	Oral Contraceptives	Vaginal Ring NuvaRing®	Contraceptive Injection	Vaginal System ANNOVERA™	IUDs
<b>Duration of Action</b>	Daily pill intake	1 month (21/7 regimen)	3 months	1 year (21/7 regimen)	3-10 years
<b>Patient Control</b>	Stop at any time	Removable at any time	Stop at any time, but residual effects 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, annual pharmacy visit	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

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# Top Contraceptive Products Based on Revenue



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

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# 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		IMVEXXY Patent Summary	
Formulation and Method Claims		Formulation and Method Claims; Design Patent	
US Issued / Allowed	12* / 0	US Issued / Allowed	4 / 3
Expiration	2032	Expiration	No earlier than 2032
US Patents Pending	8	US Patents Pending	11
International Patents Granted	5	International Patents Granted	13
International Patents Pending	52	International Patents Pending	33
International Coverage	AR, AU, BR, CA, CN, EU, IL, MX, NZ, JP, KR, RU, ZA	International Coverage	AR, AU, BR, CA, EU, HK, IL, MX, NZ, JP, KR, RU, ZA
Expiration	No earlier than 2032	Expiration	No earlier than 2033

- \* Patents of June 7, 2019. 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

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