
**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): March 12, 2019

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

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

(Address of Principal Executive Office) (Zip Code)

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

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230-405 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 7.01. Regulation FD Disclosure.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on March 12, 2019 and at subsequent meetings with investors or analysts.

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

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit
Number

Description

[99.1](#) TherapeuticsMD, Inc. presentation dated March 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: March 12, 2019

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

Investor Presentation

March 2019



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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® (TXMD)

Innovative women's health company exclusively focused on developing and commercializing products for women throughout their life cycles



DYSpareunia
(a symptom of VVA due to Menopause)

VASOMOTOR SYMPTOMS
(Hot Flashes due to Menopause)

PREGNANCY PREVENTION



Easy to use, lowest approved dose, designed to support patient adherence

First and only FDA-approved bio-identical combination hormone therapy

First and only patient-controlled, procedure-free, long-acting, reversible birth control product

32 million women affected¹

36 million women affected²

43 million women affected³

Launched

Launch expected 2Q 2019

Launch expected 2H19

1) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20(9):988-992.
2) Gass ML, Cochran BS, Larson JC, et al. Patterns and predictors of sexual activity among women in the hormone therapy trials of the Women's Health Initiative. Menopause. 2011;18(11):1160-1171.
3) Derived from U.S. Census data on women in the age group who normally experience symptoms.
4) Contraceptive Use in the United States, Guttmacher, July 2008. IQVIA Patient Tracker.

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Key Planned Levers for Growth



- **1Q 2019** - 50 additional sales reps added
- **1Q 2019** – Maximize IMVEXXY launch through BIO-IGNITE
- **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 (April)** - U.S. commercial launch of BIJUVA and draw second \$75 million debt tranche with MidCap Financial Trust
- **4Q 2019** - “new to market” 6-month payer block to end
- **4Q 2019** - Maximize BIJUVA launch through BIO-IGNITE
- **BIJUVA WAC price set at \$214.50**
 - Priced at parity to legacy hot flash products
 - Aligned with TXMD responsible pricing strategy
 - Strategic payer strategy

- **2H (targeting 3Q) 2019** - U.S. commercial launch of ANNOVERA
- **1Q 2020** - “new to market” 6-month payer block to end
- **ANNOVERA WAC price expected to be \$1,800-\$2,000**
 - Priced at a discount to NuvaRing
 - Aligned with TXMD responsible pricing strategy
 - Strategic payer strategy
 - Potential 19th category of contraception
- **2H 2019** - Currently evaluating debt funding for launch of ANNOVERA

Summer 2019 - Company to hold Analyst Day to highlight portfolio and launch strategies

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Opportunities to Strengthen our Position Once All 3 Products are Launched and Covered

- 1Q 2020 - All 3 products are expected to be covered by payers
- Based on volume generated by 3 products concentrated in women's health care, TXMD can optimize distribution costs, relationships and partnerships
- Strong women's health care platform created to negotiate and refine payer rebates and coverage
- Maximize copay assistance program through patient targeting and compliance
- Achieve critical mass and optimal voice in provider offices by offering 3 new products that cover many of the day-to-day needs of OBGYN's
- Begin lifetime of patient strategy to build brand loyalty and awareness

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Imvexxy[®]
(estradiol vaginal inserts)

4 mcg • 10 mcg

Approved for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

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Strong IMVEXXY Launch

IMVEXXY (estradiol vaginal inserts) Launch Metrics

Total paid scripts dispensed to patients ¹ (since launch through Feb. 28, 2019)	~109,600
Total paid scripts (February 1-28, 2019)	~23,600
Total patients (since launch through Feb. 28, 2019)	~37,600
Total prescribers ² (since launch through Feb. 28, 2019)	~9,000

Comparison of Average Weekly & Daily Script Volume

(Average Weekly Volume: TRx for month / # days in month * 7 days)

	For 31 Days in Jan. 2019	For 28 Days in Feb. 2019
Average weekly volume	~5,300	~5,900
Average daily volume	~758	~842

The company anticipates providing updates on a monthly basis

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

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

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Strong Patient Adherence & Compliance

through February 28, 2019

IMVEXXY Patient Compliance^{1,2}

Month Initial Prescription Filled	Average # Fills for those Patients	Maximum Allowable Fills Given the Month of Initial Fill
January 2019	1.9 Fills	2 Fills
December 2018	2.5 Fills	3 Fills
November 2018	3.2 Fills	4 Fills
October 2018	3.6 Fills	5 Fills
September 2018	4.3 Fills	6 Fills
August 2018	5.5 Fills	7 Fills

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 3.2 fills from November 2018 through February 2019

Average fills for all patients through February 28, 2019 = 2.9³

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

²Total 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.

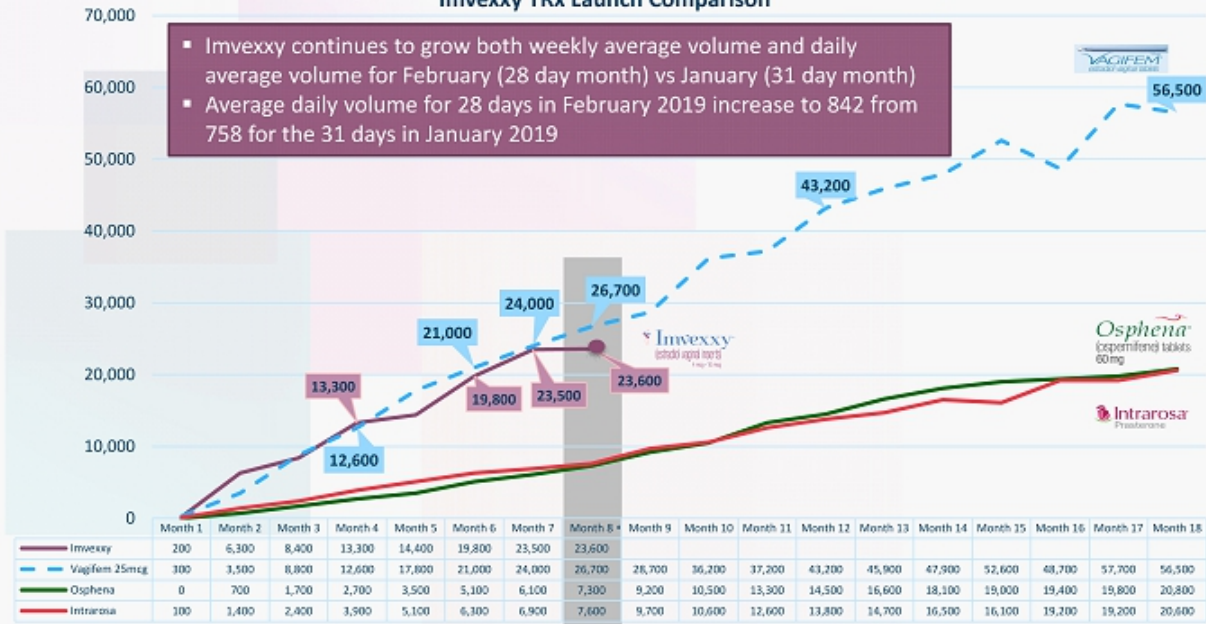
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Successful Launch Execution

Imvexxy TRx Launch Comparison

- Imvexxy continues to grow both weekly average volume and daily average volume for February (28 day month) vs January (31 day month)
- Average daily volume for 28 days in February 2019 increase to 842 from 758 for the 31 days in January 2019



*Month 8 for IMVEXXY is February 2019

References:

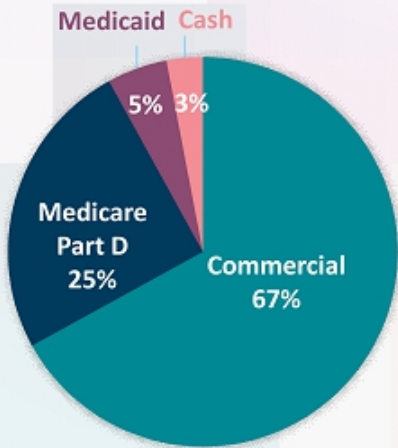
- Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.
- Osphena and Intrarosa sourced is Symphony Health Integrated Database.
- Vagifem sourced from IQVIA National Prescriber Level Data.
- All trademarks are the property of their respective owners.

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IMVEXXY Commercial Payer Update

TRx Payer Breakdown of FDA-Approved VVA Products¹



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 as of 3/1/19
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.

¹IMS Data April 2018

²Plan numbers as of January 2019

³MMIT February 2019 and Account Insights

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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

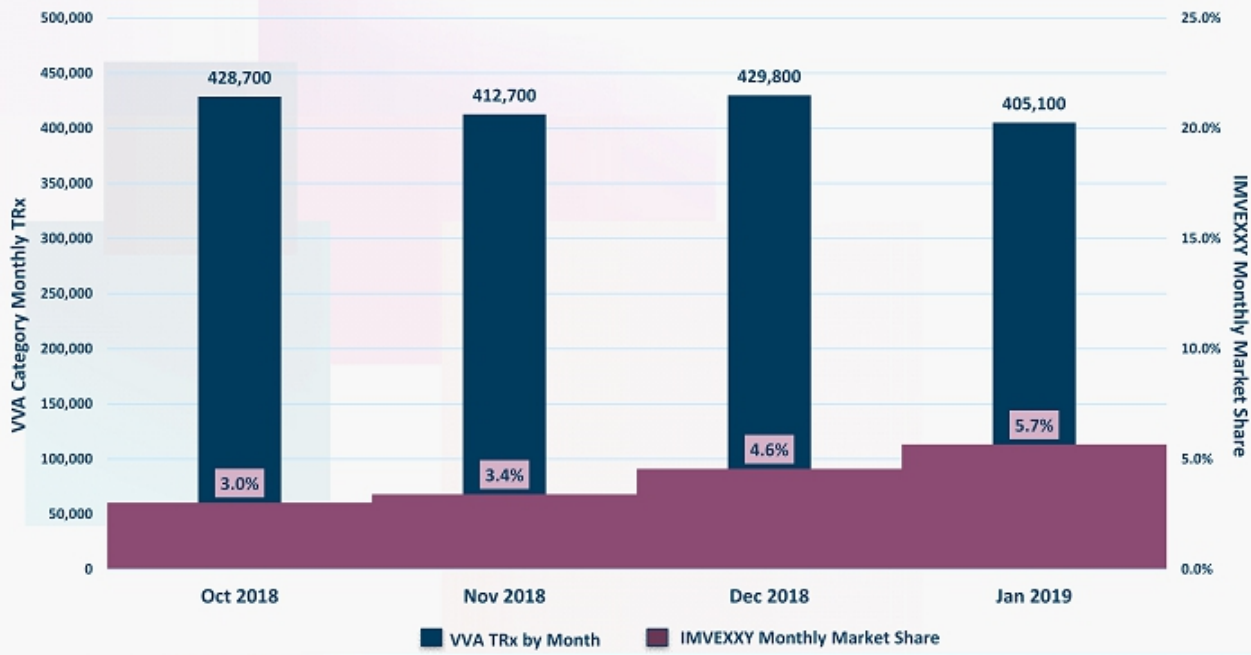
Plan	% of Lives ¹	Status ²
United	21.1%	Adjudicating as of 2/1/19
Humana	18.9%	
CVS Caremark	14.7%	
Wellcare with Aetna lives	3.8%	
Express Scripts/ Cigna	3.5%	
Kaiser	3.7%	Adjudicating Maintenance Pack as of 10/1/18

¹Plan numbers as of January 2019

²MMIT February 2019 and Account Insights

TXMD Strategy Built to Maximize Value of IMVEXXY

Growth of Imvexxy Market Share



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What is Leading to Rapid Uptake?



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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

FOR WOMEN WITH MENOPAUSE TO SEVERE POSTMENOPAUSE, A SYMPTOM OF VAGINAL DRYNESS AND BURNING. ASK YOUR DOCTOR TO RECOMMEND

IMVEXXY

(estradiol vaginal inserts)

CONVENIENT, CONFIDENT, APPLICATOR-FREE ADMINISTRATION

THE ONLY ULTRA-LOW DOSE VAGINAL ESTRADIOL AVAILABLE IN BOTH 4 mcg AND 10 mcg DOSES*

AN ELEGANT DESIGN THAT SIMPLY FITS INTO HER LIFE!

Imvexxy
ESTRADIOL VAGINAL INSERTS
4 mcg

DISCOVER A TREATMENT EXPERIENCE WITH **SIMPLICITY AT ITS CORE!**

IMPORTANT SAFETY INFORMATION

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISEASE, BREAST CANCER, AND PELOVIC DYSMETABOLISM
See full prescribing information for complete boxed warning.

Estrogen-Only Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen.
- Estrogen alone therapy should not be used for the prevention of cardiovascular disease or dementia.
- The Women's Health Initiative (WHI) estrogen alone study reported increased risks of stroke and deep vein thrombosis (DVT).
- The WHI Estrogen Study (WHI) estrogen alone study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older.

Estrogen Plus Progestin Therapy

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia.
- The WHI estrogen plus progestin study reported increased risks of stroke, DVT, pulmonary embolism (PE), and probable dementia (PE).
- The WHI estrogen plus progestin study reported increased risks of invasive breast cancer.
- The WHI estrogen plus progestin study reported increased risks of probable dementia in postmenopausal women 65 years of age and older.

Please see additional Important Safety Information on the reverse side and the Full Prescribing Information, including CONTRAINDICATIONS, in package.

Imvexxy
(estradiol vaginal inserts)
4 mcg • 10 mcg

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IMVEXXY Growth Levers in 2019



Lever 1:

HCP Education and Patient Affordability

- ~9,000 targets have written as least 1 IMVEXXY prescription
- Patients pay no more than \$35 per prescription
- Sales force expanded to approximately 200 representatives

Lever 2:

Payer Access

- Commercial contracts with majority of top payers signed
- Medicare Part D contracting underway

Lever 3:

Medical Education

- Goal of 70 Speaker programs in 1Q19
- Avg. prescriber attendance 14 vs 2.3 industry average

Lever 4:

Consumer

- DTC rollout in 2H19
- Launching when HCP awareness and education is established

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Synergies Provide Potential to Expand the Market

BIJUVA is a Significant Sales Force

Pull-Through Opportunity for IMVEXXY in 2019

- VMS and VVA are different symptoms of menopause¹ that are addressed with BIJUVA and IMVEXXY in one complementary product portfolio
- Menopausal women often experience both VVA and hot flashes together
 - Women that are being treated with hot flashes may experience VVA symptoms that need to be treated with a separate VVA prescription²
 - Systemic therapy for hot flashes may be ineffective for the treatment of VVA
 - BIJUVA can be leveraged for early awareness of VVA and IMVEXXY - to make patients aware of IMVEXXY 10-15 years earlier before patients are exposed to competitive products
- Sales force to leverage this unique opportunity to expand IMVEXXY market

Bijuva
(estradiol and progesterone) capsules
10mg/0.02mg

Imvexxy
(estradiol vaginal inserts)
4 mg - 10 mg

Same etiology –
estrogen deficiency

Similar population¹

Same prescriber base

¹The American Journal of Medicine (2005) Vol 118 (12B), 375-465.

²Notelovitz M. Urogenital aging: solutions in clinical practice. Int J Gynaecol Obstet 1997;59(suppl 1):S35-S39.

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

The first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel capsule for the treatment of moderate to severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.

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Vasomotor Symptoms are the Most Common Symptoms Associated with Menopause¹



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 transition³

- As many as 74% of menopausal women¹
- Up to 88% of perimenopausal women¹



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

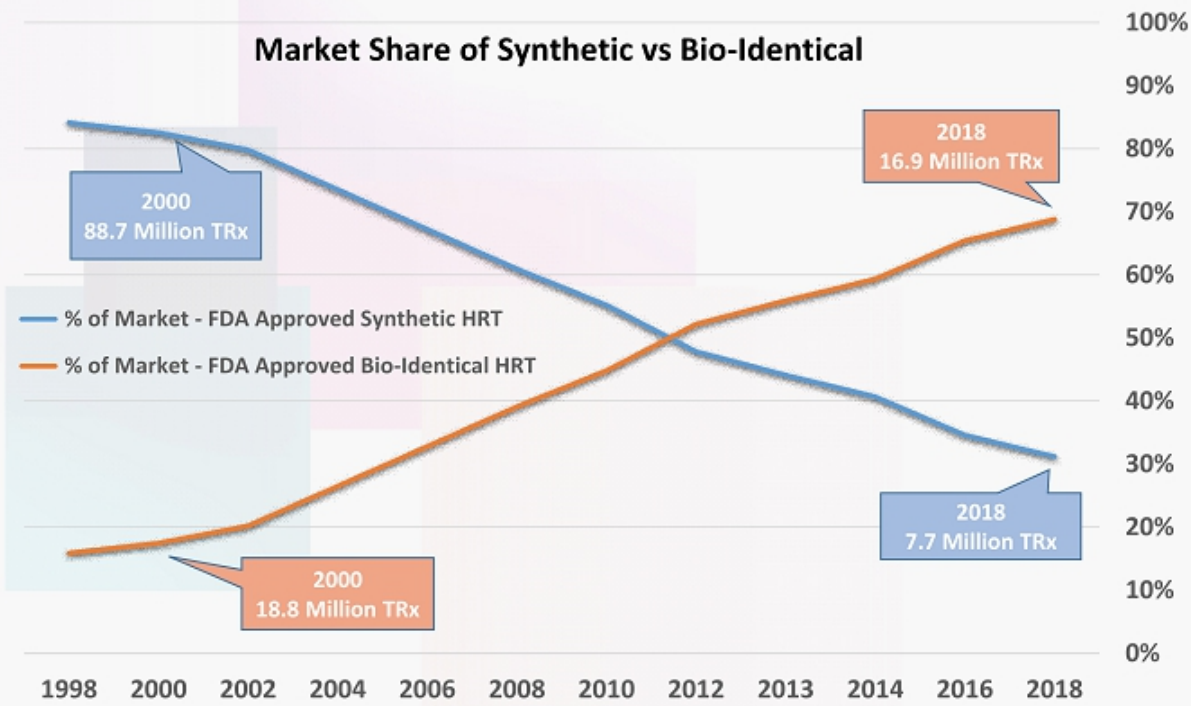
1. Rapkin AJ. *Am J Obstet Gynecol*. 2007;196(2):97-106.
2. Deecher DC et al. *Arch Womens Ment Health*. 2007;10(6):247-257.
3. Thurston RC et al. *Obstet Gynecol Clin North Am*. 2011;38(3):489-501.
4. Freeman EW et al. *Menopause*. 2014;21(9):924-932.
5. Kleinman NL et al. *JOEM*. 2013;55(4):465-470.

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WHI Impact on FDA Approved Hormone Therapy

Market Share of Synthetic vs Bio-Identical






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 million – 18 million TRx ³
~\$836M ⁴ TAM	~\$536 ⁴ TAM	~\$2.5B-\$3.8B 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: Actiwella®, FemHRT®, Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Bristelle®

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

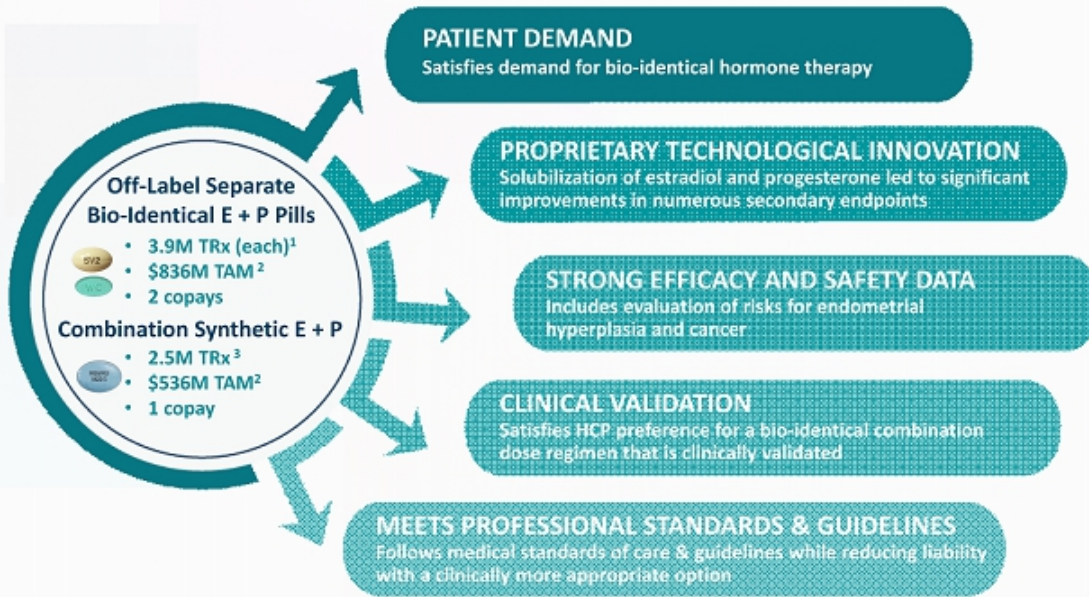
4) Based on WAC pricing of \$214.50

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BIJUVA Addressable Market: FDA Approved Products

BIJUVA – KEY CONVERSION ATTRIBUTES



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

2) Based on WAC pricing of \$214.50

3) Includes the following drugs: Actiella®, FemHRT®, Angeliq®, Generic 17b + Progestin, Prempro®, Premphase®, Duavee®, Bristelle®

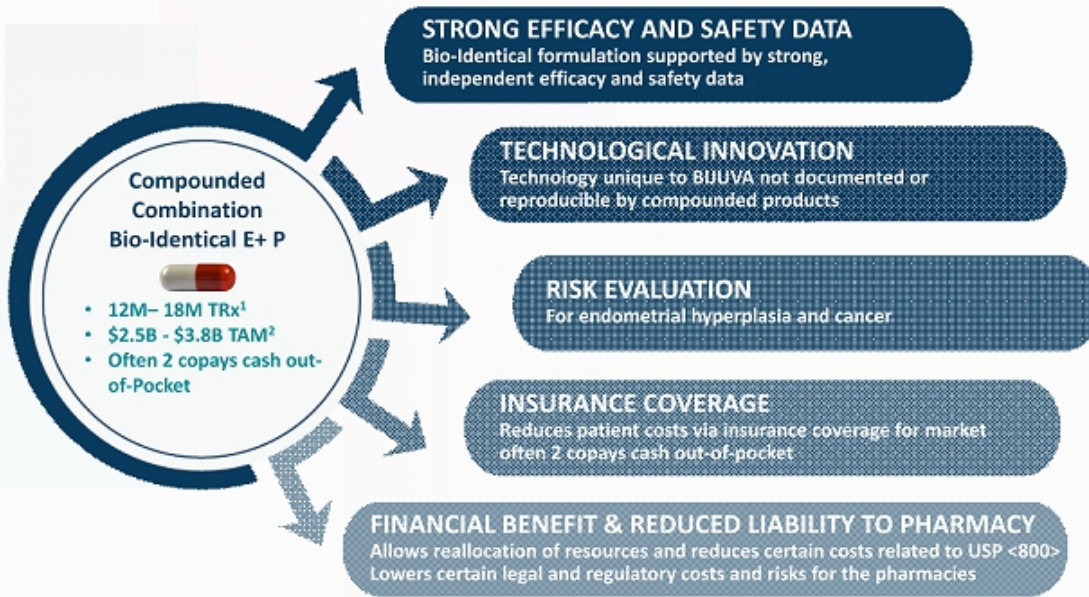
4) All trademarks are the property of their respective owners.

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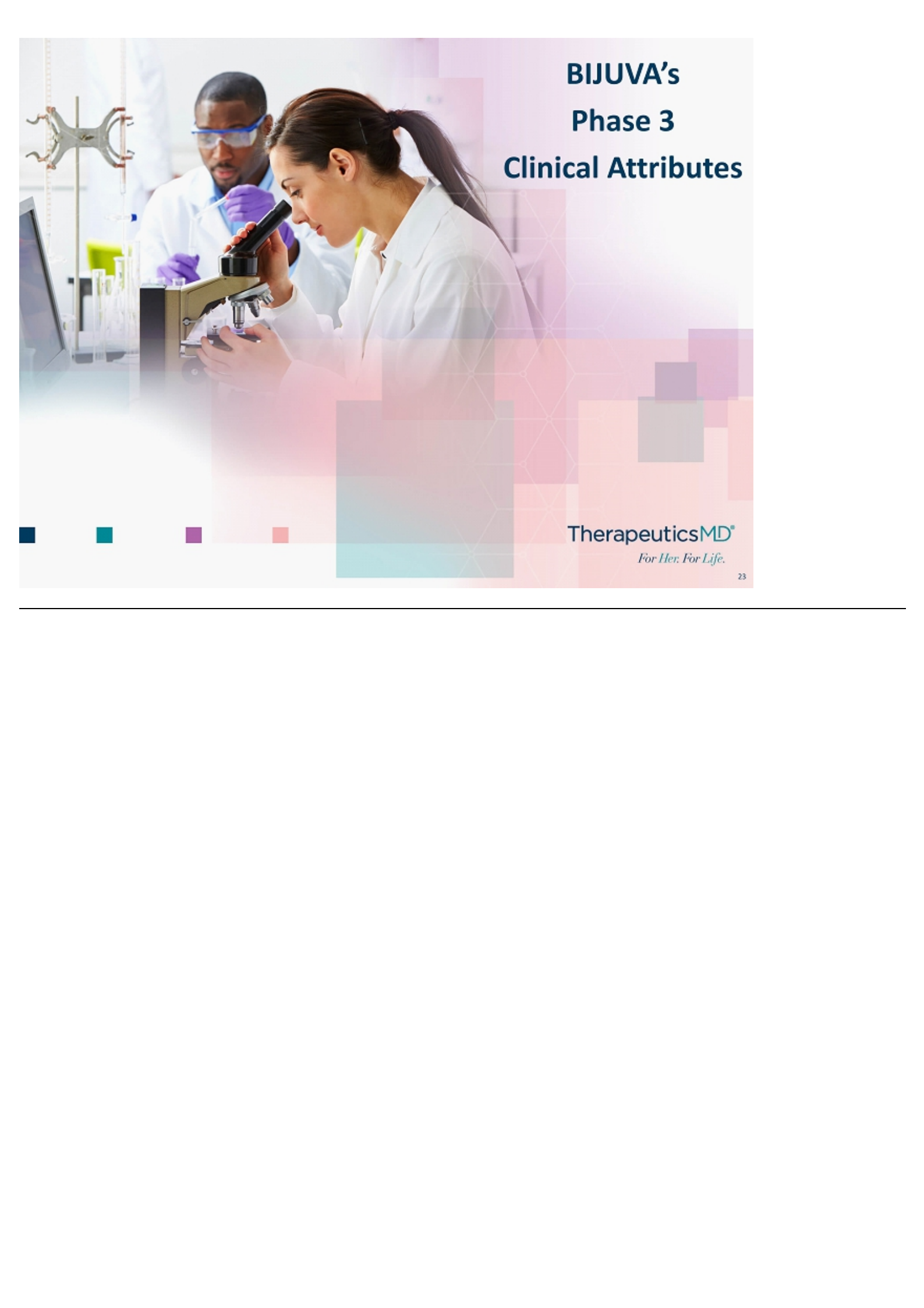
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BIJUVA Addressable Market: Compounded Products

BIJUVA – KEY ADOPTION ATTRIBUTES



1) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications
2) Based on WAC pricing of \$214.50

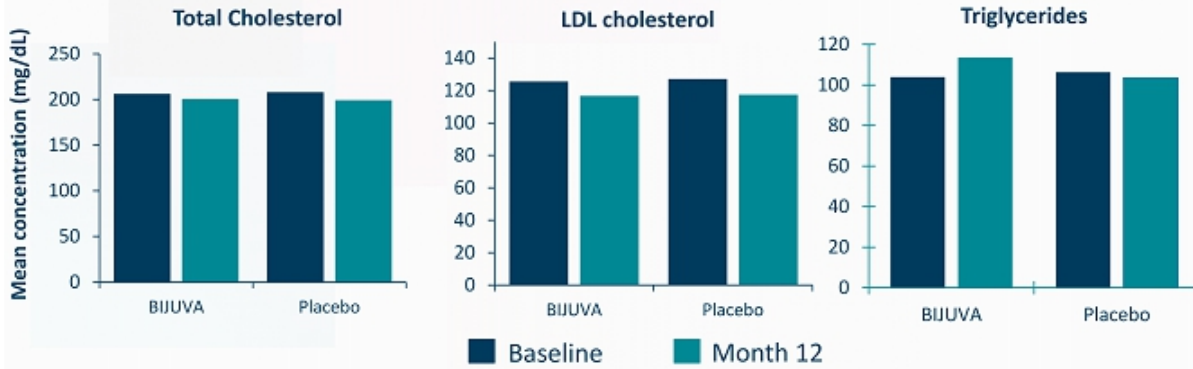


BIJUVA's Phase 3 Clinical Attributes

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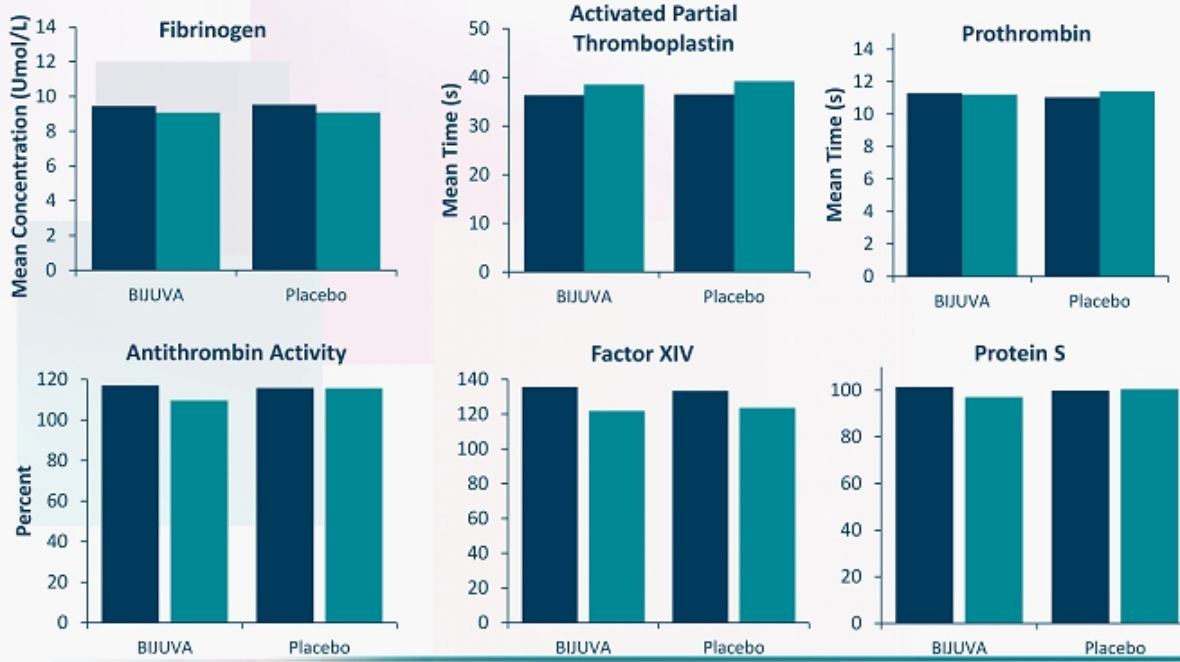
No Clinically Significant Changes in Lipid Parameters were Observed

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



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

No Clinically Significant Changes in Coagulation Parameters were Observed with BIJUVA



■ Baseline ■ Month 12

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Coagulation parameters were measured at baseline and Month 12

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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[†]

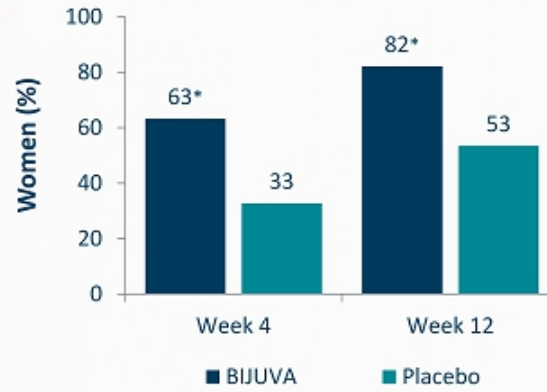
* $P < 0.001$ vs placebo.

[†]Mean change from baseline at Month 12 was not significant.

Reference

Data on file, TherapeuticsMD.

CGI response:
Clinically meaningful improvement

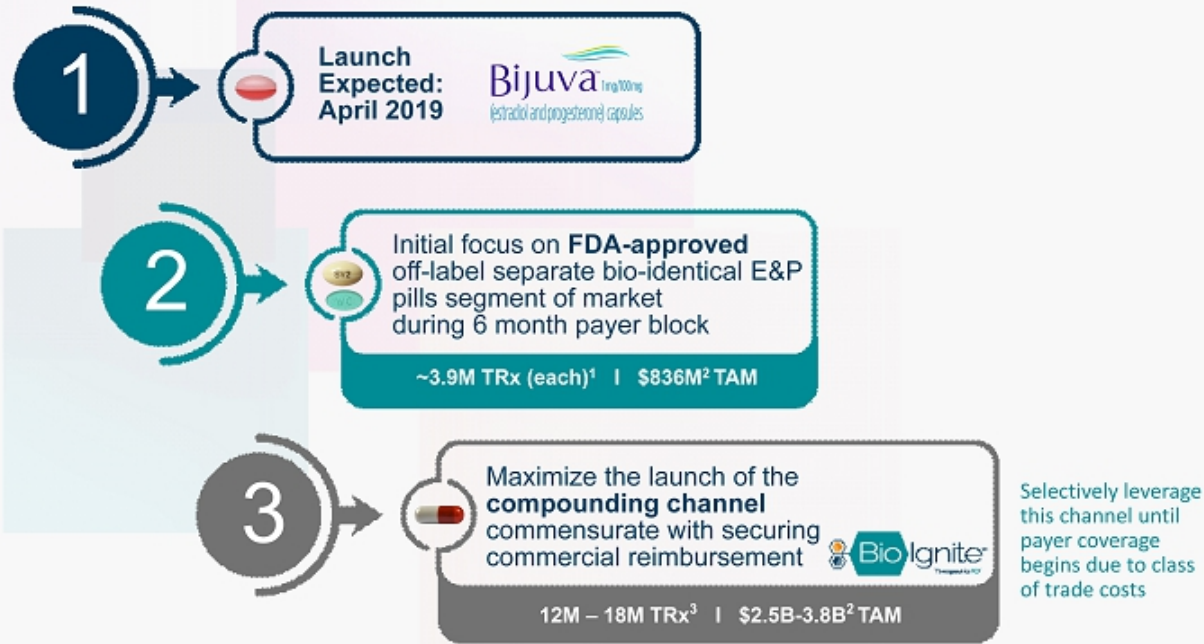


BIJUVA's Launch Strategy



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A Large Target Market for Bijuva[®] 1mg/100mg (estradiol and progesterone) capsules



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

2) Based on WAC pricing of \$214.50

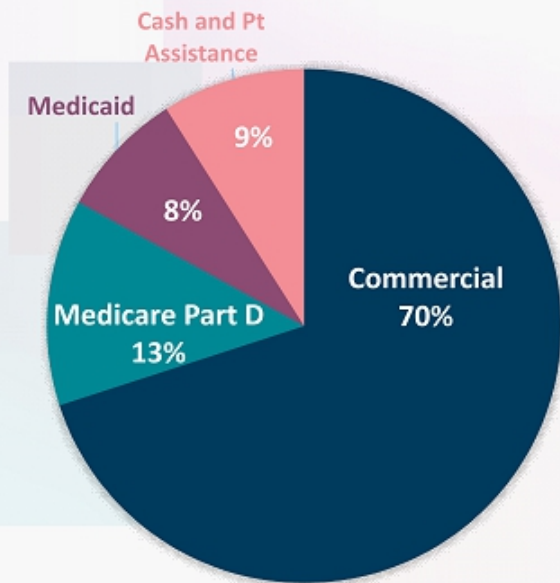
3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications

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Payer Breakdown of FDA-Approved VMS Products¹



- Compared to IMVEXXY Medicare Part D is a smaller segment of the population
- Expect 6 month commercial payer block and similar payer onboarding timeline to IMVEXXY

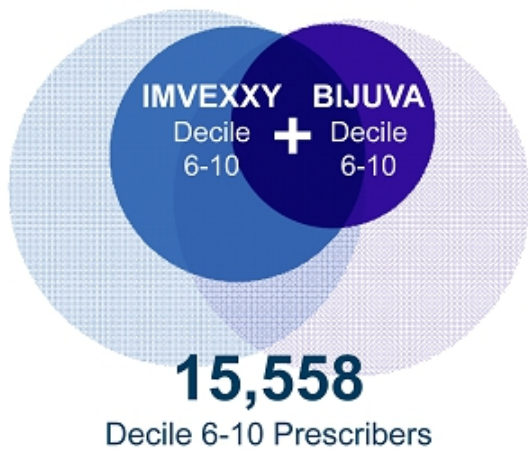
Salesforce Footprint Considers Distinct

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

Market And **Imvexxy** Overlap

Imvexxy
(estradiol vaginal inserts)
4 mg - 10 mg

Portfolio Optimization Summary



- Ensure momentum with IMVEXXY writers
 - 2019 Salesforce reaches 24,431 total targets
 - 94% Coverage of decile 6-10 target decile
 - 62% Coverage of total market TRx
- Launch focus for BIJUVA will be selected high decile VMS customers and current IMVEXXY writers

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30

Strategic Partnerships and Initiatives






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		Compounded Combination Bio-Identical E+P
Off-Label Separate Bio-Identical E & P Pills	Combination Synthetic E+P ¹	
		
~3.9M TRx (each) ¹	~2.5M TRx ²	12M – 18M million TRx ³
~\$836M ⁴ TAM	~\$536 ⁴ TAM	~\$2.5B-\$3.8B 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 IDU, 12 months as of December 31 2018

² Includes the following drugs: Actovels®, Femi-IRT®, Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Bristelle®

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

⁴ Based on WAC pricing of \$214.50

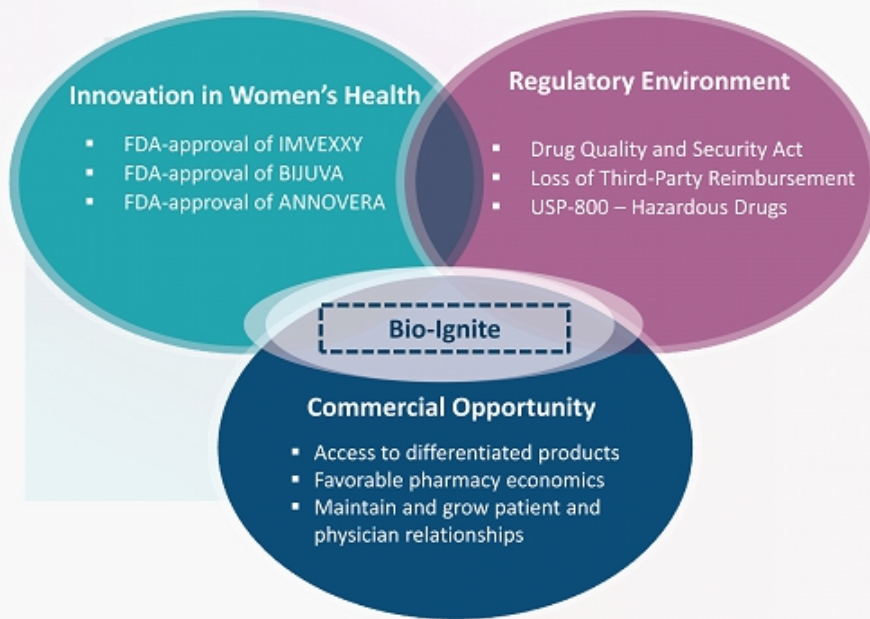
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Genesis of Bio-Ignite = Innovative Commercial Approach

Confluence of Events Support Robust Growth of TXMD Compounding Platform



Large, Untapped Market

- Over 3,000 physicians are currently writing high volumes of bio-identical hormones
- Over 700-900 pharmacies dispense high-volumes of bio-identical hormones
- Changing commercial and regulatory dynamics ultimately drive market need
- Channel is completely ignored by pharmaceutical companies
- TXMD takes a differentiated approach to maximize commercial viability of women's health products
- **We want to be where our competition is not**

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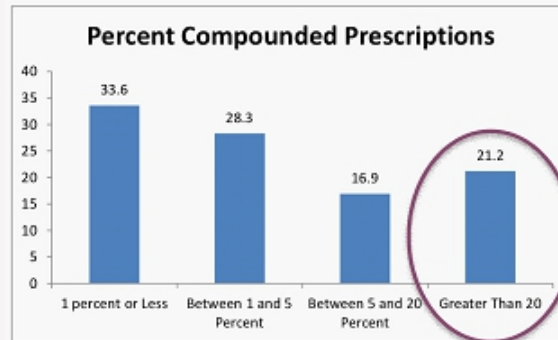
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What is an Independent Community Compounding Pharmacy?

There are more than 23,000 independent community pharmacies across the United States

These pharmacies dispense approximately 40% of the nation's retail prescription drugs

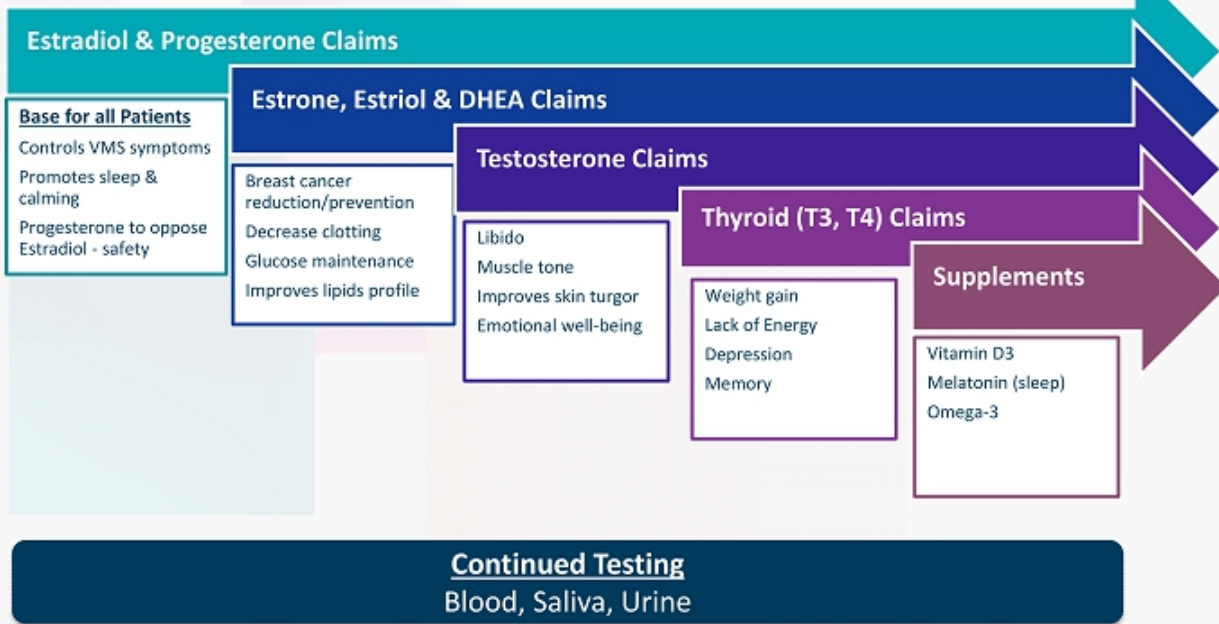
- 72% of independent community pharmacies that compound prescriptions provide **non-sterile compounding services only**.
- The target audience is independent community pharmacies that compound **20% or more** of their total business.
- 3,000+ locations meet class of trade definition of which **700+** have highest BHRT volume



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Pathway of Prescription – Holistic Approach

Customization is adding therapy...not tweaking dosages



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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 (6 Months since Pilot):

Live Accounts Dispensing IMVEXXY now or shortly in anticipation for BIJUVA: 29 (up 7 from Feb. 22, 2019)

States Reached: 31

- AK, AL, AR, AZ, CA, CO, CT, FL, GA, IA, ID, KS, LA, MA, MD, MI, MO, MS, NC, NJ, NV, NY, OH, OK, PA, RI, SC, TN, TX, VA, WA


Compounding Pharmacies in Vetting Process: 116

Unique CBHRT Prescribers Identified: 2,903 as of March 1, 2019

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BIO-IGNITE Progress and Results

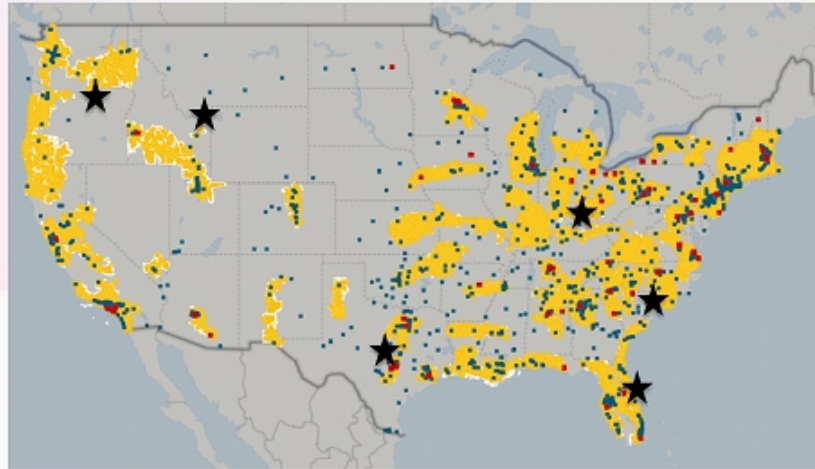
Partnerships with Large Pharmacy Network and Individual Pharmacies

Pharmacy Network and Individual Pharmacy Partners	# of Pharmacies	Combination Bio-Identical E+P Scripts
	>300 Pharmacies	~1,500,000 prescriptions annually
New National Compounding Pharmacy Partner	~100 Pharmacies (vetting process)	Currently vetting
TXMD Outreach to Individual Pharmacies	>400 Pharmacies with Prescription Data	>500,000 prescriptions annually

*Formerly known as Premier Value Pharmacy Compounding Network. Each network pharmacy has the option to participate in Bio-Ignite and is not required to as a Artiria member.

National High-Decile Compounding Pharmacies and TXMD Sales Team Overlap

- Yellow indicates field sales territory reach
- Red, Blue and Green indicate Compounding Pharmacy Targets
- Black Stars indicate TXMD pharmacy rep location



*This does not include the sales expansion territories

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ANNOVERA™

(Segesterone Acetate/Ethinyl Estradiol
Vaginal System)

Approved for use by females of
reproductive potential to prevent
pregnancy. (Limitation of use: Not
adequately evaluated in females with a
body mass index of >29 kg/m²).

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ANNOVERA - 1-Year Vaginal System

First and only **patient-controlled, procedure-free, long-acting, reversible** birth control

- ANNOVERA approved on August 10, 2018
 - 21/7 days cyclical dosing regimen for one year (13 cycles)
 - Segesterone acetate component of ANNOVERA was classified as a new chemical entity (NCE) with 5 years of regulatory exclusivity
- Developed by the Population Council – developer of multi-billion dollar long acting contraceptive products
 - **ParaGard®** and **Mirena®** IUDs; **Norplant®** and **Jadelle®** implants; and **Progering®**

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ANNOVERA Clinical & Physical Attributes

Clinical Attributes

- Highly effective in preventing pregnancy when used as directed (97.3%)
- Low daily release of ethinyl estradiol (13 mcg)
- Only product with new novel progestin - segesterone acetate¹
 - 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



Physical Attributes

- "Vaginal System" – the only product in a new class of contraception with potential for \$0 co-pay
- The vaginal system is composed of a "squishy" silicone elastomer
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship¹
- Cost and convenience (pharmacy and doc visits)
- Does not require refrigeration by HCP
- More pliable than NuvaRing

¹ Narender Kumar, Samuel S. Koide, Yun-Yen Tsong, and Kalyan Sundaram. 2000. "Nestorone: a Progestin with a Unique Pharmacological Profile," *Steroids* 65: 629-636

Phase 3 Acceptability Study

Demonstrated 1-Year Contraceptive Vaginal System High User Satisfaction

Acceptability Data¹

- Phase 3 acceptability study (n=905 subjects)
- Overall satisfaction 89% related to ease of use, side effects, expulsions/feeling the product, and physical effect during sexual activity
- High rates of adherence (94.3%) and continuation (78%)

Ease of inserting (N=905)	Ease of removing (N=905)	Ease of remembering CVS insertion (N=905)	Ease of remembering CVS removal (N=905)	No side effects reported on questionnaire (N=905)
90.8% (n=823)	88.2% (n=798)	87.6% (n=793)	85.2% (n=771)	81.8% (n=740)

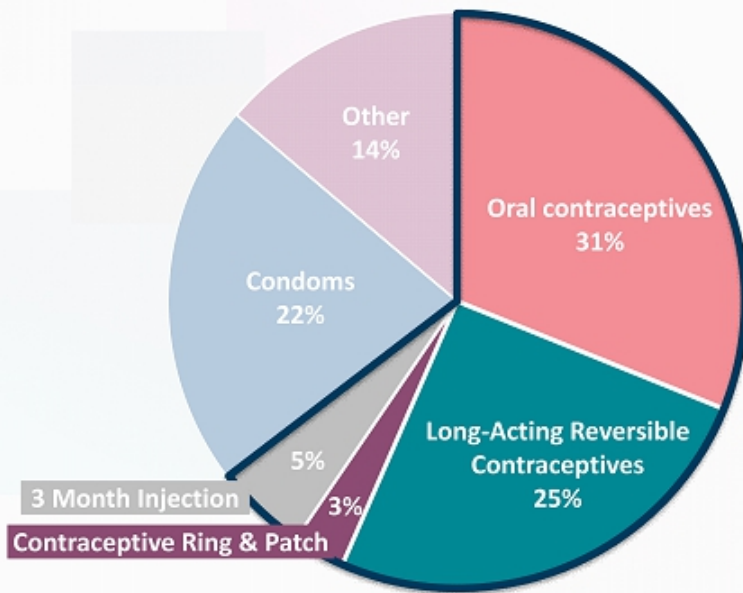
¹Merkatz, Ruth B., Marlena Plagianos, Elena Hoskin, Michael Cooney, Paul C. Hewett, and Barbara S. Mensch. 2014. "Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: Development of a model; implications for introduction." *Contraception* 90(5): 514–521.

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Reversible Birth Control Market in the U.S.

2017 Women's Use of Contraception
(Total 29 Million Women)



- OC's continue to lose market share to longer acting solutions such as IUDs, Implants and Rings
- IUDs and Implants are experiencing significant growth as the market shifts towards long-acting solutions

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 – Addressing an Unmet Need

Target Market Segments


SHORT-ACTING
CONTRACEPTIVES

Complete control but
no long acting benefits



ANNOVERA™

Long-acting benefits
without a procedure
and complete control
over fertility and
menstruation



LONG-ACTING
CONTRACEPTIVES

Long-acting
benefits but requires
a procedure and
does not offer
complete control



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ANNOVERA Key Attributes

	Oral Contraceptives	Vaginal Ring NuvaRing®	Contraceptive Injection	Vaginal System ANNOVERA™	IUDs
Duration of Action	Daily pill intake	1 month (21/ 7 regimen)	3 months	1 year (21/7 regimen)	3-10 years
Patient Control	Stop at any time	Removable at any time	Stop at any time, but residual effects for 3 months	Removable at any time	Procedure required
Nulliparous Women	Yes	Yes	Yes	Yes	Not universally acceptable
Product Administration	Oral intake	Patient administered Semi-rigid ring	Physician in-office injection every 3 months	Patient administered pliable vaginal system	Physician in-office procedure for insertion and removal
Patient Convenience	Daily pill presents compliance/ adherence risks; potential increase in unplanned pregnancies	Monthly pharmacy visit	Physician in-office injection, prescriber stocking required	1 doctor's visit, 1 pharmacy visit per year	Physician in-office procedure prescriber stocking required
Healthcare Provider Convenience	Filled at pharmacy	Filled at pharmacy; Refrigeration required prior to being dispensed	Prescriber required to hold inventory	Filled at pharmacy; No refrigeration; No inventory or capital outlay	Prescriber required to hold inventory
Yearly WAC	Lo Loestrin® Fe: \$1,829.36	NuvaRing® \$2,114.19	Depo-Provera® \$799.12	\$1,800-\$2,000	Liletta® \$749.40 + \$425.25 for insertion/removal Plus office visits and screenings

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TherapeuticsMD, A Premier Women's Health Company

ANNOVERA™

(segesterone acetate and ethinyl estradiol vaginal system)



vitaMedMD

Prenatal Vitamins

ANNOVERA™

(segesterone acetate and ethinyl estradiol vaginal system)

Bijuva™
(estradiol and progesterone) capsules

Imvexxy™

(estradiol vaginal inserts)
4 mg - 13 mg



CONTRACEPTION

PRENATAL CARE

CONTRACEPTION/
FAMILY PLANNING -
PERIMENOPAUSE

VASOMOTOR
SYMPTOMS

DYSPAREUNIA
(Vulvar &
Vaginal Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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TXMD: Financial Snapshot



A photograph of a woman with dark hair, wearing a light green sweater, laughing heartily. She is leaning over a man who is also laughing. She has her hands over his eyes. The man is wearing a light pink shirt. The background is a soft-focus indoor setting. The overall mood is joyful and intimate.

Thank You

Four small, solid-colored squares in a row: dark blue, teal, purple, and light pink.

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