

## Therapeutics MD<sup>®</sup>

For Her. For Life.

# JP Morgan Conference January 2020

Building the Premier Women's Health Company

## 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 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

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.



## 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  $\rightarrow$  pregnancy  $\rightarrow$  contraception  $\rightarrow$  vasomotor symptoms  $\rightarrow$  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

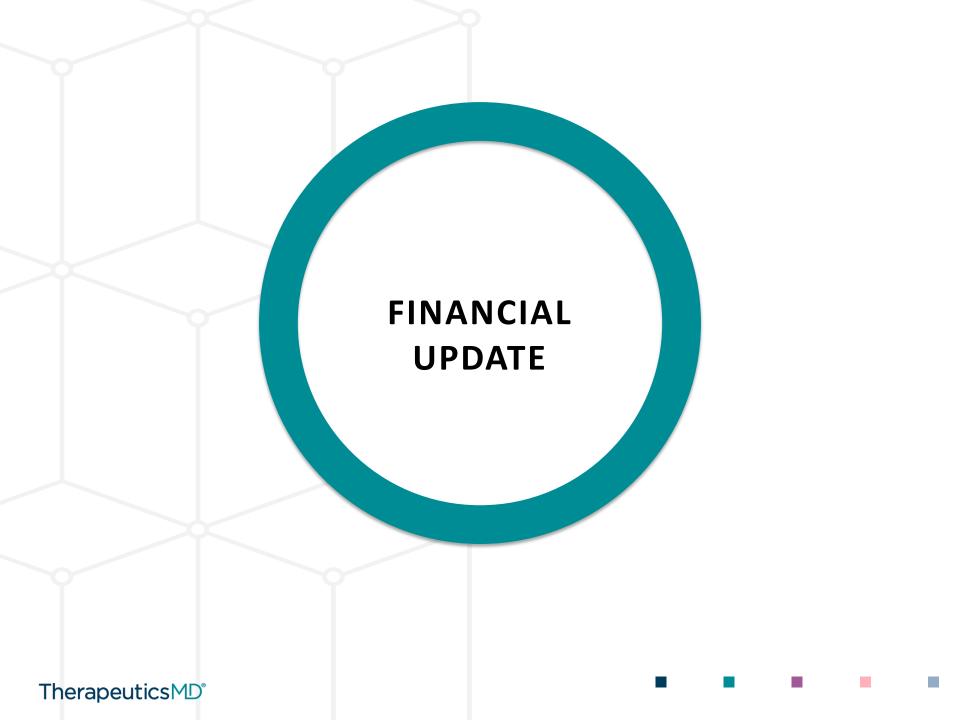
MENOPAUSE PORTFOLIO



1) Symphony Health Integrated Dataverse (2019).

TRx = Total prescriptions

NRx = New prescriptions



## **Financial Update**

#### Preliminary Unaudited 4Q19 Financial Results

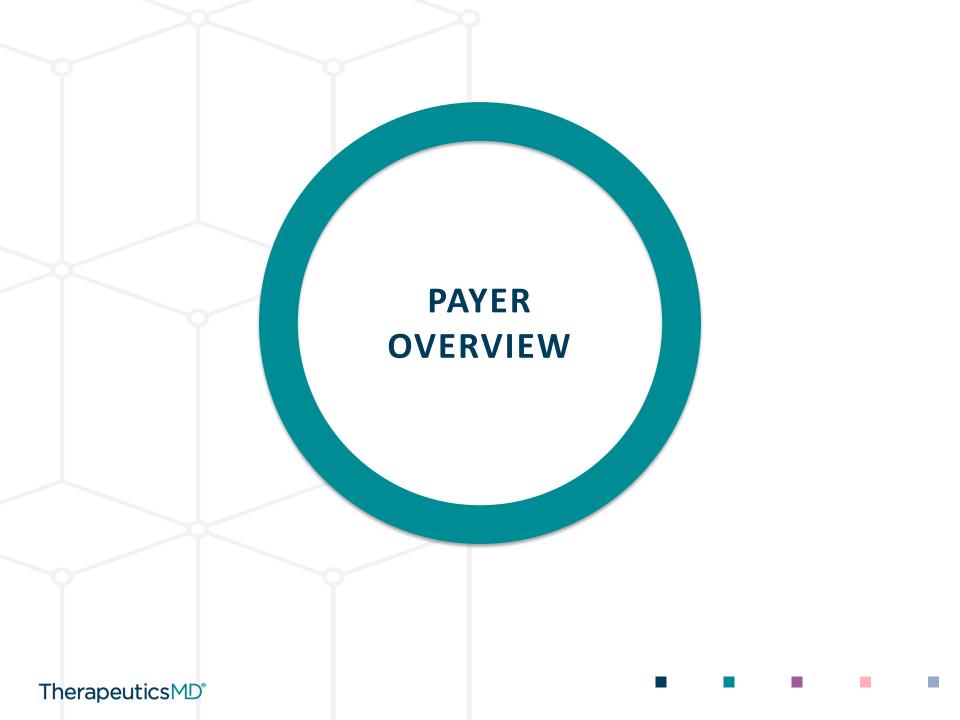
- Achieved FDA-approved product consolidated net revenue of greater than \$11M
- Made milestone payment of \$20M to Population Council for successful first commercial batch release of ANNOVERA

#### 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



## **Significant Payer Coverage and Growing**

	Coverage Today January 15 <sup>th</sup>	Target Coverage Year-end 2020
ANNOVERA		
Commercial	76%*	80%*
IMVEXXY		
Commercial	72%	75%
Part D	29%	70%
BIJUVA		
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 ProcareRx

**IMVEXXY**: Aetna

BIJUVA: Envision and ProcareRx

Source: MMIT January 2, 2020

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

# **Strategic Priorities for 2020 Execution and Focus**

2020

Full portfolio launch to leverage commercial investments





 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



## 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





- 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 1st

2



- 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



- 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







## **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%)\*\*

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



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

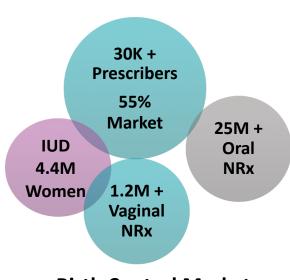
<sup>\*\*</sup>In clinical trials, 12% of participants discontinued due to an adverse reaction.

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

# ANNOVERA Growth Levers Empowering Women For Life



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



#### **Sales Force Launch**

- Full scale launch planned for March 1st
- Lead product designation for the sales force

#### **HCP Engagement**

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

## Consumer Communications and Partnership

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

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



**Birth Control Market** 



## **ANNOVERA** is a Consumer-Focused Product

#### Activate patients to try ANNOVERA that want a longterm, 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 1st

#### 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

vear (13 cycles)

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







## **IMVEXXY's Unique Product Attributes**







- 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/yr¹ (through December 2019)
  - Vaginal creams: average 1.5 fills/yr²
  - Vaginal tablets: average 3.5 fills/yr²



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

<sup>1)</sup> Average number of fills for all patients is calculated as Total Rx / Total Patients.

<sup>2)</sup> Total Rx/Patient Count



## **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 - Core Writers -- Dabblers

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

## Loyalists

- ~4.200 HCPs core loyalists
- Accounted for 86% of 2019 **IMVEXXY TRx**
- 2019 Avg ~77 **IMVEXXY TRX/HCP** per year

<sup>\*</sup>IQVIA data

## IMVEXXY's Strategic Imperatives Will ELEVATE, EDUCATE, and ACTIVATE "Her"

Show her she doesn't need to put up with symptoms, she can treat them

Introduce IMVEXXY as the standard of care to treat her symptoms

Support conversations with her HCP around treating symptoms with IMVEXXY

#### **ELEVATE**

- Help her realize her symptoms are related to menopause, and they are treatable
- Show her the way forward so she feels excited to explore treatment options

#### **EDUCATE**

- Position Rx treatments, specifically IMVEXXY and its value proposition, as the most effective treatment for her symptoms
- Help her feel more comfortable talking about her symptoms and give her the tools to have a productive conversation with her HCP

#### **ACTIVATE**

 Empower her to confidently self-advocate, get the conversation with her HCP started and ask for IMVEXXY



# 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<sup>‡\*</sup>



#### **MAMMOGRAMS**

No clinically meaningful changes in mammograms

References: 1. Mirkin S. Evidence on the use of progesterone in menopausal hormone therapy. Climacteric. 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, Cobin RH, Ginzburg SB, Katz IA, Woode 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 Promobembolism. Obstetricians (Acracillon 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. Bińkowska M. Menopausal hormone therapy and venous thromboembolism. Prz Menopauzalny. 2014;13(5):267-272.

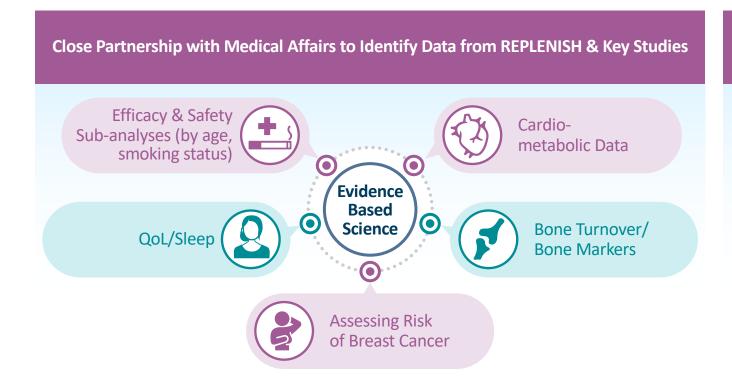


<sup>\*</sup> Efficacy was evaluated in a 12-week substudy. The pharmacokinetics of BIJUVA show a steady state of estradiol that is sustained over 24 hours. The steady state is achieved at 7 days.

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

<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 13.23

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



Introduce Low-dose BIJUVA (if approved)

#### BIJUVA 0.5mg/100mg Preliminary Launch Plan

- Virtual Launch Meeting
- Updated Sell
   Sheet & Materials
- Speaker Deck Updates

## **2020 Catalysts**

# • File BIJUVA low dose NDA efficacy supplement with FDA FEBRUARY • Launch Meeting for ANNOVERA late February

**MARCH** 

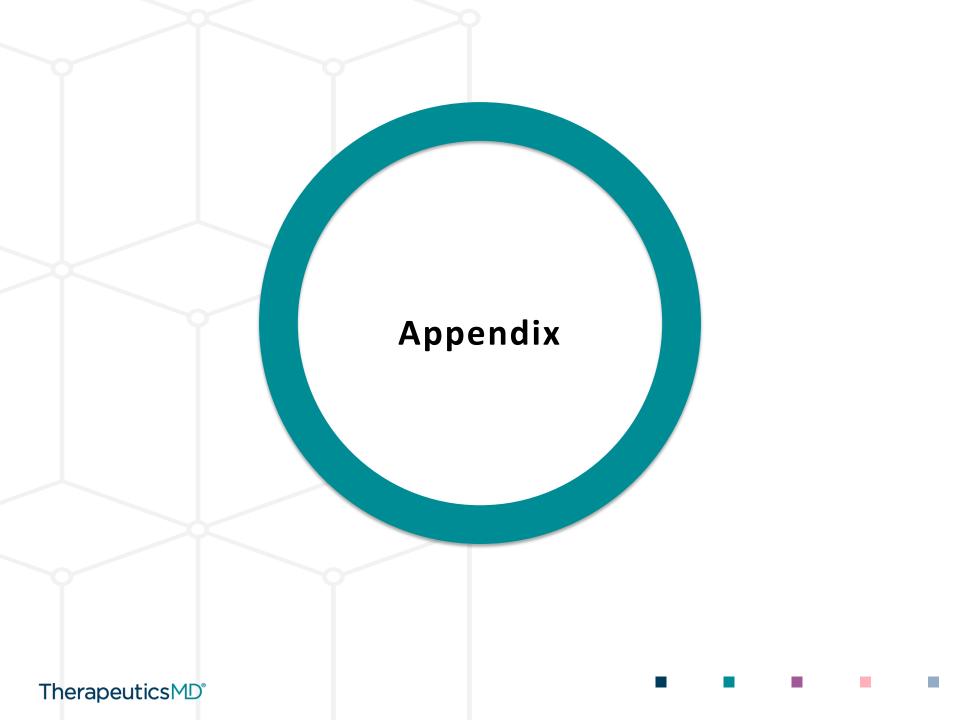
- ANNOVERA launch with full sales force and various partners
- ANNOVERA consumer campaign launch

Q1/Q2

- Begin calling on public health accounts across sectors (DoD, Medicaid and Puerto Rico)
- Consumer campaigns for IMVEXXY

Q4

Potential approval of BIJUVA low dose



## **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**

 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"



For members Effective: January 1, 2020

#### **Preventive Care Medications**

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



#### References:

1. https://one.walmart.com/content/dam/themepage/pdfs/OptumRxPreventiveCareMedications-2020.pdf

2. https://mynmhc.org/\$0-medications-list.pdf

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

#### Generic Ortho Tri-Cyclen sold as: Norgestimate/Ethinyl Estradiol

Norgesumatesemi Tri-Estaryli Tri Fernynor Tri-Linyah Tri-Mili

Tri-Previfern Tri-Sprintec Tri-Vylibra

#### Trinessa Generic For Ortho Tri-Cyclen Lo sold as:

Norgest/Ethi Estradio Tri-Lo-Estaryli Tri-Lo-Marzia Tri-Lo Mili Tri-Lo-Sprintec Tri-Vylibra Lo Trinessa Lo

#### Generic Ovcon-35 sold as:

Baiziva Briellyn Philith Vyfernia Zenchent

#### Generic Ovral sold as:

Ogestrel

#### Generic Quartette sold as: Favosim

Levonor/Ethi tab Estradio Rivelsa

#### Generic Safyral sold as: Dros/Eth Est tab Levomefo

Tydemy

Generic Seasonale sold as: Introvale

Jolessa Levonor/ethinyl estradiol Ouasense

#### Generic Seasonique sold as:

Armethia
Ashiyna
Camrese
Daysee
Levonorlethi estradio
Simpesse

#### Generic Tri-Northyl 28 sold as:

Aranelle Leena

Setlakin

#### Generic Triphasii sold as:

Enpresse-28 Levonest Levonor/Ethi Myzira Trivora-28

#### Generic Yasmin 28 3-0.03mg sold as:

Drospit/Ethi 3-0.03mg Ocelia 3-0.03mg Syeda 3-0.03mg Zarah 3-0.03mg Zurnandimine 3-0.03mg

#### Generic Yaz 3-0.02mg sold as: Drospir/Ethi 3-0.02

Drospirenone/ethy est Glarni Jasmiel Lo-Zumandimi Loryna Nikki Vestura

#### Progestin Only Birth Control Pills

Generic Ortho Micronor & Nor-QD sold as: Camila 0.35mg Debitane

Errin 0.35mg Heather 0.35mg Incassia 0.35mg Jencycla 0.35mg Jolivette 0.35mg Lyza 0.35mg Nora-Be 0.35mg Norethindron 0.35

Norethindron 0.35mg Norlyda 0.35mg Norlyroc Sharobel Tulana 0.35mg

Siyriu

#### Birth Control Rings (Vaginal)

Nuva-Ring

#### Birth Control Patches (Transdermal)

Generic Ortho Evra sold as:

#### Birth Control Shots (Injection)

Medroxyprogesterone 150mg IM (Generic Depo-Provera contraceptive)

#### Emergency Birth Control

ella

LeVonorgestrei 1.5mg, (generic Plan B One-Step)

#### Over-The-Counter (OTC) Birth

Control (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 Aer)

Contraceptive gels (e.g. Gynol II, Shur-Seal, VCF Vaginal)

#### FC female (female condom)

Generic emergency birth control (e.g. Aftera, EContra EZ, Econtra OS, Levonorgestr tab 1.5mg, My Choice, My Way, New Day, Next Choice, Opcicon, Option 2, React, Take Action)

Today Sponge

#### Birth Control IUD'S and Implants

Kyleena Liletta Mirena Nexplanon Paragard

Skyla

Some methods of birth control, such as IUDs and Implants, may be available through your medical benefit and not your pharmacy

nefit.

## **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" 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® works with your health plan to provide these benefits. The following lists! 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.
- . The dosage form is how the product is supplied. For example, tablet, capsule, liquid, syrup or chewable
- "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 medicine?
- Other rules, limits and exclusions may apply. Please contact your health plan to learn about your coverage?
- 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 can = cansule FE = ferrous sulfate (iron) EE = ethinyl estradiol hr = hour IM = intramuscular IU = international unit mog = miorogram mg = milligram mL = milliter

oral = taken by mouth OTC = over-the-counter product Rx = prescription product soin = solution SR = sustained release susp = suspension tab = tablet TD = transdermal

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

#### OTHER CONTRACEPTIVES<sup>‡</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 [blue] and in brackets are for your reference only

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

- BALCOLTRA
- LO LOESTRIN FE
- NATAZIA
- SL VND
- TAYTULLA

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

- NEXPLANON
- MIRENA
- SKVI A
- LILETTA KYLEENA
- PARAGARD T 380A
- NUVARING ANNOVERA

- Transdermal Patches (Rx)
- Xulane

#### Injectables (Rx)

- DEPO-SUBQ-PROVERA 104
- Medroxyprogesterone acetate 150 mg [DEPO-PROVERA]

#### Barrier Methods (Rx) Diaphragms

- MILEX WIDE-SEAL
- OMNIFLEX COIL SPRING SILICONE CAYA
- Cervinal Care

#### FEMCAP

#### Emergency Contraception (Rx or OTC)

- ELLA
- Levonorgestrei 1.5 mg tablet, Aftera, Econtra EZ, Econtra OS, My Choice, My Way, New Day, Opcicon, Option 2, Preventeza, Take Action, React [PLAN B]

#### Female Condoms (OTC)

FC-2

#### Vaginal Sponge (OTC)

TODAY

#### Spermicides (OTC)

- ENCARE VAGINAL SUPPOSITORIES
- GYNOL II GEL 3%
- Nonoxynol-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® 35 years of age and older, who are at an increased risk.

#### Generic, oral tablets (Rx)

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

#### References:

1. https://www.caremark.com/portal/asset/NoCost Preventive List.pdff



## **ANNOVERA Deal Terms**

Milestone Payments	Royalty %	
Upon FDA approval: \$20M	Step structure:	
<ul> <li>First commercial batch release: \$20M</li> </ul>	Annual net sales < \$50M: 5%	
\$200M in cumulative net sales: \$40M	■ Annual net sales > \$50M and < \$150M: 10%	
\$400M in cumulative net sales: \$40M	Annual net sales > \$150M: 15%	
\$1B in cumulative net sales: \$40M	Additional Cost Considerations	
	<ul> <li>TXMD and Population Council jointly responsible for one observational PMR study*</li> </ul>	

<sup>\*</sup>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 <u>134,000 units</u> for 3Q19 (up from106,000 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 <u>15,800 units</u> 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  $\sim$ \$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>&</sup>lt;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.

Therapeutics MD®