

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): MARCH 3, 2020

**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 March 3, 2020 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>
<a href="#">99.1</a>	TherapeuticsMD, Inc. presentation dated March 3, 2020.
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.

THERAPEUTICSMD, INC.

Date: March 3, 2020

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

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TherapeuticsMD®

*For Her. For Life.*

**Cowen Conference**  
**March 3, 2020**

*Building the Premier  
Women's Health  
Company*



# Forward-Looking Statements

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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 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, including the conditions to draw an additional tranche thereunder and whether our lender will make that tranche available; 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; whether the FDA will approve the efficacy supplement for the lower dose of BIJUVA; our ability to protect our intellectual property, including with respect to the Paragraph IV notice letter the company received regarding IMVEXXY; 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 ability of the company’s marketing contractors to market ANNOVERA; 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, including the effect of any sales of common stock by our executive officers or directors, whether in connection with the expiration of stock options or otherwise; and the concentration of power in our stock ownership. This non-promotional presentation is intended for investor audiences only.

# Portfolio Approach to Women's Health

## Empowering Women For Life



- Innovative customer centric products, chronic conditions, large markets
- Products transition from one to the next through the various stages of life
  - contraception → pregnancy → contraception → vasomotor symptoms → vulvar and vaginal atrophy
- 200 sales representatives focused on OB/GYN women's health call point
- Broad and growing payor coverage and reimbursement established
- Launch plans to take advantage of synergistic portfolio of products

# Foundational Elements to Accelerate Revenue Growth 2020



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## Significant Payor Coverage and Growing

	Coverage February 20, 2020	Target Coverage Year-end 2020
<b>ANNOVERA</b>		
Commercial	75%*	80%*
<b>IMVEXXY</b>		
Commercial	72%	75%
Part D	29%	70%
<b>BIJUVA</b>		
Commercial	56%	75%

**Awaiting IMVEXXY Part D decisions from Humana, Wellcare and ESI; potential total unrestricted coverage of up to 40% by April 1<sup>st</sup>**

Source: MMIT February 20, 2020

\*Annovera coverage includes unrestricted access and coverage with a step edit/prior authorization. Currently 65% unrestricted, 11% step/prior authorization.





**PRODUCT  
OVERVIEW  
& COMMERCIAL  
UPDATES**

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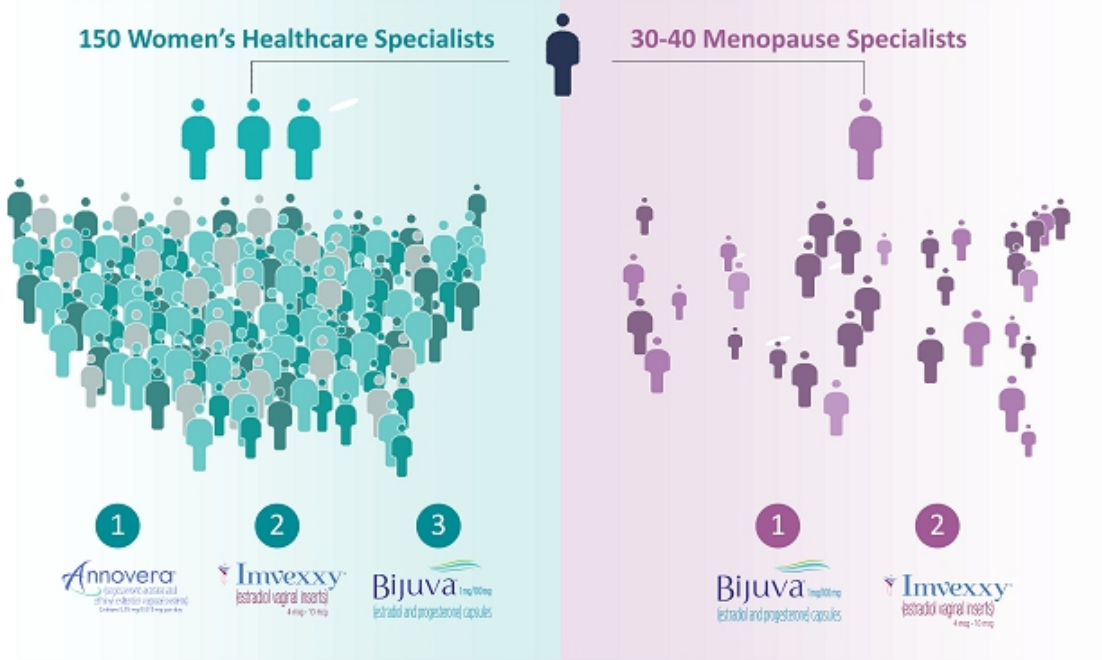


### 3 Products in Launch Mode

Shifted from a clinically innovative company to a commercially successful company



# Sales Force Redeployed to Provide More Effective Portfolio Coverage



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# 2020 Brand Strategy

Brand prioritization establishes focused and disciplined capital allocation to drive net revenue growth in 2020 with a view toward profitability in 2021

1

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

- Favorable payer dynamics and coverage
- Highest net revenue per unit across portfolio
- Largest women's health category
- Fastest payback period on marketing investments
- Full scale launch March 1<sup>st</sup>

2

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

- Goal to surpass Premarin Vaginal Cream on a monthly basis
- Broad commercial payer coverage established
- Opportunity to leverage existing large base of prescribers and patients to grow market share
- Increase HCP and DTC marketing to drive demand

3

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

- Commercial payer coverage still growing
- Increased HCP awareness and adoption needed
- Focus on expanding BIO-IGNITE partners and pull through
- Establish product differentiation through peer to peer engagement
- Potential approval of lower dose Q4 2020

- Increase sales and marketing investment to drive net revenue growth in 2020

DTC - direct to consumer

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## ANNOVERA Summary

- **Only FDA-approved long-lasting reversible contraception that is patient-controlled and procedure-free**
  - 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)
- **One of the lowest doses of ethinyl estradiol - 13 mcg**
- **Only product with new progestin - segesterone acetate<sup>1</sup>**
  - No androgenic, estrogenic, or glucocorticoid effects at contraceptive doses\*
- **As effective as a pill without the daily hassle**
- **High patient satisfaction in a phase 3 clinical trial acceptability study of 905 women<sup>2</sup>**
  - ~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%)\*\***

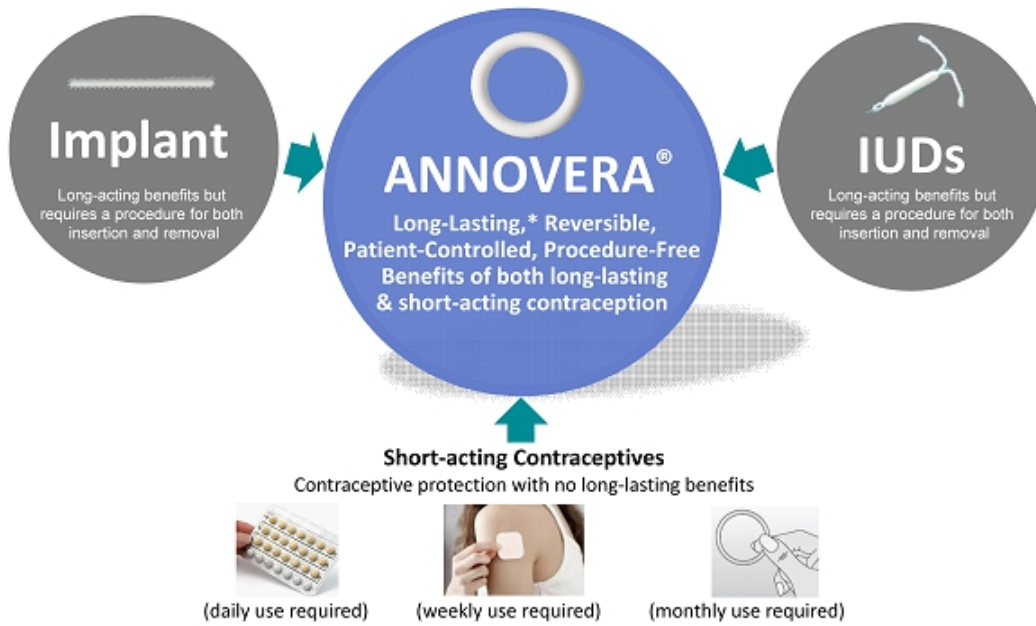


\*Based on pharmacological studies in animals and in vitro studies. The clinical significance of these data is not known.

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

1. Narender Kumar, Samuel S. Koide, Yun-Yen Tsang, and Kalyan Sundaram. 2000. "Nestorone: a Progestin with a Unique Pharmacological Profile," *Steroids* 65: 629-63
2. Merkatz, Ruth B., Marlena Plagianos, Elena Hoskin, Michael Cooney, Paul C. Hewett, and Barbara S. Mensch. 2014. "Acceptability of the Nestorone/Ethinyl estradiol contraceptive vaginal ring: Development of a model; implications for introduction," *Contraception* 90(5): 514-521.

# ANNOVERA – Patient-Controlled and Procedure-Free Long-Lasting Contraception\*



\*ANNOVERA is inserted for 21 continuous days and removed for 7 days for 13 cycles (one year).

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# ANNOVERA Growth Levers

## Lead Product for Spend and Focus



### Sales Force Focus

- Full scale launch March 1<sup>st</sup>
- Lead product designation for Women's Healthcare Salesforce



### Consumer Advertising and Public Relations Effort

- Focus on **Empowerment and Control**<sup>1,2</sup>
- Disruptive Consumer Campaign Planned Launch in March
- Public Relations Initiatives



### Expand into New Channels and Populations

- Online Platforms including Pillpack, PlushCare, and Pill Club
- WSI to market to the Department of Defense and Veteran's Administration
- Puerto Rico Distribution
- Afaxys to meet the needs of public health clinics, college and university health clinics, and city, county, state and federal facilities

<sup>1</sup>ANNOVERA is inserted for 21 continuous days and removed for 7 days for 13 cycles (one year)

# IMVEXXY's Unique Product Attributes

**Imvexxy**  
(estradiol vaginal inserts)



- Indicated for moderate to severe dyspareunia
- 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 in clinical studies
- 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**

**IMVEXXY: 4.4 fills/yr<sup>1</sup> (through December 2019)**

- Vaginal creams: average 1.5 fills/yr<sup>2</sup>
- Vaginal tablets: average 3.5 fills/yr<sup>2</sup>

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

- 1) Average number of fills for all patients is calculated as Total Rx / Total Patients.
- 2) Total Rx/Patient Count

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## IMVEXXY Investment Across Multiple Levers

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### Sales Force

- Promoted by all Sales Representatives
- 4,200 current heavy writers representing 20% of high volume VVA writers
- Goal to increase depth of writing among 20,000 prescribers who have prescribed IMVEXXY

### Marketing

- Increased overall funding
- Heavier investment in consumer marketing throughout the year

**2020 Goal:** surpass Premarin<sup>®</sup> Vaginal Cream on a monthly prescription basis by year end

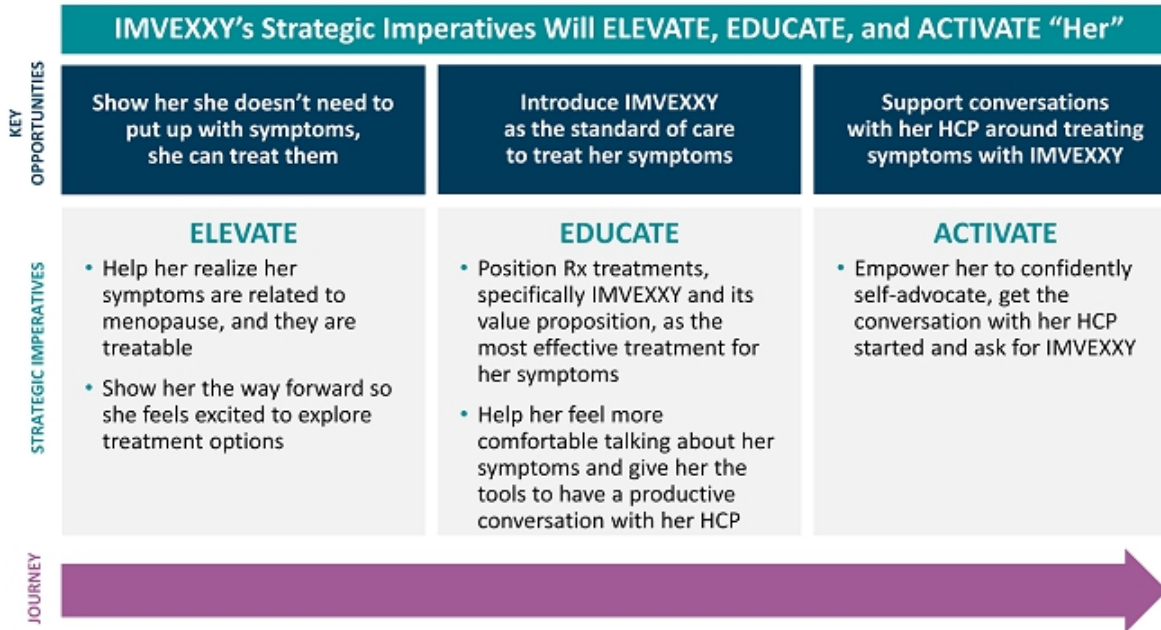
- Current average monthly TRX of Premarin Vaginal Cream: 80K TRx\*

\*IQVIA data

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# Increase Awareness of IMVEXXY That Creates the Standard of Care for VVA Patients



# BIJUVA's Unique Product Attributes

## BIJUVA OFFERS<sup>1,2,4-7</sup>



### THE CONVENIENCE OF ONE

The convenience of a single-capsule combination of 2 hormones, which may improve compliance



### A PLANT-BASED TREATMENT

Estradiol and progesterone are plant-based, not animal-sourced, and contain no peanut allergens

## BIJUVA WAS STUDIED IN A 1-YEAR CLINICAL TRIAL<sup>1,2,8,9</sup>



### DEMONSTRATED EFFICACY

A sustained steady state of estradiol reduced the frequency and severity of hot flashes<sup>\*</sup>



### WEIGHT AND BLOOD PRESSURE

No demonstrated impact on weight or blood pressure



### ENDOMETRIAL PROTECTION

Demonstrated endometrial safety<sup>†</sup> and >90% amenorrhea rates<sup>‡</sup>



### MAMMOGRAMS

No clinically meaningful changes in mammograms

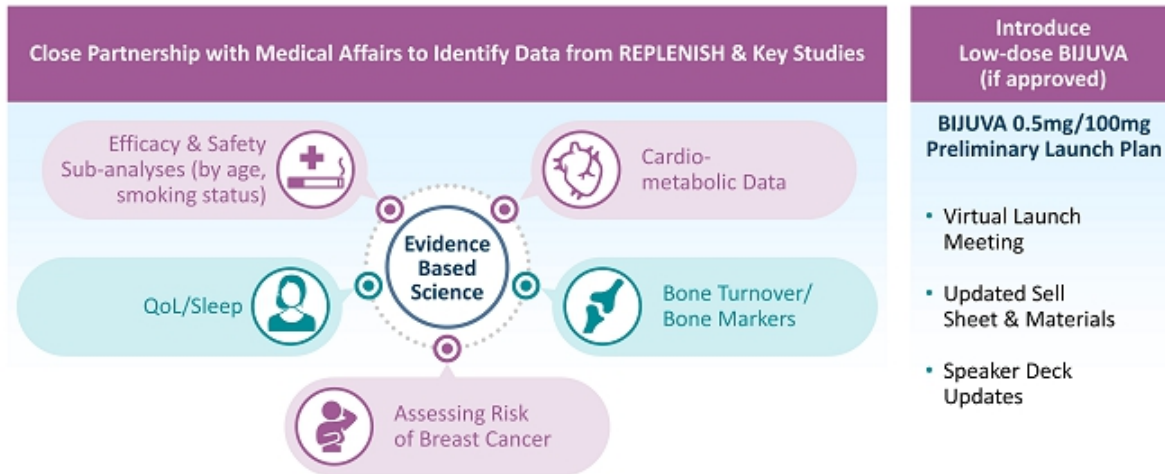
<sup>\*</sup> Efficacy was evaluated in a 12-week substudy. The pharmacokinetics of BIJUVA show a steady state of estradiol that is sustained over 24 hours. The steady state is achieved at 7 days.<sup>7</sup>

<sup>†</sup> Endometrial hyperplasia has been reported to occur at a rate of 51% in women receiving BIJUVA, which is consistent with the expected incidence rate in a menopausal population.<sup>1</sup>




<sup>‡</sup> The cumulative amenorrhea rate in patients receiving BIJUVA was 56.1% with rates increasing over time. Cumulative amenorrhea was defined as the absence of bleeding or spotting for a cumulative period from cycle 1 to 11.<sup>1,2</sup>

References: 1. Mirkin S. Evidence on the use of progesterone in menopausal hormone therapy. *Clinocentric*. 2018;21(4):346-354. 2. Prometrium [package insert]. Marietta, GA: Solvay Pharmaceuticals, Inc; 2009. 4. The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2017;24(7):728-753. 5. Goodman NF, Cahn RL, Ginsburg SR, Katz JA, Woodle DE; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the diagnosis and treatment of menopause. *Endocr Pract*. 2011;17 Suppl 6:1-25. 6. Simon JA. What if the Women's Health Initiative had used transdermal estradiol and oral progesterone instead? *Menopause*. 2014;21(7):1-15. 7. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 556: Postmenopausal estrogen therapy: route of administration and risk of venous thromboembolism. *Obstet Gynecol*. 2013;121(4):887-890. 8. Canonico M, Foumier A, Concaillon L, et al. Postmenopausal hormone therapy and risk of idiopathic venous thromboembolism: results from the E3N cohort study. *Arterioscler Thromb Vasc Biol*. 2010;30(2):340-345. 9. Birkawicz M. Menopausal hormone therapy and venous thromboembolism. *Prz Menopauzowy*. 2014;13(5):267-272.

# Elevate the BIJUVA Scientific Narrative & Reset Foundational Knowledge to Drive Meaningful Differentiation



# BIJUVA Targeted Approach in 2020 Preparing for Full Launch in 2021

Menopause Specialist Deployment	Targeted approach supporting BIO-IGNITE	Potential Second Dose
	 <p>A dedicated team of sales reps and the TXMD BIO-IGNITE staff will focus their efforts to grow BIJUVA through BIO-IGNITE partners</p> <hr/> <p><b>163 pharmacies live</b></p> <hr/>	 <hr/> <p><b>PDUFA November 2020</b></p> <hr/>



# FINANCIAL UPDATE

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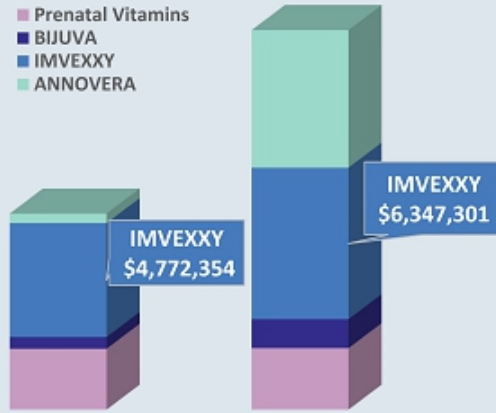


# Trend in Total Net Revenue and Calculated Net Revenue Per Unit



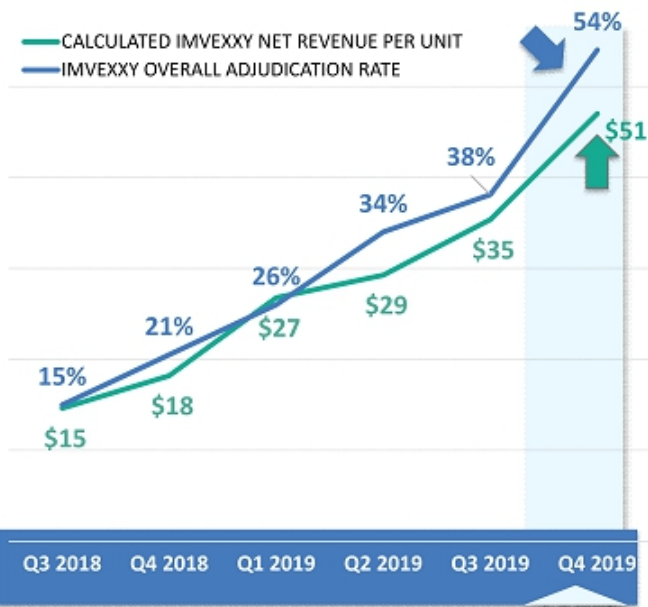
## Net Revenue by Product

- Prenatal Vitamins
- BIJUVA
- IMVEXXY
- ANNOVERA



Q3 2019

Q4 2019

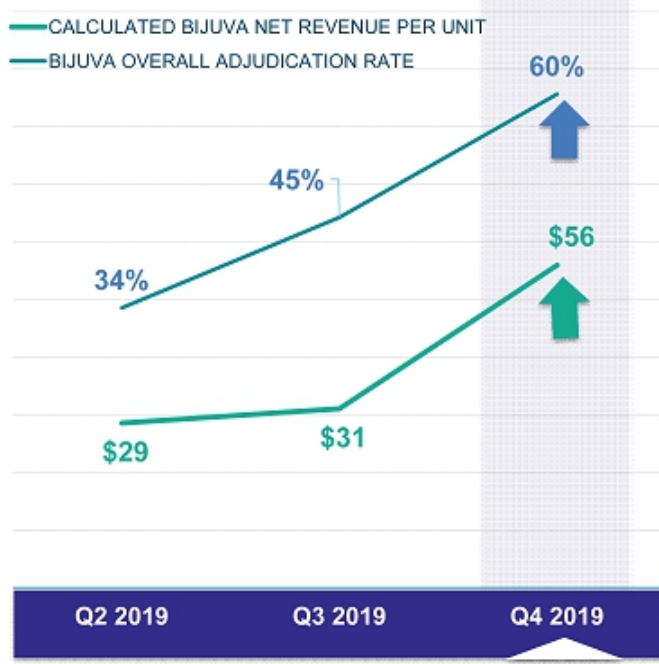
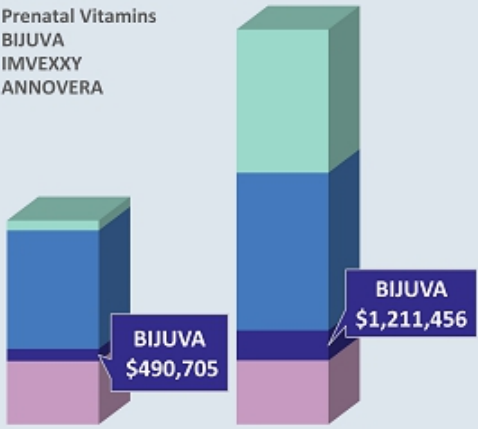


\* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period

# Trend in Total Net Revenue and Calculated Net Revenue Per Unit

## Net Revenue by Product

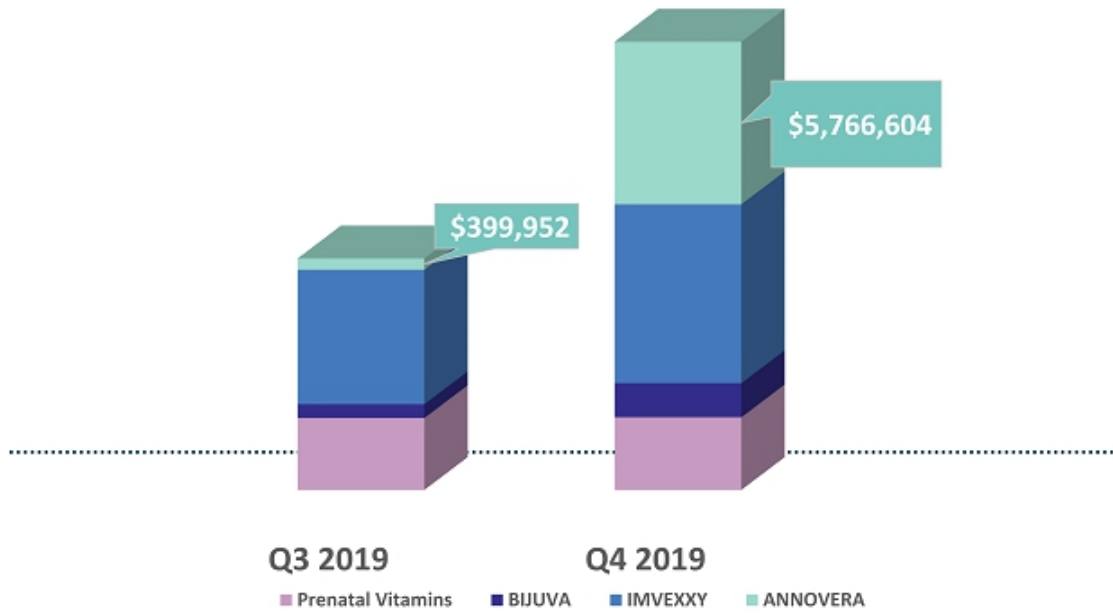
- Prenatal Vitamins
- BIJUVA
- IMVEXXY
- ANNOVERA



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



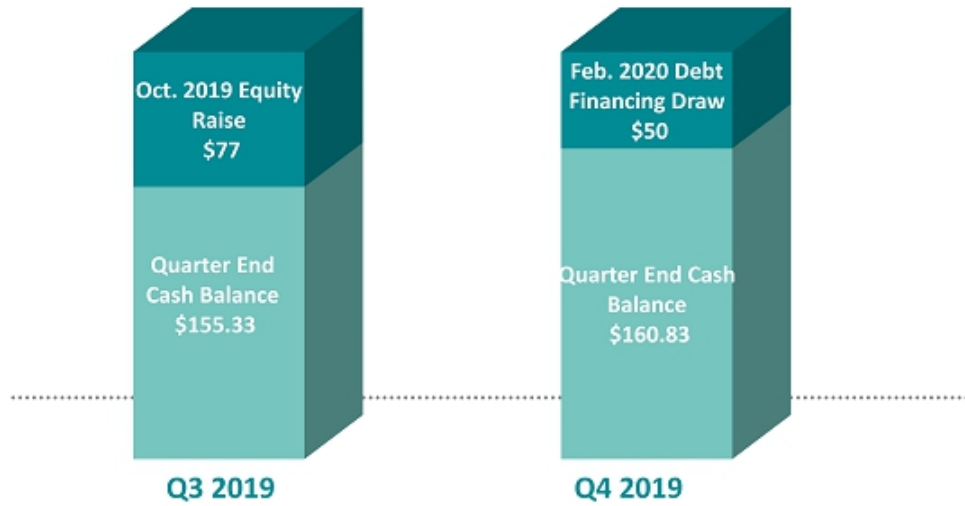
# ANNOVERA Net Revenue Actual



## Cash Balance at End of Each Quarter with Equity Raise/Debt Funding Post Quarter End

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(Millions)



## 2020 Cost Containment Measures

### Goal to reinvest the savings into marketing initiatives

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#### Drive Net Revenues:

- Invest appropriate financial resources to drive net revenue growth for our brands



#### Control Operating Expenses:

- Scrutinized internal cost structure and reduced spend on the following:
  - Non-revenue generating projects
  - Headcount optimization / reduction
  - Eliminated multiple clinical development roles
  - Paused pipeline development projects

## 2020 Financial Guidance

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### Annual Net Revenue Guidance

- Company projects 2020 net product revenue to be between \$90M to \$110M

### Key Assumptions:

- Net product revenue during the second half of the year will be significantly larger than the first half with the majority coming from ANNOVERA and IMVEXXY
- High deductible and annual copay resets expected to impact 1Q20 net revenue for the menopause products
  - Expect 1Q20 net revenue to come in below 4Q19 net revenue
  - 1Q20 industry wide headwind built into our annual 2020 financial guidance

\* Note: In 2020, the company will utilize Symphony Health IDV national data for reporting prescriptions dispensed to patient's by pharmacies as we believe Symphony Health data most accurately reflects the data.

## 2020 Goals & Milestones

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- Full launch of ANNOVERA for TXMD's sales force will begin on March 1<sup>st</sup>
- Leverage new distribution channels to enter new markets that create additional revenue opportunity outside TXMD's direct sales and marketing efforts
- For IMVEXXY, goal is to pass the VVA branded leader, Premarin vaginal cream, on a monthly prescription basis by the end of 2020
- For BIJUVA, utilize menopause specialist sales force to provide the right focus to build the foundation and allow us to scale BIJUVA in the coming years
- Become EBITDA positive in 2021

# 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 Total 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

# The Power of a Women's Health Portfolio

**Annovera**<sup>®</sup>  
(segestrone acetate and  
ethinyl estradiol vaginal system)  
Delivers 0.15 mg/0.025 mg per day

**vitaMedMD**<sup>®</sup>  
Prenatal Vitamins

**Annovera**<sup>®</sup>  
(segestrone acetate and  
ethinyl estradiol vaginal system)  
Delivers 0.15 mg/0.025 mg per day

**Bijuva**<sup>®</sup> 1mg/0.02mg  
(estradiol and progesterone) capsules

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



CONTRACEPTION

PRENATAL  
CARE

CONTRACEPTION/  
FAMILY PLANNING -  
PERIMENOPAUSE

VASOMOTOR  
SYMPTOMS

DYSpareunia  
(Vulvar & Vaginal  
Atrophy)

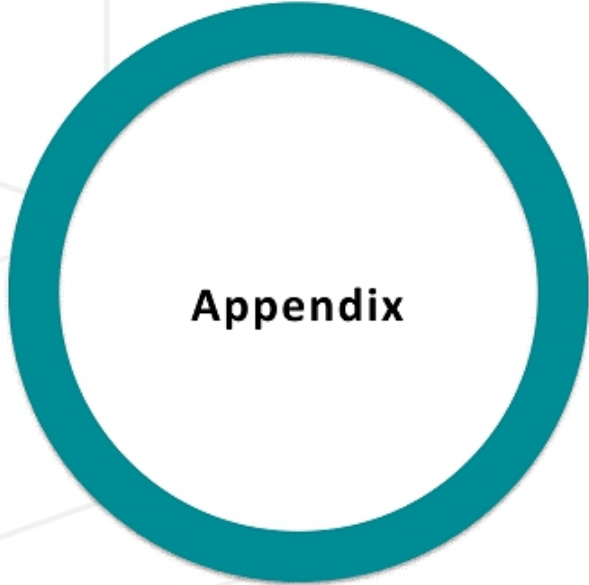


REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

TherapeuticsMD<sup>®</sup>



# Appendix





# Build out of Commercial Expertise

## Commercial Leadership Team

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### **Chris Gish – Sales Lead**

- Senior Sales Leader with 29 years of experience in pharmaceutical sales leadership
- Experience in large and small pharmaceutical companies including Pfizer, Sunovion, Alder-Bio
- Have launched 20+ brands over the course of his career
- Unique expertise in optimizing pharmaceutical sales organizations



### **Tyra Riehl – Training Lead**

- Senior leader with expertise in sales training and leadership development
- 22 years in small and large biotech and pharmaceutical companies including Searle, Sunovion, Quest and Alkermes



### **Mike Steelman – Market Access Lead**

- Senior leader access positions at Pfizer and Sanofi with United States and International responsibility
- 22 years of pharma experience with 13 years in access
- Was responsible for 1/3 of Pfizer's National Payor Accounts including government sector



### **Kristen Landon – Marketing Lead**

- Women's Health commercial leader with prior tenures at Allergan, Radius Health, and Sprout
- 24 years' experience in pharmaceutical marketing, sales, sales leadership, and business development
- Category experience in contraception, menopause, osteoporosis, sexual dysfunction, infertility, and infections
- Brands include Lo Loestrin, Estrace, Tymlos, Generess, Liletta, ella, Addyi, Crinone, and Solosec



### **Erika Guay – Menopause Brand Lead**

- Senior leader with over 15 years of marketing experience at Pfizer
- Brand experience across multiple categories including, Women's Health, Depression, Cardiovascular & Dermatology



### **Jerrold McRae- Reproductive Brand Lead**

- Sales and marketing and strategy leader at Pfizer for 14 years
- Brand experience across multiple categories including Women's Health (Estring), Pain (Lyrica), Urology (Detrol LA, Viagra)



### **Dedra Lyden – Strategic Partnerships**

- Launched and continues to lead the expansion of Bio-Ignite
- 16 years of Pharmaceutical experience across BD, Sales, Sales leadership

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## Understanding Contraceptive Reimbursement

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- Under the health reform law (Affordable Care Act), all benefit plans must cover certain Preventative Care Medications like contraceptives without a generic equivalent at 100% - without charging a copay, coinsurance or deductible
- The following slides are examples of how these programs are structured with two of the largest Payers

# OptumRx Preventative Care List Adoption \$0 Cost Share Products

“Under the Health reform law (Affordable Care Act), benefit plans must cover certain Preventative Care Medications at 100% - without charging a copay, coinsurance or deductible”

**OPTUMRx**  
For members  
Effective: January 1, 2020

**Preventive Care Medications**  
\$0 Cost-Share Medications & Products<sup>1, 2, 3</sup>

## Women's Health: Birth Control Products continued...

<p><b>Generic Ortho Tri-Cycle sold as:</b> Norgestimate/ethinyl estradiol Tri-Estaryl Tri Remynor Tri-Linyah Tri-Mini Tri-Previon Tri-Sprintec Tri-Vyllera Triessa</p>	<p><b>Generic Ortho Tri-Cycle Lo sold as:</b> Norgestimate/ethinyl estradiol Tri-Lo-Dailyrl Tri-Lo-Mardia Tri-Lo-Mini Tri-Lo-Sprintec Tri-Vyllera Lo Triessa Lo</p>	<p><b>Generic Ovcon-35 sold as:</b> Bischof Inqity Mithril Vyhena Zandiant</p>	<p><b>Generic Ovral sold as:</b> Ogestrin</p>	<p><b>Generic Quartette sold as:</b> Fajostin Levonelle/ethinyl estradiol Rivella</p>	<p><b>Generic Satylol sold as:</b> Drospirenone/ethinyl estradiol Tydemy</p>	<p><b>Generic Seasonale sold as:</b> Inmelle Jolesse Levonelle/ethinyl estradiol Quaperse Sofakri</p>	<p><b>Generic Seasonique sold as:</b> Athena Athyra Carnissa Dapive Levonelle/ethinyl estradiol Simpseal</p>	<p><b>Generic Tri-Norinyl 28 sold as:</b> Acanite Lena</p>	<p><b>Generic Triphasil sold as:</b> Empress-28 Levonest Levonelle/ethinyl estradiol Mystra Triora-28</p>	<p><b>Generic Viorin 28 3-0-0.02mg sold as:</b> Drospirenone/ethinyl estradiol Dorila 3-0-0.02mg Oyeda 3-0-0.02mg Zarah 3-0-0.02mg Zurandimine 3-0-0.02mg</p>	<p><b>Generic Yaz 2-4-0.02mg sold as:</b> Drospirenone/ethinyl estradiol Garni Jarmie Lo-Sumandini Lorina Nikki Vestura</p>	<p><b>Birth Control Patches (Transdermal)</b> Generic Ortho Evra sold as: Xulane</p>	<p><b>Birth Control Shots (Injections)</b> Medroxyprogesterone 150mg IM (Generic Depo-Provera contraceptive)</p>	<p><b>Emergency Birth Control</b> Ella Levonorgestrel 1.5mg, generic Plan B One-Step</p>	<p><b>Over-The-Counter (OTC) Birth Control</b> (must have a prescription and get them from a network pharmacy for OptumRx to cover the costs) Contraceptive films (e.g. VCF Vaginal) Contraceptive foams (e.g. VCF Vaginal Aet) Contraceptive gels (e.g. Gynol II, Shur-Seal, VCF Vaginal) FC female (female condoms) Generic emergency birth control (e.g. Aftera, Ecotra 12, Ecotra O5, Levonorgestrel 1.5mg, My Choice, My Way, New Day, Next Choice, Opkon, Option 2, React, Take Action) Today Sponge</p>	<p><b>Birth Control IUD's and Implants</b> Kyleena Liletta Mirena Nexplanon Paragard Skyla Some methods of birth control, such as IUD and implants, may be available through your medical benefit and not your pharmacy benefit.</p>
	<p><b>Generic For Ortho Tri-Cycle Lo sold as:</b> Norgestimate/ethinyl estradiol Tri-Lo-Dailyrl Tri-Lo-Mardia Tri-Lo-Mini Tri-Lo-Sprintec Tri-Vyllera Lo Triessa Lo</p>	<p><b>Generic Ovcon-35 sold as:</b> Bischof Inqity Mithril Vyhena Zandiant</p>	<p><b>Generic Ovral sold as:</b> Ogestrin</p>	<p><b>Generic Quartette sold as:</b> Fajostin Levonelle/ethinyl estradiol Rivella</p>	<p><b>Generic Satylol sold as:</b> Drospirenone/ethinyl estradiol Tydemy</p>	<p><b>Generic Seasonale sold as:</b> Inmelle Jolesse Levonelle/ethinyl estradiol Quaperse Sofakri</p>	<p><b>Generic Seasonique sold as:</b> Athena Athyra Carnissa Dapive Levonelle/ethinyl estradiol Simpseal</p>	<p><b>Generic Tri-Norinyl 28 sold as:</b> Acanite Lena</p>	<p><b>Generic Triphasil sold as:</b> Empress-28 Levonest Levonelle/ethinyl estradiol Mystra Triora-28</p>	<p><b>Generic Viorin 28 3-0-0.02mg sold as:</b> Drospirenone/ethinyl estradiol Dorila 3-0-0.02mg Oyeda 3-0-0.02mg Zarah 3-0-0.02mg Zurandimine 3-0-0.02mg</p>	<p><b>Generic Yaz 2-4-0.02mg sold as:</b> Drospirenone/ethinyl estradiol Garni Jarmie Lo-Sumandini Lorina Nikki Vestura</p>	<p><b>Birth Control Patches (Transdermal)</b> Generic Ortho Evra sold as: Xulane</p>	<p><b>Birth Control Shots (Injections)</b> Medroxyprogesterone 150mg IM (Generic Depo-Provera contraceptive)</p>	<p><b>Emergency Birth Control</b> Ella Levonorgestrel 1.5mg, generic Plan B One-Step</p>	<p><b>Over-The-Counter (OTC) Birth Control</b> (must have a prescription and get them from a network pharmacy for OptumRx to cover the costs) Contraceptive films (e.g. VCF Vaginal) Contraceptive foams (e.g. VCF Vaginal Aet) Contraceptive gels (e.g. Gynol II, Shur-Seal, VCF Vaginal) FC female (female condoms) Generic emergency birth control (e.g. Aftera, Ecotra 12, Ecotra O5, Levonorgestrel 1.5mg, My Choice, My Way, New Day, Next Choice, Opkon, Option 2, React, Take Action) Today Sponge</p>	<p><b>Birth Control IUD's and Implants</b> Kyleena Liletta Mirena Nexplanon Paragard Skyla Some methods of birth control, such as IUD and implants, may be available through your medical benefit and not your pharmacy benefit.</p>
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References:  
1. <https://one.walmart.com/content/dam/themepage/pdfs/OptumRxPreventiveCareMedications:2020.pdf>  
2. [https://mynmhc.org/\\$0-medications-list.pdf](https://mynmhc.org/$0-medications-list.pdf)

# CVS Preventative Care List Adoption \$0 Cost Share Products

## LET'S TALK PREVENTION



October 2019

### YOUR NO-COST PREVENTIVE SERVICES

Preventive services help you stay healthy. A doctor isn't someone to see only when you're sick. Doctors also provide services that help prevent medical problems and help keep you healthy. Staying healthy can help you:

- Live a fuller life
- Save your hard-earned money

Your health plan now offers certain preventive service benefits at no cost to you. This means you don't have to pay a copay<sup>1</sup> or coinsurance, even if you haven't met your deductible. These no-cost benefits are part of the Affordable Care Act (ACA). They include:

- Medicine and supplements to prevent certain health conditions for adults, women and children
- Medicine and products for quitting smoking or chewing tobacco (tobacco cessation)
- Medicine used prior to screenings for certain health conditions in adults
- Vaccines and immunizations to prevent certain illnesses in infants, children and adults
- Contraceptives for women

CVS Caremark<sup>SM</sup> works with your health plan to provide these benefits. The following lists<sup>1</sup> explain:

- Which medicines, supplements, health-related products or vaccines are covered
- Who they are covered for (such as children up to age six or adults age 65 or older)
- What health condition or illness they help prevent
- Other important information

### TIPS FOR USING THE LISTS

- Take these lists with you each time you or your family has a checkup or yearly exam.

- Your doctor must write a prescription for these preventive services to be covered by your plan, even if they are listed as over-the-counter. For example, tablet, capsule, liquid, syrup or chewable tablet.
- "Generic" or "brand name" is listed if only that product type is covered.
- Treatment recommendations may vary. Please call your doctor or pharmacist if you have questions about your health or medication<sup>1</sup>.
- Other rules, limits and exclusions may apply. Please contact your health plan to learn about your coverage<sup>1</sup>.
- An exceptions process is available for circumstances that fall outside the listed preventive services – such as, for example, a request for coverage of a brand name product because the listed generic products are not medically appropriate. A process is also available for coverage of preventive services without cost sharing for plan members identifying with a gender that differs from the member's sex assigned at birth – such as, for example, a request for coverage of contraceptives or primary prevention of breast cancer for transgender members.

### LEGEND:

chew = chewable	cap = capsule	FE = ferrous sulfate (iron)	EE = ethyl ester extract	hr = hour	IM = intramuscular	IJ = international unit	mg = milligram	ml = milliliter
OTC = over-the-counter product	Rx = prescription product	soln = solution	SR = sustained release	susp = suspension	tab = tablet	TD = transdermal		

## WOMEN'S HEALTH PREVENTIVE SERVICES<sup>1</sup>

### OTHER CONTRACEPTIVES<sup>1</sup>

- Generics and brand name only if a generic isn't available
- Generics are in **italics>. Brand-names are CAPITALIZED**
- Brand name will no longer be supplied at no cost when the generic becomes available
- Brand-names listed in *(pink)* and in brackets are for your reference only

#### Brand-Name Oral Contraceptives (Rx)

- BALCOLTRA
- LO LOESTRIN FE
- NATAZIA
- SLYND
- TAYTULLA

#### Intrauterine Devices, Subdermal Rods and Vaginal Rings (Rx)

- MEXPLANON
- MIRENA
- SKYLA
- LILETTA
- KYLEENA
- PARAGARD T 380A
- NUVARING

#### • **ASKOVIA**

#### Transdermal Patches (Rx)

- Xulane

#### Injectables (Rx)

- DEPO-SUBQ-PROVERA 104
- Medroxyprogesterone acetate 150 mg (DEPO-PROVERA)

#### Barrier Methods (Rx)

- *Diplomig*
- MILEX WIDE-SEAL
- OMNIFLEX COIL SPRING SILICONE
- CAYA

#### Cervical Caps

- FEMCAP

#### Emergency Contraception (Rx or OTC)

- ELLA
- Levonorgestrel 1.5 mg tablet, Aftera, Econtre EZ, Econtre OS, My Choice, My Way, New Day, Option, Option 2, Preventeza, Take Action, Read (PLAN B)

#### Female Condoms (OTC)

- FC-2

#### Vaginal Sponges (OTC)

- TODAY

#### Spermicides (OTC)

- ENCARE VAGINAL SUPPOSITORIES
- GYNOL II GEL 3%
- Nonyl-9 vaginal gel 4%, VCF vaginal Contraceptive Gel (CONCEPTROL GEL 4%)
- SHUR-SEAL GEL 2%
- VCF VAGINAL FILM 28%
- VCF VAGINAL FOAM 12.5%

### BREAST CANCER PREVENTION

Primary Prevention of Breast Cancer in women<sup>2</sup> 35 years of age and older, who are at an increased risk.

#### Generics, oral tablets (Rx)

- Raloxifene HCl tab 60 mg
- Tamoxifen citrate tab 10 mg and 20 mg

### References:

1. [https://www.caremark.com/portal/asset/NoCost\\_Preventive\\_List.pdf](https://www.caremark.com/portal/asset/NoCost_Preventive_List.pdf)

TherapeuticsMD<sup>®</sup>

## ANNOVERA Deal Terms

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### 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

\*\*Already paid by TXMD to Population Council