

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): September 16, 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.)

951 Yamato Road, Suite 220  
Boca Raton, FL 33431

(Address of Principal Executive Office) (Zip Code)

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

6800 Broken South Parkway NW, Third Floor, Boca Raton, FL 33487  
(Former name or former address, if changed since last report)

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

**Title of Each Class**

Common Stock, par value \$0.001 per share

**Trading Symbol**

TXMD

**Name of Each Exchange on Which Registered**

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 may be used, in whole or in part, and subject to modification, on September 16, 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 Index

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">TherapeuticsMD, Inc. presentation dated September 16, 2019.</a>
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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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: September 16, 2019

THERAPEUTICSMD, INC.

By: */s/ Daniel A. Cartwright*

Name: Daniel A. Cartwright

Title: Chief Financial Officer

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**Investor  
Presentation**

**September 2019**

*Building a Premier  
Women's Health Portfolio*

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

**Imvexxy**<sup>™</sup>  
(estradiol vaginal inserts)  
4 mg - 10 mg

**Annovera**<sup>™</sup>  
(megestrol acetate and  
ethinyl estradiol vaginal system)  
Delivers 0.15 mg/0.013 mg per day

**TherapeuticsMD**<sup>®</sup>  
*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®, ANNOVERA™, BIJUVA® and our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our products; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock and the concentration of power in our stock ownership.

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



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# General Updates

# General Updates and Near-Term Catalysts

- Began IMVEXXY direct to consumer advertising leveraging digital and social media platforms
- Held Satellite Media Tour for Menopause Awareness Month (September)
- Expanded payer coverage for BIJUVA and ANNOVERA; awaiting additional decisions on IMVEXXY
  - With the recent addition of Cigna, expanded commercial coverage for BIJUVA to 5 of the top 10 payers<sup>1</sup>
  - ANNOVERA has 40% unrestricted coverage in commercial health plans<sup>1</sup>
  - Added 2 of the top 10 commercial payers for ANNOVERA and several regional plans<sup>1</sup>
  - Additional commercial and Medicare Part D payer decisions expected 3Q/4Q 2019 for IMVEXXY and BIJUVA
  - Awaiting commercial coverage decision from CVS and Aetna for IMVEXXY
- IMVEXXY and BIJUVA data will be presented at 2019 Annual Meeting of the North American Menopause Society (Sept. 25-28, 2019)
- ANNOVERA data will be presented at 2019 Annual Meeting of the American Society for Reproductive Medicine (Oct. 12-19, 2019)
- Recent stock purchases by members of the executive team and board of directors
  - CEO purchased approximately \$280k in TXMD stock in 3Q19
  - CEO 2019 annual stock-based award of a single stock option to provide more equity to executive team with less dilution to stockholders

## August Launch Metrics

IMVEXXY Launch Metrics	
Total paid scripts <sup>1</sup> (August 1-31, 2019)	~44,600
Total patients (since launch through August 31, 2019)	~87,400
Total prescribers <sup>2</sup> (since launch through August 31, 2019)	~14,800

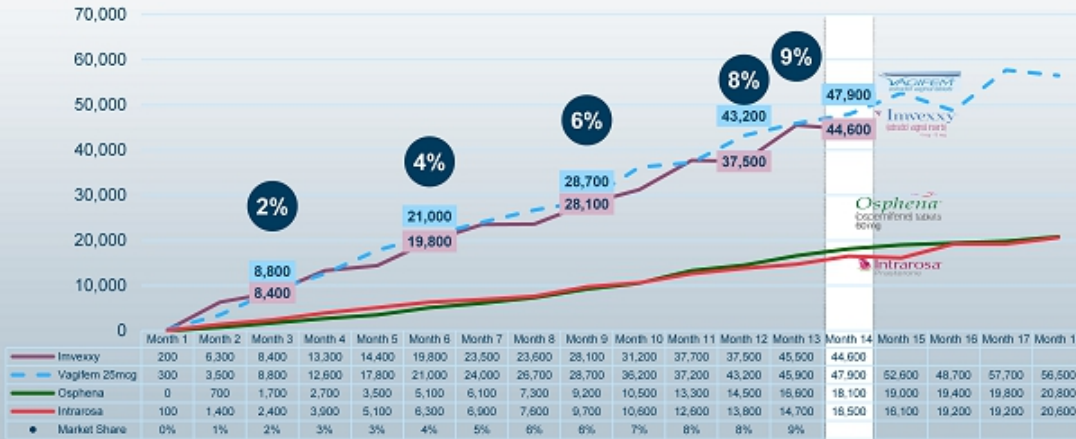
<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a two week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

<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 14 for IMVEXXY is August 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.
  4. Market share data based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program.
- All trademarks are the property of their respective owners.

# Continued Strong Patient Adherence

## 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
Aug 2019	1 Fill	1 Fill
Jul 2019	1.9 Fills	2 Fills
Jun 2019	2.4 Fills	3 Fills
May 2019	2.9 Fills	4 Fills
Apr 2019	3.5 Fills	5 Fills
Mar 2019	4.0 Fills	6 Fills
Feb 2019	4.5 Fills	7 Fills
Jan 2019	5.0 Fills	8 Fills
Dec 2018	5.4 Fills	9 Fills
Nov 2018	6.1 Fills	10 Fills
Oct 2018	6.2 Fills	11 Fills
Sep 2018	6.7 Fills	12 Fills
Aug 2018	8.0 Fills	13 Fills
Jul 2018	8.0 Fills	14 Fills

### IMVEXXY: 3.8 fills/yr<sup>3</sup> (through Aug)

- Vaginal creams: average 1.5 fills/yr<sup>4</sup>
- Vaginal tablets: average 3.5 fills/yr<sup>4</sup>

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 6.1 fills from November 2018 through August 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.
- 4) Total Rx/Patient Count

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## August Launch Metrics

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through August 31, 2019)	~14,200
Total paid scripts (August 1-31, 2019)	~5,300
Total patients (since launch through August 31, 2019)	~6,800
Total prescribers <sup>2</sup> (since launch through August 31, 2019)	~3,000

<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a 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.

# Commercial Payer Update

## Coverage Decisions Expected by 4Q19

### Quicker Process to Payer Coverage than IMVEXXY

- Commercial segment represents vast majority of BIJUVA patients
- Expect 3-4 quarters coverage cycle (from launch) to secure commercial payers
- Amendments to the company's existing payer contracts with little Medicare Part D

New

Top 10 Plans Account for ~71% of all Commercial Pharmacy Lives		
Plan	% of Lives <sup>1</sup>	Status <sup>2</sup>
CVS	15.4%	In discussions
ESI	15.3%	Adjudicating as of 4/19/19
United	7.5%	Adjudicating as of 8/1/19
Anthem	7.3%	In discussions
Prime	6.5%	In discussions
OptumRx	6.1%	Adjudicating as of 8/1/19
Kaiser	4.7%	In discussions
Aetna	4.0%	Adjudicating as of 4/2019
Cigna	3.9%	Adjudicating as of 9/2019
EnvisionRx	1.8%	In discussions

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.

<sup>1</sup>Plan numbers as of May 2019

<sup>2</sup>Adjudication status from MMIT September 2019 and Account Insights

## Key Payer Updates

### ANNOVERA has 40% Unrestricted Coverage in Commercial Health Plans<sup>1</sup>

- Anthem adjudicating ANNOVERA at Tier 3 with no copay as of August 2019<sup>1</sup>
- Kaiser Washington ACA drug list covers ANNOVERA at no copay<sup>1</sup>
- Cigna adjudicating ANNOVERA at Tier 3 as of August 2019<sup>1</sup>
- Starting on January 1, 2020, New York state insurance law requires coverage for all contraceptives, including ANNOVERA, with no copay<sup>2</sup>
- Currently with the addition of New York, 19 states, plus Washington, D.C., require insurance plans to cover all contraceptives that do not have a generic equivalent

**Test and Learn Market Introduction Planned in 4Q 2019**

<sup>1</sup>MMIT September 2019 and Accounts Insights

<sup>2</sup><https://www.nysenate.gov/legislation/bills/2019/s659/amendment/a>

## Commercial Payer Update

### Coverage Decisions Expected to be finalized 1Q20

**Top 10 Plans Account for ~71%  
of all Commercial Pharmacy Lives**

Plan	% of Lives <sup>1</sup>	Status <sup>2</sup>
CVS	15.4%	In discussions
ESI	15.3%	In discussions
United	7.5%	In discussions
<b>New</b> Anthem	7.3%	<b>Adjudicating at T3, no copay as of August 2019</b>
Prime	6.5%	In discussions
OptumRx	6.1%	In discussions
<b>New</b> Kaiser	4.7%	In discussions <b>Kaiser Washington covering at no copay</b>
Aetna	4.0%	In discussions
<b>New</b> Cigna	3.9%	<b>Adjudicating at T3 as of August 2019</b>
EnvisionRx	1.8%	In discussions

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

<sup>1</sup>Plan numbers as of May 2019

<sup>2</sup>Adjudication status from MMIT September 2019 and Account Insights

## Commercial Payer Update

### Coverage Decisions Expected to be finalized 1Q20

#### Selected Regional Plan Coverage

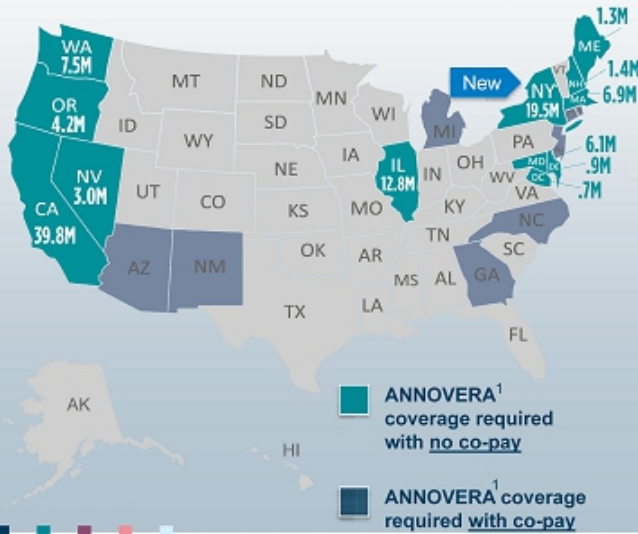
	Plan	Status <sup>1</sup>
	MC-Rx (ProcareRx)	Adjudicating as of April 2019
	BCBS of Massachusetts	Adjudicating at no copay as of August 2019
New	Excellus	Adjudicating as of September 2019
New	EmblemHealth	Adjudicating at no copay as of September 2019
New	Wellmark	Adjudicating as of August 2019
	Harvard Pilgrim	Adjudicating at no copay as of August 2019
	Independent Health Association	Adjudicating as of August 2019
New	BC of Idaho	Adjudicating at no copay as of September 2019
New	Summacare	Adjudicating at no copay as of September 2019
New	Clear Script PBM	Adjudicating as of August 2019
New	Univera Healthcare	Adjudicating as of August 2019

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

<sup>1</sup>Adjudication status from MMIT September 2019 and Account Insights

# BIRTH CONTROL STATE LAWS REGARDLESS OF ACA MANDATES

**11 STATES, plus Washington D.C., REQUIRE COVERAGE WITH NO COPAY REGARDLESS OF ACA DECISION**  
 (~51 Million women in these states)



Washington State Office of the Insurance Commissioner  
 December 4, 2019

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

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

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

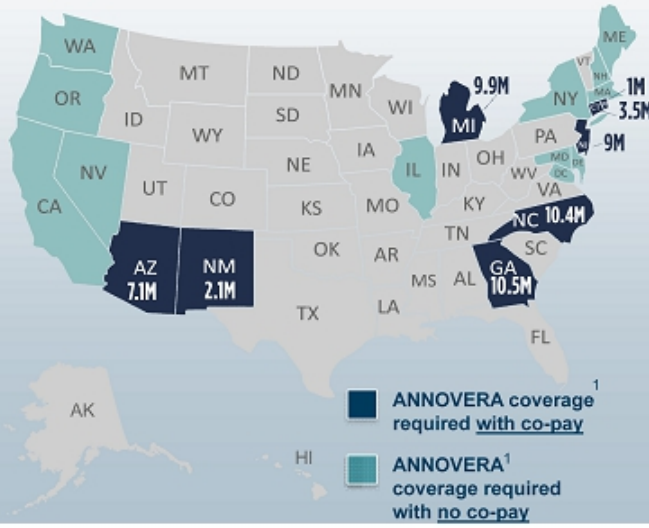
<sup>2</sup> Washington State Office of the Insurance Commissioner  
<https://www.facebook.com/WSOIC/photos/starting-in-2019-health-plans-in-washington-state-must-cover-all-forms-of-birth-2485878528095084/> (accessed July 5, 2019).

\*NY is effective 1/1/2020



# BIRTH CONTROL STATE LAWS REGARDLESS OF ACA MANDATES

**8 STATES REQUIRE COVERAGE WITH COPAY REGARDLESS OF ACA DECISION**  
 (~27 Million women in these states)



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



**IMVEXXY**



# 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 as little as \$35 with copay programs\*
  - Possibility of no out-of-pocket costs for ANNOVERA

\* Copay as little as \$35 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.

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# TherapeuticsMD® (TXMD)

Focused on developing and commercializing products for women throughout their life cycles

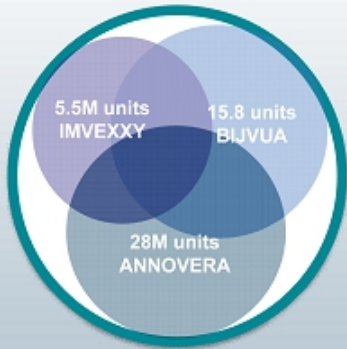


<b>Key Value Proposition</b>	Easy to use, lowest approved dose, designed to support patient compliance	First and only FDA-approved bio-identical combination product	First and only long-lasting (one year/13 cycles), procedure-free, patient-controlled, reversible birth control product
<b>Affected US Population</b>	32 million women <sup>1,2</sup>	36 million women <sup>4</sup>	43 million women <sup>6</sup>
<b>US TAM Opportunity</b>	>\$20B <sup>3</sup>	>\$25B <sup>3,5</sup>	\$5B <sup>7</sup>
<b>Status</b>	Approved May 29, 2018 Launched August 2018	Approved October 28, 2018 Launched April 2019	Approved August 10, 2018 Test & Learn Introduction: 4Q19 Full scale launch expected: 1Q20

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause*. 2013;20(9):986-992.  
 2) Glass ML, Cochrane SB, 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) Based on market pricing of current FDA-approved HT products.  
 4) Derived from U.S. Census data on women in the age group who normally experience symptoms.  
 5) Based on pre-2018 annual scripts of FDA-approved HT products.  
 6) Contraceptive Use in the United States. Guttmacher. July 2018. IDVA Patient Tracker.  
 7) 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.

# The Power of A Women's Health Portfolio

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



## Overlapping Prescribers & Patients

REPRODUCTIVE PORTFOLIO

MENOPAUSE PORTFOLIO

## The Power of 3

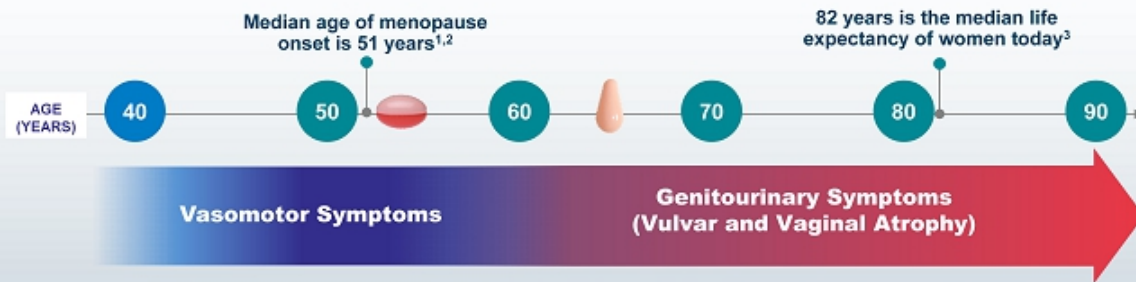


Even though there are over 400,000 total writers for these products<sup>2</sup>

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

1) Symphony Health Integrated 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)

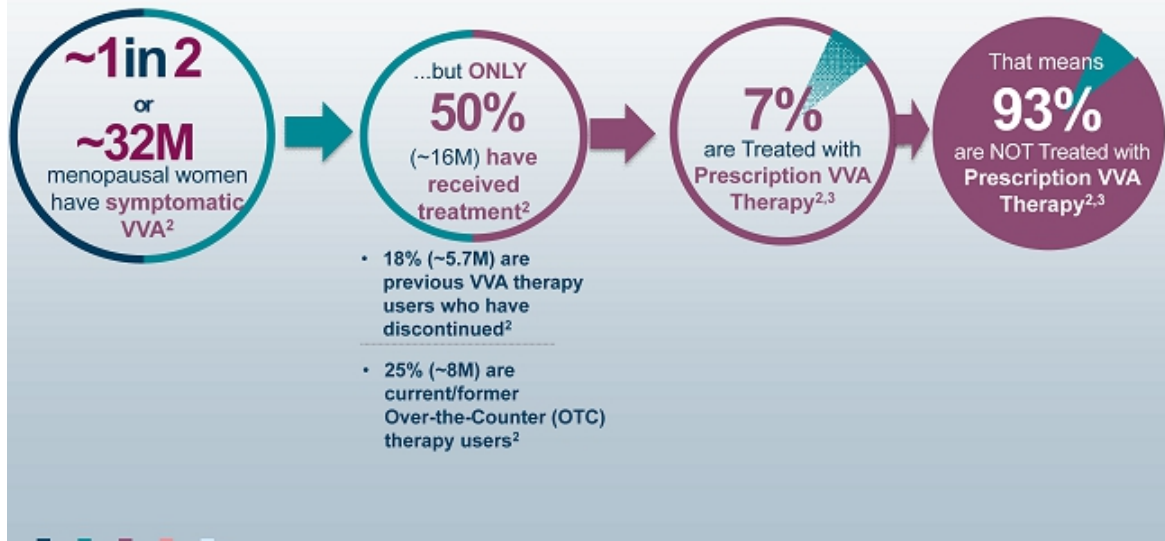
1. Parish SJ, et al. *Menopause*. 2018;25(8):937-941. 2. North American Menopause Society. *Menopause* 101. [www.menopause.org/for-women/menopause-factsheets/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal](http://www.menopause.org/for-women/menopause-factsheets/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-peri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

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# 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
- Continuous unlocking of new levers as insurance adjudication normalizes



## The VVA Market Exceeds \$1.7B Gross Revenue Annually

Product	12 Months through June 2019 Total Units <sup>1</sup>	Gross Dollars for 2018 <sup>1</sup>
<b>Estrace® Cream Brand &amp; Generics</b>	<b>2,000,000</b>	<b>\$554,450,000</b>
<b>Premarin®</b>	<b>1,190,000</b>	<b>\$460,760,000</b>
<b>Vagifem® Brand &amp; Generics</b>	<b>1,500,000</b>	<b>\$454,550,000</b>
<b>Estring®</b>	<b>259,000</b>	<b>\$114,360,000</b>
<b>Osphena®</b>	<b>217,000</b>	<b>\$75,910,000</b>
<b>Intrarosa®</b>	<b>209,000</b>	<b>\$46,940,000</b>
<b>2018 Value of the VVA Market</b>		<b>\$1,700,000,000</b>

1) Symphony Health Solutions PHAST Data powered by IQVIA. MBS dollars. All trademarks are the property of their respective owners.

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## Value of Additional Fills

**4**  
Fills/year

Percent of market based on patient count of 2.3M and 4 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$184,000,000	\$257,600,000	\$331,200,000	\$404,800,000
\$100	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000

**5**  
Fills/year

Percent of market based on patient Count of 2.3M and 5 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000
\$100	\$287,500,000	\$402,500,000	\$517,500,000	\$632,500,000

**6**  
Fills/year

Percent of market based on patient count of 2.3M and 6 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$276,000,000	\$386,400,000	\$496,800,000	\$607,200,000
\$100	\$345,000,000	\$483,000,000	\$621,000,000	\$759,000,000

Market opportunity is calculated by multiplying the number of patients on products annually times the market share times the average number of fills per patient per year times the average potential net revenue per unit. At \$100 average net revenue, the value per fill ranges from \$57M to \$126M, depending on market share.

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## Commercial Payer Status

**Top 10 Plans Account for ~71%  
of all Commercial Pharmacy Lives**

Plan	% of Lives <sup>1</sup>	Status <sup>2</sup>
CVS	15.4%	Awaiting decision in 3Q
ESI	15.3%	Adjudicating as of 10/1/18
United	7.5%	Adjudicating as of 3/1/19
Anthem	7.3%	Adjudicating as of Aug. 2018
Prime	6.5%	Adjudicating as of 1/1/19
OptumRx	6.1%	Adjudicating as of 1/1/19
Kaiser	4.7%	In discussions
Aetna	4.0%	Awaiting decision in 3Q ~1.8M of these lives are adjudicating
Cigna	3.9%	Adjudicating as of 12/15/18
EnvisionRx	1.8%	Adjudicating as of 1/1/19

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.

<sup>1</sup>Plan numbers as of May 2019

<sup>2</sup>Adjudication status from MMIT September 2019 and Account Insights

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## Medicare Part D Payer Status

### Decisions Expected 3Q/4Q19

**Top 6 Plans Account for ~78%  
of all Medicare Part D Pharmacy Lives**

Plan	% of Lives <sup>1</sup>	Status <sup>2</sup>
United	20.7%	Adjudicating as of 2/1/19
Humana	17.9%	Decision expected 3Q/4Q19
CVS Caremark	14.1%	Decision expected 3Q/4Q19
Wellcare with Aetna lives	13.6%	Decision expected 3Q/4Q19
Express Scripts/ Cigna	8.5%	Decision expected 3Q/4Q19 ~1M of these lives are adjudicating as of June 2019
Kaiser	3.6%	Adjudicating maintenance pack as of 10/1/18 and starter pack as of 3/1/19

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.

<sup>1</sup>Plan numbers as of July 2019

<sup>2</sup>Adjudication status from MMIT September 2019 and Account Insights

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# How Adjudication Rate\* Will Change When Payer Cycle Completes

Chart 1

## 2Q 2019 Actuals

	Column A	Column B	Column C
<b>IMVEXXY</b>	<b>No Insurance</b>	<b>Commercial Insurance</b>	<b>Medicare Eligible Patients</b>
% of Business	3%	62%	35%
% Adjudicated	0%	50%	8%
Contribution to Overall Adjudication Rate	0%	31%	3%
Overall Adjudication Rate	34% (up from 27% in 1Q19)		

Chart 2

## Target Adjudication as Contracting is Finalized

	Column A	Column B	Column C
<b>IMVEXXY</b>	<b>No Insurance</b>	<b>Commercial Insurance</b>	<b>Medicare Eligible Patients</b>
% of Business	6%	70%	24%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	53%	17%
Overall Adjudication Rate	70%		

\*Adjudication Rate= Percent of Business multiplied by percent of claims being covered.

# IMVEXXY Catalysts








# BIJUVA





# Hormone Therapy Options for Vasomotor Symptoms Before BIJUVA

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

FDA-APPROVED		NOT FDA-APPROVED
<b>Combination Synthetic Estrogens + Progestins</b> 	<b>Separate Bio-identical Estradiol &amp; Progesterone</b> 	<b>Compounded Bio-identical Estradiol + Progesterone</b> 
~ 2.5 million total annual prescriptions <sup>2</sup>	~ 3.9 million total annual prescriptions (each) <sup>1</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



**Launched**  
April 17, 2019




**Target FDA-approved separate bio-identical Estrogen & Progesterone pills segment**

~3.9M TRx (each)<sup>1</sup> | \$836M<sup>2</sup> TAM



**BIJUVA introduced into Bio-Ignite Channel, once payer coverage established**

12M – 18M TRx<sup>3</sup> | \$2.5B-3.8B<sup>2</sup> TAM

Reps directed to focus on ~10 prescribers in their territory until improved payer coverage

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 as little as \$35\*

- As little as \$35 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.

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# Impact of Faster Payer Cycle on Adjudication Rate\*

Chart 1

## 2Q 2019 Actuals

BIJUVA	Column A	Column B	Column C
	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	3.1%	89.1%	7.8%
% Adjudicated	0%	37.6%	7.6%
Contribution to Overall Adjudication Rate	0%	33.4%	0.6%
Overall Adjudication Rate	34% (up from 25% in May 2019)		

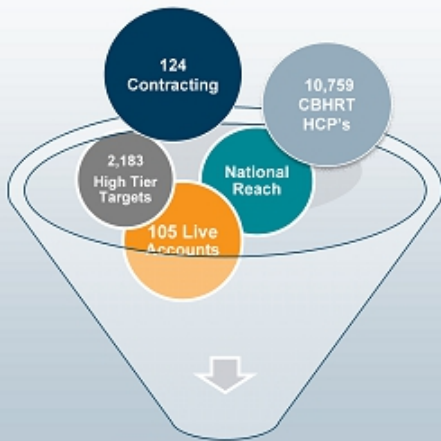
Chart 2

## Target at Fully Established Insurance Coverage

BIJUVA	Column A	Column B	Column C
	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	6%	87%	8%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	65%	5%
Overall Adjudication Rate	70%		

\*Adjudication Rate= Percent of Business multiplied by % of claims being covered.

# Compounding Pharmacy Onboarding Process and Status



- **Unique compounded bio-identical hormone replacement therapy (CBRT) prescribers Identified: 10,759**
  - 2,328 are identified as high-value CBHRT HCP's targeted by Key Account Managers

## Market Opportunity

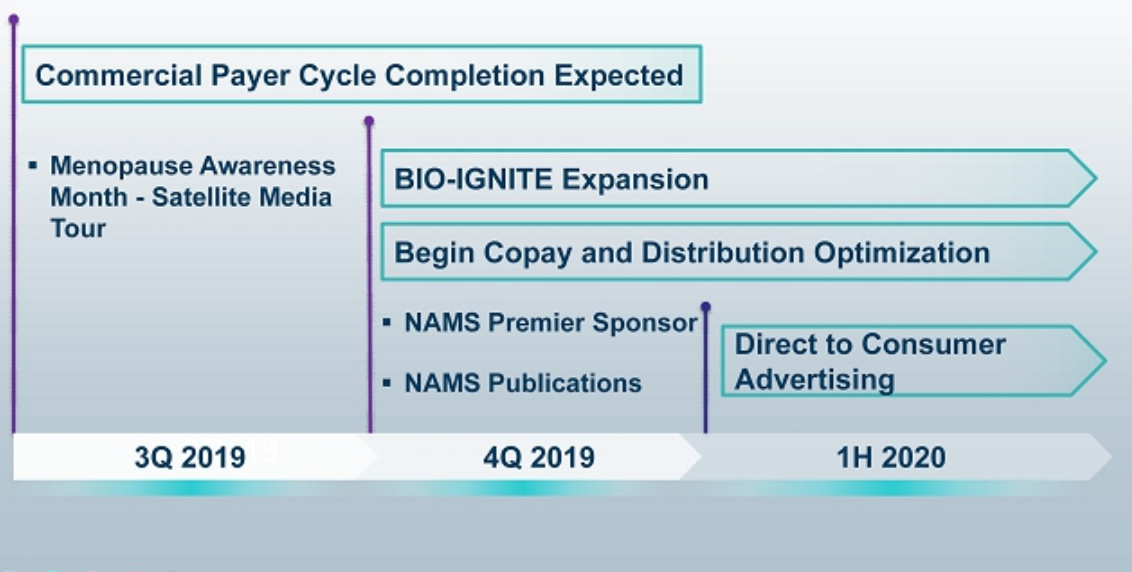
<b>Total Addressable FDA Market: 3,900,000</b>				
<b>Total Addressable Compounding Market: 12,000,000</b>				
<b>Percent of Addressable Market</b>				
<b>Average Net Revenue / Unit</b>	<b>25%</b>	<b>35%</b>	<b>45%</b>	<b>55%</b>
<b>\$80</b>	\$316,000,000	\$442,400,000	\$568,800,000	\$695,200,000
<b>\$100</b>	\$395,000,000	\$553,000,000	\$711,000,000	\$869,000,000

Market opportunity is calculated by multiplying the annual addressable market units (3.9M units of FDA-approved E+P plus the low-end of the estimated compounded market of 12M prescriptions) times the market share times the average potential net revenue per unit.

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## BIJUVA Catalysts







# ANNOVERA



# ANNOVERA: 2019 Prix Galien USA Award Nominee

The Prix Galien Award, counted among the global health innovation industry's most prized honors, recognizes outstanding biomedical and medical technology product achievement that improves the human condition



## Best Pharmaceutical Product 2019 Nominee:



## Past Award Winners in the Category

	2018 TRx MBS Dollars <sup>1</sup>
Ibrance®	\$2,293,000,000
IMBRUVICA®	\$2,334,000,000
Gleevec®	\$362,000,000
Januvia®	\$6,237,000,000
Chantix®	\$1,258,000,000

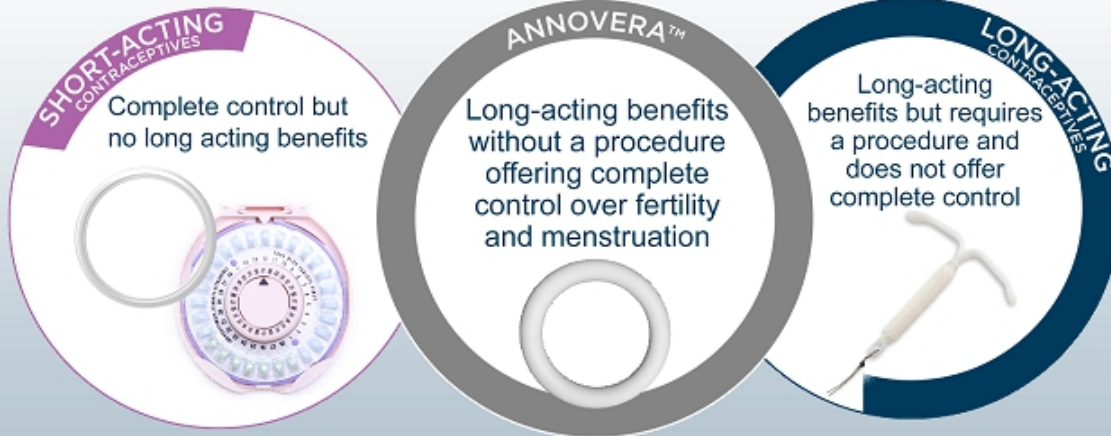
All trademarks are the property of their respective owners.  
1. MBS Data

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# U.S. Contraceptive Market

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

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



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

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

## Access Attributes

- Market shift to long-acting contraception
- 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

- 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., Mariena Paganos, Elena Hoskin, Michael Cooney, Paul C. Hewitt, 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> Narendar 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. The clinical significance is not known.  
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# High Patient Satisfaction

- **Phase 3 acceptability study (n=905 subjects)<sup>1</sup>**
- **Overall satisfaction (~90%) related to:**
  - Ease of use
  - Side effects
  - Expulsions/feeling the product
  - Physical effect during sexual activity
- **High rates of adherence (94.3%) and continuation (78%)**

Ease of Use			
Ease of inserting (N=905)	Ease of removing (N=905)	Ease of remembering CVS insertion (N=905)	Ease of remembering CVS removal (N=905)
<b>90.8%</b> (n=823)	<b>88.2%</b> (n=798)	<b>87.6%</b> (n=793)	<b>85.2%</b> (n=771)

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

## 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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# Launch Approach

## Pre-Launch Activities

- WAC Price set at \$2,000/unit (1 year)
- Continue dialogue with FDA regarding potential ACA decision designating ANNOVERA as a new method of contraception
- Start payer discussions
- Test and learn market introduction
- Production ramps to ~10,000 units for the 4Q19

## National Launch

- Initial focus on OBGYN target overlap with Menopause Products
- Early consumer focus given how influential women are in the choice of birth control
- Full-scale production anticipated 1Q20

3Q 2019

4Q 2019

1Q-3Q 2020



## Market Opportunity

Addressable Birth Control Market Rx Options NRx		28,000,000			
Percent of Overall Birth Control Market NRx					
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%	
\$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	

Addressable NuvaRing Market NRx		1,200,000			
Percent of NuvaRing Market NRx					
Average Net Revenue / Unit	25%	35%	45%	55%	
\$1,000	\$300,000,000	\$420,000,000	\$540,000,000	\$660,000,000	
\$1,500	\$450,000,000	\$630,000,000	\$810,000,000	\$990,000,000	
\$1,750	\$525,000,000	\$735,000,000	\$945,000,000	\$1,155,000,000	

Market opportunity is calculated by multiplying the annual addressable market times the market share times the average potential net revenue per unit.

# The Power of the Portfolio

## Multiple Paths to \$1B of Peak Sales

Percent of Market Based on Patient Count of 2.3M and 4 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$184,000,000	\$257,600,000	\$331,200,000	\$404,800,000
\$100	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000

Total Addressable FDA Market: 3,800,000 Total Addressable Compounding Market: 12,000,000				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316,000,000	\$442,400,000	\$568,800,000	\$695,200,000
\$100	\$395,000,000	\$553,000,000	\$711,000,000	\$869,000,000

Total Addressable Birth Control Market NRx 28,000,000				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$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



Diversified risk with 3 FDA-approved products, creating multiple paths to \$1B peak sales opportunity

Example: \$230M (IMVEXXY), \$395M (BIJUVA) and \$420M (ANNOVERA) = \$1B peak sales potential

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# Financial Overview

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## 2019 Financial Guidance

	3Q2019 Estimate	4Q2019 Estimate	FY2019 Estimate
<b>FDA-Approved Products Net Revenue</b>	\$4.50 - 6.50M	\$11.00 - 13.00M	\$20.75 - 24.75M
<b>Prenatal Vitamins Net Revenue</b>	\$2.25 - 2.50M	\$1.75 - 2.25M	\$8.70 - 9.45M
<b>Total TXMD Net Revenue</b>	\$6.75 - 9.00M	\$12.75 - 15.25M	\$29.45 - 34.20M

**Important Guidance Notes:**

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

# 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**  
 (levonorgestrel acetate and  
 ethinyl estradiol vaginal system)  
 Dabbers 0.15 mg/0.020 mg per day

**vitaMedMD**  
 Prenatal Vitamins

**Annovera**  
 (levonorgestrel acetate and  
 ethinyl estradiol vaginal system)  
 Dabbers 0.15 mg/0.020 mg per day

**Bijuva**  
 (estradiol and progesterone) capsules  
 Imp/Wimp

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



CONTRACEPTION

PRENATAL  
 CARE

CONTRACEPTION/  
 FAMILY PLANNING -  
 PERIMENOPAUSE

VASOMOTOR  
 SYMPTOMS

DYSPAREUNIA  
 (Vulvar & Vaginal  
 Atrophy)



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

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

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

## Appendix

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# IMVEXXY Model Different Than Typical Pharmaceutical Launch

Gross Revenue	
Patient Copay Assistance	← Where We Focused
Wholesale Costs	
Pharmacy Discounts	
Payer Rebates	
Returns, Allowances & Other Accruals	
Net Revenue	
Cost of Sales	

---

Gross Margin	
Sales & Marketing Cost	← Copay Assistance substituted for Marketing Cost





## 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	\$215	\$40	\$0
Payment from Insurance Company	\$0	\$0	\$175	\$205
Payment from Patient	\$35	\$35	\$35	\$40
Total Amount Received by Pharmacy	\$235	\$250	\$250	\$245

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