

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): May 15, 2019

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW, Third Floor
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230-405) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2).

Emerging growth company

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	TXMD	The Nasdaq Stock Market LLC

Item 7.01 Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on May 15, 2019 and at subsequent meetings with investors or analysts.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. Presentation dated May 15, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 15, 2019

THERAPEUTICSMD, INC.

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



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

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

ANNOVERA[™]
(segesterone acetate and ethinyl
estradiol vaginal system)

**INVESTOR
UPDATE**

MAY 2019

*Building a Premier
Women's Health Portfolio*

TherapeuticsMD[®]
For Her. For Life.

Forward-Looking Statements

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

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled “Risk Factors” in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: our ability to maintain or increase sales of our products; our ability to develop and commercialize IMVEXXY®, ANNOVERA™, BIJUVA™ and our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan facility; 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; the ability of our licensees to commercialize and distribute our product and product candidates; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; 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.

IMVEXXY LAUNCH STRATEGY



Remove Barriers to Early Adoption in a market with entrenched estrogen product behavior built over the past 30 years

- Patients pay no more than \$35/prescription*
- Build insurance coverage

Why?

- We believe IMVEXXY is a best-in-class product that will change treatment decisions because IMVEXXY's product attributes deliver a highlight differentiated experience for women

*\$35 off is valid for patients with commercial coverage. Offer not valid for use by patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs (including any state pharmaceutical assistance programs). Patients may be eligible for IMVEXXY cash pay program.

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LAUNCH RESULTS REMAIN STRONG AND ON-TRACK: STRATEGY IS WORKING

Imvexxy TRx Launch Comparison



*Month 10 for IMVEXXY is April 2019

- IMVEXXY continues to grow both weekly average volume and daily average volume for April (30 day month) vs March (31 day month)
- Average daily volume for 30 days in April 2019 increased to ~1,000 from ~900 for the 31 days in March 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 a one week 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 Database.
 3. Vagifem data sourced from IQVIA National Prescriber Level Data.
- All trademarks are the property of their respective owners.

STRONG PATIENT ADHERENCE = WOMEN ARE STAYING ON IMVEXXY

IMVEXXY Patient Adherence ^{1,2}		
Month Initial Prescription Filled	Average # Fills for those Patients	Maximum Allowable Fills Given the Month of Initial Fill
April 2019	1 Fill	1 Fill
March 2019	1.7 Fills	2 Fills
February 2019	2.3 Fills	3 Fills
January 2019	2.9 Fills	4 Fills
December 2018	3.5 Fills	5 Fills
November 2018	4.1 Fills	6 Fills
October 2018	4.5 Fills	7 Fills
September 2018	5.1 Fills	8 Fills
August 2018	6.5 Fills	9 Fills

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 4.1 fills from November 2018 through April 2019

Average fills for all patients through April 30, 2019 = 3.14³

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

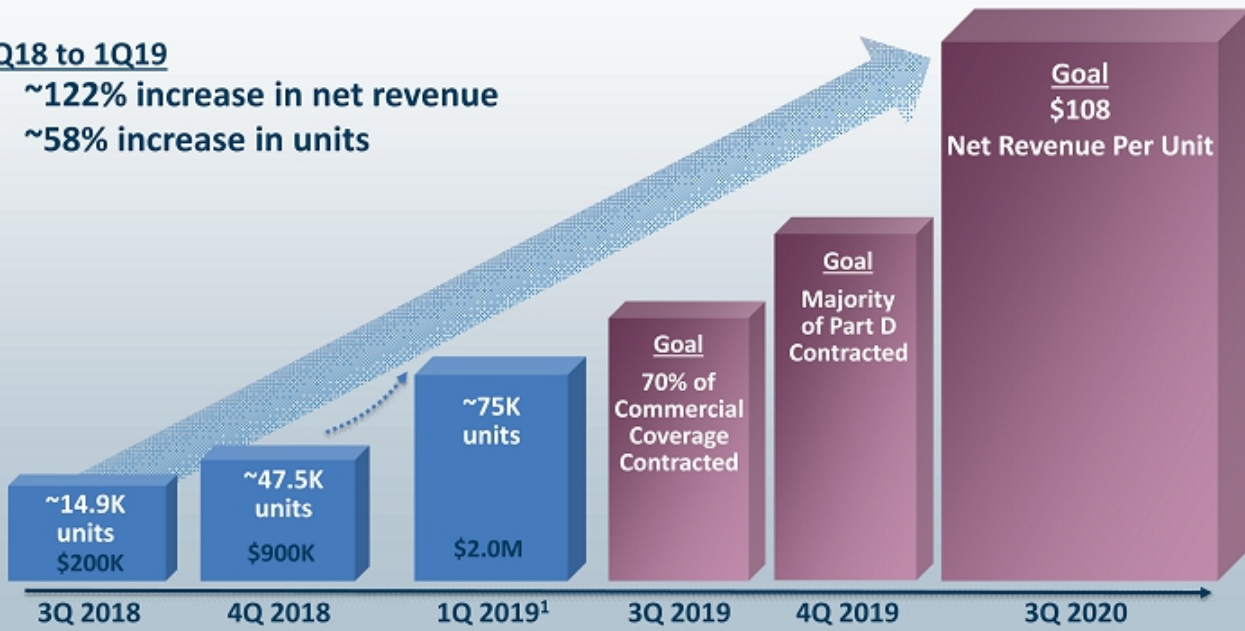
2) Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.

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

GOAL TO NORMALIZE NET REVENUE PER UNIT TO \$108 IN 3Q20

4Q18 to 1Q19

- ~122% increase in net revenue
- ~58% increase in units



1) Due to improvement of adjudication rates the overall cost of our affordability program improved revenue per unit by ~\$8. This improvement was limited by the increased cost associated with high deductible plans and copay resets which was ~\$8 for those prescriptions that were insurance paid.

PATIENT MIX BY PAYER TYPE

		Medicare Part D	Commercial Patients	Cash Pay & Other Patients
1	2018 US Patient Mix for all VVA products	25%	66%	9%
2	1Q 2019 IMVEXXY Actual Patient Mix	34%	60%	6%
3	IMVEXXY Patient Mix Heavy in Part D Where Current Coverage is Limited	Overweight	Underweight	Underweight

IMVEXXY PATIENT MIX

- IMVEXXY patient mix overweight in Medicare Part D
 - Currently an area of lowest coverage and adjudication
 - As we complete payor contracts in Part D, coverage and adjudication should adjust accordingly

1) Patient mix based upon total script volume and payer type sourced from Symphony Health Integrated Database
 2) IMVEXXY patient mix is based on IQVIA prescriber level data plus additional volume identified through utilization of our affordability program.



IMVEXXY ADJUDICATION RATES

	Medicare Part D	Commercial Patients	Cash Pay & Other Patients
IMVEXXY 1Q19 Actual Patient Mix	34%	60%	6%
IMVEXXY Adjudication Rate – 1Q19	5%	41%	0%
IMVEXXY Overall Adjudication – 1Q19	27% Actual		

- **Commercial adjudication gap** expected to adjust as additional commercial payers begin to adjudicate
- **Medicare Part D adjudication gap** expected to adjust as majority of Part D is contracted in 4Q19
- 1Q19 also affected by high deductible plans

1) Patient mix based upon total script volume and payer type sourced from Symphony Health Integrated Database.
 2) IMVEXXY adjudication rates are based on IQVIA prescriber level data plus additional volume identified through utilization of our affordability program.

APRIL IMPROVEMENT IMVEXXY ADJUDICATION RATES

	Medicare Part D	Commercial Patients	Cash Pay & Other Patients
IMVEXXY Adjudication Rate – 1Q19	5%	41%	0%
IMVEXXY Adjudication Rate – April 2019	6% 	48% 	0%
IMVEXXY Overall Adjudication - 1Q19	27% Q1		
IMVEXXY Overall Adjudication – April 2019	32% April		

Adjudication rates improving in April as new plans begin to adjudicate

1) IMVEXXY adjudication rates are based on IQVIA prescriber level data plus additional volume identified through utilization of our affordability program.

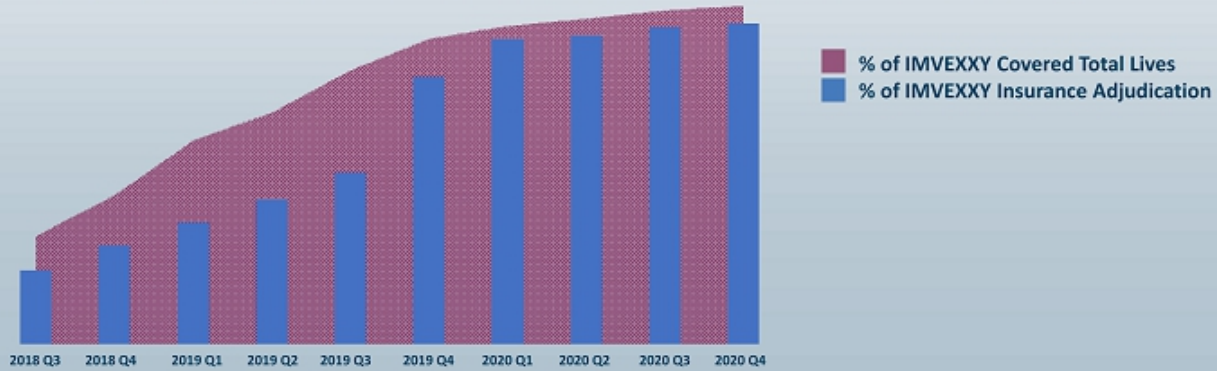
IMVEXXY REVENUE EXPECTED TO NORMALIZE AT \$108 IN 3Q20

Expected Payer Coverage Normalization in 2019

- 3Q19 - Complete commercial contracts comprising ~70%
- 4Q19 - Complete majority of Part D contracts

Expected Distribution and Co-Pay Optimization in 2020

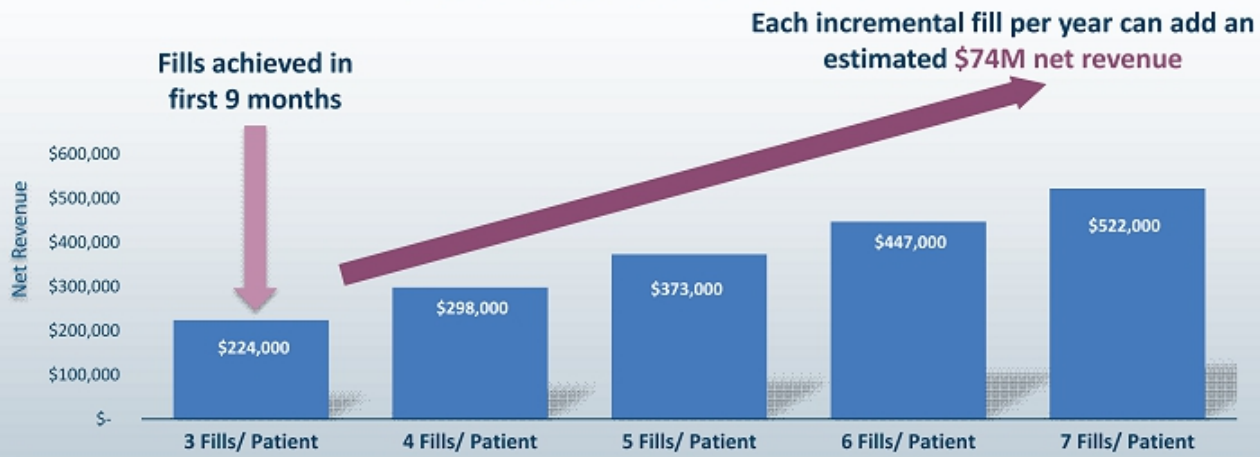
- 1H20 - IMVEXXY copay optimization; cash pay and commercial insurance outliers identified and optimized
- 3Q20 - Net revenue goal of **\$108** per unit
- 2H20 - IMVEXXY, BIJUVA and ANNOVERA volume expected to reduce distribution costs



CONSERVATIVE MARKET POTENTIAL OF IMVEXXY



THE VALUE OF FILLS PER PATIENT



Conservative Assumptions – Each additional fill can add estimated net revenue of **\$74M**

- 25-30% market share
- No Price Increases
- No New Patients Enter the VVA market (2,300,000¹)
- \$108 in net revenue per unit

1) IQVIA Total Patient Tracker (2017 Data)

IMVEXXY GROWTH LEVERS IN 2019



Level 1:

Patient Affordability

- Added 50 sales reps for a total of 200
- Allows reach to add additional ~5,000 targets
- Patients pay no more than \$35/prescription



Level 2:

Payer Access

- 3Q19 ~70%+ of Commercial lives expected to be contracted
- 4Q19 Medicare Part D contracting expected to be complete



Level 3:

Market Expansion

- Launch IMVEXXY through BIO-IGNITE



Level 4:

Consumer

- DTC rollout in 2H19 to target new patients

33 Live Accounts Dispensing IMVEXXY Since Late Feb

- First 27 accounts approximately 8-10 new fills per month
- Strong early refill rates matching other channels
- 200,000 total scripts identified in the compounded VVA product space
- Leverage IMVEXXY BIO-IGNITE experience to prepare for BIJUVA and ANNOVERA



15 Vetted Accounts Waiting for First Order

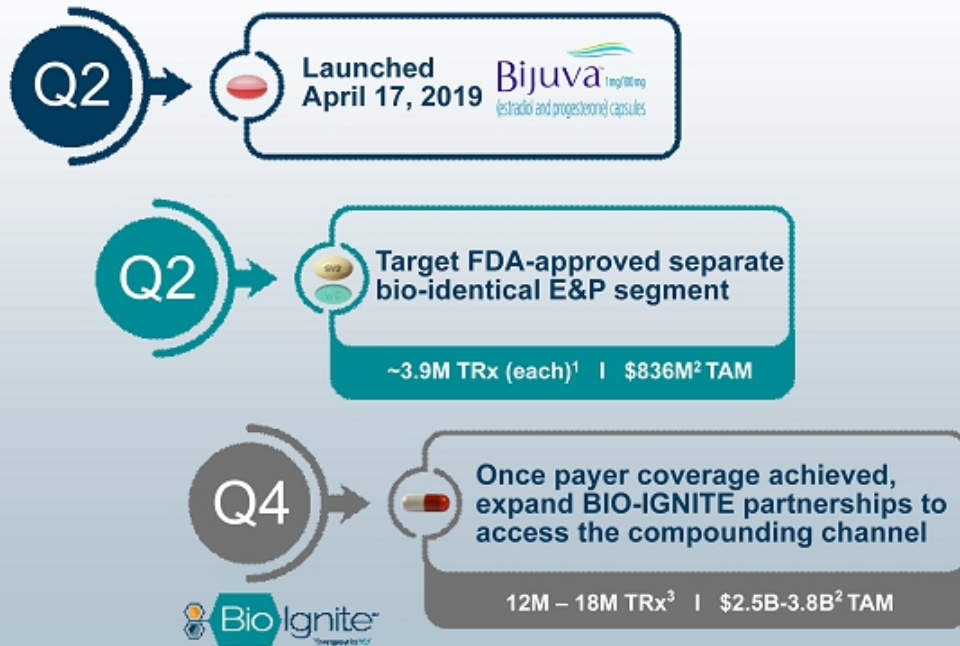
153 Compounding Pharmacies in Vetting and Processing Stage

31 States Reached



BIJUVA UPDATE

A LARGE TARGET MARKET FOR BIJUVA



1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2018

2) Based on WAC pricing of \$214.50

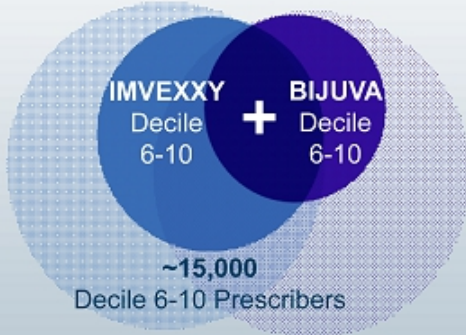
3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications

LAUNCH PLAN MIRRORS IMVEXXY

Focused on Driving Early Behavior Change that Leads to Long Term Adoption



Sales Targeting



- Focus on IMVEXXY first given payer coverage build
- Focused launch of BIJUVA while coverage is building
- Portfolio advantage on overlap in menopause with IMVEXXY and BIJUVA
- Salesforce expansion to approximately 200

Core HCP Marketing Campaign



LAUNCH PLAN MIRRORS IMVEXXY

Focused on Driving Early Behavior Change that Leads to Long Term Adoption



- Pay No More Than \$35 from Day 1 of launch*

- \$35 or less out-of-pocket cost*
- Addresses the cost and coverage concerns which are often barriers to early adoption
- “Keep Cool” Early Experience Program drives appropriate patient and prescriber education
- Positive early clinical experience has the potential to drive momentum

*\$35 off is valid for patients with commercial coverage. Offer not valid for use by patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs (including any state pharmaceutical assistance programs). Patients may be eligible for BIJUVA cash pay program.

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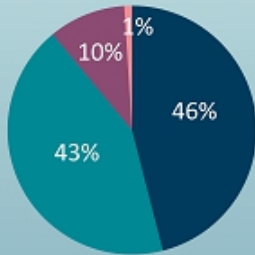
ANNOVERA UPDATE

ANNOVERA LAUNCH APPROACH

TAM of Contraception Market @ \$5 Billion¹

TXMD Physician Survey

Universal Acceptance to Prescribe²



■ Very likely ■ Somewhat likely
■ Not too likely ■ Not at all likely

3Q19

Meet Inbound Demand

4Q19

Align Initial Sales Focus where States Mandate Coverage (19 states) while ACA Decision is Made

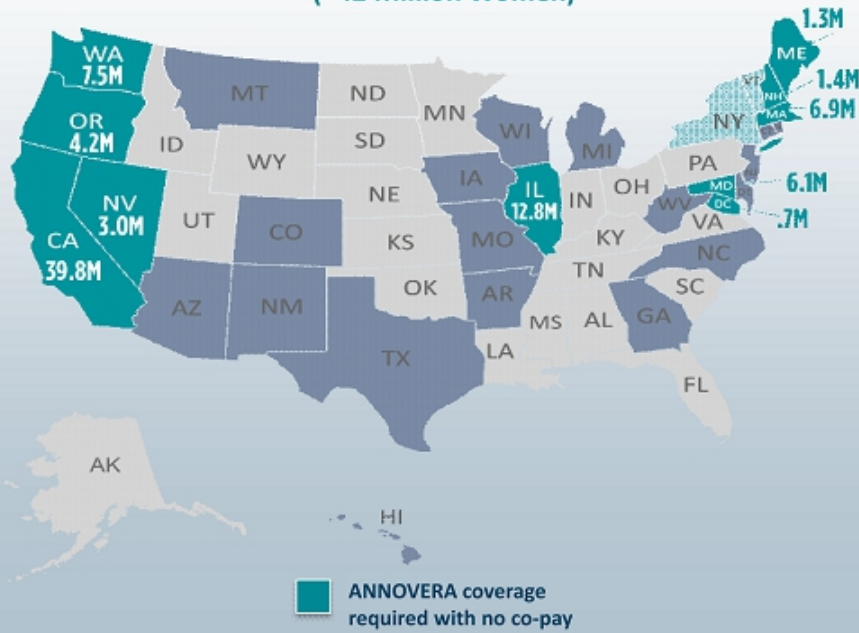
1Q20-3Q20

Full Launch with Initial Focus on OBGYN target overlap with Menopause Products
Payer Coverage expected to normalize in 3Q20

1) Symphony Health Integrated Database.
2) TXMD market research survey of 200 physicians

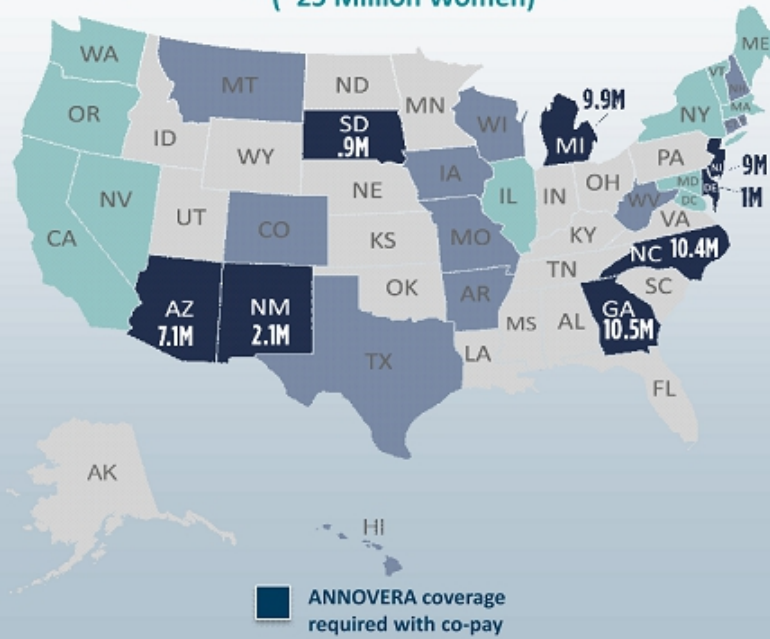
STATE LAWS REGARDLESS OF ACA MANDATES

8-10 STATES REQUIRE COVERAGE WITH **NO COPAY** REGARDLESS OF ACA DECISION
(~42 Million Women)



STATE LAWS REGARDLESS OF ACA MANDATES

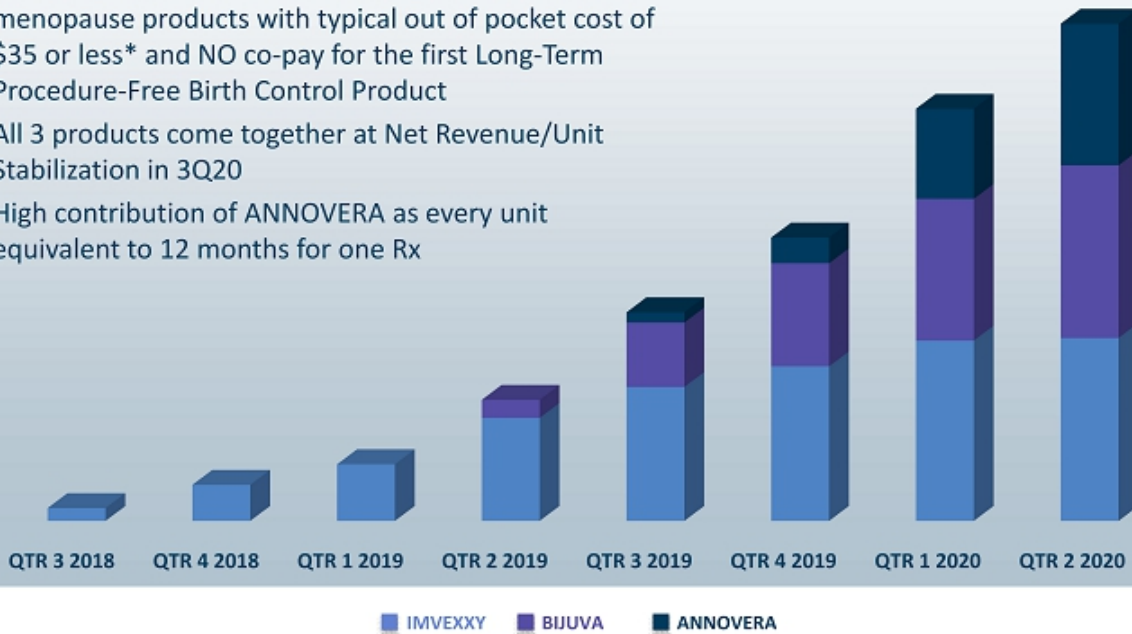
9 STATES REQUIRE COVERAGE WITH **COPAY** REGARDLESS OF ACA DECISION
(~25 Million Women)



PATH OF STABILIZATION OF NET REVENUE FOR 3 PRODUCTS

By 3Q20 All Products Anticipated to Achieve Average Net Revenue Per Unit Stabilization

- Company Value – Goal of becoming the best-in-class menopause products with typical out of pocket cost of \$35 or less* and NO co-pay for the first Long-Term Procedure-Free Birth Control Product
- All 3 products come together at Net Revenue/Unit Stabilization in 3Q20
- High contribution of ANNOVERA as every unit equivalent to 12 months for one Rx



*\$35 off is valid for patients with commercial coverage. Offer not valid for use by patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs (including any state pharmaceutical assistance programs). Patients may be eligible for IMVEXXY and BIJUVA cash pay program.

Transforming Women's Healthcare with Next Generation Products



- 3 highly differentiated overlapping products for chronic conditions
- Large market opportunities with little to no promotional competition
 - BIJUVA TAM of \$2 to \$4.5 B^{1,2}
 - IMVEXXY TAM of \$1.5B¹
 - ANNOVERA TAM of \$5B¹
- Customer centric – \$35 or less menopause products and unique copay for ANNOVERA³

1) Symphony Health Integrated Database.

2) TXMD research of addressable compounding market.

3) \$35 off is valid for patients with commercial coverage. Offer not valid for use by patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs (including any state pharmaceutical assistance programs). Patients may be eligible for IMVEXXY and BIJUVA cash pay program.



THANK YOU

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Appendix

Example Manufacturer Flow of Funds Per Unit

Applying ASC 606 Under GAAP

Product with WAC \$1,000

Revenue received by Manufacturer

Gross revenue	\$	1,000	
Distributor fees (10%)	\$	100	
Total revenue received			\$ 900

Expenses paid by Manufacturer

Rebates paid to insurance companies (15%)	\$	150	
Co-Pay assistance (30%)	\$	300	
Fees/discounts paid to pharmacies (2%)	\$	20	
Total expenses paid			\$ 470

Reserves and allowances (3.5%)			\$ 35
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Net revenue per unit to statement of operations			\$ 395
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Individual line items are example only and not indicative of actual amounts for TherapeuticsMD products.

TSSP

MidCap

Maximum Term Loan Facility Size	\$300 million	\$200 million
Interest Rate	3-month LIBOR + 7.75%, payable quarterly	1-month LIBOR + 7.75%, payable monthly
Maturity Date	March 31, 2024	May 1, 2023
Tranche 1	\$200 million drawn at closing on April 24, 2019 - ~\$81 million to repay MidCap - Remaining for working capital after transaction costs	Drawn June 7, 2018 for \$75 million (IMVEXXY launch)
Tranche 2	\$50 million will be available upon the designation of ANNOVERA as a new category of birth control by the FDA prior to December 31, 2019	\$75 million (first commercial sale of BIJUVA on or before May 31, 2019)
Tranche 3	\$50 million will be available upon the company achieving \$11 million in net revenues from IMVEXXY, BIJUVA, and ANNOVERA for the fourth quarter of 2019	\$50 million (must generate \$75 million combined revenue on or before December 31, 2019)
Equity or warrants	No equity or warrants attached	No equity or warrants attached
Amortization Schedule	Amortization schedule over the final year of the term loan; principal repaid in four equal quarterly installments beginning on June 30, 2023, with the term loan facility maturing on March 31, 2024	Amortization schedule over the final 3-years of the term loan; begin principal payback in 2020
Required cash balance	Required cash balance of \$50 million upon close; if the company draws either Tranche 2 or Tranche 3, the required cash balance increases to \$60 million	Required cash balance of \$50 million

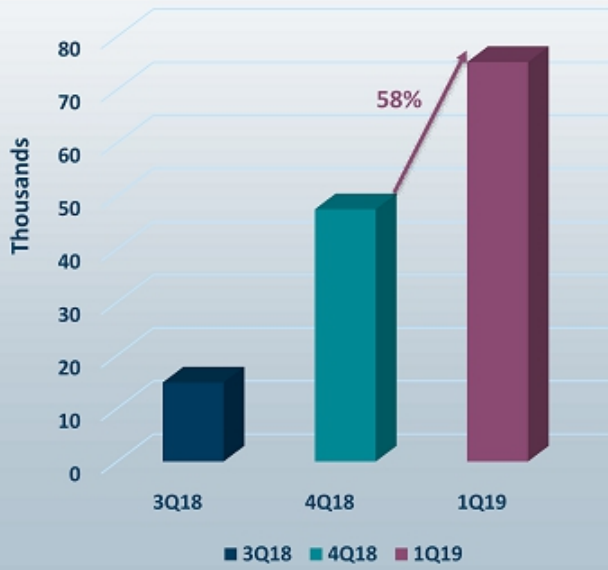
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IMVEXXY Quarterly Performance

1Q19 Net Revenue Grew At Twice The Rate Of Units

Quarterly Scripts to Patients



Quarterly Net Revenue

