

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): August 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

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	TXMD	The Nasdaq Stock Market LLC

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.

Item 2.02 Results of Operations and Financial Condition.

On August 6, 2019, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 August 6, 2019, the Company issued a press release announcing the Company's financial results for its second quarter ended June 30, 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>
99.1	Press Release from TherapeuticsMD, Inc., dated August 6, 2019, entitled TherapeuticsMD Announces Second Quarter 2019 Financial Results.
99.2	TherapeuticsMD, Inc. Presentation dated August 6, 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: August 6, 2019

THERAPEUTICSMD, INC.

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



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Second Quarter 2019 Financial Results

- IMVEXXY® Net Revenue \$3.1 Million for the Second Quarter of 2019-
- Total Net Revenue for the Second Quarter of 2019 Above Guidance at \$6.1 Million-
- Company Raises Full-Year Net Revenue Guidance to Range of \$29.45 Million to \$34.20 Million-
- Conference Call Scheduled for 4:30 p.m. ET Today-

BOCA RATON, Fla. – August 6, 2019 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

“We are pleased to report a solid quarter that came in ahead of our expectations and believe the next few quarters will be transformative,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. “As we move into the second half of the year, we plan to conduct pre-launch activities for ANNOVERA™ and continue to expand market access for our menopause portfolio. We expect IMVEXXY and BIJUVA® to have extensive coverage for commercially insured lives by the end of the year. We are pursuing preferred status for IMVEXXY on Medicare Part D plans and expect coverage decisions by the fourth quarter, which is significant given the higher proportion of IMVEXXY Medicare Part D business.”

Second Quarter and Recent Developments

- IMVEXXY (estradiol vaginal inserts) prescription growth continues as highlighted by a record month in July 2019 with approximately 45,500 prescriptions dispensed and paid for by patients. Approximately 106,000 prescriptions of IMVEXXY were dispensed and paid for by patients during the second quarter of 2019. This is an increase of approximately 41% in prescription volume for the second quarter of 2019 as compared to the first quarter of 2019. Strong refill rates continue to indicate that women are having a positive experience with IMVEXXY.
 - IMVEXXY currently has unrestricted access with seven of the top commercial payers of VVA products and two of the top Medicare Part D payers of VVA products. The company expects additional coverage decisions by the top commercial and Medicare Part D payers of VVA products during the third and fourth quarters of 2019.
 - The commercial launch of BIJUVA (estradiol and progesterone capsules) commenced on April 17, 2019 and approximately 8,900 prescriptions have been dispensed and paid for by patients through July 31, 2019.
 - BIJUVA currently has unrestricted access with four of the top ten commercial payers. This includes two new plans, United Healthcare and OptumRX, that began adjudicating BIJUVA on August 1, 2019.
 - Pre-launch activities have commenced for ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system). The company plans to continue discussions with the U.S. Food and Drug Administration (FDA) on the potential for ANNOVERA to be designated a new, 19th method of contraception, and begin discussions with payers with a full-scale launch planned for the first quarter of 2020.
 - The company recently closed an exclusive license and supply transaction with Theramex, a leading, global specialty pharmaceutical company dedicated to women’s health, to commercialize BIJUVA and IMVEXXY outside of the United States. On August 5, 2019, the company received an upfront payment under this agreement of approximately \$15.4 million and is eligible to receive additional regulatory and sales milestone payments, as well as a royalty on net sales.
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Summary of Second Quarter 2019 Financial Results

Total net revenues for the second quarter of 2019 increased 62%, to approximately \$6.1 million, compared with net revenues of approximately \$3.8 million for the prior year's quarter. The increase was primarily due to sales of approximately \$3.1 million of IMVEXXY and \$134,000 of BIJUVA in the second quarter of 2019, partially offset by a decrease in the company's prescription prenatal vitamin business of approximately \$940,000 from the comparable quarter in 2018.

Net revenues have been greatly affected by the company's co-pay assistance programs introduced to launch IMVEXXY and BIJUVA, which allowed eligible enrolled patients to access the products at a reasonable cost of no more than \$35 per prescription regardless of insurance coverage. The company expects revenues related to IMVEXXY and BIJUVA will improve as commercial and Medicare Part D payer coverage increases, and plans complete the process needed to adjudicate prescriptions at pharmacies.

Research and development (R&D) expenses for the second quarter of 2019 decreased to approximately \$5.0 million, compared with approximately \$6.8 million for the prior year's quarter. R&D costs decreased primarily as a result of transferring certain costs and activities from R&D expenses to support commercial and launch efforts after the FDA approval of IMVEXXY and BIJUVA. R&D expenses include costs related to manufacturing validation as well as pre-clinical work to support the company's R&D activities.

Sales, general and administrative (SG&A) expenses increased for the second quarter of 2019 to approximately \$41.4 million, compared with approximately \$29.5 million for the prior year's quarter. The increase in second quarter 2019 SG&A expenses was primarily a result of increased expenses associated with sales and marketing efforts and personnel costs 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.

During the second quarter of 2019, the company took a one-time charge for extinguishment of debt of approximately \$10.1 million in connection with the refinancing of its term loan. As a result of the foregoing, net loss increased to approximately \$55.2 million, or \$0.23 per basic and diluted share, for the second quarter of 2019. Excluding the one-time charge for extinguishment of debt, the net loss for the second quarter was approximately \$45.2 million, or \$0.19 per basic and diluted share, compared with approximately \$33.2 million, or \$0.15 per basic and diluted share, for the second quarter of 2018.

Balance Sheet

As of June 30, 2019, the company's cash on hand totaled approximately \$182.8 million, compared with approximately \$161.6 million at December 31, 2018. Total outstanding debt, net of issuance costs, was approximately \$194.1 million as of June 30, 2019.

Financial Guidance

The following table outlines TherapeuticsMD's revised 2019 financial guidance (in millions).

	3Q 2019		4Q 2019		FY 2019	
	Original	Revised	Original	Revised	Original	Revised
FDA-Approved Products	\$4.50-\$6.50	Unchanged	\$11.00-\$13.00	Unchanged	\$20.00-\$24.5	\$20.75-\$24.75
Prescription Prenatal Vitamins	\$1.75-\$2.25	\$2.25-\$2.50	\$1.50-\$2.00	\$1.75-\$2.25	\$7.15-\$8.65	\$8.70-\$9.45
Total Net Revenues	\$6.25-\$8.75	\$6.75-\$9.00	\$12.50-\$15.00	\$12.75-\$15.25	\$27.10-\$33.10	\$29.45-\$34.20

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.

Date:	Tuesday, August 6, 2019
Time:	4:30 p.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	1392883

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. 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: 1392883.

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

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 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[®], ANNOVERA[™], BIJUVA[®] 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 ability of the company's licensees to commercialize and distribute the company's products; 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.

Investor Contact

Nichol Ochsner
Vice President, Investor Relations
561-961-1900, ext. 2088
Nochsner@TherapeuticsMD.com

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	<u>June 30, 2019</u> (Unaudited)	<u>December 31, 2018</u>
ASSETS		
Current Assets:		
Cash	\$ 182,846,301	\$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of \$764,102 and \$596,602, respectively	18,383,012	11,063,821
Inventory	7,494,440	3,267,670
Other current assets	7,739,048	10,834,693
Total current assets	<u>216,462,801</u>	<u>186,779,261</u>
Fixed assets, net	<u>1,432,137</u>	<u>472,683</u>
Other Assets:		
License rights	20,000,000	20,000,000
Intangible assets, net	4,688,114	4,092,679
Other assets	3,635,227	324,855
Security deposit	334,866	314,446
Total other assets	<u>28,658,207</u>	<u>24,731,980</u>
Total assets	<u>\$ 246,553,145</u>	<u>\$ 211,983,924</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 19,499,238	\$ 22,743,841
Other current liabilities	22,376,617	18,334,948
Total current liabilities	<u>41,875,855</u>	<u>41,078,789</u>
Long-Term Liabilities:		
Long-term debt	194,095,220	73,381,014
Operating lease liability	2,488,101	—
Total liabilities	<u>238,459,176</u>	<u>114,459,803</u>
Commitments and Contingencies		
Stockholders' Equity:		
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	621,871,919	616,559,938
Accumulated deficit	(614,019,172)	(519,276,280)
Total stockholders' equity	<u>8,093,969</u>	<u>97,524,121</u>
Total liabilities and stockholders' equity	<u>\$ 246,553,145</u>	<u>\$ 211,983,924</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues, net	\$ 6,078,865	\$ 3,763,010	\$ 10,025,516	\$ 7,536,402
Cost of goods sold	1,248,860	454,161	2,011,687	1,087,784
Gross profit	4,830,005	3,308,849	8,013,829	6,448,618
Operating expenses:				
Sales, general, and administrative	41,387,451	29,466,770	76,251,533	50,224,007
Research and development	4,964,368	6,798,380	11,282,250	13,837,677
Depreciation and amortization	115,059	65,603	221,997	125,224
Total operating expenses	46,466,878	36,330,753	87,755,780	64,186,908
Operating loss	(41,636,873)	(33,021,904)	(79,741,951)	(57,738,290)
Other (expense) income				
Loss on extinguishment of debt	(10,057,632)	—	(10,057,632)	—
Miscellaneous income	486,597	334,238	1,175,318	648,795
Interest expense	(4,028,609)	(531,382)	(6,118,627)	(531,382)
Total other (expense) income	(13,599,644)	(197,144)	(15,000,941)	117,413
Loss before income taxes	(55,236,517)	(33,219,048)	(94,742,892)	(57,620,877)
Provision for income taxes	—	—	—	—
Net loss	\$ (55,236,517)	\$ (33,219,048)	\$ (94,742,892)	\$ (57,620,877)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.15)	\$ (0.39)	\$ (0.27)
Weighted average number of common shares outstanding, basic and diluted	241,221,840	216,640,186	241,114,532	216,583,067

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

	Six Months Ended	
	June 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (94,742,892)	\$ (57,620,877)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	133,049	79,201
Amortization of intangible assets	88,948	46,023
Write off of patent and trademark cost	78,864	—
Non-cash operating lease expense	443,734	—
Provision for doubtful accounts	167,500	38,024
Loss on extinguishment of debt	10,057,632	—
Share-based compensation	5,224,212	4,128,440
Amortization of deferred financing fees	316,880	30,155
Changes in operating assets and liabilities:		
Accounts receivable	(7,486,691)	(1,335,209)
Inventory	(4,226,770)	(395,219)
Other current assets	1,710,697	2,539,394
Accounts payable	(3,244,603)	7,329,560
Accrued expenses and other liabilities	2,801,717	561,615
Net cash used in operating activities	(88,677,723)	(44,598,893)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(763,247)	(434,677)
Purchase of fixed assets	(1,092,504)	(45,720)
Payment of security deposit	(20,420)	(11,486)
Net cash used in investing activities	(1,876,171)	(491,883)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options and warrants	100,107	1,128,996
Repayment of the Credit Agreement	(81,660,719)	—
Proceeds from the Financing Agreement	200,000,000	75,000,000
Payment of deferred financing fees	(6,652,270)	(3,786,918)
Net cash provided by financing activities	111,787,118	72,342,078
Increase in cash	21,233,224	27,251,302
Cash, beginning of period	161,613,077	127,135,628
Cash, end of period	\$ 182,846,301	\$ 154,386,930
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	\$ 6,989,570	\$ —
Cash paid for income taxes	\$ —	\$ —

**2Q 2019
Earnings**

August 6, 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 products; 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.

2Q 2019 Quarterly Financial Results Above Guidance Range

	2Q2019 Estimate	2Q2019 Actual*
FDA-Approved Drugs Net Revenue	\$2.50-3.00M	\$3.25M*
Prenatal Vitamins Net Revenue	\$2.00-2.50M	\$2.80M
Total TXMD Net Revenue	\$4.50-5.50M	~\$6.10M

*Includes net revenues of approximately \$3.12 million for IMVEXXY and \$134,000 for BIJUVA.

IMVEXXY Launch Metrics

IMVEXXY Launch Metrics		
Total paid scripts dispensed to patients ¹ (since launch through July 31, 2019)	~289,500	
Total paid scripts (July 1-31, 2019)	~45,500	
Total patients (since launch through July 31, 2019)	~78,300	
Total prescribers ² (since launch through July 31, 2019)	~13,800	
Comparison of Average Weekly & Daily Script Volume (Average Weekly Volume: TRx for month / # days in month * 7 days)		
	For 30 Days in June 2019	For 31 Days in July 2019
Average weekly volume	~8,750	~10,300
Average daily volume	~1,250	~1,500

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

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

Launch Results Remain Strong and On-Track: Strategy is Working

Imvexxy TRx Launch Comparison



Market Share

*Month 13 for IMVEXXY is July 2019

- IMVEXXY continues to grow both weekly average volume and daily average volume for July (31 day month) vs June (30 day month)
- Average daily volume for 31 days in July 2019 increased to ~1,500 from ~1,250 for the 30 days in June 2019

References:

- Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. This includes two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
 - Ospheana and Intrarosa data sourced from Symphony Health Integrated Database.
 - 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.

The VVA Market Exceeds \$1.7B Gross Revenue Annually

Product	12 Months through June 2019 Total Units ¹	Gross Dollars of Brand & Generic for 2018 ¹
Estrace® Cream Brand & Generics	2,000,000	\$554,450,000
Premarin®	1,190,000	\$460,760,000
Vagifem® Brand & Generics	1,500,000	\$454,550,000
Estring®	259,000	\$114,360,000
Osphena®	217,000	\$75,910,000
Intrarosa®	209,000	\$46,940,000
2018 Value of the VVA Market		\$1,700,000,000

1) Symphony Health Solutions PHAST Data powered by IDB; MBS dollars. 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
Jul 2019	1 Fill	1 Fill
Jun 2019	1.8 Fills	2 Fills
May 2019	2.4 Fills	3 Fills
Apr 2019	3.0 Fills	4 Fills
Mar 2019	3.5 Fills	5 Fills
Feb 2019	4.0 Fills	6 Fills
Jan 2019	4.5 Fills	7 Fills
Dec 2018	5.0 Fills	8 Fills
Nov 2018	5.7 Fills	9 Fills
Oct 2018	5.9 Fills	10 Fills
Sep 2018	6.5 Fills	11 Fills
Aug 2018	7.8 Fills	13 Fills

IMVEXXY: 3.7 fills/yr³ (through July)

Average fills per year:
Vaginal creams: 1.5/yr⁴
Vaginal tablets: 3.5/yr⁴

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 5.7 fills from November 2018 through July 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

Value of Additional Fills

4
Fills/year

Percent of market based on patient count of 2.3M and 4 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$184,000,000	\$257,600,000	\$331,200,000	\$404,800,000
\$100	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000

5
Fills/year

Percent of market based on patient Count of 2.3M and 5 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000
\$100	\$287,500,000	\$402,500,000	\$517,500,000	\$632,500,000

6
Fills/year

Percent of market based on patient count of 2.3M and 6 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$276,000,000	\$386,400,000	\$496,800,000	\$607,200,000
\$100	\$345,000,000	\$483,000,000	\$621,000,000	\$759,000,000

Market opportunity is calculated by multiplying the number of patients on products annually times the market share times the average number of fills per patient per year times the average potential net revenue per unit. At \$100 average net revenue, the value per fill ranges from \$57M to \$126M, depending on market share.

*Based on patient count not units

Commercial Payer Update

Additional Coverage Decisions Expected 3Q19

**Top 10 Plans Account for ~71%
of all Commercial Pharmacy Lives**

Plan	% of Lives ¹	Status ²
CVS	15.4%	Awaiting decision in 3Q
ESI	15.3%	Adjudicating as of 10/1/18
United	7.5%	Adjudicating as of 3/1/19
Anthem	7.3%	Adjudicating as of Aug. 2018
Prime	6.5%	Adjudicating as of 1/1/19
OptumRx	6.1%	Adjudicating as of 1/1/19
Kaiser	4.7%	In discussions
Aetna	4.0%	Awaiting decision in 3Q - 1.8M of these lives are adjudicating
Cigna	3.9%	Adjudicating as of 12/15/18
EnvisionRx	1.8%	Adjudicating as of 1/1/19

¹Plan numbers as of May 2019
²MMIT July 2019 and Account Insights

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.

Medicare Part D Payer Update

Decisions Expected 3Q/4Q19

**Top 6 Plans Account for ~78%
of all Medicare Part D Pharmacy Lives**

Plan	% of Lives ¹	Status ²
United	20.7%	Adjudicating as of 2/1/19
Humana	17.9%	Decision expected 3Q/4Q19
CVS Caremark	14.1%	Decision expected 3Q/4Q19
Wellcare with Aetna lives	13.6%	Decision expected 3Q/4Q19
Express Scripts/ Cigna	8.5%	Decision expected 3Q/4Q19 - 1M of these lives are adjudicating as of June 2019
Kaiser	3.6%	Adjudicating maintenance pack as of 10/1/18 and starter pack as of 3/1/19

¹Plan numbers as of July 2019
²MMIT July 2019 and Account Insights

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.

How Adjudication Rate* Will Change When Payer Cycle Completes

NOW: 2Q 2019 Actuals

Chart 1

	Column A	Column B	Column C
IMVEXXY	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	3%	62%	35%
% Adjudicated	0%	50%	8%
Contribution to Overall Adjudication Rate	0%	31%	3%
Overall Adjudication Rate	34% (up from 27% in 1Q19)		

Chart 2

Target Adjudication as Contracting is Finalized

	Column A	Column B	Column C
IMVEXXY	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	6%	70%	24%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	53%	17%
Overall Adjudication Rate	70%		

*Adjudication Rate= Percent of Business multiplied by percent of claims being covered.

IMVEXXY CATALYSTS

Direct to Consumer Advertising

Medicare Part D Decisions

- Expect commercial coverage decisions from CVS and Aetna

- Menopause Awareness Month - Satellite Media Tour

Begin Copay Optimization

- NAMS Premier Sponsor
- NAMS Publications

3Q 2019

4Q 2019





BIJUVA




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A Large Target Market For BIJUVA

Q2 →  **Launched April 17, 2019** 

Q2 →  **Target FDA-approved separate bio-identical Estrogen & Progesterone pills segment**
~3.9M TRx (each)¹ | \$836M² TAM

Q4 →  **BIJUVA introduced into Bio-Ignite Channel, once payer coverage established**
12M – 18M TRx³ | \$2.5B-3.8B² TAM

Reps directed to focus on ~10 prescribers in their territory until improved payer coverage

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

BIJUVA Launch Metrics

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients ¹ (since launch through July 31, 2019)	~8,900
Total paid scripts (July 1-31, 2019)	~4,300
Total patients (since launch through July 31, 2019)	~4,700
Total prescribers ² (since launch through July 31, 2019)	~2,300

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

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

BIJUVA Payer Update

Quicker Process to Payer Coverage

- Contract amendments in larger category with little Medicare Part D
- Commercial segment represents vast majority of BIJUVA patients
- Expect 3-4 quarters cycle to secure commercial payers; decisions expected by 4Q19

New

New

Top 10 Plans Account for ~71% of all Commercial Pharmacy Lives		
Plan	% of Lives ¹	Status ²
CVS	15.4%	
ESI	15.3%	Adjudicating as of 4/19/19
United	7.5%	Adjudicating as of 8/1/19
Anthem	7.3%	
Prime	6.5%	
OptumRx	6.1%	Adjudicating as of 8/1/19
Kaiser	4.7%	
Aetna	4.0%	Adjudicating as of 4/2019
Cigna	3.9%	
EnvisionRx	1.8%	

¹Plan numbers as of May 2019
²MMIT July 2019 and Account Insights

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.

Impact of Faster Payer Cycle on Adjudication Rate*

Chart 1

NOW: 2Q 2019 Actuals

BIJUVA	Column A	Column B	Column C
	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	3.1%	89.1%	7.8%
% Adjudicated	0%	37.6%	7.6%
Contribution to Overall Adjudication Rate	0%	33.4%	0.6%
Overall Adjudication Rate	34% (up from 25% in May 2019)		

Chart 2

Target at Fully Established Insurance Coverage

BIJUVA	Column A	Column B	Column C
	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	6%	87%	8%
% Adjudicated	0%	75%	65%
Contribution to Overall Adjudication Rate	0%	65%	5%
Overall Adjudication Rate	70%		

Adjudication Rate= Percent of Business multiplied by % of claims being covered.

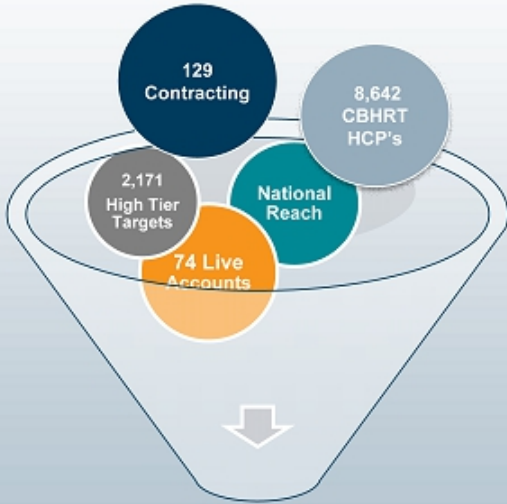
Pharmacy Targeting

- Over 2,171 are high tier targets
 - These locations produce the highest volume of compounded bio-identical hormone replacement therapy (CBHRT) scripts

PROCESS & STATUS



- Unique CBHRT Prescribers Identified: 8,642
 - 1,533 are identified as high-value CBHRT HCP's targeted by Key Account Managers



BIJUVA Market Opportunity

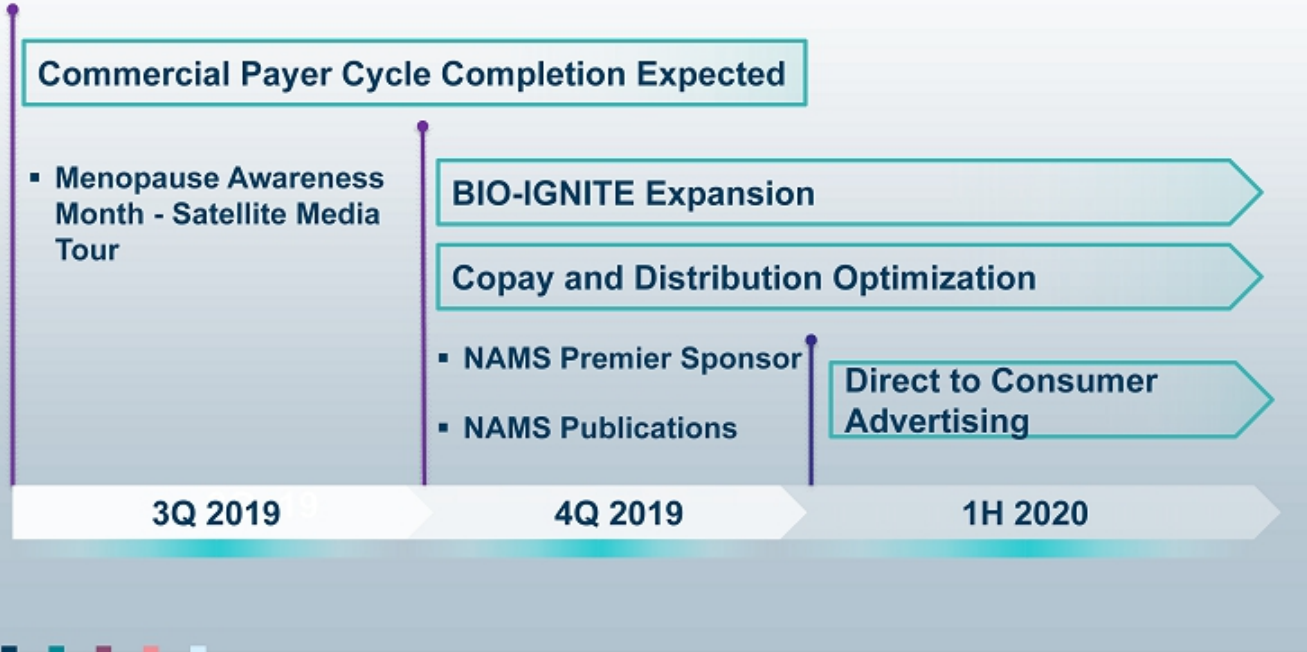
Total Addressable FDA Market: 3,900,000				
Total Addressable Compounding Market: 12,000,000				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316,000,000	\$442,400,000	\$568,800,000	\$695,200,000
\$100	\$395,000,000	\$553,000,000	\$711,000,000	\$869,000,000

Market opportunity is calculated by multiplying the annual addressable market units (3.9M units of FDA-approved E+P plus the low-end of the estimated compounded market of 12M prescriptions) times the market share times the average potential net revenue per unit.

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BIJUVA CATALYSTS





ANNOVERA



ANNOVERA: 2019 Prix Galien USA Award Nominee



The Prix Galien Award, counted among the global health innovation industry's most prized honors, recognizes outstanding biomedical and medical technology product achievement that improves the human condition

Best Pharmaceutical Product 2019 Nominee:



Past Award Winners in the Category

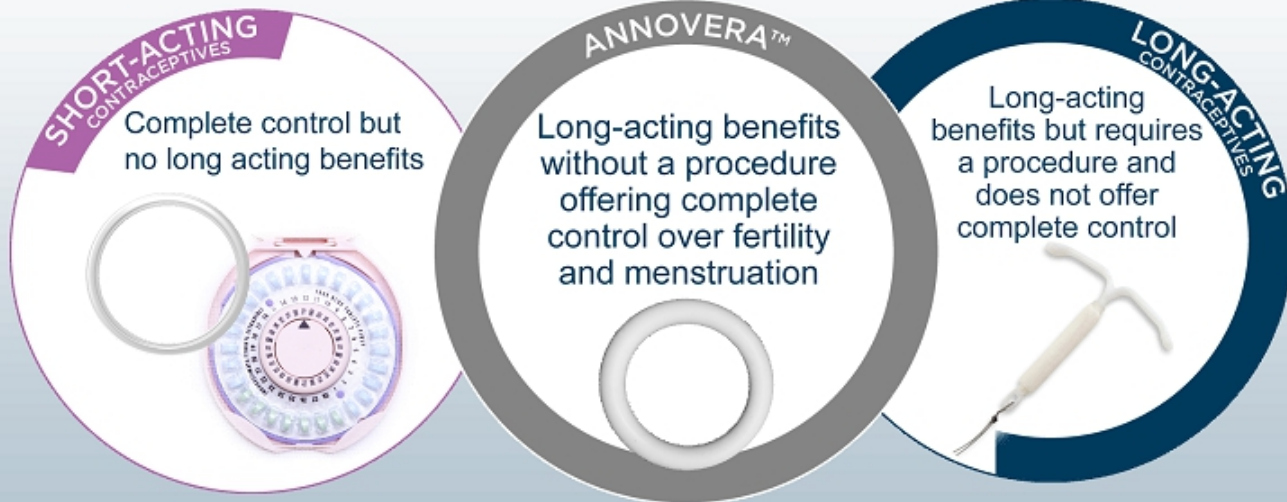
	2018 TRx MBS Dollars ¹
Ibrance®	\$2,293,000,000
IMBRUVICA®	\$2,334,000,000
Gleevec®	\$362,000,000
Januvia®	\$6,237,000,000
Chantix®	\$1,258,000,000

All trademarks are the property of their respective owners.
1. MBS Data

U.S. Contraceptive Market

\$5B U.S. net sales¹

~ 90mm annual scripts to ~20 million women²



Oral contraceptives continue to lose market share (CAGR -4.2% 2012 to 2017) to long acting methods¹

1. QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings.
2. Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2017

ANNOVERA Launch Approach

Pre-Launch Activities

- WAC Price set at \$2,000/unit (1 year)
- Continue dialogue with FDA regarding potential ACA decision designating ANNOVERA as a new method of contraception
- Begin payer discussions
- Plans currently covering
 - Independent Health in Buffalo
 - Health Alliance in Washington
 - Harvard Pilgrim in MA
 - BCBS of MA
 - Procure PBM in Georgia
 - HMSA in Hawaii
- Test and learn market introduction
- Production ramps to ~10,000 units for the 4Q19

National Launch

- Initial focus on OBGYN target overlap with Menopause Products
- Early consumer focus given how influential women are in the choice of birth control
- Full-scale production anticipated 1Q20

3Q 2019

4Q 2019

1Q-3Q 2020

ANNOVERA Market Opportunity

Addressable Birth Control Market Rx Options NRx		28,000,000		
Percent of Overall Birth Control Market NRx				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280,000,000	\$420,000,000	\$560,000,000	\$700,000,000
\$1,500	\$420,000,000	\$630,000,000	\$840,000,000	\$1,050,000,000
\$1,750	\$490,000,000	\$735,000,000	\$980,000,000	\$1,225,000,000

Addressable NuvaRing Market NRx		1,200,000		
Percent of NuvaRing Market NRx				
Average Net Revenue / Unit	25%	35%	45%	55%
\$1,000	\$300,000,000	\$420,000,000	\$540,000,000	\$660,000,000
\$1,500	\$450,000,000	\$630,000,000	\$810,000,000	\$990,000,000
\$1,750	\$525,000,000	\$735,000,000	\$945,000,000	\$1,155,000,000

Market opportunity is calculated by multiplying the annual addressable market times the market share times the average potential net revenue per unit.



Financial Overview

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2Q 2019 Quarterly Financial Results Above Guidance Range

	2Q2019 Estimate	2Q2019 Actual*
FDA-Approved Drugs Net Revenue	\$2.50-3.00M	\$3.25M*
Prenatal Vitamins Net Revenue	\$2.00-2.50M	\$2.80M
Total TXMD Net Revenue	\$4.50-5.50M	~\$6.10M

*Includes net revenues of approximately \$3.12 million for IMVEXXY and \$134,000 for BIJUVA.

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Near-Term Access to Non-Dilutive Capital

- \$300M Non-Dilutive Term Loan Financing with TPG Sixth Street Partners
 - \$200M accessed to date with up to additional \$100M through Specific Company Milestones
 - Incurred a one-time charge in 2Q19 for extinguishment of debt of approximately \$10 million as company refinanced previous term loan into a more favorable, upsized facility
- Closed our ex-US license deal with Theramex in July 2019
 - Received upfront fee of \$15.5 million on August 5, 2019
- Combining these two transactions, TherapeuticsMD will have the potential to access over \$115 million of non-dilutive capital over the coming 8 months
- As of June 30, 2019, cash position of approximately \$183 million

Revised 2019 Quarterly Financial Guidance

	Original 3Q2019 Estimate	Revised 3Q2019 Estimate	Original 4Q2019 Estimate	Revised 4Q2019 Estimate	Delta ¹
FDA-Approved Products Net Revenue	\$4.50-6.50M	unchanged	\$11.00-13.00M	unchanged	-
Prenatal Vitamins Net Revenue	\$1.75-2.25M	\$2.25-2.50M	\$1.50-2.00M	\$1.75-2.25M	+\$0.6M
Total TXMD Net Revenue	\$6.25-8.75M	\$6.75-9.00M	\$12.50-15.00M	\$12.75-15.25M	+\$0.6M

1. Calculated at midpoint

Revised Full-Year 2019 Financial Guidance

	Original FY2019 Actual	Revised FY2019 Estimate	Delta ¹
FDA-Approved Products Net Revenue	\$20.00-24.50M	\$20.75-24.75M	+0.5M
Prenatal Vitamins Net Revenue	\$7.15-8.65M	\$8.70-9.45M	+1.2M
Total TXMD Net Revenue	\$27.10-33.10M	\$29.45-34.20M	+1.7M

▪ **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

1. Calculated at midpoint

The Power of a Women's Health Portfolio

Annovera™
 (megestrol acetate and ethinyl estradiol vaginal system)
Dabura 5.15 mg/0.012 mg per day

vitaMedMD®
 Prenatal Vitamins

Annovera™
 (megestrol acetate and ethinyl estradiol vaginal system)
Dabura 5.15 mg/0.012 mg per day

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

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



CONTRACEPTION

PRENATAL CARE

CONTRACEPTION/
 FAMILY PLANNING -
 PERIMENOPAUSE

VASOMOTOR SYMPTOMS

DYSPAREUNIA
 (Vulvar & Vaginal Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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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	\$184,000,000	\$257,600,000	\$331,200,000	\$404,800,000
\$100	\$230,000,000	\$322,000,000	\$414,000,000	\$506,000,000

Total Addressable FDA Market: 3,800,000 Total Addressable Compounding Market: 12,000,000				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316,000,000	\$442,400,000	\$568,800,000	\$695,200,000
\$100	\$395,000,000	\$553,000,000	\$711,000,000	\$869,000,000

Total Addressable Birth Control Market NRx 28,000,000				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280,000,000	\$420,000,000	\$560,000,000	\$700,000,000
\$1,500	\$420,000,000	\$630,000,000	\$840,000,000	\$1,050,000,000
\$1,750	\$490,000,000	\$735,000,000	\$980,000,000	\$1,225,000,000



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

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