

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): November 19, 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

N/A

(Former name or former address, if changed since last report)

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))

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

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

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) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2).

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 November 19, 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	TherapeuticsMD, Inc. presentation dated November 19, 2019.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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: November 19, 2019

THERAPEUTICSMD, INC.

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

The slide features three overlapping circles on the left side, each containing a product logo. The top circle is for Imvexxy, the middle-left for Bijuva, and the bottom-right for Anovera. To the right of these circles, the text reads: "Investor Presentation", "November 19, 2019", and "Building a Premier Women's Health Portfolio".

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

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

Anovera[™]
(segesterone acetate and
ethinyl estradiol vaginal system)
Delivers 0.15 mg/0.013 mg per day

Investor Presentation

November 19, 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 (SEC), 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 its 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, including the conditions to draw additional tranches there under; 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; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the ability of our licensees to commercialize and distribute our products; the effects of laws, regulations and enforcement; the competitive nature of the industries in which we conduct our business; 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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The Power of a Women's Health Portfolio

Annovera™
 (levonorgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

vitaMedMD®
 Prenatal Vitamins

Annovera™
 (levonorgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

Bijuva™
 (estradiol and progesterone) capsules

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



CONTRACEPTION

PRENATAL CARE

**CONTRACEPTION/
 FAMILY PLANNING -
 PERIMENOPAUSE**

VASOMOTOR SYMPTOMS

**DYSPAREUNIA
 (Vulvar & Vaginal Atrophy)**



TherapeuticsMD®
For Her. For Life.

TherapeuticsMD® (TXMD)

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



Key Value Proposition	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
Affected US Population	32 million women ^{1,2}	36 million women ⁴	43 million women ⁶
US TAM Opportunity	>\$20B ³	>\$25B ^{3,5}	\$5B ⁷
Status	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):956-962.

2) Gass ML, Coviello BB, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. *Menopause*. 2011;18(11):1109-1117.

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-IVR annual scripts of FDA-approved HT products.

6) Contraceptive Use in the United States, Outrigger, July 2018. IQVIA Patient Tracker.

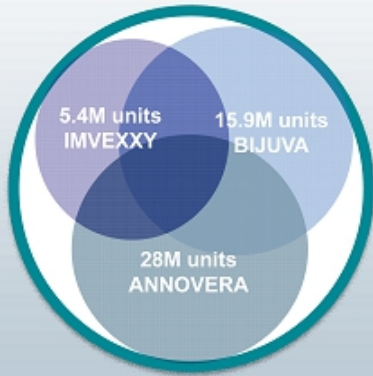
7) QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. Long-acting reversible contraceptive market includes: Nexplanon/Implanon, Miana family, Paragard and Liletta. Net sales as reported in company filings.

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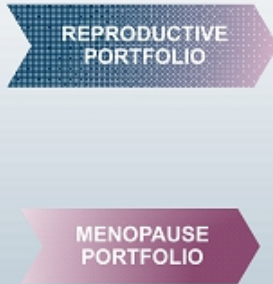
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The Power of A Women's Health Portfolio

Market Opportunity¹



Overlapping Prescribers & Patients



The Power of 3



Even though there are over 400,000 total writers for these products²

~26,000 targets we call on represent over 60% of market opportunity for each product²

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

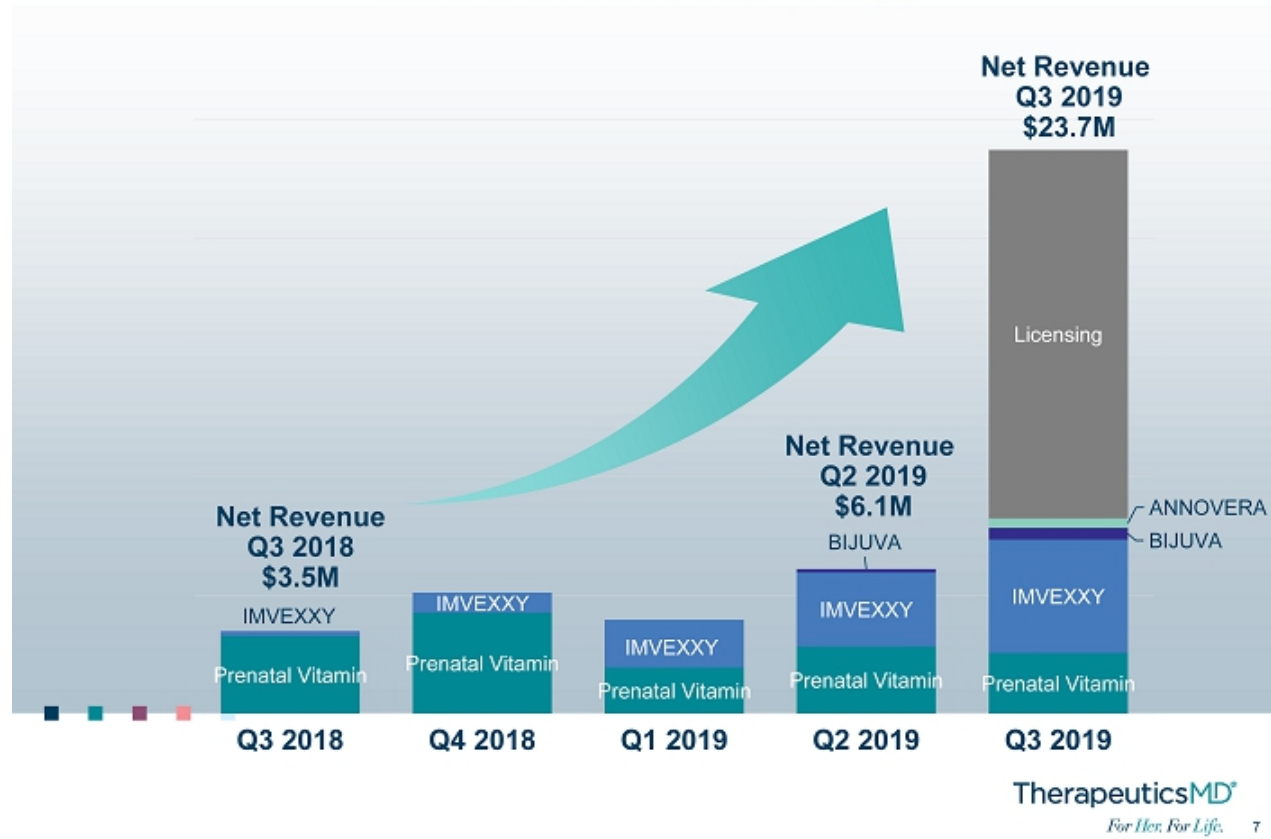


3Q 2019 Updates

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Trend in Net Revenue



3Q19 Financial Results

-Total Product Revenue Came in at Upper End of Guidance-

	3Q2019 Guidance	3Q2019 Financial Results
FDA-Approved Products Net Revenue	\$4.50 - \$6.50M	\$5.7M
Prenatal Vitamins Net Revenue	\$2.25 - \$2.50M	\$2.5M
Total TXMD Product Net Revenue	\$6.75 - \$9.00M	\$8.2M

- 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

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3Q 2019 Key Performance Metrics

IMVEXXY



- IMVEXXY net revenue totaled \$4.8M for 3Q19 (up from \$3.1M for 2Q19)
 - Net revenue continues to grow faster than units due to improving adjudication rates
 - TRx increased 26% to 134,000 units for 3Q19 (up from 106,000 for 2Q19)
 - Overall adjudication increased to 38% (up from 34% for 2Q19)

BIJUVA



- BIJUVA net revenue totaled \$491,000 for 3Q19 (up from \$134,000 for 2Q19)
 - TRx increased to 15,800 units for 3Q19 (up from 4,600 for 2Q19)
 - Overall adjudication increased to 45% (up from 34% for 2Q19)

ANNOVERA



- ANNOVERA net revenue totaled \$400,000 for 3Q19
 - Strong initial commercial net revenue of ~\$1,250 per unit with the potential for improvement¹



¹ \$1,250 assumes patients meeting the criteria of 1) commercially insured patient or 2) approved via a Medical Necessity Letter. Does not include cash pay sales.

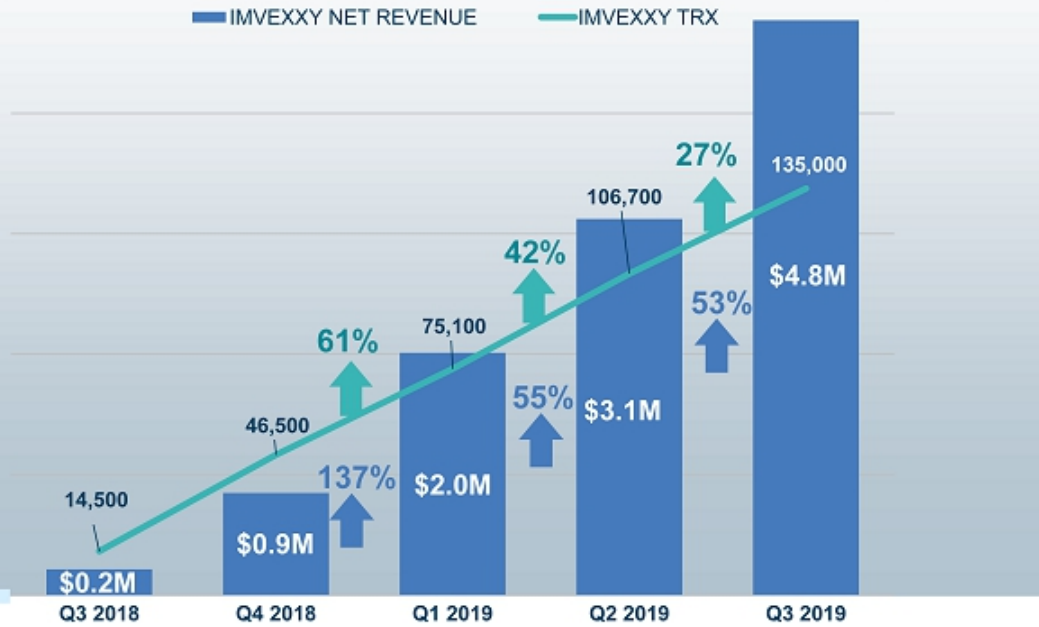
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IMVEXXY Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients

■ IMVEXXY NET REVENUE ▲ IMVEXXY TRX



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 up to two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

BIJUVA Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients

■ BIJUVA NET REVENUE — BIJUVA TRX



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 up to two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

ANNOVERA 3Q19 LAUNCH INSIGHTS

- ANNOVERA launched late in third quarter with recorded sales of \$400,000
- Initial average net revenue of ~\$1,250 per unit

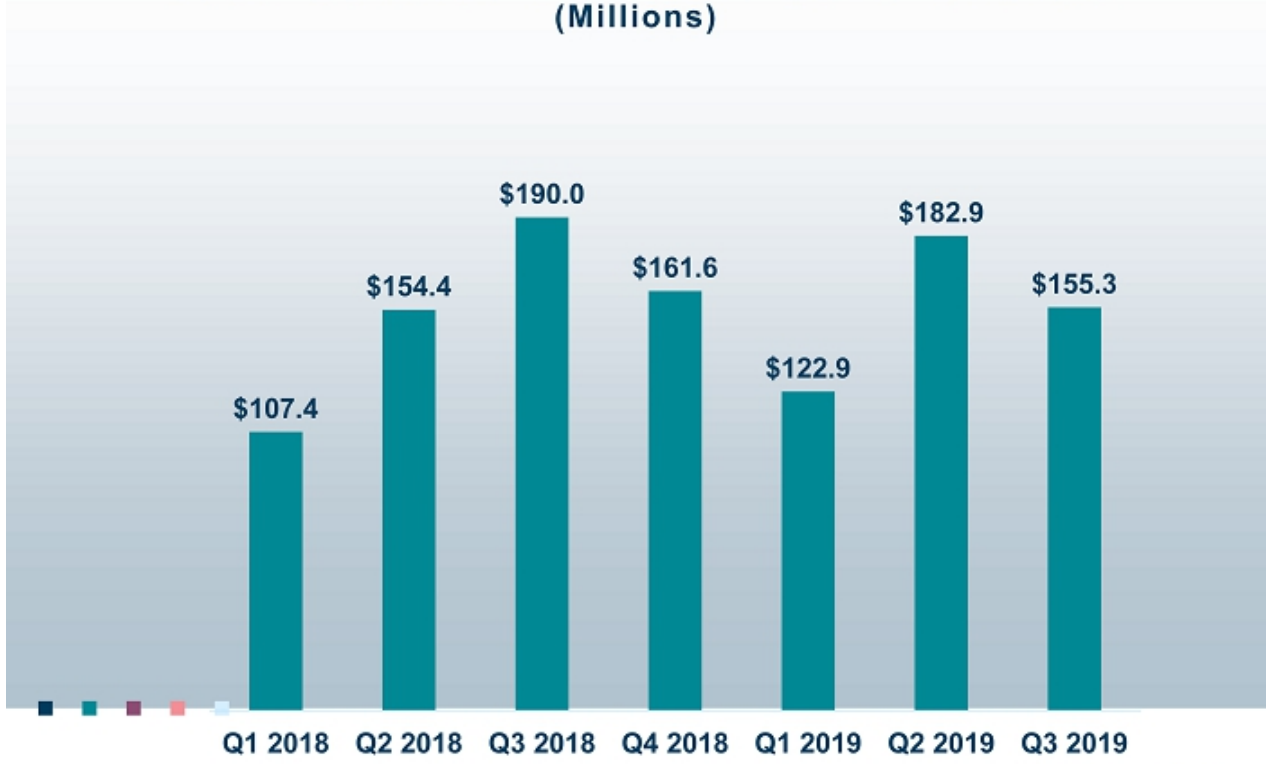


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Cash Balance at End of Each Quarter

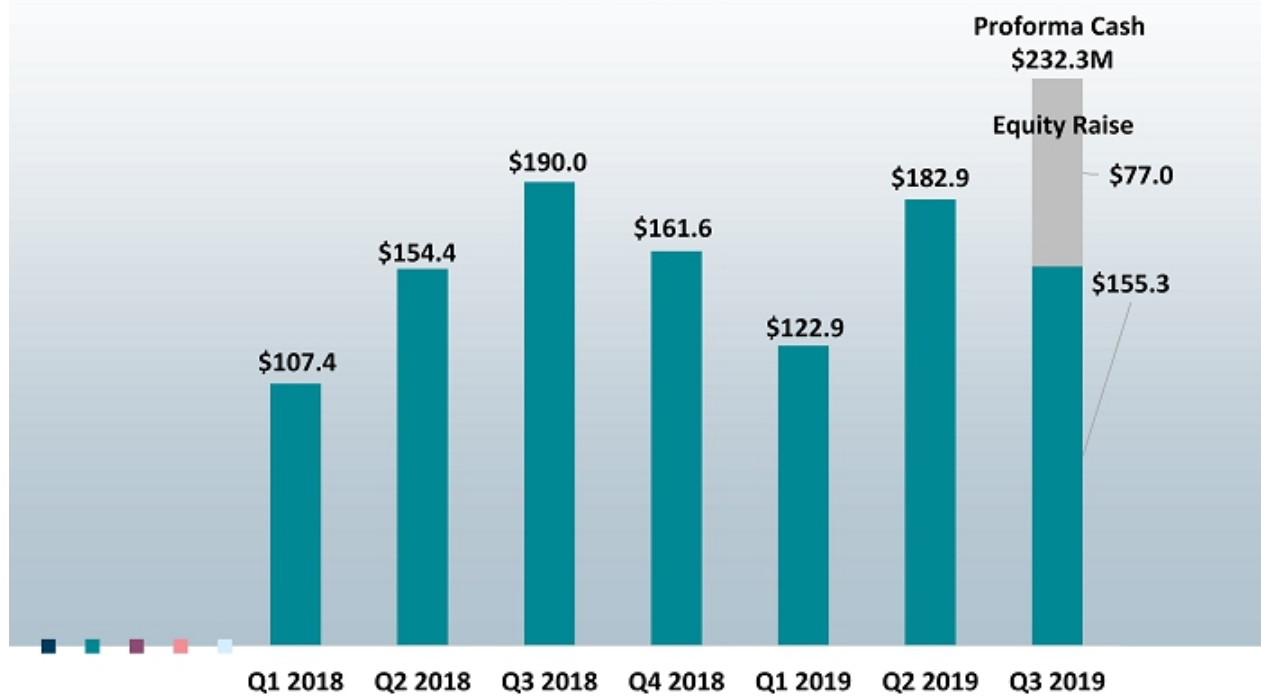
(Millions)



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Proforma Cash Balance at End of Each Quarter with Equity Raise (Millions)



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Non-Dilutive Term Loan Financing

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

	Amount (\$)	TXMD Company Milestone ¹	Contractual Timing	
Tranche 1	\$200M	Closing of the facility	Completed in April 2019	
Tranche 2	\$50M	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	4Q 2019	
Tranche 3	\$50M	Achieving \$11M in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019	First Quarter of 2020 Audited financials required (Feb/Mar 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.

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Reaffirm 4Q2019 Financial Guidance

4Q2019 Estimate

FDA-Approved Products
Net Revenue

\$11.00 - \$13.00M

Prenatal Vitamins
Net Revenue

\$1.75 - \$2.25M

Total TXMD Product
Net Revenue

\$12.75 - \$15.25M

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

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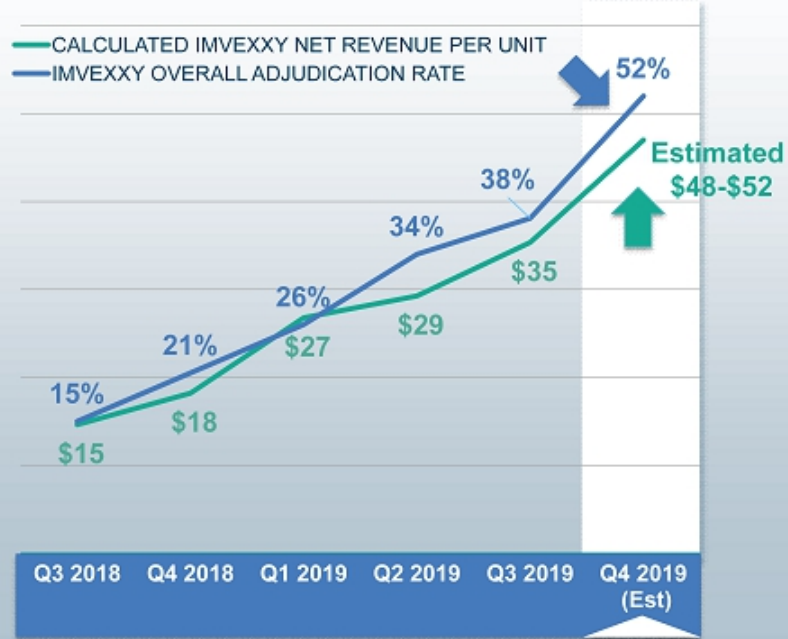


**COMMERCIAL
UPDATE**



IMVEXXY Calculated Net Revenue Per Unit Increases as Adjudication Rates Increases

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for 4Q19
- Overall adjudication rate in October increased 14% over 3Q19



* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of Prescriptions filled by patients in period

Improvement in Adjudication Rates

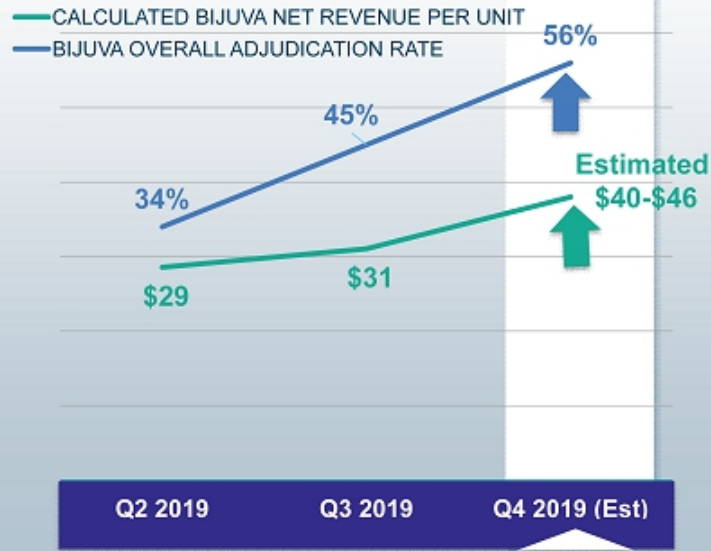


- Addition of CVS in September contributing to overall adjudication rates
- Adjudication in Commercial Patients at 72% in October

	2Q19	3Q19	Sept 2019	Oct 2019
Commercial Adjudication %	50%	55%	62%	72%
Medicare Part D Adjudication %	8%	12%	13%	17%
Overall %	34%	38%	43%	52%

BIJUVA Calculated Net Revenue Per Unit Increases as Adjudication Rates Increase

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for Q419
- Overall adjudication rate in October increased 11% over Q319



* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of Prescriptions filled by patients in period

Improvement in Adjudication Rates



- Addition of United and OptumRx in August; Cigna in September contributing to overall adjudication rates
- Addition of EnvisionRx adjudicating in November

	2Q19	3Q19	Sept 2019	Oct 2019
Commercial Adjudication %	38%	50%	54%	62%
Medicare Part D Adjudication %	7%	15%	14%	21%
Overall %	34%	45%	49%	56%

ANNOVERA Commercial Payer Update

Already Achieved ~62% Unrestricted Access¹

Top 10 Plans Account for ~74%
 of all Commercial Pharmacy Lives¹

	Plan	% of Lives ²	Status ³
New	CVS	16%	Adjudicating with no copay as of October 2019
	ESI	16%	Adjudicating at T3 as of September 2019
	United	8%	In discussions
	Anthem	7%	Adjudicating at T3, no copay as of August 2019
	Prime	6%	In discussions
	OptumRx	6%	In discussions
	Kaiser	5%	In discussions
			Kaiser Washington covering at no copay
New	Aetna	4%	No copay at in network pharmacies for a majority of lives as of October 2019
	Cigna	4%	Adjudicating at T3 as of August 2019
New	EnvisionRx	2%	Adjudicating as of November 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.

¹MMIT November 2019 (Account Insights) and CVS Preventative Drug List

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

ANNOVERA Status



STARTED
SOFT- LAUNCH
36 REPS + SALES
MANAGEMENT



PILLPACK
PARTERSHIP
LAUNCHED



4Q19 EXPECTED NET
REVENUE PER UNIT
RANGE

The Power of the Portfolio

Multiple Paths to \$1B of 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	\$184M	\$257.6M	\$331.2M	\$404.8M
\$100	\$230M	\$322M	\$414M	\$506M

Total Addressable FDA Market: 3.8M				
Total Addressable Compounding Market: 12M				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316M	\$442.4M	\$568.8M	\$695.2M
\$100	\$395M	\$553M	\$711M	\$869M

Total Addressable Birth Control Market NRx: 28M				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280M	\$420M	\$560M	\$700M
\$1,250	\$350M	\$525M	\$700M	\$875M
\$1,500	\$420M	\$630M	\$840M	\$1.05B
\$1,750	\$490M	\$735M	\$980M	\$1.2B



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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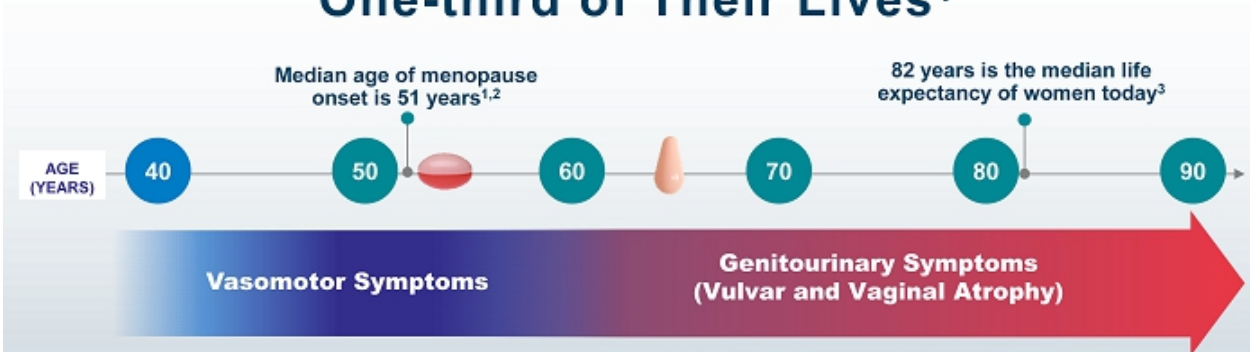
IMVEXXY



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Women are Menopausal More Than One-third of Their Lives¹



Vulvar and Vaginal Atrophy (VVA) is a chronic and progressive condition and is unlikely to resolve without medical intervention^{4,5}

Symptoms of VVA may include:^{6,7}

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

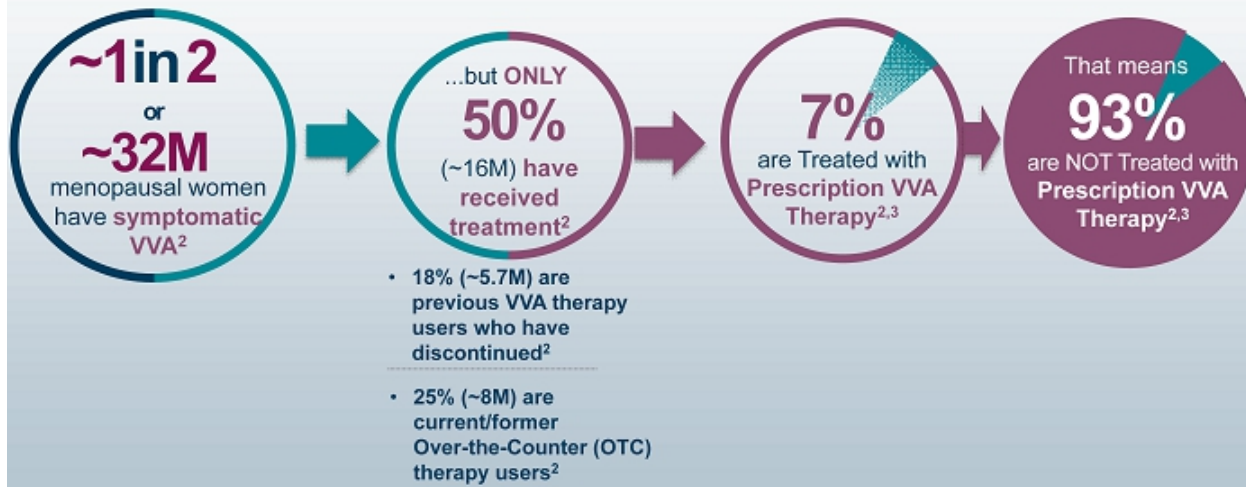
1. Parish SJ, et al. *Menopause*. 2018;25(8):937-941. 2. North American Menopause Society. *Menopause* 101. www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal. Accessed March 25, 2019. 3. US Census Bureau. <http://worldpopulationreview.com/countries/united-states-population/>. 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.

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The Scope of VVA in the US

64 Million Menopausal Women in the US¹



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, softgel vaginal 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



2019

Drive Early Experience for a Differentiated Product



2020

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 insurance coverage

- Open access approach removed barriers from a lack of insurance coverage
- \$ spent went toward copay program, removed barrier to HCP writing and less expensive than pushing early through DTC
- Volume gives negotiating power with insurance company
- Patient will experience new product with the goal of being best-in-class treatment option

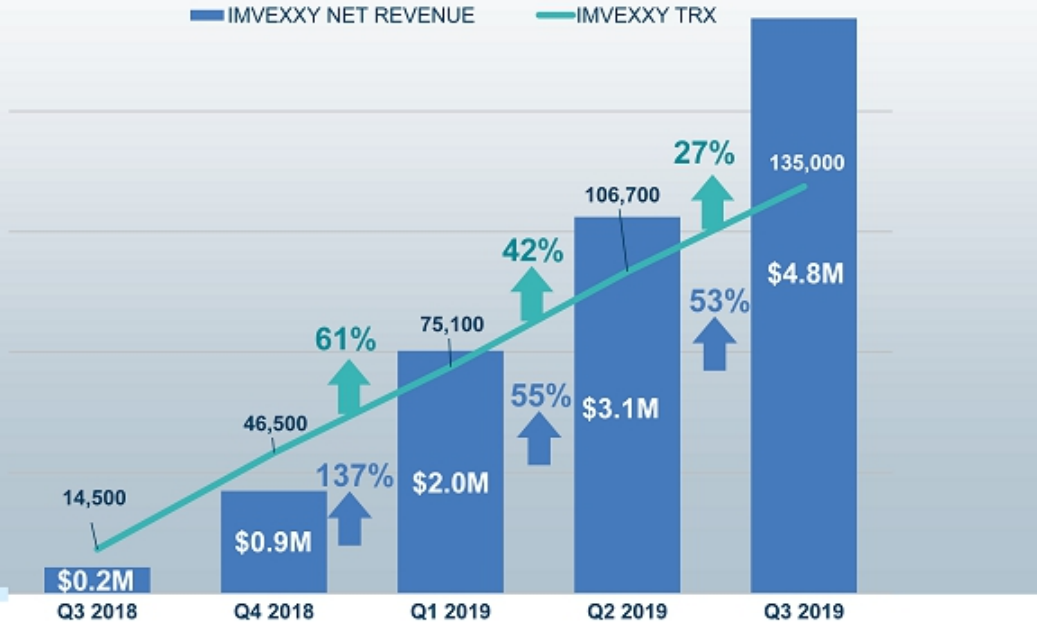
- Target cream writers and patients (\$1B in sales)
- Continue DTC to drive new women to therapy and grow writers
- Initiatives to lower cost of distribution and increase use of starter packs



IMVEXXY Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients

■ IMVEXXY NET REVENUE ▲ IMVEXXY TRX



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 up to two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.

IMVEXXY October Launch Metrics

IMVEXXY Launch Metrics	
Total paid scripts ¹ (October 1-31, 2019)	~41,500
Total patients (since launch through October 31, 2019)	~103,900
Total prescribers ² (since launch through October 31, 2019)	~16,400



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

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

Launch Results Remain Strong

Imvexxy TRx Launch Comparison



Market Share

*Month 16 for IMVEXXY is October 2019

References:

- Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. This includes up to two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
 - Ospheña and Intrarosa data sourced from Symphony Health Integrated Database.
 - Vagifem data sourced from IQVIA National Prescriber Level Data.
 - 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^{1,2}

Month Initial Prescription Filled	Average # Fills for Those Patients	Maximum Allowable Fills Given the Month of Initial Fill
Oct 2019	1 Fill	1 Fill
Sep 2019	1.7 Fills	2 Fills
Aug 2019	2.3 Fills	3 Fills
Jul 2019	2.9 Fills	4 Fills
Jun 2019	3.3 Fills	5 Fills
May 2019	3.7 Fills	6 Fills
Apr 2019	4.3 Fills	7 Fills
Mar 2019	4.8 Fills	8 Fills
Feb 2019	5.2 Fills	9 Fills
Jan 2019	5.7 Fills	10 Fills
Dec 2018	6.0 Fills	11 Fills
Nov 2018	6.7 Fills	12 Fills
Oct 2018	6.8 Fills	13 Fills
Sep 2018	7.2 Fills	14 Fills
Aug 2018	8.5 Fills	15 Fills

IMVEXXY: 4.0 fills/yr³ (through Oct)

- Vaginal creams: average 1.5 fills/yr⁴
- Vaginal tablets: average 3.5 fills/yr⁴

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 6.7 fills from November 2018 through October 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

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	\$184M	\$257.6M	\$331.2M	\$404.8M
\$100	\$230M	\$322M	\$414M	\$506M

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	\$230M	\$322M	\$414M	\$506M
\$100	\$287.5M	\$402.5M	\$517.5M	\$632.5M

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	\$276M	\$386.4M	\$496.8M	\$607.2M
\$100	\$345M	\$483M	\$621M	\$759M

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.

The VVA Market Exceeds \$1.7B Gross Revenue Annually

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

1) Symphony Health Solutions PHAST Data powered by IDB; MBS dollars.
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Commercial Payer Status

Achieved ~68% Unrestricted Commercial Access¹
9 of the Top 10 Commercial Payers Secured

Top 10 Plans Account for ~74%
of all Commercial Pharmacy Lives¹

Plan	% of Lives ²	Status ³
CVS	16%	Adjudicating as of September 2019
ESI	16%	Adjudicating as of 10/1/18
United	8%	Adjudicating as of 3/1/19
Anthem	7%	Adjudicating as of August 2018
Prime	6%	Adjudicating as of 1/1/19
OptumRx	6%	Adjudicating as of 1/1/19
Kaiser	5%	In discussions
New Aetna	4%	Adjudicating as of 1/1/2020 on a majority of plan designs
Cigna	4%	Adjudicating as of 12/15/18
New EnvisionRx	2%	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.

¹MMIT November 2019 (Account Insights)

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

Medicare Part D Payer Status Additional Decisions Expected This Quarter

**Top 8 Plans Account for ~83%
of all Medicare Part D Pharmacy Lives¹**

Plan	% of Lives ²	Status ³
United	21%	Adjudicating as of 2/1/19
Humana	18%	Decision expected 4Q19
CVS Caremark	14%	Decision expected 4Q19
Wellcare with Aetna lives	14%	Decision expected 4Q19
Express Scripts/ Cigna	8%	Decision expected 4Q19
Kaiser	4%	Adjudicating maintenance pack as of 10/1/18 and starter pack as of 3/1/19
Anthem	3%	Decision expected 4Q19
Envision	1%	Decision expected 4Q19

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.

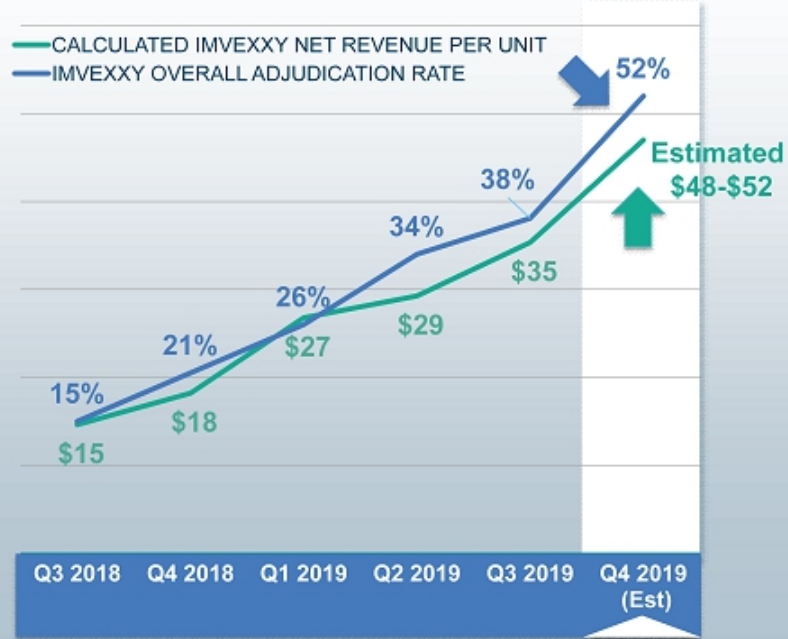
¹MMIT November 2019 (Account Insights)

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

IMVEXXY Calculated Net Revenue Per Unit Increases as Adjudication Rates Increases

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for 4Q19
- Overall adjudication rate in October increased 14% over 3Q19



* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of Prescriptions filled by patients in period

Improvement in Adjudication Rates



- Addition of CVS in September contributing to overall adjudication rates
- Adjudication in Commercial Patients at 72% in October

	2Q19	3Q19	Sept 2019	Oct 2019
Commercial Adjudication %	50%	55%	62%	72%
Medicare Part D Adjudication %	8%	12%	13%	17%
Overall %	34%	38%	43%	52%

Target Adjudication Rate* Over Time for IMVEXXY

3Q 2019 Actuals

Step 1

IMVEXXY	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	4%	62%	33%
% Adjudicated	0%	55%	12%
Contribution to Overall Adjudication Rate	0%	34%	4%
Overall Adjudication Rate	38% (up from 34% 2Q19)		

Target Overall Adjudication of 70% in Second Half 2020 before Optimization Complete

Step 2



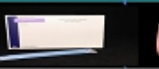









IMVEXXY	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	3%	62%	35%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	47%	23%
Overall Adjudication Rate	70%		

Target Overall Adjudication of 85% as Optimization is Complete

Step 3

IMVEXXY	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	3%	62%	35%
% Adjudicated	0%	87%	87%
Contribution to Overall Adjudication Rate	0%	54%	31%
Overall Adjudication Rate	85%		

IMVEXXY Product Characteristics Compare Favorably¹⁻⁹

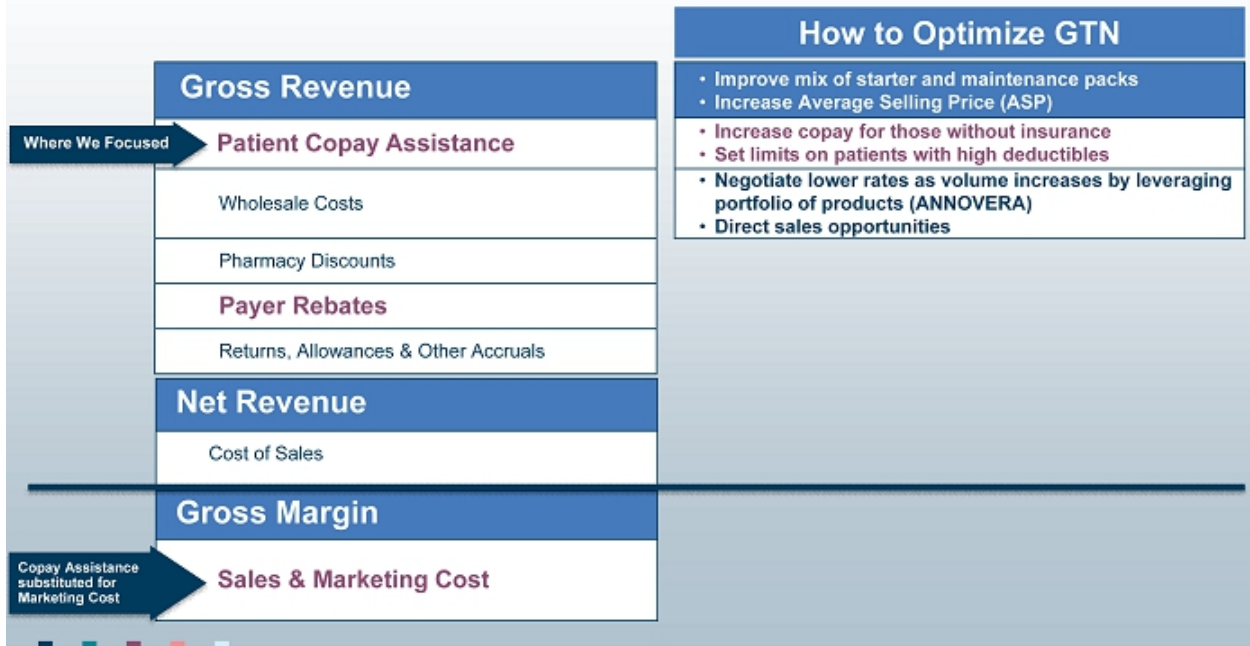
Product	Estrogens				Non-estrogens	
	Estrace® Cream (estradiol vaginal cream, USP, 0.01%) ¹	Premarin® (conjugated estrogens) Vaginal Cream ²	Vagifem® (estradiol vaginal inserts) ⁴	IMVEXXY® (estradiol vaginal inserts) ⁵	Intrarosa® (prasterone) vaginal inserts ⁷	Osphena® (ospemifene) tablets, for oral use ⁸
						
						
FDA approval	1984	1978	1999	2018	2016	2013
TRx MSB Dollars of Brand & Generic 2018 ⁹	\$540,000,000	\$462,226,000	\$420,030,000	\$44,000,000	\$35,001,000	\$73,908,000
2018 Total Units ⁹	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 (2019) ¹⁰	\$344.78 (42.5-g tube)	\$373.56 (30-g tube)	\$170.16 (8 tablets)	\$180.00 (8 softgel capsules)	\$202.00 (28 inserts)	\$648.00 (90 tablets)
WAC 28-day supply (2019) ¹⁰	\$97.35	\$130.75	\$170.16	\$180.00	\$202.00	\$201.60

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. January 2019.

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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IMVEXXY Model Different Than Typical Pharmaceutical Launch



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

	Column A No Insurance or 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>	\$185	\$200	\$40	\$0
Payment from Insurance Company	\$0	\$0	\$160	\$195
Payment from Patient	\$50	\$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



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 encourage the prescribing of FDA approved hormones**
- **NEED FOR AN FDA-APPROVED COMBINATION BIO-IDENTICAL HORMONE THERAPY**

Hormone Therapy Options for Vasomotor Symptoms Before BIJUVA

After WHI (2002), a majority of women and clinicians shifted to bio-identical hormone therapy¹

FDA-APPROVED		NOT FDA-APPROVED
Combination <u>Synthetic</u> Estrogens + Progestins² 	Separate <u>Bio-identical</u> Estradiol & Progesterone 	Compounded <u>Bio-identical</u> Estradiol + Progesterone 
~ 2.5 million total annual prescriptions ³	~ 3.9 million total annual prescriptions (each) ¹	12 - 18 million total annual prescriptions ⁴
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) Products include synthetic progestin with synthetic or bio-identical estrogen.

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

4) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NABP applications

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 continuous combined progesterone and estradiol product
- No peanut oil unlike other FDA-approved progesterone products
- One prescription, one copay
- BIJUVA is available in blister packages containing 30 capsules

*Based on a 1-year clinical study

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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BIJUVA October Launch Metrics

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients ¹ (since launch through October 31, 2019)	~26,900
Total paid scripts (October 1-31, 2019)	~6,500
Total patients (since launch through October 31, 2019)	~11,300
Total prescribers ² (since launch through October 31, 2019)	~4,200

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

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

BIJUVA Commercial Payer Update

Additional Coverage Decisions Expected This Quarter

Achieved ~55% Unrestricted Commercial Access¹
6 of the Top 10 Commercial Payers Secured¹

**Top 10 Plans Account for ~74%
of all Commercial Pharmacy Lives¹**

Plan	% of Lives ²	Status ³
CVS	16%	In discussions
ESI	16%	Adjudicating as of 4/19/19
United	8%	Adjudicating as of 8/1/19
Anthem	7%	In discussions
Prime	6%	In discussions
OptumRx	6%	Adjudicating as of 8/1/19
Kaiser	5%	In discussions
Aetna	4%	Adjudicating as of 4/2019
Cigna	4%	Adjudicating as of 9/2019
EnvisionRx	2%	Adjudicating as of 11/2019

New

New

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.

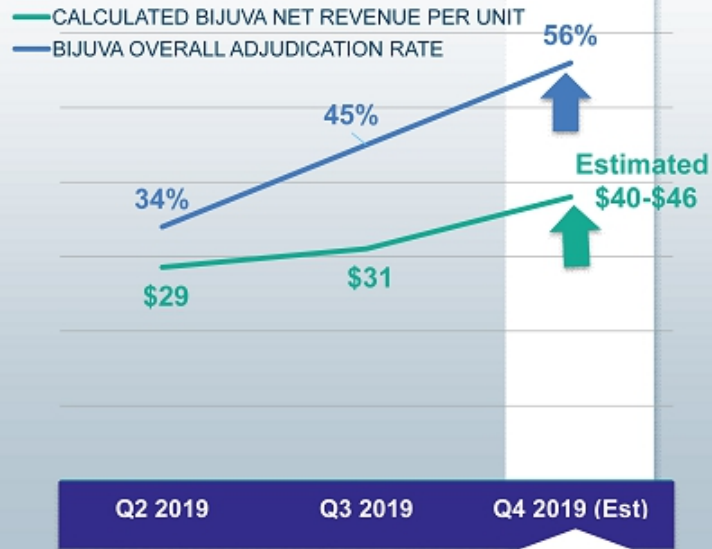
¹MMIT November 2019 and Account Insights

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

BIJUVA Calculated Net Revenue Per Unit Increases as Adjudication Rates Increase

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for Q419
- Overall adjudication rate in October increased 11% over Q319



* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of Prescriptions filled by patients in period

Improvement in Adjudication Rates



- Addition of United, OptumRx in August and Cigna in September contributing to overall adjudication rates

	2Q19	3Q19	Sept 2019	Oct 2019
Commercial Adjudication %	38%	50%	54%	62%
Medicare Part D Adjudication %	7%	15%	14%	21%
Overall %	34%	45%	49%	56%

Target Adjudication Rate* Over Time for BIJUVA

3Q 2019 Actuals

Step 1

BIJUVA	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	5%	89%	6%
% Adjudicated	0%	50%	15%
Contribution to Overall Adjudication Rate	0%	44%	1%
Overall Adjudication Rate	45% (up from 34% 2Q19)		

Target Overall Adjudication in Second Half 2020 before Optimization Complete

Step 2

BIJUVA	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	3%	89%	8%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	67%	5%
Overall Adjudication Rate	72%		

Target Overall Adjudication as Optimization is Complete

Step 3

BIJUVA	Column A No Insurance	Column B Commercial Insurance	Column C Medicare Eligible Patients
% of Business	3%	89%	8%
% Adjudicated	0%	87%	87%
Contribution to Overall Adjudication Rate	0%	78%	7%
Overall Adjudication Rate	85%		

Market Opportunity

Total Addressable FDA Market: 3.9M				
Total Addressable Compounding Market: 12M				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316M	\$442.4M	\$568.8M	\$695.2M
\$100	\$395M	\$553M	\$711M	\$869M

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 Update

Plan to Submit BIJUVA 0.5/100 mg Dose

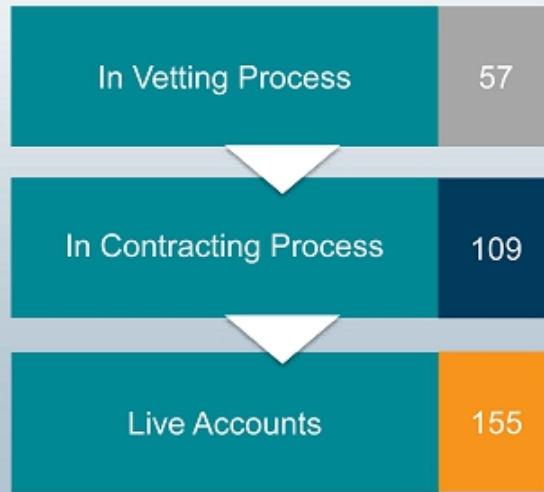
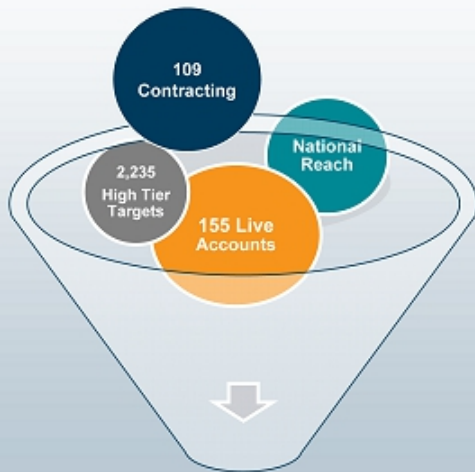
- TXMD plans to submit a New Drug Application (NDA) supplement for the 0.5/100 mg dose of BIJUVA to FDA for approval
 - After meeting with FDA, TXMD plans to submit an NDA efficacy supplement using existing REPLENISH Phase 3 data with new analyses
 - Anticipate no new clinical trials required
 - Plan to submit efficacy supplement in 4Q19
 - 10 month PDUFA date expected if the efficacy supplement is accepted for review

Reason for Submission

- Similar to IMVEXXY, TXMD expects majority of prescriptions to be the higher dose (1/100 mg)
- We believe a subset of healthcare providers would prescribe a lower dose option when titrating patients off of hormone replacement therapy (HRT), specifically in the BIO-IGNITE channel

Pharmacy Targeting

PROCESS & STATUS





ANNOVERA



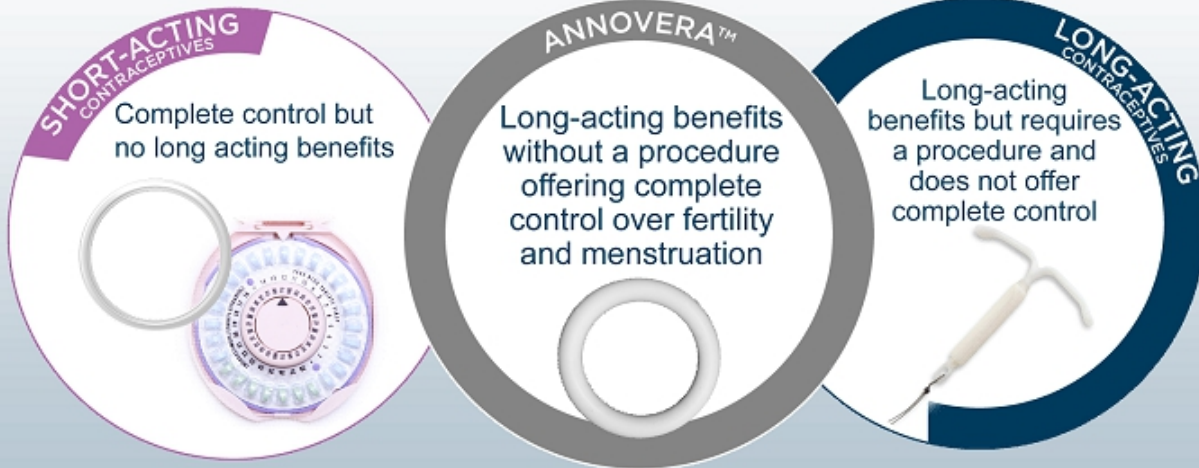
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U.S. Contraceptive Market

\$5B U.S. net sales¹

~ 90mm annual scripts to ~20 million women²



Oral contraceptives continue to lose market share (CAGR -4.2% 2012 to 2017) to long acting methods¹

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

ANNOVERA Key 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 1-year (13-cycles) birth control product (used in repeated cycles for 3-weeks in/1-week out)
- **Ultra-low dose 13 mcg ethinyl estradiol**
- **Only product with new progestin - segesterone acetate¹**
 - No androgenic, estrogenic, or glucocorticoid effects at contraceptive doses⁴
- **As effective as a pill without the daily hassle**
- **High patient satisfaction in a phase 3 clinical trial acceptability study of 905 women²**
 - ~90% overall satisfaction, adherence (94.3%) and continuation (78%)
- **Soft, pliable ring**
- **Does not require refrigeration**
- **Demonstrated acceptable side effect profile including low rates of discontinuation related to irregular bleeding (1.7%)⁵**

*Based on pharmacological studies in animals and in vitro studies. The clinical significance of these data is not known.

**In clinical trials, 12% of participants discontinued due to an adverse reaction.

1. Narender Kumar, Samuel S. Koide, Yun-Yen Tsong, and Kalyan Sundaram. 2000. "Nestorone: a Progestin with a Unique Pharmacological Profile," *Steroids* 65: 629-63

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

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ANNOVERA Patient Types

Annovera™
(levonorgestrel acetate and ethinyl estradiol vaginal system)
Delivers 0.15 mg/0.013 mg per day

- **Broadest based product – a single contraceptive product for most patient and prescriber types**
 - Benefits for the diversity of women – supports patient preference
 - Amenable to women of all ages and demographics¹
 - Available to all prescribers – no special training, equipment, or inventory
- **Control of both fertility and menstruation²**
- **Self-administered, long-lasting benefits with immediate reversibility (without requiring a procedure for insertion and removal like IUDs or Implants)**

Nulliparous women and those not in monogamous relationships

Ideal for adolescents who don't want to take a product everyday, but don't want a procedure



Between children – birth spacing

College women – no need for monthly refills

Women in the military – control fertility and menstruation for 1 year (13 cycles)

¹ANNOVERA has not been adequately studied in females with a BMI > 29 kg/m²
²When left in place 21 days and removed 7 days per cycle

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ANNOVERA Status



STARTED
SOFT- LAUNCH
36 REPS + SALES
MANAGEMENT



PILLPACK
PARTERSHIP
LAUNCHED



4Q19 EXPECTED NET
REVENUE PER UNIT
RANGE

ANNOVERA Unique Commercial Payer Environment

- **Commercial payer environment for contraceptives provides patient affordability without the need for a TXMD open access program**
- **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 without a generic equivalent 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
 - ANNOVERA does not have a generic equivalent, creating a strong dynamic for coverage in all 50 states
- **Affordable Care Act Implementation (Part XXVI) specifies:**
 - “If an individual’s attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider.”
 - Typical response within 48 hours on decision

ANNOVERA Commercial Payer Update

Already Achieved ~62% Unrestricted Access¹

Top 10 Plans Account for ~74%
 of all Commercial Pharmacy Lives¹

	Plan	% of Lives ²	Status ³
New	CVS	16%	Adjudicating with no copay as of October 2019
	ESI	16%	Adjudicating at T3 as of September 2019
	United	8%	In discussions
	Anthem	7%	Adjudicating at T3, no copay as of August 2019
	Prime	6%	In discussions
	OptumRx	6%	In discussions
	Kaiser	5%	In discussions
			Kaiser Washington covering at no copay
New	Aetna	4%	No copay at in network pharmacies for a majority of lives as of October 2019
	Cigna	4%	Adjudicating at T3 as of August 2019
New	EnvisionRx	2%	Adjudicating as of November 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.

¹MMIT November 2019 (Account Insights) and CVS Preventative Drug List

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

ANNOVERA Commercial Payer Update

Fast Uptake in Regional Plans

Selected Regional Plan Coverage

Plan	% of Lives ¹	Status ²
MC-Rx (ProcureRx)	0.64%	Adjudicating as of April 2019
Magellan Rx	0.4%	Adjudicating as of August 2019
BCBS of Massachusetts	0.47%	Adjudicating at no copay as of August 2019
EmblemHealth	0.26%	Adjudicating at no copay as of September 2019
Excelsus	0.24%	Adjudicating as of September 2019
Wellmark	0.23%	Adjudicating as of August 2019
Harvard Pilgrim	0.18%	Adjudicating at no copay as of August 2019
Independent Health Association	0.06%	Adjudicating as of August 2019
New Geisinger	0.05%	Adjudicating at no copay as of October 2019
BC of Idaho	0.00%	Adjudicating at no copay as of September 2019
Summacare	0.00%	Adjudicating at no copay as of September 2019
Clear Script PBM	0.00%	Adjudicating as of August 2019
Univera Healthcare	0.00%	Adjudicating as of August 2019

¹Plan numbers as of October 2019

²MMIT October 2019 and Account Insights

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.

ANNOVERA SUMMARY

Annovera™
(segesterone acetate and
ethinyl estradiol vaginal system)
Delivers 0.15 mg/0.013 mg per day

- **A new long-lasting reversible contraception that is procedure-free**
- **Empowers women to be in control of their fertility and menstruation**
- **Non-androgenic progestin - segesterone acetate¹**
 - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses*
 - Highest anti-ovulatory potential of available progestins
- **One of the lowest average daily release ethinyl estradiol – 13 mcg/day**
- **High patient satisfaction (~90%)**
- **No alteration in vaginal ecosystem or increased occurrence of vaginal infections in a substudy with 13 cycles of use**



* Based on pharmacological studies in animals and in vitro studies. The clinical significance of these data is not known.

1. Narender Kumar, Samuel S. Koide, Yun-Yen Tsong, and Kalyan Sundaram. 2000. "Nestorone: a Progestin with a Unique Pharmacological Profile," *Steroids* 65: 629-63.

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ANNOVERA Market Opportunity

ANNOVERA Net Revenue Opportunity

Total Addressable Birth Control Market NRx: 28M				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
	Total Addressable Birth Control Market NRx	Total Addressable Birth Control Market NRx	Total Addressable Birth Control Market NRx	Total Addressable Birth Control Market NRx
\$1,000	\$280M	\$420M	\$560M	\$700M
\$1,250	\$350M	\$525M	\$700M	\$875M
\$1,500	\$420M	\$630M	\$840M	\$1.05B
\$1,750	\$490M	\$735M	\$980M	\$1.2B

Current

Addressable NuvaRing Market NRx: 1.2M				
Average Net Revenue / Unit	25%	35%	45%	55%
	NuvaRing Market NRx	NuvaRing Market NRx	NuvaRing Market NRx	NuvaRing Market NRx
\$1,000	\$300M	\$420M	\$540M	\$660M
\$1,250	\$375M	\$525M	\$675M	\$825M
\$1,500	\$450M	\$630M	\$810M	\$990M
\$1,750	\$525M	\$735M	\$945M	\$1.15B

- Strong initial commercial net revenue of ~\$1,250 per unit with the potential for improvement¹

¹\$1,250 assumes patients meeting the criteria of 1) commercially insured patient or 2) approved via a Medical Necessity Letter. Does not include cash pay sales.

ANNOVERA Deal Terms

Milestone Payments

- Upon FDA approval: \$20M
- First commercial batch release: \$20M
- \$200M in cumulative net sales: \$40M
- \$400M in cumulative net sales: \$40M
- \$1B in cumulative net sales: \$40M

Royalty %

Step structure:

- Annual net sales \leq \$50M: 5%
- Annual net sales $>$ \$50M and \leq \$150M: 10%
- Annual net sales $>$ \$150M: 15%

Additional Cost Considerations

- TXMD and Population Council jointly responsible for one observational PMR study*

*Costs exceeding \$20M to be shared with Population Council

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ANNOVERA Key Attributes

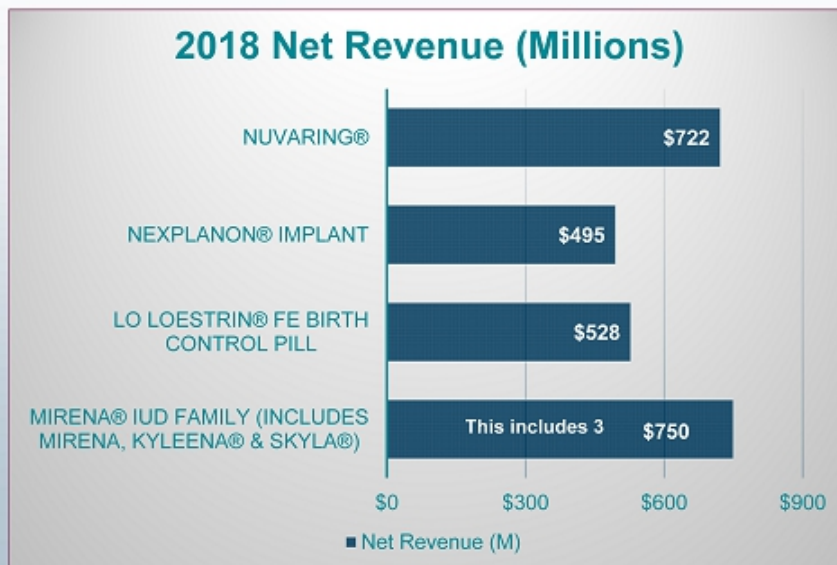
	Oral Contraceptives	Vaginal Ring NuvaRing®	Contraceptive Injection	Vaginal System ANNOVERA™	IUDs
Duration of Action	Daily pill intake	1 month (21/7 regimen)	3 months	1 year (21/7 regimen)	3-10 years
Patient Control	Stop at any time	Removable at any time	Stop at any time, but residual effects for 3 months	Removable at any time	Procedure required
Nulliparous Women	Yes	Yes	Yes	Yes	Not universally acceptable
Product Administration	Oral intake	Patient administered Flexible vaginal ring	Physician in-office injection every 3 months	Patient administered Soft and pliable ring-shaped vaginal system	Physician in-office procedure for insertion and removal
Patient Convenience	Daily pill presents compliance and adherence risks; potential increase in unplanned pregnancies	Monthly pharmacy visit	Physician in-office injection, prescriber stocking required	Annual pharmacy visit	Physician in-office procedure, prescriber stocking required
Healthcare Provider Convenience	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
Yearly WAC	Lo Loestrin® Fe: \$1,829.36	NuvaRing® \$2,114.19	Depo-Provera® \$799.12	\$2,000	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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The Power of the Portfolio

Multiple Paths to \$1B of 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	\$184M	\$257.6M	\$331.2M	\$404.8M
\$100	\$230M	\$322M	\$414M	\$506M

Total Addressable FDA Market: 3.8M				
Total Addressable Compounding Market: 12M				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316M	\$442.4M	\$568.8M	\$695.2M
\$100	\$395M	\$553M	\$711M	\$869M

Total Addressable Birth Control Market NRx: 28M				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280M	\$420M	\$560M	\$700M
\$1,250	\$350M	\$525M	\$700M	\$875M
\$1,500	\$420M	\$630M	\$840M	\$1.05B
\$1,750	\$490M	\$735M	\$980M	\$1.2B



Diversified risk with 3 FDA-approved products, creating multiple paths to \$1B sales opportunity
 Example: \$230M (IMVEXXY), \$395M (BIJUVA) and \$420M (ANNOVERA) = \$1B sales potential

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The Power of a Women's Health Portfolio

Annovera™
 (levonorgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

vitaMedMD®
 Prenatal Vitamins

Annovera™
 (levonorgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

Bijuva™
 (estradiol and progesterone) capsules

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



CONTRACEPTION

PRENATAL CARE

CONTRACEPTION/
 FAMILY PLANNING -
 PERIMENOPAUSE

VASOMOTOR SYMPTOMS

DYSPAREUNIA
 (Vulvar & Vaginal Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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