

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 6, 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 2.02 Results of Operations and Financial Condition.**

On May 6, 2019, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2019. In addition, the Company will be using a slide presentation during its earnings conference call. A copy of the press release and slide presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K (including the exhibits) is furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in Item 2.02 of this Current Report on Form 8-K (including the exhibits) shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in its expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

**Item 7.01 Regulation FD Disclosure.**

On May 6, 2019, the Company issued a press release announcing the Company's financial results for its first quarter ended March 31, 2019. In addition, the Company will be using a slide presentation during its earnings conference call. The information included in this Item 7.01 and in Exhibits 99.1 and 99.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits*

**Exhibit Index**

<u>Exhibit Number</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	Press Release from TherapeuticsMD, Inc., dated May 6, 2019, entitled TherapeuticsMD Announces First Quarter 2019 Financial Results.
<a href="#"><u>99.2</u></a>	TherapeuticsMD, Inc. Presentation dated May 6, 2019.

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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.

Date: May 6, 2019

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

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FOR IMMEDIATE RELEASE

**TherapeuticsMD Announces First Quarter 2019 Financial Results**

- BIJUVA™ Commercial Launch in April 2019-
- Completed \$300 Million Non-Dilutive Term Loan Financing Facility in April 2019-
- IMVEXXY® Continues Strong Positive Trends for Prescriptions and Patient Refills-
- Conference Call Scheduled for 4:30 p.m. ET Today-

**BOCA RATON, Fla. – May 6, 2019** – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today announced its commercial and corporate update for the first quarter ended March 31, 2019.

“We are pleased with our recent progress on achieving several business objectives, which include the on-time launch of BIJUVA, the expansion of our sales force to 200 sales representatives who are now selling BIJUVA and IMVEXXY, the continued strong prescriptions and refills for IMVEXXY, and the significant strengthening of the company’s financial position with the completion of our \$300 million non-dilutive term loan facility, which also increases our flexibility to support the launches of BIJUVA and ANNOVERA™,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD.

**IMVEXXY Continues Strong Prescriptions and Refills**

IMVEXXY prescription growth continues as highlighted by a record month in April 2019 with approximately 31,200 prescriptions dispensed and paid for by patients. Approximately 75,000 prescriptions of IMVEXXY were dispensed and paid for by patients during the first quarter of 2019. This is an increase of approximately 58% in prescription volume for the first quarter of 2019 as compared to the fourth quarter of 2018. Strong refill rates continue to indicate that women are having a positive experience with IMVEXXY.

Through April 30, 2019, the company achieved unrestricted coverage for IMVEXXY with seven of the top ten commercial payers of VVA products. One of these plans, United Healthcare, began adjudication on March 1, 2019. The company also achieved unrestricted Medicare Part D coverage on United Healthcare and Kaiser.

**Summary of First Quarter 2019 Financial Results**

Net revenues for the first quarter of 2019 were approximately \$3.9 million, compared with net revenues of approximately \$3.8 million for the prior year’s quarter. Net revenues for IMVEXXY for the first quarter of 2019 were approximately \$2.0 million and were greatly affected by the company’s patient savings program introduced to launch IMVEXXY, which allows eligible patients to access the product at a reasonable cost of no more than \$35 per prescription regardless of insurance coverage. The company expects revenues related to IMVEXXY to improve as commercial payer coverage for IMVEXXY increases and insurance plans complete the process needed to adjudicate IMVEXXY prescriptions at pharmacies.

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Net revenues from the company's prescription prenatal vitamin business were approximately \$1.9 million for the first quarter of 2019, compared with approximately \$3.8 million for the first quarter of 2018. A portion of the lower revenue was created by a price increase in the first quarter of 2019, causing some customers to increase purchases of the company's prescription prenatal vitamins in the fourth quarter of 2018.

R&D expenses for the first quarter of 2019 were approximately \$6.3 million, compared with approximately \$7.0 million for the prior year's quarter. The decrease in first quarter 2019 R&D expenses was primarily a result of the completion of the REPLENISH trial for BIJUVA and the FDA approval of IMVEXXY and BIJUVA, partially offset by scale-up and manufacturing activities for BIJUVA before FDA approval, as well as increased pre-clinical work to support our product pipeline.

Sales, general and administrative (SG&A) expenses for the first quarter of 2019 increased to approximately \$34.9 million, compared with approximately \$20.8 million for the prior year's quarter. The increase in first quarter 2019 sales and marketing expenses was primarily a result of increased expenses associated with sales and marketing efforts to support the launch and commercialization of IMVEXXY and BIJUVA, including costs related to sales force expansion, outsourced sales personnel and their related expenses, physician education and product samples, and other expenses related to product commercialization. The company expects sales and marketing expenses to continue to increase as it continues the launch of BIJUVA, prepares for the launch of ANNOVERA and continues to support its growing business and commercialization of its products.

Net loss for the first quarter of 2019 was approximately \$39.5 million, or \$0.16 per basic and diluted share, compared with approximately \$24.4 million, or \$0.11 per basic and diluted share, for the first quarter of 2018.

### **Balance Sheet**

As of March 31, 2019, the company's cash on hand totaled approximately \$122.9 million, compared with approximately \$161.6 million at December 31, 2018. Total outstanding debt, net of issuance costs, was approximately \$73.5 million as of March 31, 2019.

In April 2019, the company entered into a financing agreement for a \$300 million non-dilutive term loan facility with TPG Sixth Street Partners (TSSP). The initial tranche of \$200 million was drawn on April 24, 2019, with additional tranches of \$50 million available to the company upon the designation of ANNOVERA as a new category of contraception by the U.S. Food and Drug Administration on or prior to December 31, 2019 and another \$50 million available to the company upon achieving \$11 million in net revenues from IMVEXXY, ANNOVERA and BIJUVA for the fourth quarter of 2019. A portion of the proceeds from the initial tranche of the TSSP facility was used to repay all amounts outstanding under the company's prior credit facility.

### **Conference Call and Webcast Details**

TherapeuticsMD will host a conference call and audio webcast today at 4:30 p.m. ET to discuss these financial results and provide a business update.

<b>Date:</b>	Monday, May 6, 2019
<b>Time:</b>	4:30 p.m. ET
<b>Telephone Access (US):</b>	866-665-9531
<b>Telephone Access (International):</b>	724-987-6977
<b>Access Code for All Callers:</b>	5799911

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A live webcast and audio archive for the event may be accessed on the home page or from the “Investors & Media” section of the TherapeuticsMD website at [www.therapeuticsmd.com](http://www.therapeuticsmd.com). Please connect to the website prior to the start of the presentation to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for at least 30 days. In addition, a digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days, with the dial-in 855-859-2056 or international 404-537-3406 and Conference ID: 5799911.

Please see the Full Prescribing Information, including indication and Boxed WARNING, for each TherapeuticsMD product as follows:

- IMVEXXY (estradiol vaginal inserts) at <https://imvexxy.com/pi.pdf>
- BIJUVA (estradiol and progesterone capsules) at <https://www.bijuva.com/pi.pdf>
- ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) at [www.annovera.com/pi.pdf](http://www.annovera.com/pi.pdf)

#### **About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is an innovative, leading healthcare company, focused on developing and commercializing novel products exclusively for women. Our products are designed to address the unique changes and challenges women experience through the various stages of their lives with a therapeutic focus in family planning, reproductive health, and menopause management. The company is committed to advancing the health of women and championing awareness of their healthcare issues. To learn more about TherapeuticsMD, please visit [www.therapeuticsmd.com](http://www.therapeuticsmd.com) or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

#### **Forward-Looking Statements**

This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as “believes,” “hopes,” “may,” “anticipates,” “should,” “intends,” “plans,” “will,” “expects,” “estimates,” “projects,” “positioned,” “strategy” and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes 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 are outside of the company's 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 the company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize IMVEXXY<sup>®</sup>, ANNOVERA<sup>™</sup>, BIJUVA<sup>™</sup> and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of the company's current or future approved products or preclude the approval of the company's future drug candidates; the length, cost and uncertain results of future clinical trials; the company's reliance on third parties to conduct its manufacturing, research and development and clinical trials; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the company's common stock and the concentration of power in its stock ownership. PDF copies of the company's historical press releases and financial tables can be viewed and downloaded at its website: [www.therapeuticsmd.com/pressreleases.aspx](http://www.therapeuticsmd.com/pressreleases.aspx).

#### **Investor Contact**

Nichol Ochsner  
Vice President, Investor Relations  
561-961-1900, ext. 2088  
[Nochsner@TherapeuticsMD.com](mailto:Nochsner@TherapeuticsMD.com)

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash	\$ 122,883,852	\$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of \$678,886 and \$596,602, respectively	14,944,750	11,063,821
Inventory	4,955,715	3,267,670
Other current assets	9,846,899	10,834,693
<b>Total current assets</b>	<b>152,631,216</b>	<b>186,779,261</b>
<b>Fixed assets, net</b>	<b>668,607</b>	<b>472,683</b>
<b>Other Assets:</b>		
License rights	20,000,000	20,000,000
Intangible assets, net	4,455,730	4,092,679
Other assets	3,821,566	324,855
Security deposit	314,446	314,446
<b>Total other assets</b>	<b>28,591,742</b>	<b>24,731,980</b>
<b>Total assets</b>	<b>\$ 181,891,565</b>	<b>\$ 211,983,924</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 25,365,243	\$ 22,743,841
Other current liabilities	19,607,439	18,334,948
<b>Total current liabilities</b>	<b>44,972,682</b>	<b>41,078,789</b>
<b>Long-Term Liabilities:</b>		
Long-term debt	73,501,160	73,381,014
Operating lease liability	2,724,501	—
<b>Total liabilities</b>	<b>121,198,343</b>	<b>114,459,803</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity:</b>		
Preferred stock - par value \$0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value \$0.001; 350,000,000 shares authorized: 241,221,840 and 240,462,439 issued and outstanding, respectively	241,222	240,463
Additional paid-in capital	619,234,655	616,559,938
Accumulated deficit	(558,782,655)	(519,276,280)
<b>Total stockholders' equity</b>	<b>60,693,222</b>	<b>97,524,121</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 181,891,565</b>	<b>\$ 211,983,924</b>

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2019</b>	<b>March 31, 2018</b>
Revenues, net	\$ 3,946,651	\$ 3,773,392
Cost of goods sold	762,827	633,623
Gross profit	3,183,824	3,139,769
Operating expenses:		
Sales, general, and administrative	34,864,082	20,757,237
Research and development	6,317,882	7,039,297
Depreciation and amortization	106,938	59,621
Total operating expenses	41,288,902	27,856,155
Operating loss	(38,105,078)	(24,716,386)
Other (expense) income		
Miscellaneous income	688,721	314,557
Interest expense	(2,090,018)	—
Total (expense) income	(1,401,297)	314,557
Loss before income taxes	(39,506,375)	(24,401,829)
Provision for income taxes	—	—
Net loss	<u>\$ (39,506,375)</u>	<u>\$ (24,401,829)</u>
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.11)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>241,006,032</u>	<u>216,525,316</u>



**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2019</b>	<b>March 31, 2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (39,506,375)	\$ (24,401,829)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	66,494	38,424
Amortization of intangible assets	40,444	21,197
Non-cash operating lease expense	219,765	—
Provision for doubtful accounts	82,284	22,955
Share-based compensation	2,586,948	1,751,358
Amortization of deferred financing costs	120,146	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,963,214)	(790,885)
Inventory	(1,688,045)	(135,514)
Other current assets	987,794	1,506,152
Accounts payable	2,621,402	2,186,224
Accrued expenses and other liabilities	268,939	152,223
Net cash used in operating activities	<u>(38,163,418)</u>	<u>(19,649,695)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Patent costs	(403,496)	(142,136)
Purchase of fixed assets	(262,418)	(26,908)
Payment of security deposit	—	(11,486)
Net cash used in investing activities	<u>(665,914)</u>	<u>(180,530)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of options	100,107	44,057
Net cash provided by financing activities	<u>100,107</u>	<u>44,057</u>
Decrease in cash	(38,729,225)	(19,786,168)
Cash, beginning of period	161,613,077	127,135,628
Cash, end of period	<u>\$ 122,883,852</u>	<u>\$ 107,349,460</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	1,913,956	—

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

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

**ANNOVERA™**  
(segesterone acetate and ethinyl  
estradiol vaginal system)

**1Q19 TXMD  
UPDATE**

*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

**Imvexxy**  
(estradiol vaginal inserts)



**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?

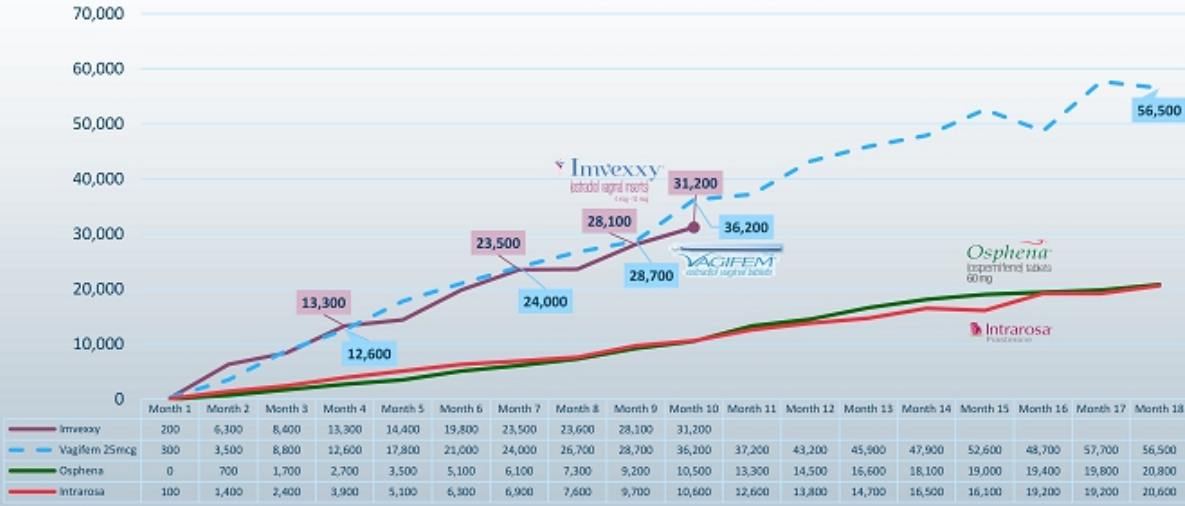
- We believe IMVEXXY is a best-in-class product that will change treatment decisions because IMVEXXY's product attributes deliver a highlight differentiated experience for women

\*\$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.

**TherapeuticsMD**  
*For Her. For Life.*

# 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 <sup>1,2</sup>		
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 = 3.14<sup>3</sup>**

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

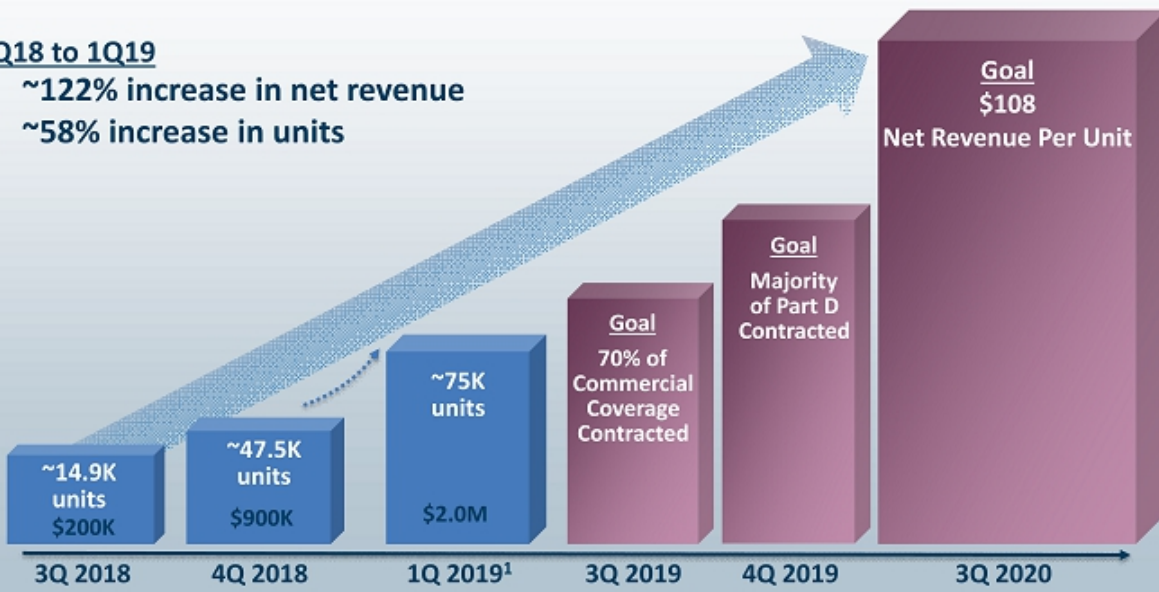
2) Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.

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	<b>27% Actual</b>		

- **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	<b>27% Q1</b>		
IMVEXXY Overall Adjudication – April 2019	<b>32% April</b>		

**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.

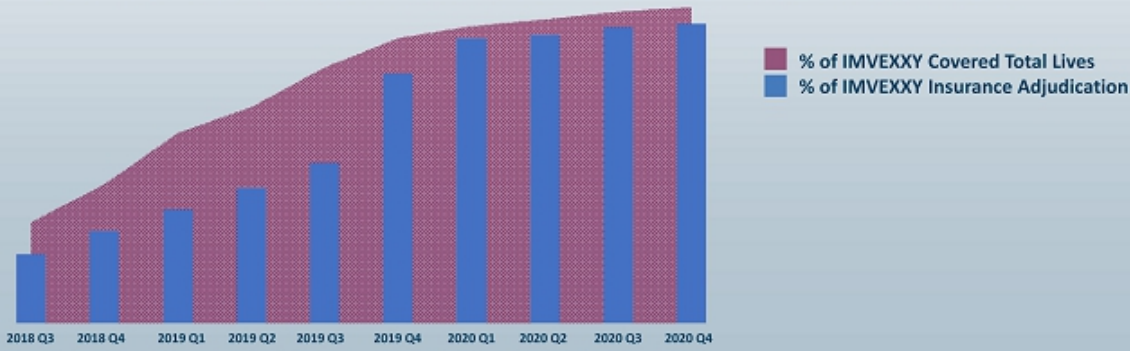
## IMVEXXY REVENUE EXPECTED TO NORMALIZE AT \$108 IN 3Q20

### 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

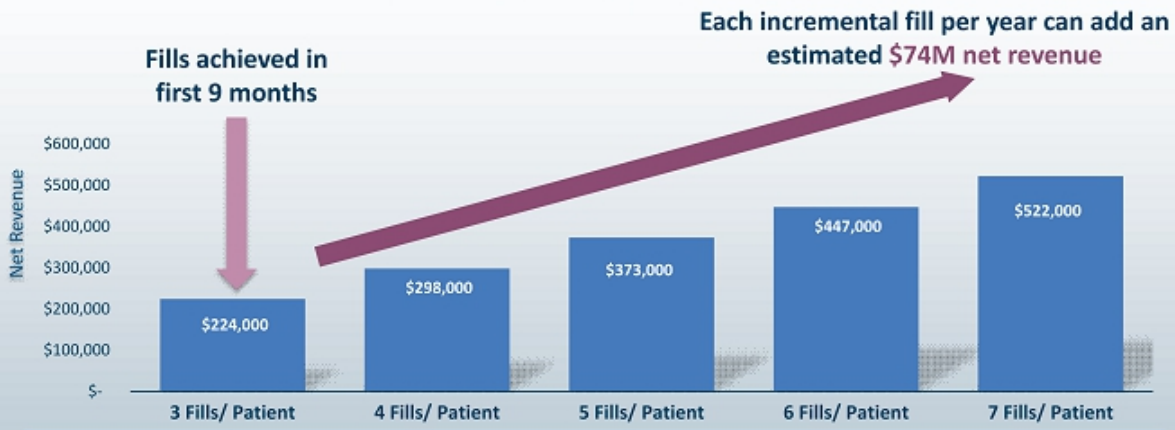
- 1H20 - IMVEXXY copay optimization; cash pay and commercial insurance outliers identified and optimized
- 3Q20 - Net revenue goal of **\$108** per unit
- 2H20 - IMVEXXY, BIJUVA and ANNOVERA volume expected to reduce distribution costs



# 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 (2,300,000<sup>1</sup>)
- \$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

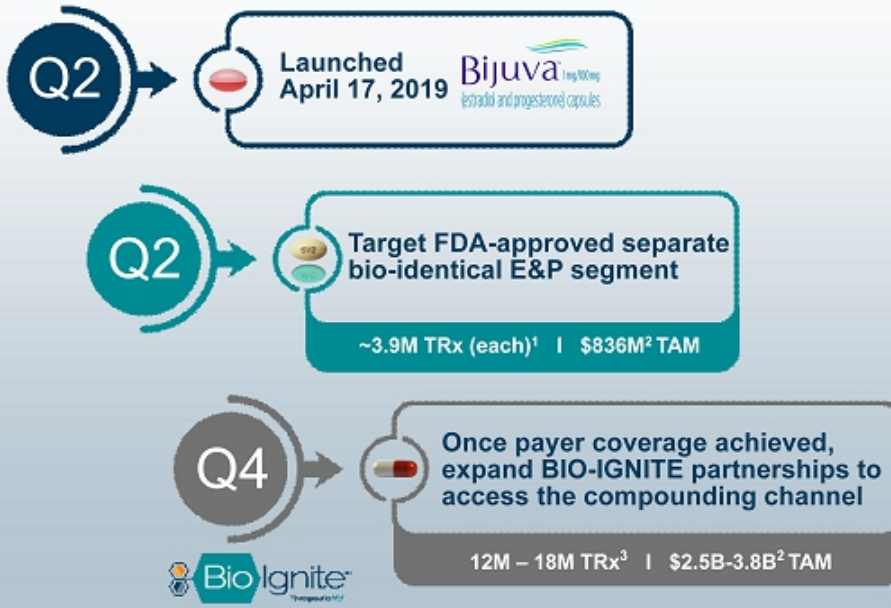


# 1Q19 BIJUVA UPDATE

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## 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

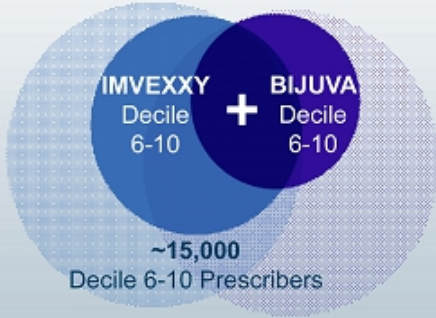


# LAUNCH PLAN MIRRORS IMVEXXY

## 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



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## 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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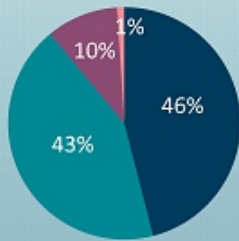
# 1Q19 ANNOVERA UPDATE

# ANNOVERA LAUNCH APPROACH

TAM of Contraception Market @ \$5 Billion<sup>1</sup>

## TXMD Physician Survey

Universal Acceptance to Prescribe<sup>2</sup>



■ 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

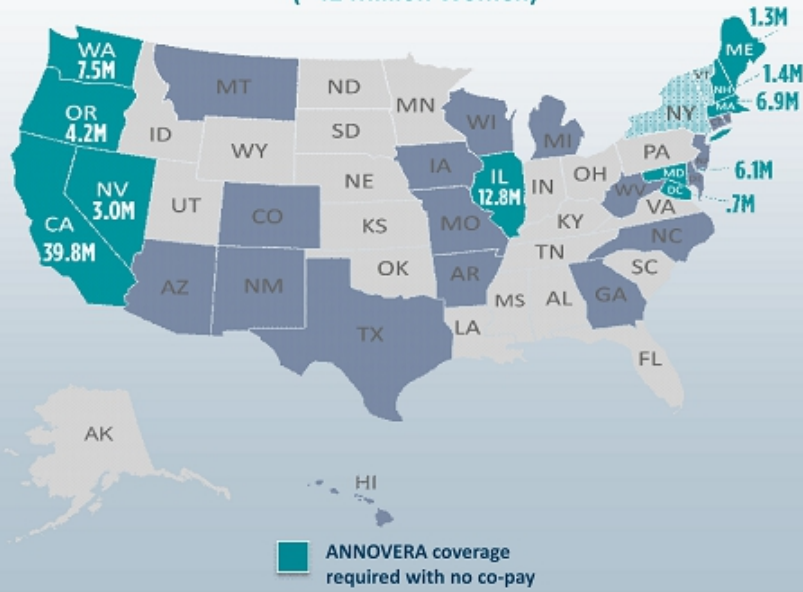
1) Symphony Health Integrated Database.  
2) TXMD market research survey of 200 physicians

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## STATE LAWS REGARDLESS OF ACA MANDATES

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

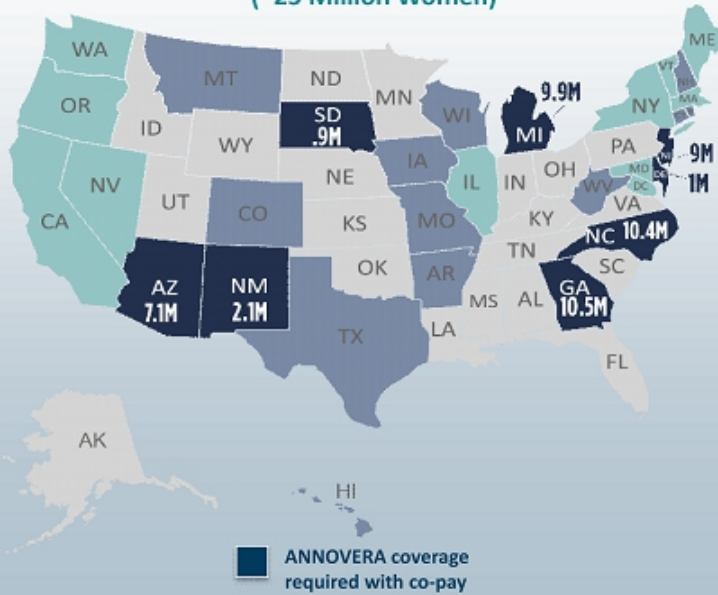


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## STATE LAWS REGARDLESS OF ACA MANDATES

9 STATES REQUIRE COVERAGE WITH CO-PAY REGARDLESS OF ACA DECISION  
(~25 Million Women)



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# 1Q 2019 FINANCIAL UPDATE

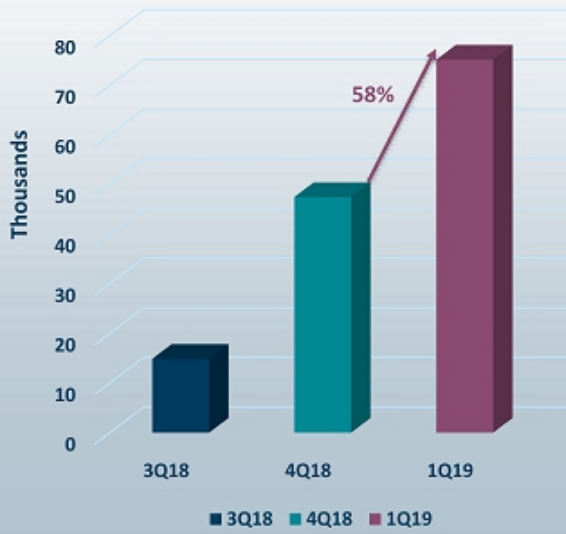
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# IMVEXXY Quarterly Performance

## 1Q19 Net Revenue Grew At Twice The Rate Of Units

Quarterly Scripts to Patients



Quarterly Net Revenue





## TSSP

## MidCap

<b>Maximum Term</b>	<b>\$300 million</b>	\$200 million
<b>Loan Facility Size</b>		
<b>Interest Rate</b>	3-month LIBOR + 7.75%, payable quarterly	1-month LIBOR + 7.75%, payable monthly
<b>Maturity Date</b>	March 31, 2024	May 1, 2023
<b>Tranche 1</b>	<b>\$200 million</b> 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)
<b>Tranche 2</b>	<b>\$50 million</b> 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)
<b>Tranche 3</b>	<b>\$50 million</b> 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)
<b>Equity or warrants</b>	No equity or warrants attached	No equity or warrants attached
<b>Amortization Schedule</b>	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
<b>Required cash balance</b>	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

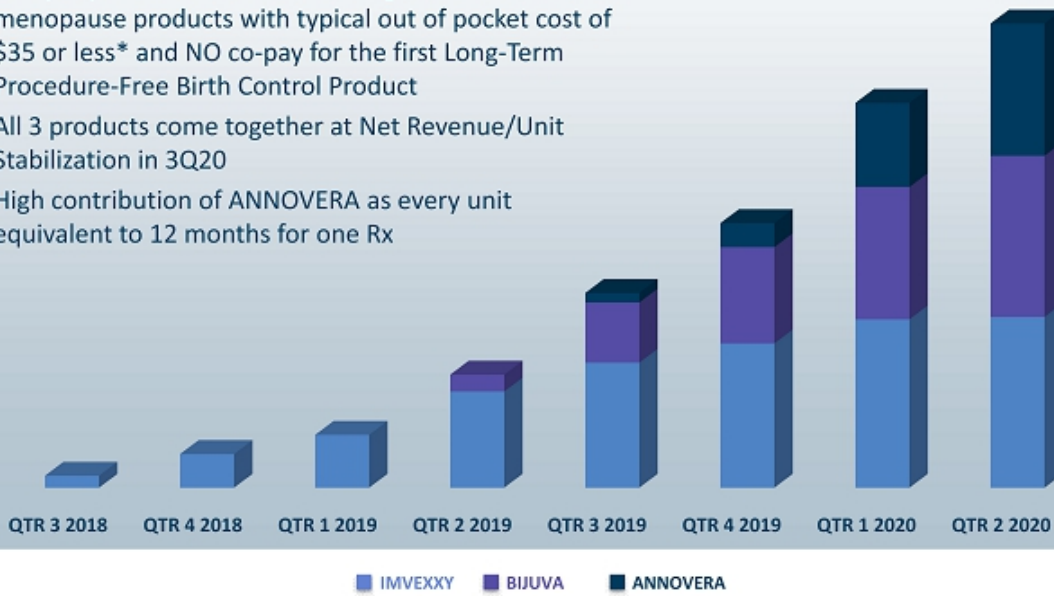
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# PATH OF STABILIZATION OF NET REVENUE FOR 3 PRODUCTS

## 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<sup>1,2</sup>
  - IMVEXXY TAM of \$1.5B<sup>1</sup>
  - ANNOVERA TAM of \$5B<sup>1</sup>
- Customer centric – \$35 or less menopause products and unique copay for ANNOVERA<sup>3</sup>

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.

