

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): January 14, 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

Not Applicable  
(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
<b>Common Stock, par value \$0.001 per share</b>	<b>TXMD</b>	<b>The Nasdaq Stock Market LLC</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

**Item 2.02 Results of Operations and Financial Condition.**

TherapeuticsMD, Inc., a Nevada corporation (the “Company”), is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation dated January 2020, which will be used in discussions with investors and analysts beginning on January 14, 2020 and at the 38th Annual J.P. Morgan Healthcare Conference on January 15, 2020 at 12:30 p.m. EST, and which may also be used, in whole or in part, and subject to modification, at subsequent meetings with investors or analysts. The investor presentation, which is incorporated herein by reference, discloses, among other information, certain preliminary financial information for the quarter ended December 31, 2019.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Items 2.02 and 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 7.01 Regulation FD Disclosure.***Investor Presentation*

The disclosure in Item 2.02 above is hereby incorporated by reference into this Item 7.01.

*Mitchell Krassan 10b5-1 Trading Plan*

In December 2019, Mitchell Krassan, the Chief Strategy & Performance Officer of the Company, entered into a 10b5-1 trading plan (the “Krassan 10b5-1 Plan”) with respect to an aggregate of 789,658 ten-year options to acquire common stock, \$0.001 per share (“Common Stock”), of the Company, with exercise prices equal to \$0.19 and \$0.20 per share. The options expire in May 2020 and September 2020. Pursuant to the terms of the Krassan 10b5-1 Plan, Mr. Krassan intends to exercise these options and sell the underlying shares of Common Stock in two blocks in early February 2020 and early April 2020.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits*

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
<a href="#">99.1</a>	TherapeuticsMD, Inc. Presentation dated January 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: January 14, 2020

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

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TherapeuticsMD®

*For Her. For Life.*

JP Morgan Conference  
*January 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 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 thereunder; 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, 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.

This presentation also includes financial amounts which are unaudited and preliminary, and do not present all information necessary for an understanding of our financial condition as of December 31, 2019. The review of our consolidated financial statements for the three months and 12 months ended December 31, 2019 is ongoing and could result in changes to these amounts due to the completion of financial closing procedures, final adjustments and other developments that may arise between now and the time the consolidated financial statements for the three months and 12 months ended December 31, 2019 are finalized and publicly released. Our independent registered public accounting firm, Grant Thornton LLP, has not audited, reviewed, or compiled these estimates. See “Risk factors,” “Cautionary statement about forward looking information,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our financial statements and related notes included elsewhere in the reports we file from time to time with the SEC.

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# Portfolio Approach to Women's Health

## Empowering Women For Life



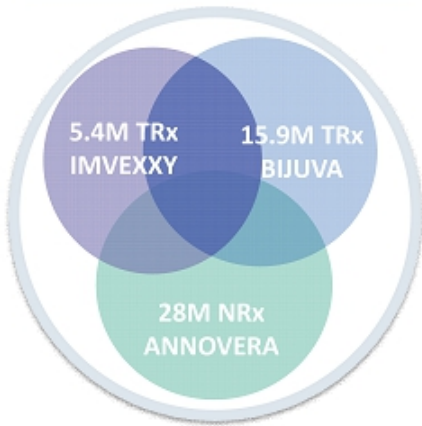
- Innovative customer centric products, chronic conditions, large markets
- Products transition from one to the next through the various stages of life
  - contraception → pregnancy → contraception → vasomotor symptoms → vulvar and vaginal atrophy
- 200 sales representatives focused on OB/GYN women's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

# The Power of A Women's Health Portfolio

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

## Overlapping Prescribers & Patients

## The Power of 3



REPRODUCTIVE  
PORTFOLIO

MENOPAUSE  
PORTFOLIO



1) Symphony Health Integrated Database (2019).

TRx = Total prescriptions  
NRx = New prescriptions



# FINANCIAL UPDATE

TherapeuticsMD<sup>®</sup>





# Financial Update

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- **Preliminary Unaudited 4Q19 Financial Results**

- Achieved FDA-approved product consolidated net revenue of greater than \$11M
- Made milestone payment of \$20M to Population Council for successful first commercial batch release of ANNOVERA

- **TPG Sixth Street Partners (Sixth Street) Loan Facility Update**

- Preparing funding notice to Sixth Street for \$50M loan tranche tied to 4Q19 FDA-approved product consolidated net revenue of greater than \$11M
  - Expect to receive loan tranche proceeds in March 2020
- Amendment for second \$50M loan tranche completed in December 2019
  - No longer required that ANNOVERA be designated as a new category of birth control by FDA
  - Availability of capital at Sixth Street's sole discretion either contemporaneously with delivery of Q2 2020 financial statements or at such earlier date as Sixth Street may consent to

- **2020 Financial Guidance**

- Company plans to provide full-year 2020 total net revenue guidance with 4Q19 earnings in February



# PAYER OVERVIEW

TherapeuticsMD<sup>®</sup>



## Significant Payer Coverage and Growing

	Coverage Today January 15 <sup>th</sup>	Target Coverage Year-end 2020
<b>ANNOVERA</b>		
Commercial	76%*	75%
<b>IMVEXXY</b>		
Commercial	72%	75%
Part D	29%	70%
<b>BIJUVA</b>		
Commercial	57%	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>**

**Payers starting reimbursement 1Q20:**

ANNOVERA: OptumRx/preventative, Envision and ProcureRx

IMVEXXY: Aetna

BIJUVA: Envision and ProcureRx

Source: MMIT January 2, 2020

\*ANNOVERA unrestricted commercial coverage 65%, step 11%

# Strategic Priorities for 2020

## Execution and Focus

**2020**

Full portfolio  
launch to leverage  
commercial  
investments



### Drive Net Revenues:

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



### Control Operating Expenses:

- Control internal spend in non-revenue generating functions
- Scrutinize internal cost structure to reduce spend
- Optimize supply chain/cost of goods
- Leverage internal capabilities vs external resources

# 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



# PRODUCT OVERVIEW & COMMERCIAL UPDATES

TherapeuticsMD<sup>®</sup>



# 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**  
(segestrone 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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The logo for Annovera is centered in the upper half of the page. It features the brand name 'Annovera' in a blue, sans-serif font with a registered trademark symbol. Below the name, the active ingredients '(segestrone acetate and ethinyl estradiol vaginal system)' are listed in a smaller, grey font. Underneath that, the dosage 'Delivers 0.15 mg/0.013 mg per day' is provided in an even smaller font. The background of the top half of the page is light grey with faint, stylized molecular structures and circular patterns in shades of blue and green.

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

TherapeuticsMD<sup>®</sup>

Please see Important Safety Information, including BOXED WARNING, available at [www.annovera.com/pi.pdf](http://www.annovera.com/pi.pdf).



## 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 Growth Levers

## Empowering Women For Life



Contraceptive Market Covered with OB/GYN Overlap from Field Force and Marketing

Sales Force Launch

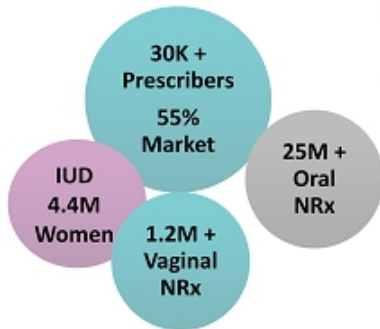
HCP Engagement

Consumer Communications and Partnership

- Full scale launch planned for March 1<sup>st</sup>
- Lead product designation for the sales force

- Focus on awareness, product features and benefits, and patient type
- HCP Media, Multi-channel and Peer to Peer

- Focus on **Empowerment** and **Control**<sup>1,2</sup>
- Disruptive Consumer Campaign
- Exploring Social Influencer Programs
- Exploring College Campus programs
- Online Platforms and Partnerships



Birth Control Market

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

# ANNOVERA is a Consumer-Focused Product

## Activate patients to try ANNOVERA that want a long-term, patient-controlled and procedure-free option

- It's all about "Control and Empowerment" of fertility and menstruation<sup>1,2</sup>
- Bringing the ring into mainstream awareness as an easy, comfortable and effective birth control option
- Consumer campaign launching March 1<sup>st</sup>

## Increase patient access and pull-through

- Leverage 3<sup>rd</sup> party partnerships with emerging companies to support patient access
- Partnered with WSI to market to the Department of Defense and Veteran's Administration
- Completed National Drug Rebate Agreement to enter into Medicaid
- Partnerships with consumer driven online platforms

Nulliparous women and those not in monogamous relationships

Ideal for adolescents and anyone who doesn't want to take a product everyday, but doesn'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)

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



 **Imvexxy**<sup>®</sup>  
(estradiol vaginal inserts)

Please see Important Safety Information, including BOXED WARNING, available at [www.imvexxy.com/pi.pdf](http://www.imvexxy.com/pi.pdf)

TherapeuticsMD<sup>™</sup>



# 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 2020 Focus

**2020 Goal:** surpass Premarin Vaginal Cream on a monthly basis by year end

- Current average monthly TRX of Premarin Vaginal Cream: 80K TRx\*
- IMVEXXY's December TRx is up to ~42,500 units
- Maintain or increase average fills for 2020 (Avg fills at 4.4 in 2019)

## MARKETING AND SALES FOCUS

### Provider Focus – Sales Force

- Focus on targets and increase depth of prescribing to move HCPs from Dabbler to Loyalist
- Right mix of calls and samples have a positive impact on NRx
- Supplement frequency with Emails/Direct Mail and Media
- Expand Medical to Medical

### MARKETING FOCUS:

#### Targets Not Yet Writing IMVEXXY

- ~20,000 HCP marketing targets have not yet prescribed IMVEXXY
- Avg ~77 VVA scripts per year/HCP

### FIELD SALES FOCUS:

#### Occasional Writers - Dabblers

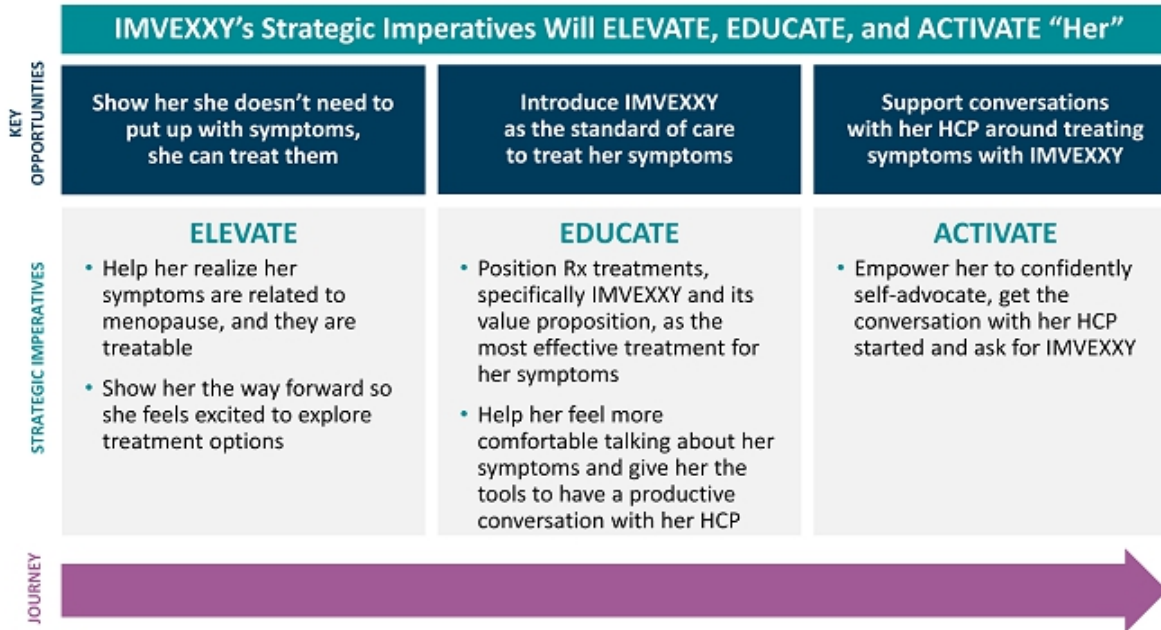
- ~7,800 HCPs - dabblers
- Accounted for 14% of 2019 IMVEXXY TRx
- 2019 Avg ~6.5 IMVEXXY TRx/HCP per year

#### Core Writers - Loyalists

- ~4,200 HCPs – core loyalists
- Accounted for 86% of 2019 IMVEXXY TRx
- 2019 Avg ~77 IMVEXXY TRx/HCP per year

\*IQVIA data

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





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

TherapeuticsMD<sup>®</sup>

■ ■ ■ ■ ■  
Please see Important Safety Information, including BOXED WARNING, available at [www.bijuva.com/pi/pdf](http://www.bijuva.com/pi/pdf)



# Menopause Portfolio Approach to Grow the Prescriber Base to Ensure Reach & Frequency



BIJUVA offers an FDA-approved, reliably manufactured, accessible, convenient & affordable treatment option

## Targeted approach supporting BIO-IGNITE



A dedicated team of sales reps and the TXMD BIO-IGNITE staff will focus their efforts to grow BIJUVA through BIO-IGNITE partners

*For prescribers who regularly partner with compounding pharmacies to treat women with hot flashes;*

*For women with hot flashes who prefer going to compounding pharmacies;*

**163** BIO-IGNITE compounding pharmacies live



# 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\*



### WEIGHT AND BLOOD PRESSURE

No demonstrated impact on weight or blood pressure



### ENDOMETRIAL PROTECTION

Demonstrated endometrial safety† and >90% amenorrhea rates‡



### MAMMOGRAMS

No clinically meaningful changes in mammograms

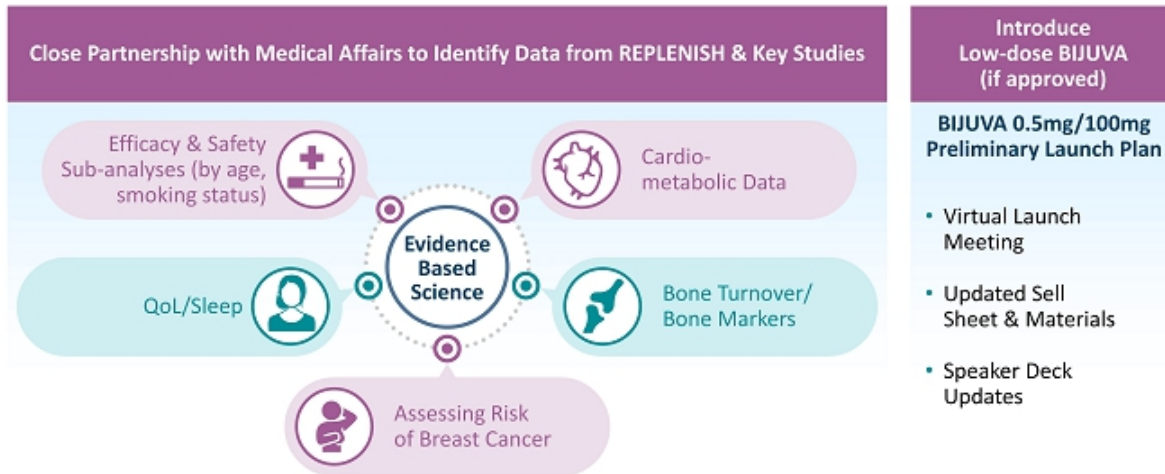
\* Efficacy was evaluated in a 12-week substudy. The pharmacokinetics of BIJUVA show a steady state of estradiol that is sustained over 24 hours. The steady state is achieved at 7 days.<sup>7</sup>

† 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>

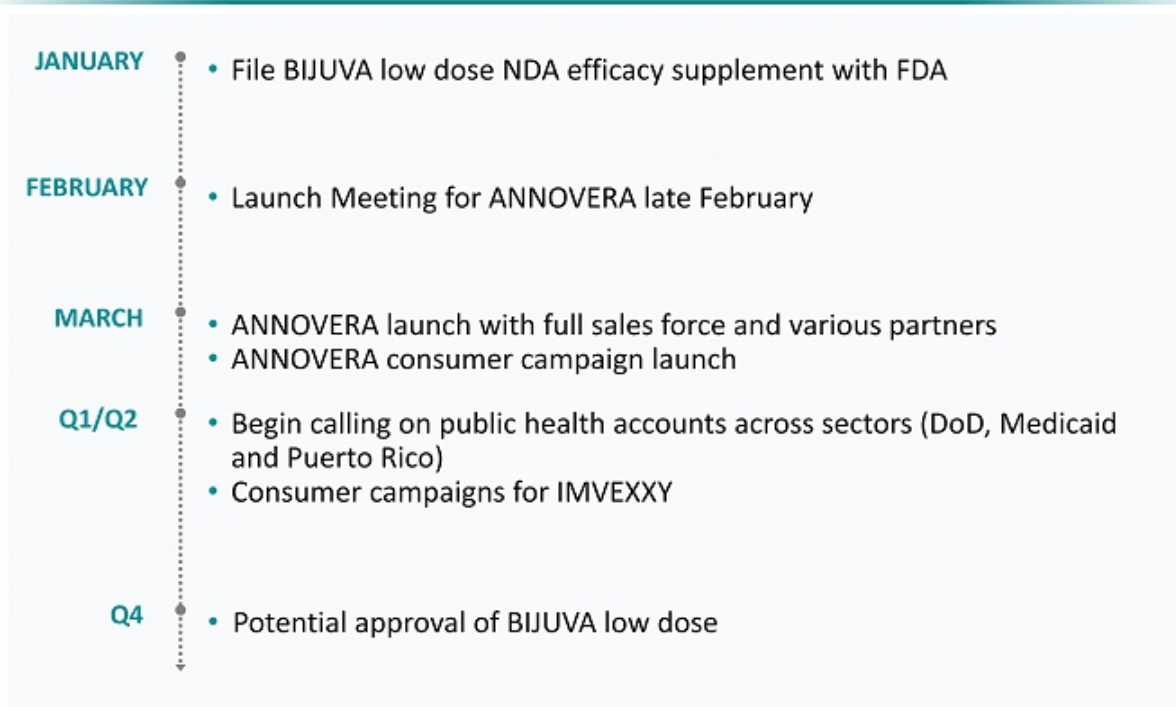
‡ The cumulative amenorrhea rate in patients receiving BIJUVA was 56.1% with rates increasing over time. Cumulative amenorrhea was defined as the absence of bleeding or spotting for a cumulative period from cycle 1 to 11.<sup>1,2</sup>

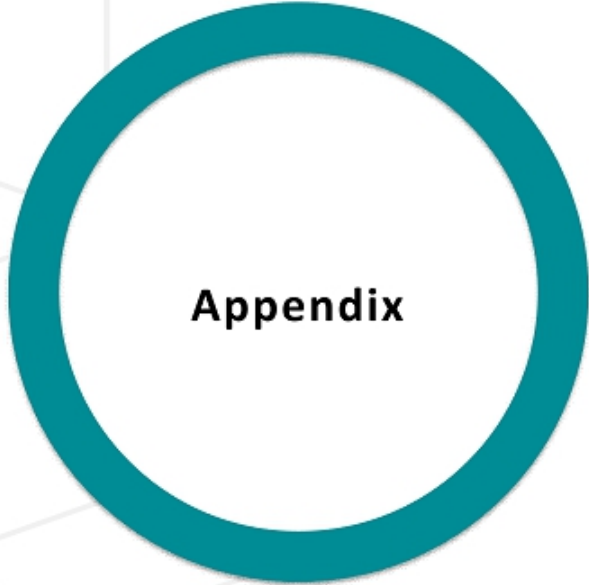
References: 1. Mirkin S. Evidence on the use of progesterone in menopausal hormone therapy. *Clinocentric*. 2018;21(4):346-354. 2. Prometrium [package insert]. Marietta, GA: Solvay Pharmaceuticals, Inc; 2009. 4. The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy 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. Birkawka 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



## 2020 Catalysts





# Appendix



# IMVEXXY Medicare Part D Payer Status

Top 8 Plans Account for ~83%  
of all Medicare Part D Pharmacy Lives<sup>1</sup>

Plan	% of Lives <sup>2</sup>	Status <sup>3</sup>
United	21%	Adjudicating as of 2/1/19
Awaiting Decision → Humana	18%	Bid submitted; awaiting decision
Awaiting Decision → CVS Caremark	14%	Bid submitted; awaiting decision
Awaiting Decision → Wellcare with Aetna lives	14%	Bid submitted; awaiting decision
Awaiting Decision → Express Scripts/ Cigna	8%	Bid submitted; awaiting decision
Kaiser	4%	Adjudicating maintenance pack as of 10/1/18 and starter pack as of 3/1/19
Awaiting Decision → Anthem	3%	Bid submitted; awaiting decision
Envision	1%	Adjudication will start Feb 2020

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

<sup>1</sup>MMIT JANUARY 2020

<sup>2</sup>Plan numbers as of January 2020

<sup>3</sup>Adjudication status from MMIT January 2020 and Account Insights

## 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-Vivitra Triessa</p>	<p><b>Generic Ortho Tri-Cycle lo sold as:</b> Norgestimate/ethinyl estradiol Tri-Lo-Diaryl Tri-Lo-Maria Tri-Lo-Mini Tri-Lo-Sprintec Tri-Vivitra Lo Triessa Lo</p>	<p><b>Generic Ovcon-35 sold as:</b> Bisphol Bisphol Mithril Viviana Zandiant</p>	<p><b>Generic Ovral sold as:</b> Ogestrin</p>	<p><b>Generic Quartette sold as:</b> Fayostin Levonelle/ethinyl estradiol Rivella</p>	<p><b>Generic Satylol sold as:</b> Drospirenone/ethinyl estradiol Tydemy</p>	<p><b>Generic Seasonale sold as:</b> Inmivale Joesse Levonelle/ethinyl estradiol Quaperse Sofakri</p>	<p><b>Generic Seasonique sold as:</b> Athena Athena Carnissa Dapive Levonelle/ethinyl estradiol Simpesal</p>	<p><b>Generic Tri-Norinyl 28 sold as:</b> Acanella Lemra</p>	<p><b>Generic Triphasil sold as:</b> Empress-28 Levonest Levonelle/ethinyl estradiol Mystra Triora-28</p>	<p><b>Generic Viamin 28 3-4-0.02mg sold as:</b> Drospirenone/ethinyl estradiol Dorilla 3-0.02mg Ovyda 3-0.02mg Zarah 3-0.02mg Zurandamine 3-0.02mg</p>	<p><b>Generic Yaz 3-4-0.02mg sold as:</b> Drospirenone/ethinyl estradiol 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 OS, Levonorgestrel 1.5mg, My Choice, My Way, New Day, Next Choice, Option, 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>Progestin Only Birth Control Pills</b> Generic Ortho Micronor &amp; Non-OD sold as: Carsiis 0.25mg Debitone Ethin 0.25mg Hebster 0.25mg Incasso 0.25mg Jencyte 0.25mg Jollette 0.25mg Laza 0.25mg Nova-4e 0.25mg Noveltrinon 0.25mg Novlyra 0.25mg Shardell Tulana 0.25mg Slynd</p>	<p><b>Birth Control Rings (Vaginal)</b> Annovera Nuva-Ring</p>						

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	oral = taken by mouth	OTC = over-the-counter product	Rx = prescription product	soln = solution	SR = sustained release	susp = suspension	tab = tablet	TD = transdermal
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## 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 **italics** 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
- MVA/RING

#### • ANNOVERA

#### 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

## 3Q 2019 Key Performance Metrics

### IMVEXXY



- IMVEXXY net revenue totaled \$4.8M for 3Q19 (up from \$3.1M for 2Q19)
  - Net revenue continued 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 improvement<sup>1</sup>

<sup>1</sup> \$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.

## Non-Dilutive Term Loan Financing

\$200M accessed to date with up to additional \$100M through specific milestones

	Amount (\$)	TXMD Company Milestone <sup>1</sup>	Contractual Timing	
Tranche 1	\$200M	Closing of the facility	Completed in April 2019	
Tranche 2	\$50M	As amended, TPG Sixth Street Partners ("Sixth Street") has sole and absolute discretion to make tranche available either contemporaneously with the delivery of the Company's financial statements for June 30, 2020 fiscal quarter or at such earlier date as Sixth Street may consent to	Delivery of financial statements for the fiscal quarter ending June 30, 2020 or at such earlier date as Sixth Street may consent to	
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)	

<sup>1</sup>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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