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): February 21, 2019

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-00100**	**87-0233535**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 February 21, 2019, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2018. 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) are 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 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 February 21, 2019, the Company issued a press release announcing the Company’s financial results for its fourth quarter and full year ended December 31, 2018. 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 Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated February 21, 2019, entitled "TherapeuticsMD Announces Fourth Quarter and Full-Year 2018 Financial Results."
99.2	TherapeuticsMD, Inc. Presentation dated February 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: February 21, 2019

THERAPEUTICSMD, INC.

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Fourth Quarter and Full-Year 2018 Financial Results

-Successful Launch of IMVEXXY®, Strong Positive
Trends Continue for Prescriptions and Patient Refills-

-BIJUVA™ Commercial Launch on Track for the Second Quarter of 2019-

-ANNOVERA™ Commercial Launch planned as Early as the Third Quarter of 2019-

-Conference Call Scheduled for 4:30 p.m. ET Today-

BOCA RATON, Fla. – **February 21, 2019** – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women's healthcare company, today announced its commercial and corporate update for the fourth quarter and full-year ended December 31, 2018.

"In 2018, we completed our most successful year to date and transformed into a leading women's healthcare company," said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. "As we begin 2019, we are focused on executing the next phases of our commercialization strategy. IMVEXXY continues to deliver strong growth in prescriptions and in patient refill activity. Its success has laid the foundation for the upcoming launches of BIJUVA in the second quarter of this year and ANNOVERA as early as the third quarter of this year. We are enthusiastic about expanding our BIO-IGNITE℠ program with our compounding pharmacy partners that represent a large and important channel for physicians and patients in hormone therapy."

IMVEXXY Launch Continues to Highlight Successful Launch Execution

- The company commenced the U.S. commercial launch of IMVEXXY (estradiol vaginal inserts) 10-mcg dose in August 2018 and the 4-mcg dose in September 2018 with the support of 150 sales representatives. IMVEXXY is currently available in major U.S. pharmacy chains and through BIO-IGNITE compounding pharmacy partners.
    - Approximately 47,500 prescriptions of IMVEXXY were dispensed to approximately 22,200 patients during the fourth quarter of 2018. The 3-fold increase in prescription volume for the fourth quarter of 2018 as compared to our launch during the third quarter of 2018.
    - From launch through December 31, 2018, approximately 62,400 prescriptions were dispensed to approximately 25,500 patients and approximately 7,300 prescribers had a filled prescription for the product.
    - Strong refill rates suggest women are having a positive experience with IMVEXXY. Patients who began treatment in August 2018 have obtained an average of 4.9 refills through January 2019, out of a possible 6 refills.
    - Through December 31, 2018, the company achieved unrestricted coverage with six of the top ten commercial payers, with three of them adjudicating on January 1, 2019. This includes two commercial payers that were added in the fourth quarter of 2018, which was a large contributor to the 4-fold increase in net revenue growth for IMVEXXY for the fourth quarter of 2018 as compared to our launch during the third quarter of 2018.

- After year end, the company came to agreement for commercial coverage of IMVEXXY with United Healthcare, the third largest commercial payer in the U.S, to begin adjudication on March 1, 2019. Additionally, the company secured coverage from United Healthcare and Kaiser (limited to only the maintenance pack) for their Medicare Part D plans.
- IMVEXXY prescription growth continues into 2019 as highlighted by a record month in January 2019.
- IMVEXXY average weekly prescription volume for the first two weeks of February 2019 increased to approximately 5,800 as compared to average weekly volume of approximately 5,300 in January 2019.

Key Expected Events in 2019

- 1Q 2019 - Speaker medical education programs throughout the United States highlighting the clinical and physical attributes of IMVEXXY
- 1Q 2019 through 3Q 2019 – Expand IMVEXXY Part D coverage
- 1Q 2019 – Expand sales force by 25% to 200 sales representatives to increase reach of IMVEXXY and launch BIJUVA
- 2H 2019 - Begin direct-to-consumer marketing for IMVEXXY
- 2Q 2019 – U.S. commercial launch of BIJUVA (estradiol and progesterone) capsules and draw second $75 million debt tranche with MidCap Financial Trust
- 2H (targeting 3Q) 2019 - U.S. commercial launch of ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system)
- 2H 2019 – Debt funding for ANNOVERA
- Summer 2019 - Company to hold Analyst Day
- Late 4Q 2019 - BIJUVA 6-month “new to market” payer block expected to end
- Full year 2019 - Oral presentations and posters related to clinical benefits of IMVEXXY, BIJUVA and ANNOVERA at medical meetings
- Throughout 2019 - Continue to expand BIO-IGNITE with a fuller expansion towards the end of 2019 when the six-month payer block for BIJUVA is expected to end

Summary of Fourth Quarter and Full Year 2018 Financial Results

For the year ended December 31, 2018, net revenues were approximately $16.1 million compared with approximately $16.8 million for the prior year. Net revenues for the fourth quarter of 2018 were approximately $5.1 million compared with net revenues of approximately $4.1 million for the prior year’s quarter. Net revenues from the company’s prescription prenatal vitamin business were approximately $4.2 million for the fourth quarter of 2018, compared with approximately $4.1 million for the fourth quarter of 2017. Net revenues for IMVEXXY for the fourth quarter of 2018 were approximately $0.9 million and were greatly affected by our co-pay assistance program introduced to launch IMVEXXY, which is a maximum $35 out-of-pocket copay assistance program that allows eligible patients to access the product for a reasonable cost regardless of the insurance coverage. The decrease in full-year 2018 net revenues related to lower prenatal vitamins revenues of approximately $1.6 million, primarily due to a lower number of units sold and higher utilization of coupons offered to customers in 2018 as compared to the prior year, partially offset by approximately $1.1 million in net revenues for IMVEXXY. Net revenues for IMVEXXY were greatly affected by our co-pay assistance program. The company expects the net revenues for IMVEXXY to improve as commercial payer coverage for IMVEXXY increases and insurance plans complete the process needed to adjudicate IMVEXXY prescriptions at pharmacies.

Research and development (R&D) expenses for the full-year 2018 decreased to approximately $27.3 million, compared with approximately $33.9 for the prior year. R&D expenses for the fourth quarter of 2018 were approximately $6.8 million compared with approximately $11.0 million for the prior year's quarter. The decrease in full-year 2018 R&D expenses was primarily as a result of the completion of the REPLENISH Trial for BIJUVA and 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 full-year 2018 increased to approximately $116.0 million, compared with approximately $57.7 million for the prior year. SG&A expenses for the fourth quarter of 2018 were approximately $35.4 million compared with approximately $14.2 million for the prior year's quarter. The increase in full-year 2018 sales and marketing expenses was primarily a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of IMVEXXY and BIJUVA, including costs related to outsourced sales personnel and their related expenses, physician education and product samples, 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, prepares for the launch of ANNOVERA and continues to support its growing business and commercialization of its products.

Net loss for the full-year 2018 was approximately $132.6 million, or $0.59 per basic and diluted share, compared with approximately $76.9 million, or $0.37 per basic and diluted share, for the full-year of 2017. Net loss for the fourth quarter of 2018 was approximately $39.4 million, or $0.17 per basic and diluted share, compared with approximately $21.4 million, or $0.10 per basic and diluted share, for the fourth quarter of 2017.

Balance Sheet
As of December 31, 2018, the company's cash on hand totaled approximately $161.6 million, compared with approximately $127.1 million at December 31, 2017. Total outstanding debt, net of issuance costs, was approximately $73.4 million as of December 31, 2018.

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:	Thursday, February 21, 2019
Time:	4:30 p.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	3494187

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: 3494187.

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

- IMVEXXY at https://imvexxy.com/pi.pdf
- BIJUVA at https://www.bijuva.com/pi.pdf
- ANNOVERA at www.annovera.com/pi.pdf

About TherapeuticsMD, Inc.
TherapeuticsMD, Inc. is an innovative 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^{Ò}, ANNOVERA^{TM}, BIJUVA^{TM} 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 agreement; 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.

Investor Contact

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2018	**2017**
ASSETS		
Current Assets:		
Cash	$ 161,613,077	$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of $596,602 and $380,580, respectively	11,063,821	4,328,802
Inventory	3,267,670	1,485,358
Other current assets	10,834,693	6,604,284
Total current assets	186,779,261	139,554,072
Fixed assets, net	472,683	437,055
Other Assets:		
License rights	20,000,000	—
Intangible assets, net	4,092,679	3,099,747
Other assets	324,855	—
Security deposit	314,446	139,036
Total other assets	24,731,980	3,238,783
Total assets	$ 211,983,924	$ 143,229,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 22,743,841	$ 4,097,600
Accrued expenses and other current liabilities	18,334,948	9,223,595
Total current liabilities	41,078,789	13,321,195
Long-Term Liabilities:		
Long-term debt	73,381,014	—
Total liabilities	114,459,803	13,321,195
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: 240,462,439 and 216,429,642 issued and outstanding, respectively	240,463	216,430
Additional paid-in capital	616,559,938	516,351,405
Accumulated deficit	(519,276,280)	(386,659,120)
Total stockholders' equity	97,524,121	129,908,715
Total liabilities and stockholders' equity	$ 211,983,924	$ 143,229,910

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,		
	2018	**2017**	**2018**	**2017**	**2016**
Revenues, net	$ 5,089,523	$ 4,124,218	$ 16,099,460	$ 16,777,713	$ 19,356,450
Cost of goods sold	950,750	594,769	2,737,652	2,636,943	4,185,708
Gross profit	4,138,773	3,529,449	13,361,808	14,140,770	15,170,742
Operating expenses:					
Sales, general, and administrative	35,410,875	14,178,958	115,988,954	57,703,370	51,348,414
Research and development	6,753,190	10,974,956	27,299,138	33,852,993	53,943,477
Depreciation and amortization	95,341	56,174	293,886	213,117	132,451
Total operating expenses	42,259,406	25,210,088	143,581,978	91,769,480	105,424,342
Operating loss	(38,120,633)	(21,680,639)	(130,220,170)	(77,628,710)	(90,253,600)
Other (expense) income					
Miscellaneous income	823,027	253,309	2,280,844	695,631	367,317
Interest expense	(2,093,375)	—	(4,677,834)	—	—
Accreted interest	—	—	—	7,699	10,824
Total other (expense) income	(1,270,348)	253,309	(2,396,990)	703,330	378,141
Loss before income taxes	(39,390,981)	(21,427,330)	(132,617,160)	(76,925,380)	(89,875,459)
Provision for income taxes	—	—	—	—	—
Net loss	$ (39,390,981)	$ (21,427,330)	$ (132,617,160)	$ (76,925,380)	$ (89,875,459)
Loss per share, basic and diluted:					
Net loss per share, basic and diluted	$ (0.17)	$ (0.10)	$ (0.59)	$ (0.37)	$ (0.46)
Weighted average number of common shares outstanding, basic and diluted	238,556,492	216,429,642	225,026,300	205,523,288	196,088,196

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2018	**2017**	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (132,617,160)	$ (76,925,380)	$ (89,875,459)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of fixed assets	181,412	141,601	77,906
Amortization of intangible assets	112,474	71,516	54,545
Provision for doubtful accounts	216,022	4,206	2,524,909
Share-based compensation	8,661,967	6,889,323	17,411,021
Amortization of deferred financing costs	269,859	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(6,951,041)	167,691	(3,975,893)
Inventory	(1,782,312)	(409,037)	(386,168)
Other current assets	(2,332,335)	(4,434,130)	709,907
Other assets	(324,855)	—	—
Accounts payable	18,646,241	(3,260,914)	4,232,340
Accrued expenses and other current liabilities	9,107,947	1,599,510	84,559
Net cash used in operating activities	(106,811,781)	(76,155,614)	(69,142,333)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for intellectual property license	(20,000,000)	—	—
Patent costs	(1,105,407)	(765,291)	(845,266)
Purchase of fixed assets	(217,040)	(61,817)	(396,154)
Payment of security deposit	(175,410)	—	(14,036)
Net cash used in investing activities	(21,497,857)	(827,108)	(1,255,456)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	89,907,797	68,572,635	134,863,475
Proceeds from term loan	75,000,000	—	—
Payment of deferred financing fees	(3,786,918)	—	—
Proceeds from exercise of options	1,666,208	212,615	989,060
Proceeds from exercise of warrants	—	3,798,999	1,373,000
Net cash provided by financing activities	162,787,087	72,584,249	137,225,535
Increase (decrease) in cash	34,477,449	(4,398,473)	66,827,746
Cash, beginning of period	127,135,628	131,534,101	64,706,355
Cash, end of period	$ 161,613,077	$ 127,135,628	$ 131,534,101
Supplemental disclosure of cash flow information			
Interest paid	$ 1,890,166	$ —	$ —

Exhibit 99.2


4Q and Full-Year 2018
Financial Results
February 21, 2019
TherapeuticsMD®
For Her. For Life.
TherapeuticsMD.com

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 agreement; 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.

TherapeuticsMD, *A Premier Women's Health Company*

TherapeuticsMD®

For Her. For Life.

Strong IMVEXXY Launch

IMVEXXY (estradiol vaginal inserts) Launch Metrics	
Total paid scripts dispensed to patients[1] (since launch through Jan. 31, 2019)	~86,000
Total paid scripts (January 1-31, 2019)	~23,500
Total patients (since launch through Jan. 31, 2019)	~30,100
Total prescribers[2] (since launch through Jan. 31, 2019)	~8,100

Comparison of Average Weekly Script Volume		
	Jan. 2019	1st two weeks of Feb. 2019
Average weekly volume	~5,300	~5,800

The company anticipates providing updates on a monthly basis moving forward

[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 one 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.

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Strong Patient Adherence & Compliance

through January 31, 2019

IMVEXXY Patient Compliance[1,2]		
Month Initial Prescription Filled	Average # Fills for those Patients	Maximum Allowable Fills Given the Month of Initial Fill
December 2018	1.9 Fills	2 Fills
November 2018	2.6 Fills	3 Fills
October 2018	3.1 Fills	4 Fills
September 2018	3.8 Fills	5 Fills
August 2018	4.9 Fills	6 Fills

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 2.6 fills from November 2018 through January 2019

Average fills for all patients through January 31, 2019 = 2.85

[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.

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IMVEXXY is Clearly Differentiated from Other Treatment Options

Owning clinical attributes with the underpinning of a highly effective patient experience

Key Clinical Attributes:

1	New lowest approved dose
2	Strong efficacy and safety data
3	Improvement seen as early as 2 weeks (secondary endpoint)
4	PK data where systemic hormone levels remain within normal postmenopausal range

Key Physical Attributes:

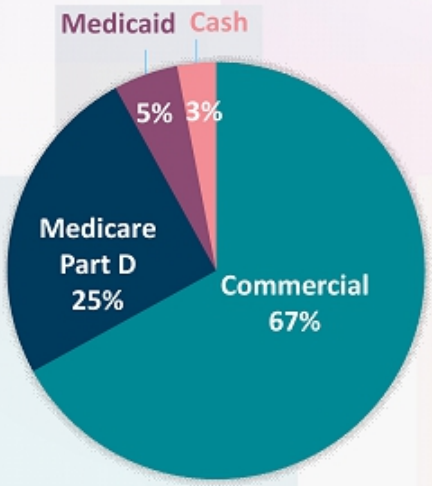
5	Ease of use and absence of applicator
6	Ability to be used any time of day
7	A mess-free way to administer
8	Dose packaging to optimize patient compliance and enhance provider and patient acceptance

Imvexxy (estradiol vaginal inserts) 4 mcg • 10 mcg

TherapeuticsMD® *For Her. For Life.*

IMVEXXY Commercial Payer Update

TRx Payer Breakdown of FDA-Approved VVA Products[1]



Top 10 Plans Account for ~73% of all Commercial Pharmacy Lives

Plan	% of Lives[2]	Status[3]
CVS	15.5%	
ESI	15.4%	Adjudicating as of 10/1/18
United	7.6%	Adjudicating on 3/1/19[4]
Anthem	7.4%	Adjudicating as of Aug. 2018
Prime	6.6%	Adjudicating as of 1/1/19
OptumRx	6.1%	Adjudicating as of 1/1/19
Kaiser	4.7%	
Aetna	4%	
Cigna	4%	Adjudicating as of 12/15/18
EnvisionRx	1.8%	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.

[1]IMS Data April 2018
[2]Plan numbers as of January 2019
[3]MMIT February 2019 and Account Insights
[4]Contract signed, adjudication expected March 1, 2019

TherapeuticsMD®
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IMVEXXY Medicare Part D Payer Update

United and Kaiser Medicare Part D are Now Adjudicating (Paying)

Medicare Part D Update

- United Healthcare and Kaiser Medicare Part D are now adjudicating
- United Healthcare is the largest Medicare Part D payer
- Bids submitted for other Medicare Part D plans

Top 6 Plans Account for ~75% of all Medicare Part D Pharmacy Lives

Plan	% of Lives[1]	Status[2]
United	21.1%	Adjudicating as of 2/1/19
Humana	18.9%	
CVS Caremark	14.7%	
Wellcare with Aetna lives	3.8%	
Express Scripts/ Cigna	3.5%	
Kaiser	3.7%	Adjudicating Maintenance Pack as of 10/1/18

[1]Plan numbers as of January 2019
[2] MMIT February 2019 and Account Insights

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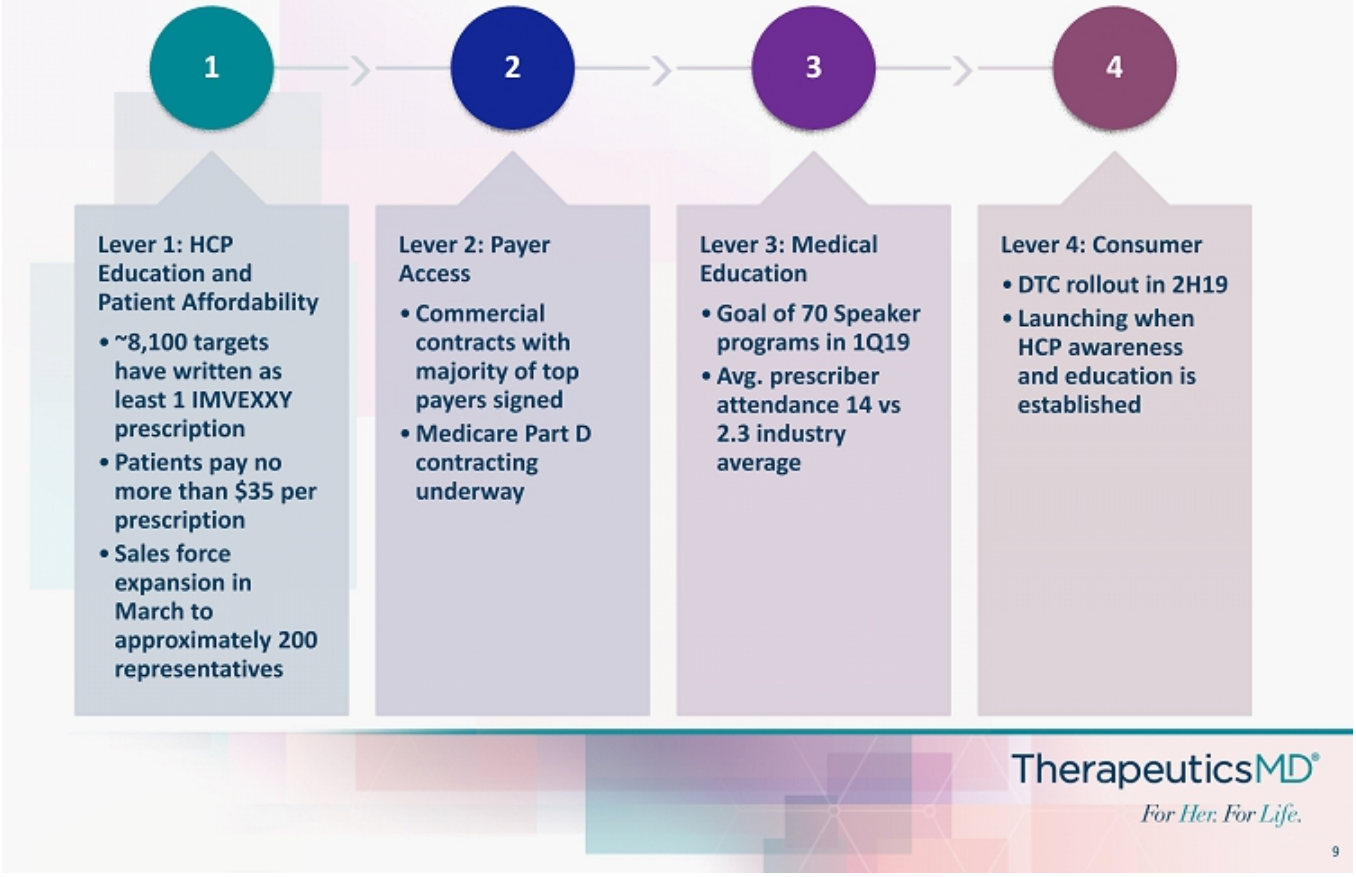
IMVEXXY Growth Levers in 2019



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Vasomotor Symptoms are the Most Common Symptoms Associated with Menopause[1]

Vasomotor symptoms are extreme thermoregulatory responses characterized by episodes of profuse heat accompanied by sweating and flushing[2,3]

- Also known as hot flashes or strong feelings of heat or sweating
- Occur predominantly around the head, neck, chest, and upper back

Vasomotor symptoms are experienced by the majority of women during the menopausal transition[3]

- As many as 74% of menopausal women[1]
- Up to 88% of perimenopausal women[1]

Moderate to severe vasomotor symptoms typically continue for 4 to 5 years following menopause and may last more than 10 years after final menstrual period in some women[4,5]

References
1. Rapkin AJ. *Am J Obstet Gynecol*. 2007;196(2):97-106. **2.** Deecher DC et al. *Arch Womens Ment Health*. 2007;10(6):247-257. **3.** Thurston RC et al. *Obstet Gynecol Clin North Am*. 2011;38(3):489-501. **4.** Freeman EW et al. *Menopause*. 2014;21(9):924-932. **5.** Kleinman NL et al. *JOEM*. 2013;55(4):465-470.

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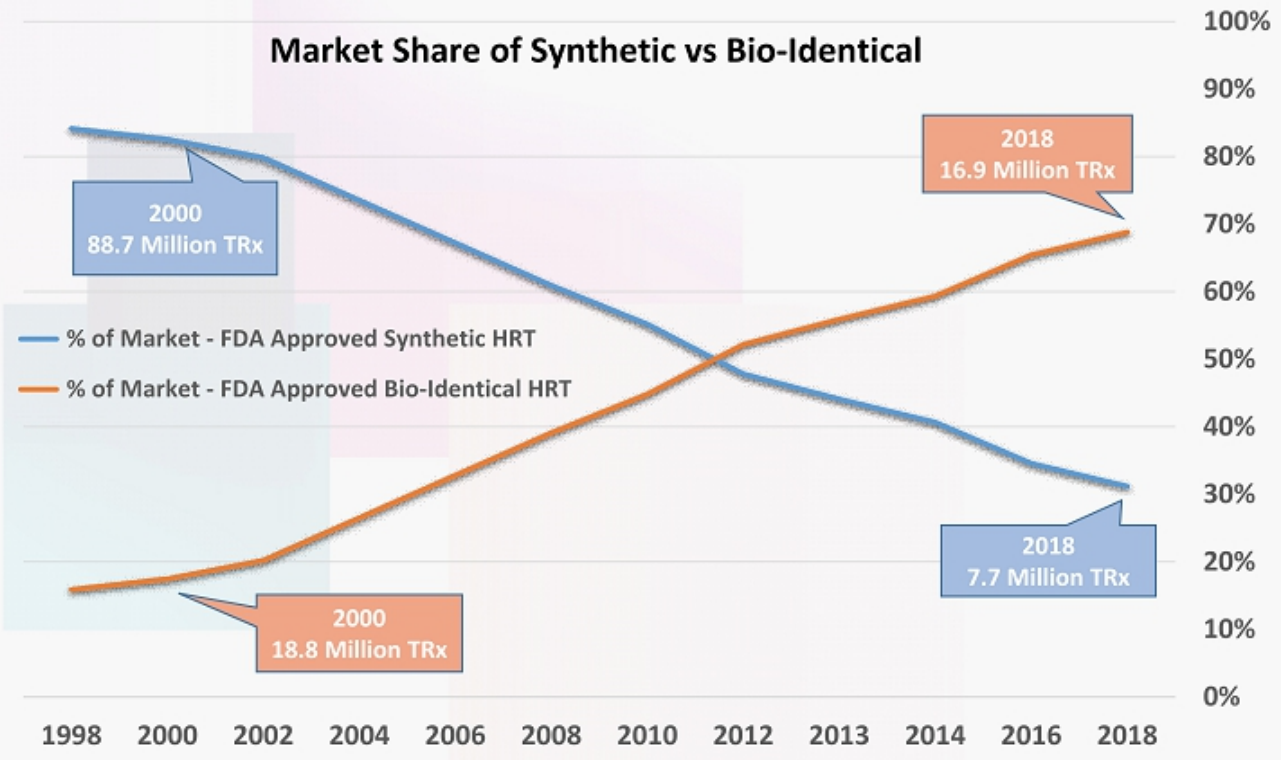
WHI Impact on FDA Approved Hormone Therapy



Symphony Health PHAST Data
Excludes products for VVA category of products

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BIJUVA Addressable Markets

BIJUVA Substitutable Market

FDA-Approved		
Off-Label Separate Bio-Identical E & P Pills 	Combination Synthetic E+P[1] 	Compounded Combination Bio-Identical E+P 
~3.9 million TRx (each)[1]	~2.5 million TRx[2]	12 – 18 million TRx[3]
$780M-$975M[4] TAM	$500M-$625M[4] TAM	$2.4B-$4.5B[4] TAM
2 copays	1 copay	Often 2 copays cash out of pocket
Compliance risk	No compliance risk	Compliance risk
Insurance coverage	Insurance coverage	Almost 100% out of pocket

1] Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2018
2] Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®
3] Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications
4] Assume WAC pricing between $200-250

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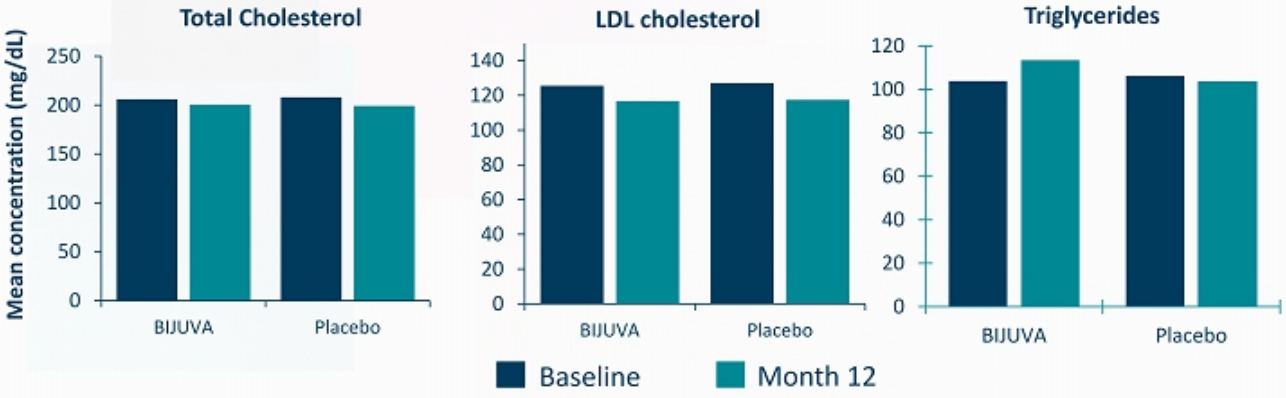
No Clinically Significant Changes in Lipid Parameters were Observed

In REPLENISH, lipid parameters were measured at baseline and Month 12



HDL= high-density lipoprotein; LDL=low-density lipoprotein

Bijuva (estradiol and progesterone) capsules 1.0 mg/100 mg

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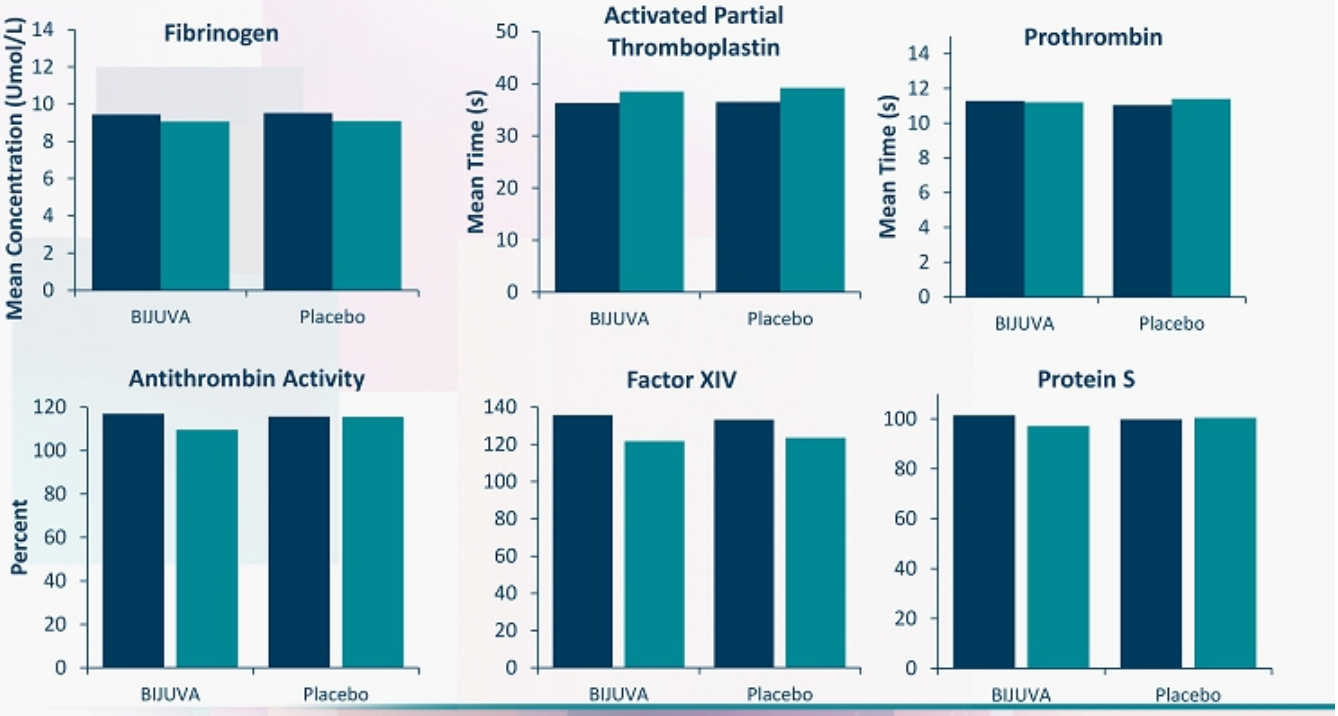
No Clinically Significant Changes in Coagulation Parameters were Observed with BIJUVA



Baseline Month 12

Coagulation parameters were measured at baseline and Month 12

Bijuva (estradiol and progesterone) capsules

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Patient-reported Outcomes Secondary Endpoints: CGI, MENQOL, and MOS-Sleep

Clinical Global Impression (CGI)

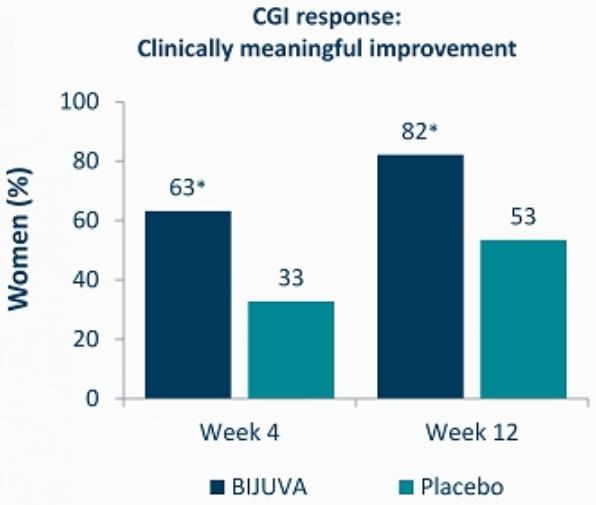
- Significantly more women rated their condition as very much or much improved with BIJUVA compared with placebo at Weeks 4 and 12

Menopause-Specific Quality of Life Questionnaire (MENQOL)

- Statistically significant improvements in total score were observed at Week 12, Month 6, and Month 12 compared with placebo

Medical Outcomes Study Sleep Scale (MOS-Sleep)

- Statistically significant improvements in total score were observed at Months 6 and 12 compared with placebo†



*P<0.001 vs placebo.
†Mean change from baseline at Month 12 was not significant.

Reference
Data on file, TherapeuticsMD.

Bijuva
(estradiol and progesterone) capsules
1.0 mg/100 mg

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BIJUVA Fulfills the Unmet Need of an FDA-approved Combination Bio-identical Estrogen and Progesterone Hormone Therapy Option[1]

	BIJUVA[1-3]	Synthetic FDA-Approved Combination Products (example Prempro®)[1,4]	Separate FDA-Approved Estradiol pills and Progesterone pills[1,5-7]	Compounded Combination Estradiol and Progesterone products[2,3]
FDA-approved for daily combination usage	✓	✓	X	X
VMS Efficacy & Endometrial Safety Data	✓	✓	X	X
WHI risks (breast cancer, stroke, heart attack, thrombosis)	(not studied in WHI)	X	(not studied in WHI)	(not studied in WHI)
Bio-identical	✓	X	✓	✓
Reduced risk for endometrial hyperplasia or cancer (no option to take estradiol without progestogen)	✓	✓	X	✓

Prometrium® and generic progesterone only FDA-approved for women using conjugated estrogens at 200 mg orally for 12 days sequentially per 28-day cycle[8]

E=estrogen; P=progesterone.

References
1. Mirkin S et al. *Matwritas.* 2015;81(1):28-35. **2.** Compounded bioidentical menopausal hormone therapy. The American College of Obstetricians and Gynecologists website. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Compounded-Bioidentical-Menopausal-Hormone-Therapy. Accessed October 13, 2018. **3.** Compounding and the FDA: questions and answers. US Food and Drug Administration website. https://www.fda.gov/drugs/guidancecompliance regulatoryinformation/pharmacycompounding/ucm339764.htm. Accessed October 13, 2018. **4.** Prempro Prescribing Information. **5.** Estradiol Prescribing Information. **6.** Prometrium Prescribing Information. **7.** Holtorf K. *Postgrad Med.* 2009;121(1):73-85. **8.** Prometrium Prescribing Information

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A Large Target Market for BIJUVA

Launch Expected: Early 2Q19

Phase 1: Initial focus on FDA-approved segment of market during 6 month payer block

Phase 2 Bio-Ignite: Maximize the launch of the compounding channel commensurate with securing commercial reimbursement

Selectively leverage this channel until payer coverage begins due to class of trade costs

FDA-Approved			Compounded Combination Bio-Identical E+P
BIJUVA Combination Bio-Identical E+P	Off-Label Separate Bio-Identical E & P Pills	Combination Synthetic E+P[1]	
	~3.9 million TRx (each)[1]	~2.5 million TRx[2]	12 – 18 million TRx[3]
>$25B[4,5] TAM	$780M-$975M[4] TAM	$500M-$625M[4] TAM	$2.4B-$4.5B[4] TAM
1 copay	2 copays	1 copay	Often 2 copays cash out of pocket
No compliance risk	Compliance risk	No compliance risk	Compliance risk
Expect 6 month commercial payer block	Insurance coverage	Insurance coverage	Almost 100% out of pocket

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2018
2) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®
3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications
4) Assume WAC pricing between $200-250
5) Based on pre-WHI annual scripts of FDA-approved HT products and market pricing of current FDA-approved HT products.

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Independent Community Pharmacy
IMVEXXY and BIJUVA Addressable Markets

IMVEXXY Substitutable Market

Product	TRx Count
Osphena®	217,000
Estrace® & Generic	1,902,000
Premarin®	1,220,000
Vagifem® & Generic	1,500,000
Estring®	262,000
Compounded Vaginal E	200,000+*
Grand Total	**5,301,000**

BIJUVA Substitutable Market

FDA-Approved		
Off-Label Separate Bio-Identical E & P Pills 	Combination Synthetic E+P[1] 	Compounded Combination Bio-Identical E+P 
~3.9 million TRx (each)[1]	~2.5 million TRx[2]	12 – 18 million TRx[3]
$780M-$975M[4] TAM	$500M-$625M[4] TAM	$2.4B-$4.5B[4] TAM
2 copays	1 copay	Often 2 copays cash out of pocket
Compliance risk	No compliance risk	Compliance risk
Insurance coverage	Insurance coverage	Almost 100% out of pocket

* Estimated number of vaginal scripts. Assumption based on consultant feedback and extrapolation of survey response data.

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

2) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®

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

4) Assume WAC pricing between $200-250

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BioIgnite
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Pharmacy Targeting:

- **700+** are high tier targets (T1-T4 based on byte data)
  - These locations produce the highest potential volume of compounded bio-identical hormone replacement therapy (CBHRT) scripts

Program Stats (5 Months of Launch):

Live Accounts: 22

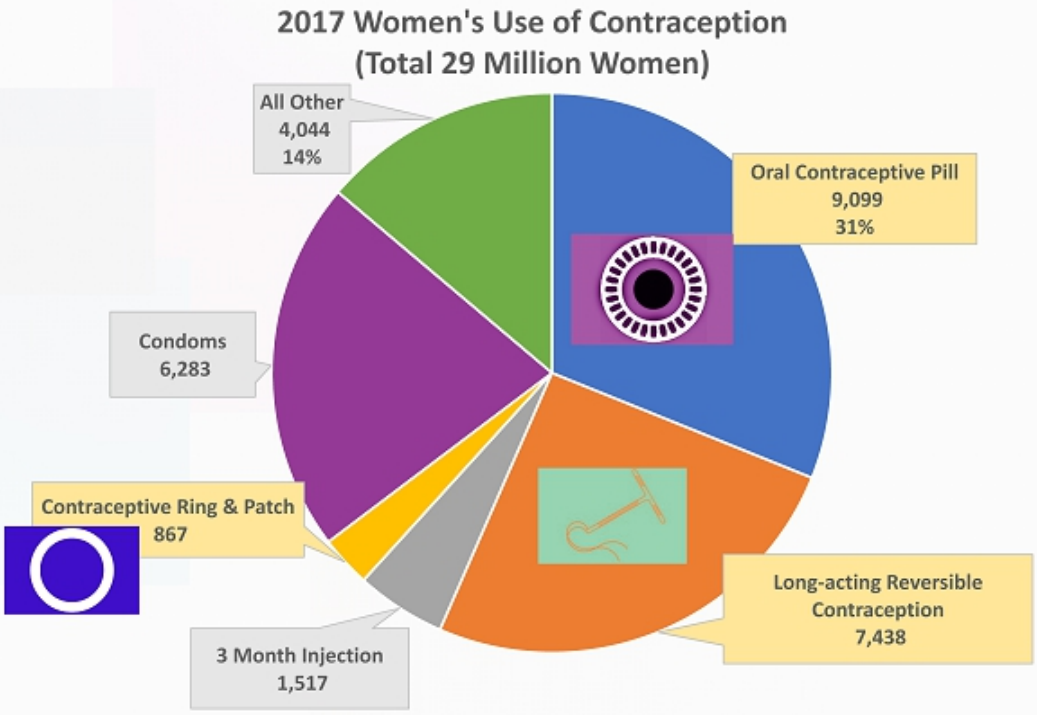
States Reached: MA, OH, TX, VA, TN, AL, NH, PA, FL, SC, NY, OK, NJ, GA

In Vetting Process: 25

Unique CBHRT Prescribers Identified- 2,787 (Jan. 22, 2019)

Recently Partnered (has not yet started Vetting Process): Second largest network of ~100 pharmacies

Reversible Birth Control Market in the U.S.



Source:
Centers for Disease Control and Preventions, NCHS, December 2018, No. 327
Data Brief 173, Current Contraceptive Status Among Women Aged 15-44: United States, 2011-2013

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ANNOVERA
(Segesterone Acetate and Ethinyl Estradiol Vaginal System)

Clinical Attributes

- Only FDA approved long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
  - Empowers women to be in control of their fertility and menstruation
  - Annovera is the only user-directed single 12-month birth control product (used in repeated 4-week cycles for 13 cycles)
- Highly effective in preventing pregnancy when used as directed (97.3%)
- High patient satisfaction in clinical trials[1] (89% overall satisfaction)
- Low daily release of ethinyl estradiol (13 mcg)
- Only product with new novel progestin - segesterone acetate[2]
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Favorable side effect profile including low rates of discontinuation related to irregular bleeding (1.7%)
- Safety profile generally consistent with other CHC products, including boxed warning

[1] Merkatz, Ruth B., Marlena Plagianos, Elena Hoskin, Michael Cooney, Paul C. Hewett, and Barbara S. Mensch. 2014. "Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: Development of a model; implications for introduction," *Contraception* 90(5): 514–521.
[2] Narender Kumar, Samuel S. Koide, Yun-Yen Tsong, and Kalyan Sundaram. 2000. *"Nestorone: a Progestin with a Unique Pharmacological Profile,"* Steroids 65: 629-636

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ANNOVERA Physical Attributes

Physical Attributes

- Softer and more pliable than NuvaRing
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship[1]
- "Vaginal System" – the only product in a new class of contraception with potential for $0 co-pay
- Cost and convenience (pharmacy and doc visits)
- Does not require refrigeration by HCP

[1] Lohr, et al. Use of intrauterine devices in nulliparous women. Contraception 95 (2017); 529-537

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ANNOVERA – Long-Acting and Patient Controlled

Target Market Segments

1

NuvaRing®: Short-acting

2

Oral Contraceptives: Potential Compliance Issues

3

Long-acting, prescription reversible contraceptives (IUDs, implants): Requires a Procedure for insertion and removal

ANNOVERA: The Only Long-Acting, Procedure Free, Reversible, Patient Controlled

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TXMD Presence at Upcoming Medical Meetings

- International Society for the Study of Women's Sexual Health (ISSWSH), March
  - BIJUVA secondary endpoints - vaginal health
  - ANNOVERA sexual outcomes and acceptability
- Endocrine Society meeting, March
  - ANNOVERA
    - strong efficacy
    - bleeding profile
    - lack of androgenic side effects
  - BIJUVA
    - sleep improvements
- American College of Obstetricians and Gynecologists (ACOG), May
  - IMVEXXY - novel data
  - BIJUVA - novel data
  - ANNOVERA - novel data
- European Menopause Society (EMAS), May
  - IMVEXXY - novel data
  - BIJUVA - novel data

IMVEXXY Prescription Performance

IMVEXXY Launch Metrics			
	3Q18	4Q18	FY18
Total paid scripts[1]	~14,900	~47,500	~64,400

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

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Looking Ahead:
Key Expected Events in 2019

- **1Q 2019 -** Speaker programs throughout the U.S. highlighting the clinical and physical attributes of IMVEXXY
- **1Q 2019 - through 3Q 2019 –** Expand IMVEXXY Part D coverage
- **2H 2019 -** Begin direct-to-consumer marketing for IMVEXXY
- **2Q 2019 –** U.S. commercial launch of BIJUVA and draw second $75 million debt tranche with MidCap Financial Trust
- **2H (targeting 3Q) 2019 -** U.S. commercial launch of ANNOVERA
- **2H 2019 -** Debt funding for ANNOVERA launch
- **Summer 2019 -** Company to hold Analyst Day
- **Late 4Q 2019 -** BIJUVA 6-month "new to market" payer block expected to end
- **Full-Year 2019 -** Oral presentations and posters related to clinical benefits of IMVEXXY, BIJUVA and ANNOVERA at medical meetings
- **Throughout 2019 -** Continue to expand BIO-IGNITE with a fuller expansion towards the end of 2019 when the six-month payer block for BIJUVA is expected to end

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