

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): November 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.)

951 Yamato Road, Suite 220
Boca Raton, FL 33431

(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 November 6, 2019, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 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 November 6, 2019, the Company issued a press release announcing the Company's financial results for its third quarter ended September 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>
<u>99.1</u>	Press Release from TherapeuticsMD, Inc., dated November 6, 2019, entitled TherapeuticsMD Announces Third Quarter 2019 Financial Results.
<u>99.2</u>	TherapeuticsMD, Inc. Presentation dated November 6, 2019.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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.

THERAPEUTICSMD, INC.

Date: November 6, 2019

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2019 Financial Results

- 3Q19 Net Revenue (Product and License) Increased to \$23.7 Million -
- 3Q19 Product Net Revenue Increased 34% to \$8.2 Million Compared to 2Q19-
- The Company Reaffirms 4Q19 Financial Guidance -
- Conference Call Scheduled for 4:30 p.m. ET Today -

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

“We are very pleased with our results for the quarter, which are in-line with our financial guidance, and reaffirm our fourth quarter 2019 financial guidance,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. “This reiterates our confidence that we will be able to access an additional \$50 million in capital from our term loan facility when fourth quarter 2019 results are announced. Additionally, we recently completed an equity raise that netted the company approximately \$77 million and improved our liquidity. We believe we now have the resources and momentum to continue to fully execute our plans into 2020 and beyond.”

Third Quarter and Recent Developments

- IMVEXXY[®] (estradiol vaginal inserts) third quarter 2019 product net revenue increased by 53% to approximately \$4.8 million and prescriptions dispensed and paid for by patients increased 26% to approximately 134,000 as compared to the second quarter of 2019. Strong refill rates continued with patients adhering to therapy at an average rate of four fills per year through September 2019.
- IMVEXXY has market access for the majority of lives under commercial plans with approximately 68% unrestricted commercial access. IMVEXXY is now covered by eight of the ten top commercial payers of vulvar and vaginal atrophy (VVA) products. A ninth top-ten commercial payer will adjudicate beginning in January 2020. Two of the top six Medicare Part D payers of VVA products cover IMVEXXY and additional Medicare coverage decisions are expected by the end of 2019.
- BIJUVA[®] (estradiol and progesterone) capsules third quarter 2019 product net revenue and prescriptions increased two-fold to approximately \$0.5 million and approximately 15,800 prescriptions dispensed and paid for by patients during the third quarter as compared to the second quarter of 2019.
- BIJUVA currently has approximately 55% unrestricted commercial access and is covered by six of the top ten commercial payers.
- ANNOVERA[™] (segesterone acetate and ethinyl estradiol vaginal system) generated third quarter product net revenue of approximately \$0.4 million. The company is in the “test and learn” market introduction phase of launch for ANNOVERA, the first and only long-lasting, patient-controlled, procedure-free, reversible prescription contraceptive option for women.
- ANNOVERA has already achieved approximately 62% unrestricted commercial access and is covered by six of the top ten commercial payers by commercial payer lives.
- On October 29, 2019, the company received net proceeds of approximately \$77.0 million from an underwritten public offering of its common stock to support commercialization efforts for its three FDA-approved products and to maximize ANNOVERA’s consumer-focused commercialization strategy.

Summary of Third Quarter 2019 Financial Results

Total net revenue increased to approximately \$23.7 million, for the third quarter of 2019 compared with net revenue of approximately \$3.5 million for the prior year's quarter. During the third quarter of 2019, the company recognized license revenue of approximately \$15.5 million from the upfront fee, a non-refundable payment, under the company's license agreement with Theramex, which is included in total revenue for the quarter.

Product net revenue increased to approximately \$8.2 million, for the three months ended September 30, 2019 compared with approximately \$3.5 million for the three months ended September 30, 2018. Product net revenue increased primarily due to increases in sales of approximately \$4.5 million of IMVEXXY in the current period, partially offset by a decrease in prenatal vitamin sales of approximately \$0.7 million. Product net revenue for the three months ended September 2019 also included sales of BIJUVA of approximately \$0.5 million and sales of ANNOVERA of approximately \$0.4 million. The revenue decrease related to our prenatal vitamins was primarily affected by a lower number of units sold as compared to the prior year period, partially offset by increased revenue per unit. The company launched IMVEXXY in the third quarter of 2018, BIJUVA in the second quarter of 2019, and ANNOVERA in the third quarter of 2019.

The following table provides information about disaggregated revenue by product mix for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,	
	2019	2018
Prenatal vitamins	\$ 2,550,330	\$ 3,261,459
IMVEXXY	4,772,354	212,076
BIJUVA	490,705	—
ANNOVERA	399,952	—
License revenue	15,506,400	—
Net revenue	<u>\$ 23,719,741</u>	<u>\$ 3,473,535</u>

Net revenue for IMVEXXY and BIJUVA has been greatly affected by the company's co-pay assistance programs introduced to provide products at a reasonable cost regardless of insurance coverage. We expect our product revenues to improve as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA and ANNOVERA prescriptions at pharmacies.

Research and development (R&D) expenses for the third quarter of 2019 decreased to approximately \$4.1 million, compared with approximately \$6.7 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 operations as they begin 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 early development trials and employment costs of personnel involved in R&D activities.

Sales, general and administrative (SG&A) expenses increased for the third quarter of 2019 to approximately \$45.1 million, compared with approximately \$30.4 million for the prior year's quarter. The increase of SG&A expenses for third quarter 2019 was primarily a result of increased expenses associated with sales and marketing efforts and personnel costs to support the launch and commercialization of IMVEXXY, BIJUVA, and ANNOVERA including outsourced sales personnel and their related expenses, physician education, advertising, and travel expenses related to product commercialization. The company expects sales and marketing expenses to continue to increase as it continues the launch of BIJUVA and ANNOVERA and continues to support its growing business and commercialization of its products.

For the third quarter of 2019, net loss decreased to approximately \$32.0 million, or \$0.13 per basic and diluted share, compared with approximately \$35.6 million, or \$0.16 per basic and diluted share, for the third quarter of 2018.

Balance Sheet

As of September 30, 2019, the company's cash on hand totaled approximately \$155.3 million, compared with approximately \$161.6 million at December 31, 2018. On October 29, 2019, the company received net proceeds of approximately \$77.0 million from an underwritten public offering of its common stock.

Total outstanding debt, net of issuance costs, was approximately \$194.4 million as of September 30, 2019.

Financial Guidance

The company reaffirms its previously announced fourth quarter 2019 financial guidance outlined below:

- FDA-approved product net revenue is expected to be in a range of \$11 million to \$13 million;
- Prescription prenatal vitamin net revenue is expected to be in a range of \$1.75 million to \$2.25 million; and
- Total product net revenue is expected to be in a range of \$12.75 million to \$15.25 million.

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:	Wednesday, November 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:	7045719

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: 7045719.

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, including the conditions to draw additional tranches thereunder; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of 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.

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Investor Contact

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

THERAPEUTICSM D, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash	\$ 155,330,050	\$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of \$691,699 and \$596,602, respectively	15,323,614	11,063,821
Inventory	10,532,844	3,267,670
Other current assets	10,578,260	10,834,693
Total current assets	<u>191,764,768</u>	<u>186,779,261</u>
Fixed assets, net	<u>2,338,346</u>	<u>472,683</u>
Other Assets:		
License rights, net	39,984,002	20,000,000
Intangible assets, net	4,942,151	4,092,679
Right-of-use asset	10,459,635	—
Other assets	473,009	639,301
Total other assets	<u>55,858,797</u>	<u>24,731,980</u>
Total assets	<u>\$ 249,961,911</u>	<u>\$ 211,983,924</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 24,133,506	\$ 22,743,841
Other current liabilities	43,196,032	18,334,948
Total current liabilities	<u>67,329,538</u>	<u>41,078,789</u>
Long-Term Liabilities:		
Long-term debt	194,361,169	73,381,014
Operating lease liability	9,500,133	—
Total liabilities	<u>271,190,840</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: 241,277,076 and 240,462,439 issued and outstanding, respectively	241,277	240,463
Additional paid-in capital	624,515,559	616,559,938
Accumulated deficit	(645,985,765)	(519,276,280)
Total stockholders' (deficit) equity	<u>(21,228,929)</u>	<u>97,524,121</u>
Total liabilities and stockholders' equity	<u>\$ 249,961,911</u>	<u>\$ 211,983,924</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product revenue, net	\$ 8,213,341	\$ 3,473,535	\$ 18,238,857	\$ 11,009,937
License revenue	15,506,400	—	15,506,400	—
Total revenue, net	<u>23,719,741</u>	<u>3,473,535</u>	<u>33,745,257</u>	<u>11,009,937</u>
Cost of goods sold	<u>1,444,308</u>	<u>699,118</u>	<u>3,455,995</u>	<u>1,786,902</u>
Gross profit	<u>22,275,433</u>	<u>2,774,417</u>	<u>30,289,262</u>	<u>9,223,035</u>
Operating expenses:				
Sales, general, and administrative	45,126,986	30,354,072	121,378,519	80,578,079
Research and development	4,077,738	6,708,271	15,359,988	20,545,948
Depreciation and amortization	141,959	73,321	363,956	198,545
Total operating expenses	<u>49,346,683</u>	<u>37,135,664</u>	<u>137,102,463</u>	<u>101,322,572</u>
Operating loss	(27,071,250)	(34,361,247)	(106,813,201)	(92,099,537)
Other expense				
Loss on extinguishment of debt	—	—	(10,057,632)	—
Miscellaneous income	703,662	809,022	1,878,980	1,457,817
Interest expense	(5,599,005)	(2,053,077)	(11,717,632)	(2,584,459)
Total other expense	<u>(4,895,343)</u>	<u>(1,244,055)</u>	<u>(19,896,284)</u>	<u>(1,126,642)</u>
Loss before income taxes	(31,966,593)	(35,605,302)	(126,709,485)	(93,226,179)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (31,966,593)</u>	<u>\$ (35,605,302)</u>	<u>\$ (126,709,485)</u>	<u>\$ (93,226,179)</u>
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.16)</u>	<u>\$ (0.53)</u>	<u>\$ (0.42)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>241,261,299</u>	<u>228,107,240</u>	<u>241,163,994</u>	<u>220,466,673</u>

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

Nine Months Ended
September 30,

2019 **2018**

CASH FLOWS FROM OPERATING ACTIVITIES

Net loss	\$ (126,709,485)	\$ (93,226,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	223,750	121,423
Amortization of intangible assets	140,206	77,123
Write off of patent and trademark cost	78,864	—
Non-cash operating lease expense	711,836	—
Provision for doubtful accounts	95,097	231,475
Loss on extinguishment of debt	10,057,632	—
Share-based compensation	7,859,357	6,388,635
Amortization of intellectual property license fee	15,998	—
Amortization of deferred financing fees	582,829	149,909
Changes in operating assets and liabilities:		
Accounts receivable	(4,354,890)	(8,705,325)
Inventory	(7,265,174)	(892,863)
Other current assets	(1,128,515)	1,233,482
Accounts payable	1,389,665	7,284,493
Accrued expenses and other liabilities	3,402,511	8,670,986
Net cash used in operating activities	(114,900,319)	(78,666,841)

CASH FLOWS FROM INVESTING ACTIVITIES

Payment for intellectual property license	—	(20,000,000)
Patent costs	(1,068,542)	(748,906)
Purchase of fixed assets	(2,089,413)	(66,295)
Payment of security deposit	(20,420)	(11,485)
Net cash used in investing activities	(3,178,375)	(20,826,686)

CASH FLOWS FROM FINANCING ACTIVITIES

Proceeds from Financing Agreement	200,000,000	—
Proceeds from exercise of options and warrants	108,656	1,236,313
Proceeds from sale of common stock, net of costs	—	89,907,797
Proceeds from Credit Agreement	—	75,000,000
Payment of deferred financing fees	(6,652,270)	(3,786,918)
Repayment of Credit Agreement	(81,660,719)	—
Net cash provided by financing activities	111,795,667	162,357,192
(Decrease) increase in cash	(6,283,027)	62,863,665
Cash, beginning of period	161,613,077	127,135,628
Cash, end of period	<u>\$ 155,330,050</u>	<u>\$ 189,999,293</u>

Supplemental disclosure of cash flow information

Interest paid	<u>\$ 12,446,792</u>	<u>\$ 1,759,316</u>
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Non-cash investing activity

Amount accrued for intellectual property license	\$ 20,000,000	\$ —
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3Q 2019 Earnings

November 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.

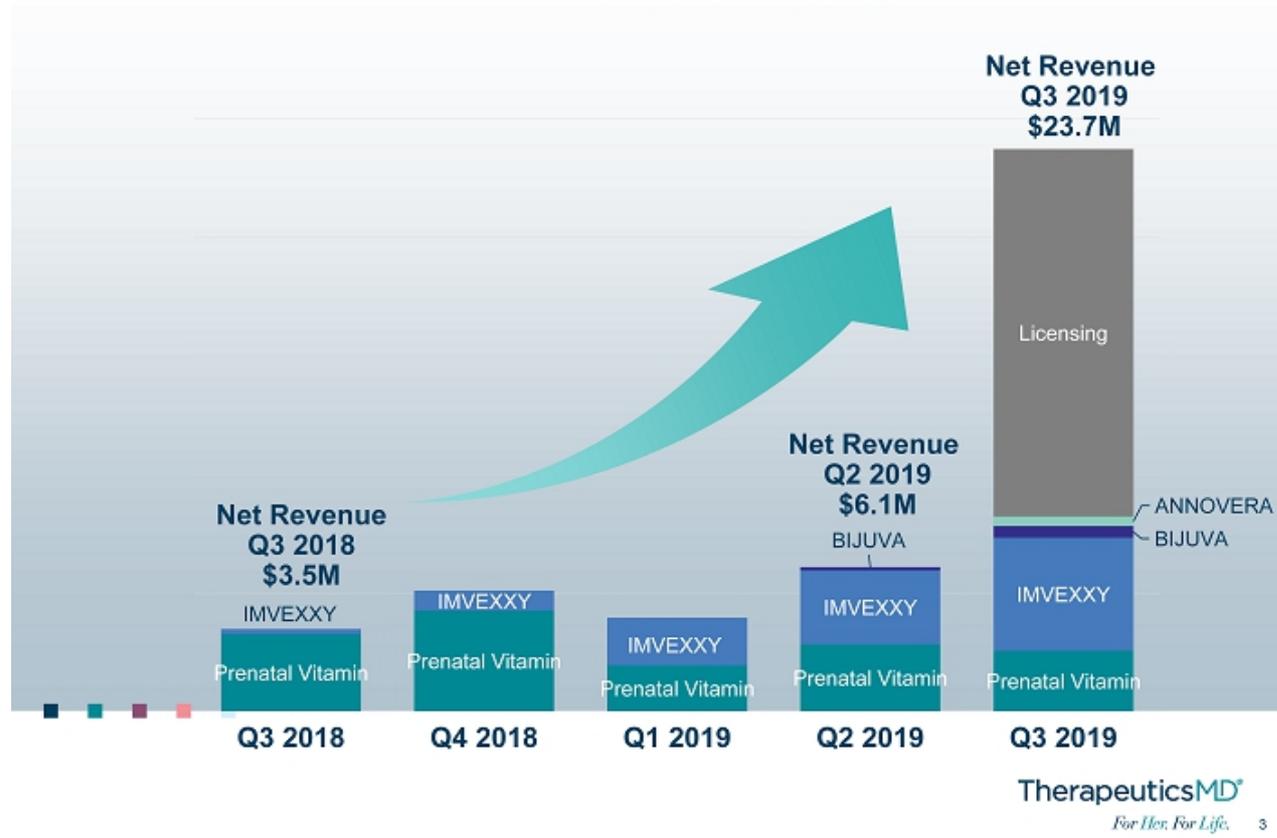
Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are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



TherapeuticsMD[®]

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Trend in Net Revenue



3Q19 Financial Results

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

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

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

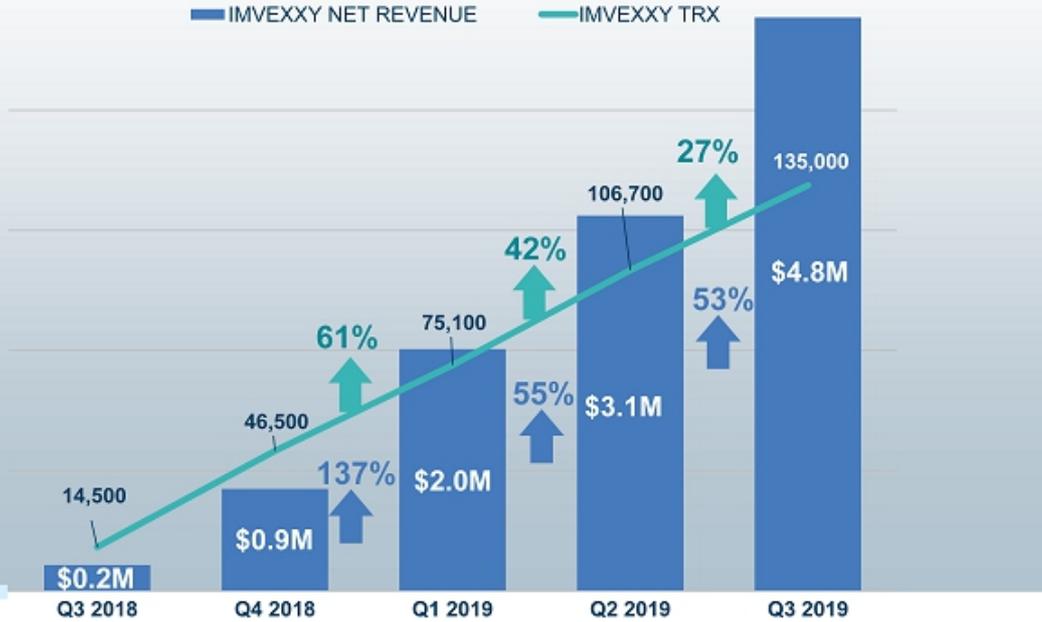
TherapeuticsMD[®]

For Her. For Life. 4

IMVEXXY Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients

■ IMVEXXY NET REVENUE ▲ IMVEXXY TRX



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

BIJUVA Net Revenue Growth Faster than Unit Growth

Net Revenue vs. Sales of Units to Patients

■ BIJUVA NET REVENUE — BIJUVA TRX



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

ANNOVERA LAUNCH INSIGHTS

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



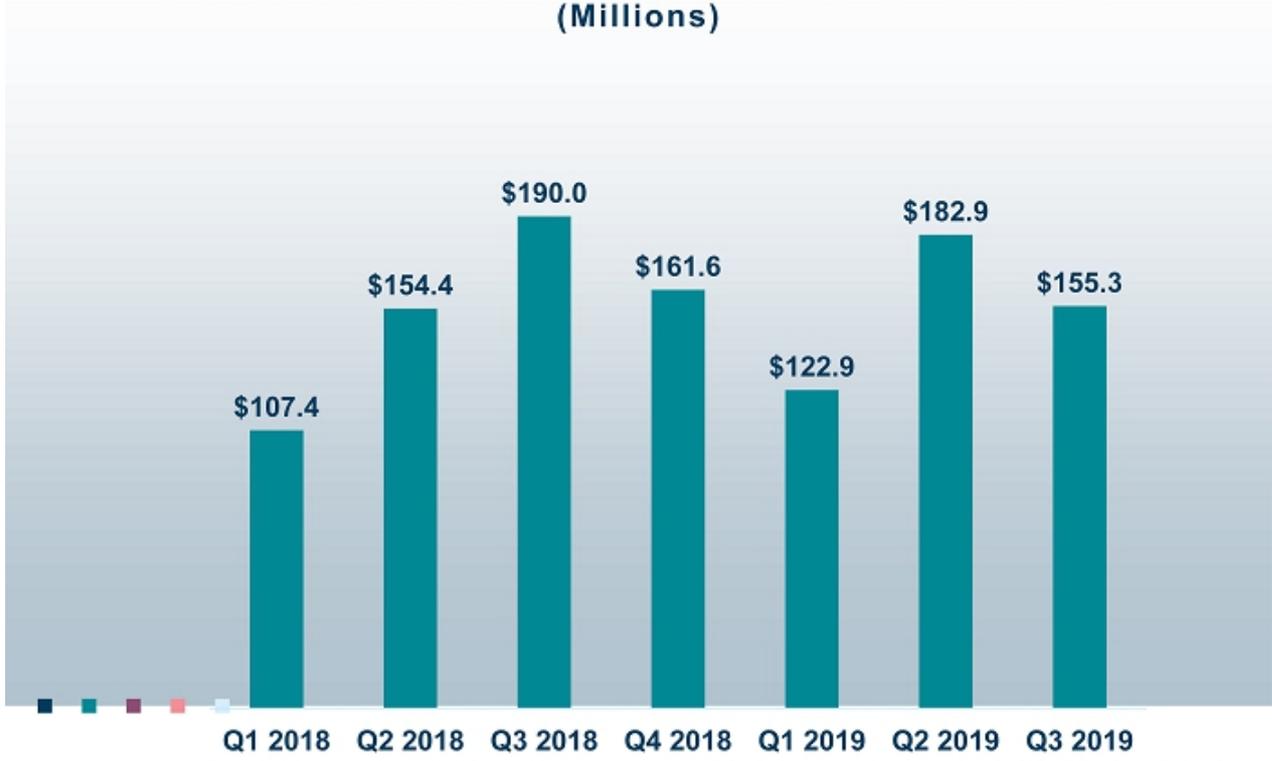
Financial Summary

- Operating expenses – SG&A expenses
- Net loss and basic & diluted per share



Cash Balance at End of Each Quarter

(Millions)



TherapeuticsMD

For Her. For Life. 9

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



TherapeuticsMD

For Her. For Life. 10

Non-Dilutive Term Loan Financing

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

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

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

Reaffirm 4Q2019 Financial Guidance

4Q2019 Estimate

FDA-Approved Products
Net Revenue

\$11.00 - \$13.00M

Prenatal Vitamins
Net Revenue

\$1.75 - \$2.25M

Total TXMD Product
Net Revenue

\$12.75 - \$15.25M

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

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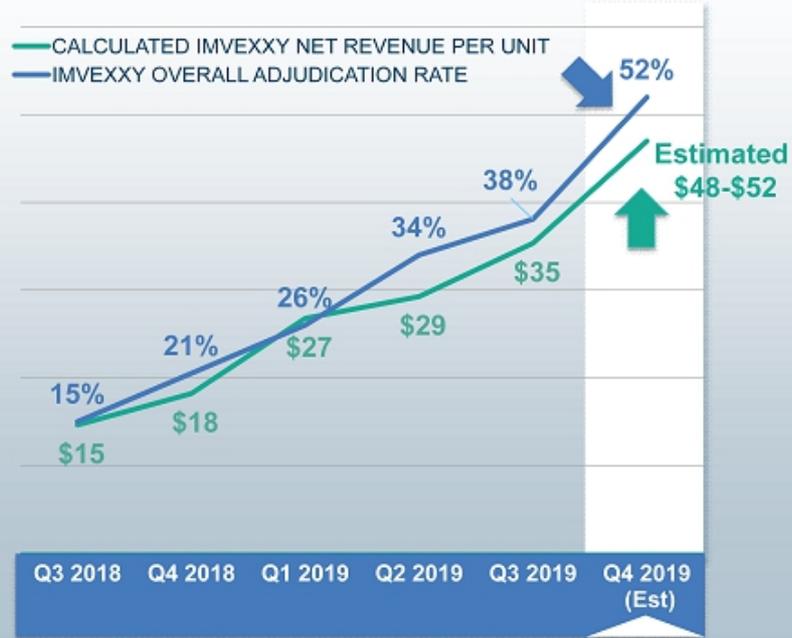


**COMMERCIAL
UPDATE**



IMVEXXY Calculated Net Revenue Per Unit Increases as Adjudication Rates Increases

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



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

Improvement in Adjudication Rates

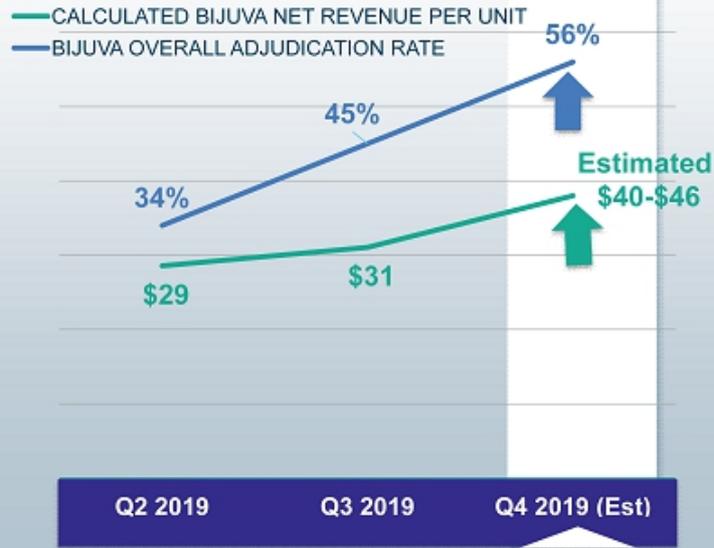


- Addition of CVS in September contributing to overall adjudication rates
- Adjudication in Commercial Patients at 72% in October

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

BIJUVA Calculated Net Revenue Per Unit Increases as Adjudication Rates Increase

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



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

Improvement in Adjudication Rates



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

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



Annovera™

(segesterone acetate and
ethinyl estradiol vaginal system)
Delivers 0.15 mg/0.013 mg per day

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ANNOVERA Commercial Payer Update

Already Achieved ~62% Unrestricted Access¹

Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives¹

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

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

¹MMIT November 2019 (Account Insights) and CVS Preventative Drug List

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

ANNOVERA Status



STARTED
SOFT- LAUNCH
36 REPS + SALES
MANAGEMENT



PILLPACK
PARTERSHIP
LAUNCHED



4Q19 EXPECTED NET
REVENUE PER UNIT
RANGE

The Power of a Women's Health Portfolio

Annovera™
 (norgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

vitaMedMD®
 Prenatal Vitamins

Annovera™
 (norgestrel acetate and ethinyl estradiol vaginal system)
 Delivers 0.02 mg/0.01 mg per day

Bijuva™
 (estradiol and progesterone) capsules

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



CONTRACEPTION

PRENATAL CARE

**CONTRACEPTION/
 FAMILY PLANNING -
 PERIMENOPAUSE**

**VASOMOTOR
 SYMPTOMS**

**DYSPAREUNIA
 (Vulvar & Vaginal
 Atrophy)**



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APPENDIX



ANNOVERA Deal Terms

Milestone Payments

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

Royalty %

Step structure:

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

Additional Cost Considerations

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

*Costs exceeding \$20M to be shared with Population Council

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3Q 2019 Key Performance Metrics

IMVEXXY



- IMVEXXY net revenue totaled \$4.8M for 3Q19 (up from \$3.1M for 2Q19)
 - Net revenue continues to grow faster than units due to improving adjudication rates
 - TRx increased 26% to ~134,000 units for 3Q19 (up from 106,000 for 2Q19)
 - Overall adjudication increased to 38% (up from 34% for 2Q19)

BIJUVA



- BIJUVA net revenue totaled \$491,000 for 3Q19 (up from \$134,000 for 2Q19)
 - TRx increased to 15,800 units for 3Q19 (up from 4,600 for 2Q19)
 - Overall adjudication increased to 45% (up from 34% for 2Q19)

ANNOVERA



- ANNOVERA net revenue totaled \$400,000 for 3Q19
 - Strong initial commercial net revenue of ~\$1,250 per unit with the potential for improvement²



¹ \$1,250 assumes patients meeting the criteria of 1) commercially insured patient or 2) approved via a Medical Necessity Letter. Does not include cash pay sales.

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IMVEXXY October Launch Metrics

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

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

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

Launch Results Remain Strong

Imvexxy TRx Launch Comparison



Market Share

*Month 16 for IMVEXXY is October 2019

References:

1. Total prescription data is based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program. This includes up to two weeks of estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
 2. Ospheña and Intrarosa data sourced from Symphony Health Integrated Database.
 3. Vagifem data sourced from IQVIA National Prescriber Level Data.
 4. Market share data based on IQVIA prescriber level data plus additional unique patient data identified through utilization of our affordability program.
- All trademarks are the property of their respective owners.

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Continued Strong Patient Adherence

IMVEXXY Patient Adherence^{1,2}

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

IMVEXXY: 4.0 fills/yr³ (through Oct)

- Vaginal creams: average 1.5 fills/yr⁴
- Vaginal tablets: average 3.5 fills/yr⁴

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

1) Average number of fills per patient is the average number of fills per patient grouped by their initial month on therapy.
 2) Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.
 3) Average number of fills for all patients is calculated as Total Rx / Total Patients.
 4) Total Rx/Patient Count

Commercial Payer Status

Achieved ~68% Unrestricted Commercial Access¹
9 of the Top 10 Commercial Payers Secured

Top 10 Plans Account for ~74%
of all Commercial Pharmacy Lives¹

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

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

¹MMIT November 2019 (Account Insights)

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

Medicare Part D Payer Status Additional Decisions Expected This Quarter

**Top 8 Plans Account for ~83%
of all Medicare Part D Pharmacy Lives¹**

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

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

¹MMIT November 2019 (Account Insights)

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

BIJUVA Update

Plan to Submit BIJUVA 0.5/100 mg Dose

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

Reason for Submission

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

BIJUVA Commercial Payer Update

Additional Coverage Decisions Expected This Quarter

Achieved ~55% Unrestricted Commercial Access¹
6 of the Top 10 Commercial Payers Secured¹

**Top 10 Plans Account for ~74%
of all Commercial Pharmacy Lives¹**

Plan	% of Lives ²	Status ³
CVS	16%	In discussions
ESI	16%	Adjudicating as of 4/19/19
United	8%	Adjudicating as of 8/1/19
Anthem	7%	In discussions
Prime	6%	In discussions
OptumRx	6%	Adjudicating as of 8/1/19
Kaiser	5%	In discussions
Aetna	4%	Adjudicating as of 4/2019
Cigna	4%	Adjudicating as of 9/2019
EnvisionRx	2%	Adjudicating as of 11/2019

New

New

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.

¹MMIT November 2019 and Account Insights

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

BIJUVA October Launch Metrics

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

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

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

ANNOVERA Commercial Payer Update

Already Achieved ~62% Unrestricted Access¹

Top 10 Plans Account for ~74% of all Commercial Pharmacy Lives¹

	Plan	% of Lives ²	Status ³
New	CVS	16%	Adjudicating with no copay as of October 2019
	ESI	16%	Adjudicating at T3 as of September 2019
	United	8%	In discussions
	Anthem	7%	Adjudicating at T3, no copay as of August 2019
	Prime	6%	In discussions
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	Cigna	4%	Adjudicating at T3 as of August 2019
New	EnvisionRx	2%	Adjudicating as of November 2019

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

¹MMIT November 2019 (Account Insights) and CVS Preventative Drug List

²Plan numbers as of October 2019

³Adjudication status from MMIT November 2019 and Account Insights

ANNOVERA Commercial Payer Update

Fast Uptake in Regional Plans

Selected Regional Plan Coverage

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

¹Plan numbers as of October 2019

²MMIT October 2019 and Account Insights

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

The Power of the Portfolio

Multiple Paths to \$1B of Peak Sales

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

Total Addressable FDA Market: 3.8M				
Total Addressable Compounding Market: 12M				
Percent of Addressable Market				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$316M	\$442.4M	\$568.8M	\$695.2M
\$100	\$395M	\$553M	\$711M	\$869M

Total Addressable Birth Control Market NRx: 28M				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280M	\$420M	\$560M	\$700M
\$1,250	\$350M	\$525M	\$700M	\$875M
\$1,500	\$420M	\$630M	\$840M	\$1.05B
\$1,750	\$490M	\$735M	\$980M	\$1.2B



Diversified risk with 3 FDA-approved products, creating multiple paths to \$1B peak sales opportunity
 Example: \$230M (IMVEXXY), \$395M (BIJUVA) and \$420M (ANNOVERA) = \$1B peak sales potential

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