

# 3Q 2019 Earnings

### November 6, 2019

Building a Premier Women's Health Portfolio



For Her. For Life.

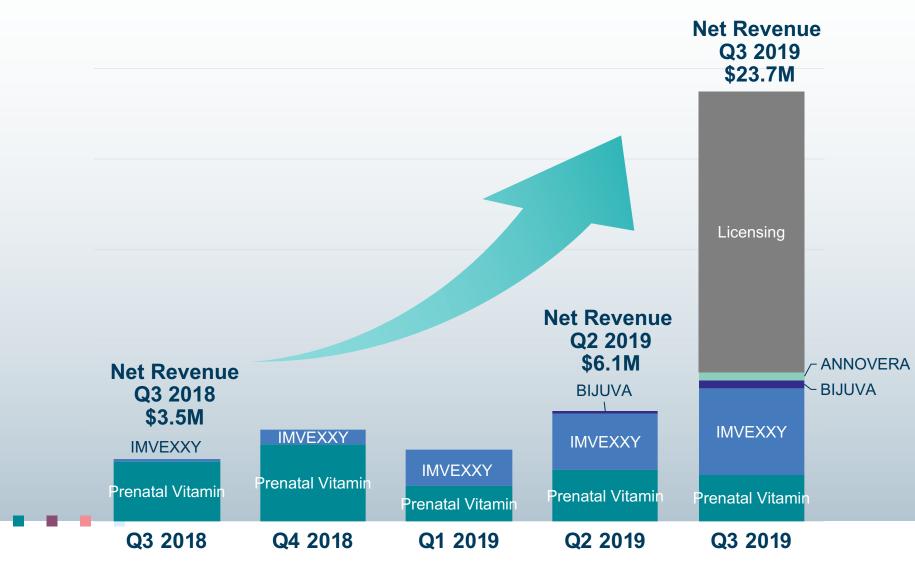
### **Forward-Looking Statements**

This presentation by TherapeuticsMD, Inc. (referred to as "we" and "our") may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believe," "hope," "may," "anticipate," "should," "intend," "plan," "will," "expect," "estimate," "project," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission (SEC), including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop and commercialize IMVEXXY, ANNOVERA, BIJUVA and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan facility, including the conditions to draw additional tranches there under; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the ability of our licensees to commercialize and distribute our products; the effects of laws, regulations and enforcement; the competitive nature of the industries in which we conduct our business; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock; and the concentration of power in our stock ownership. This non-promotional presentation is intended for investor audiences only.



### **Trend in Net Revenue**



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### **3Q19 Financial Results**

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

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

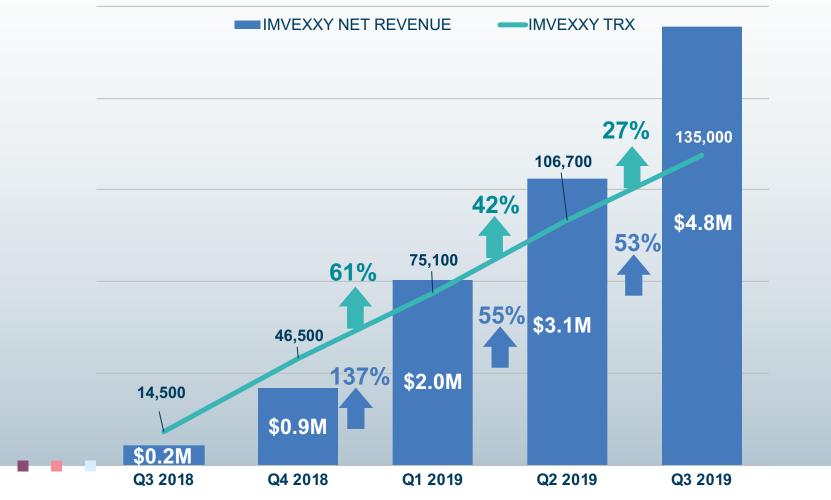
 As our sales force focus shifts to our FDA-approved products and payer headwinds continue to increase for prenatal vitamins, we anticipate prenatal vitamins will continue to become a smaller percentage of overall company revenues





### IMVEXXY Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients



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

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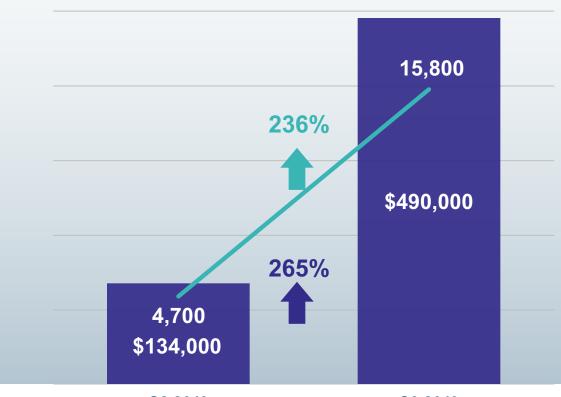
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### **BIJUVA Net Revenue Growth** Faster than Unit Growth

#### Net Revenue vs. Sales of Units to Patients





Q2 2019

#### Q3 2019

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

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### ANNOVERA LAUNCH INSIGHTS

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





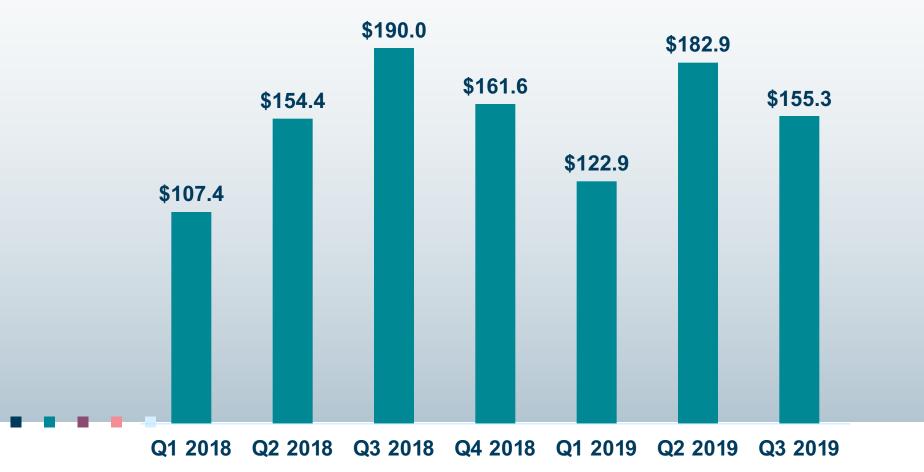
### **Financial Summary**

Operating expenses – SG&A expenses

Net loss and basic & diluted per share

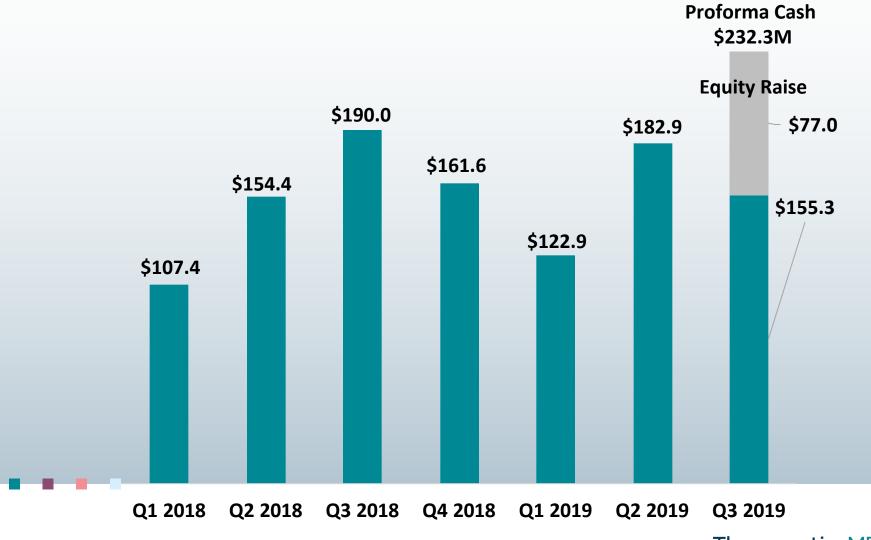


### Cash Balance at End of Each Quarter (Millions)



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



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### **Non-Dilutive Term Loan Financing**

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

	Amount (\$)	TXMD Company Milestone <sup>1</sup>	Contractual Timing	
Tranche 1	\$200M	Closing of the facility	Completed in April 2019	
Tranche 2	\$50M	Designation of ANNOVERA as a new category of birth control by the U.S. Food and Drug Administration on or prior to December 31, 2019	4Q 2019	
Tranche 3	\$50M	Achieving \$11M in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019	First Quarter of 2020 Audited financials required (Feb/Mar 2020)	

1. TXMD Company Milestones are draw triggers for additional tranches of funding only and are not affirmative covenants that the company must otherwise meet. Ability to draw additional tranches is also subject to satisfaction (or waiver) of other customary conditions precedent.

### **Reaffirm 4Q2019 Financial Guidance**



#### **Important Guidance Notes:**

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



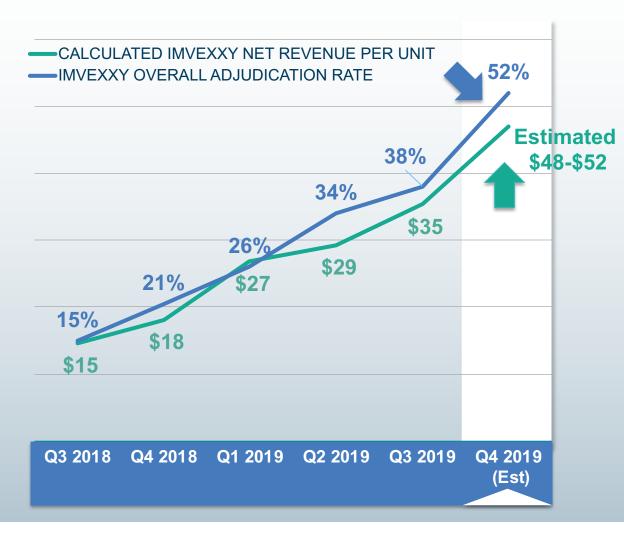
## COMMERCIAL UPDATE





#### **IMVEXXY** Calculated Net Revenue Per Unit Increases as Adjudication Rates Increases

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for fourth quarter as patients with high deductible plans meet their OOP
- Overall adjudication rate in October increased 14% over 3Q19



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



# Improvement in Adjudication Rates



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

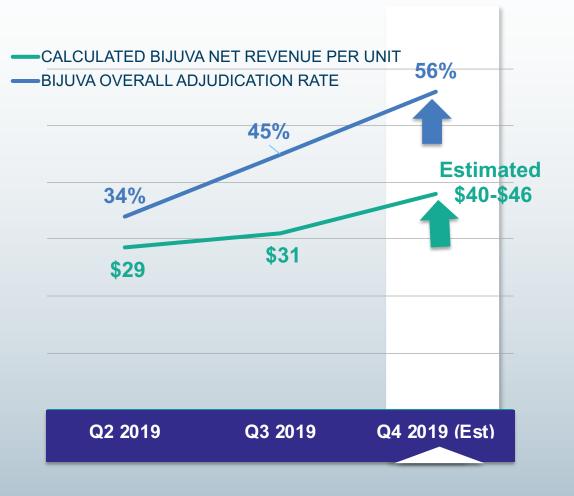
	2Q19	3Q19	Sept 2019	Oct 2019
Commercial Adjudication %	50%	55%	62%	72%
Medicare Part D Adjudication %	8%	12%	13%	17%
Overall %	34%	38%	43%	52%





### **BIJUVA Calculated Net Revenue Per Unit Increases as Adjudication Rates Increase**

- Start of copay optimization on 10/1/19 increased cost from \$35 to \$50 for non-covered patients
- Cost of copay program anticipated to continue to decrease for fourth quarter as patients with high deductible plans meet their OOP
- Overall adjudication rate in October increased 11% over Q3



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



# Improvement in Adjudication Rates



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

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











# **ANNOVERA Commercial Payer Update**

#### Already Achieved ~62% Unrestricted Access<sup>1</sup>

# Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives<sup>1</sup>

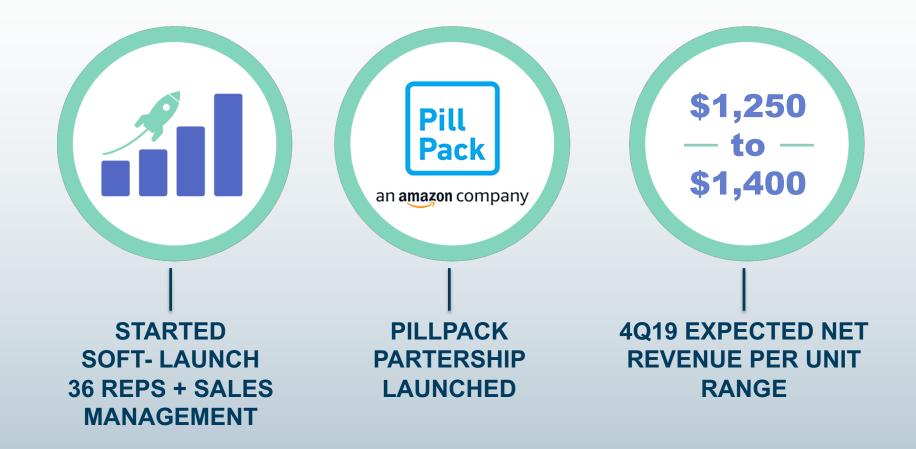
	Plan	% of Lives <sup>2</sup>	Status <sup>3</sup>
New	CVS	16%	Adjudicating with no copay as of October 2019
	ESI	16%	Adjudicating at T3 as of September 2019
	United	8%	In discussions
	Anthem	7%	Adjudicating at T3, no copay as of August 2019
	Prime	6%	In discussions
	OptumRx	6%	In discussions
	Kaiser	5%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

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

<sup>1</sup>MMIT November 2019 (Account Insights) and CVS Preventative Drug List <sup>2</sup>Plan numbers as of October 2019 <sup>3</sup>Adjudication status from MMIT November 2019 and Account Insights



### **ANNOVERA Status**



### The Power of a Women's Health Portfolio





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# **APPENDIX**



# **ANNOVERA Deal Terms**

#### **Milestone Payments**

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

#### **Royalty %**

Step structure:

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

#### **Additional Cost Considerations**

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



# **3Q 2019 Key Performance Metrics**

#### IMVEXXY

- IMVEXXY net revenue totaled <u>\$4.8M</u> for 3Q19 (up from \$3.1M for 2Q19)
  - Net revenue continues to grow faster than units due to improving adjudication rates
  - TRx increased 26% to ~<u>134,000 units</u> for 3Q19 (up from106,000 for 2Q19)
  - Overall adjudication increased to 38% (up from 34% for 2Q19)

#### BIJUVA



\* Invexxy

4 mca (estradiol vacinal inserts)

- BIJUVA net revenue totaled <u>\$491,000</u> 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" (opesierre actule and
- ANNOVERA net revenue totaled <u>\$400,000</u> for 3Q19
  - Strong initial commercial net revenue of <u>~\$1,250</u> per unit with the potential for improvement<sup>2</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.

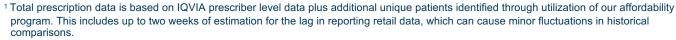
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### **IMVEXXY October Launch Metrics**

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



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



### Launch Results Remain Strong

#### Imvexxy TRx Launch Comparison



% Market Share

\*Month 16 for IMVEXXY is October 2019

#### References:

1. Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program.

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

2. Osphena and Intrarosa data sourced from Symphony Health Integrated Dataverse.

3. Vagifem data sourced from IQVIA National Prescriber Level Data.

 Market share data based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. All trademarks are the property of their respective owners.

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#### **IMVEXXY** Patient Adherence<sup>1,2</sup>

(estradiol vaginal inserts)

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

#### IMVEXXY: 4.0 fills/yr<sup>3</sup> (through Oct)

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

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 6.7 fills from November 2018 through October 2019

1) Average number of fills per patient is the average number of fills per patient grouped by their initial month on therapy.

2) Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.

3) Average number of fills for all patients is calculated as Total Rx / Total Patients.

4) Total Rx/Patient Count

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### **Commercial Payer Status**

#### Achieved ~68% Unrestricted Commercial Access<sup>1</sup> 9 of the Top 10 Commercial Payers Secured

Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives<sup>1</sup>

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

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

MMIT November 2019 (Account Insights)
<sup>2</sup>Plan numbers as of October 2019
<sup>2</sup>Adjudication status from MMIT November 2019 and Account Insights



### **Medicare Part D Payer Status**

#### **Additional Decisions Expected This Quarter**

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

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

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

1MMIT November 2019 (Account Insights)and Is being2Plan numbers as of October 20193Adjudication status from MMIT November 2019 and Account Insights



## **BIJUVA Update**

#### Plan to Submit BIJUVA 0.5/100 mg Dose

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

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#### Reason for Submission

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



### **BIJUVA Commercial Payer Update** Additional Coverage Decisions Expected This Quarter

Achieved ~55% Unrestricted Commercial Access<sup>1</sup> 6 of the Top 10 Commercial Payers Secured<sup>1</sup>

	Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives <sup>1</sup>		
Plan	% of Lives <sup>2</sup>	Status <sup>3</sup>	
CVS	16%	In discussions	
ESI	16%	Adjudicating as of 4/19/19	
United	8%	Adjudicating as of 8/1/19	
Anthem	7%	In discussions	
Prime	6%	In discussions	
OptumRx	6%	Adjudicating as of 8/1/19	
Kaiser	5%	In discussions	
Aetna	4%	Adjudicating as of 4/2019	
Cigna	4%	Adjudicating as of 9/2019	
EnvisionRx	2%	Adjudicating as of 11/2019	

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

<sup>1</sup>MMIT November 2019 and Account Insights <sup>2</sup>Plan numbers as of October 2019 <sup>3</sup>Adjudication status from MMIT November 2019 and Account Insights

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### **BIJUVA October Launch Metrics**

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

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

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



#### ANNOVERA Commercial Payer Update Already Achieved ~62% Unrestricted Access<sup>1</sup>

# Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives<sup>1</sup>

	Plan	% of Lives <sup>2</sup>	Status <sup>3</sup>
New	CVS	16%	Adjudicating with no copay as of October 2019
	ESI	16%	Adjudicating at T3 as of September 2019
	United	8%	In discussions
	Anthem	7%	Adjudicating at T3, no copay as of August 2019
	Prime	6%	In discussions
	OptumRx	6%	In discussions
	Kaiser	5%	In discussions Kaiser Washington covering at no copay
New	Aetna	4%	No copay at in network pharmacies for a majority of lives as of October 2019
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#### ANNOVERA Commercial Payer Update Fast Uptake in Regional Plans

#### **Selected Regional Plan Coverage**

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

<sup>1</sup>Plan numbers as of October 2019 <sup>2</sup>MMIT October 2019 and Account Insights

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

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### The Power of the Portfolio **Multiple Paths to \$1B of Peak Sales**

Percent of Market Based on Patient Count of 2.3M and 4 fills per year					
Average Net					
Revenue / Unit	25%	35%	45%	55%	
\$80	\$184M	\$257.6M	\$331.2M	\$404.8M	
\$100	\$230M	\$322M	\$414M	\$506M	

Total Addressable FDA Market : 3.8M Total Addressable Compounding Market : 12M Percent of Addressable Market					
Average Net Revenue / Unit		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 Therapeutics MD\*

Bijuva estradiol and progesterone) capsule