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): January 8, 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 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 January 8, 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 January 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: January 8, 2019

THERAPEUTICSMD, INC.

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

Exhibit 99.1


Investor
Presentation
January 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

3 Recently Approved Products

Imvexxy® (estradiol vaginal inserts) 4 mcg • 10 mcg	Bijuva™ 1mg/100mg (estradiol and progesterone) capsules	ANNOVERA™ (segesterone acetate and ethinyl estradiol vaginal system)
DYSPAREUNIA (a symptom of VVA due to Menopause)	**VASOMOTOR SYMPTOMS** (Hot Flashes due to Menopause)	**PROCEDURE-FREE, LONG-ACTING REVERSIBLE CONTRACEPTION**
		
Launched	**Launch expected early 2Q19**	**Launch expected 2H19**

TherapeuticsMD®
For Her. For Life.

New Product Launches Address Large Market Opportunities in Women's Health

	Imvexxy	Bijuva	ANNOVERA™
Key Value Proposition	Easy to use, lowest effective dose, designed to support patient adherence	First and only bio-identical FDA-approved combination product	First and only patient-controlled, procedure-free, long-acting, reversible birth control product
Affected US Population	32 million women[5,6]	36 million women[3]	43 million women[1]
US TAM Opportunity	>$20B[7]	>$25B[4,7]	$5B[2]
Status	Approved May 29, 2018 Commercial Launch: August 2018	Approved October 28, 2018 Commercial Launch Expected: Early 2Q19	Approved August 10, 2018 Commercial Launch Expected: 2H19

1) Contraceptive Use in the United States. Guttmacher, July 2018. IQVIA Patient Tracker.
2) QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.
3) Derived from U.S. Census data on women in the age group who normally experience symptoms.
4) Based on pre-WHI annual scripts of FDA-approved HT products.
5) The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause. 2013;20(9):888–902.
6) Gass ML, Cochrane BB, 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.
7) Based on market pricing of current FDA-approved HT products.

TherapeuticsMD®
For Her. For Life.


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.
TherapeuticsMD®
For Her. For Life.
5

Strong Positive Launch

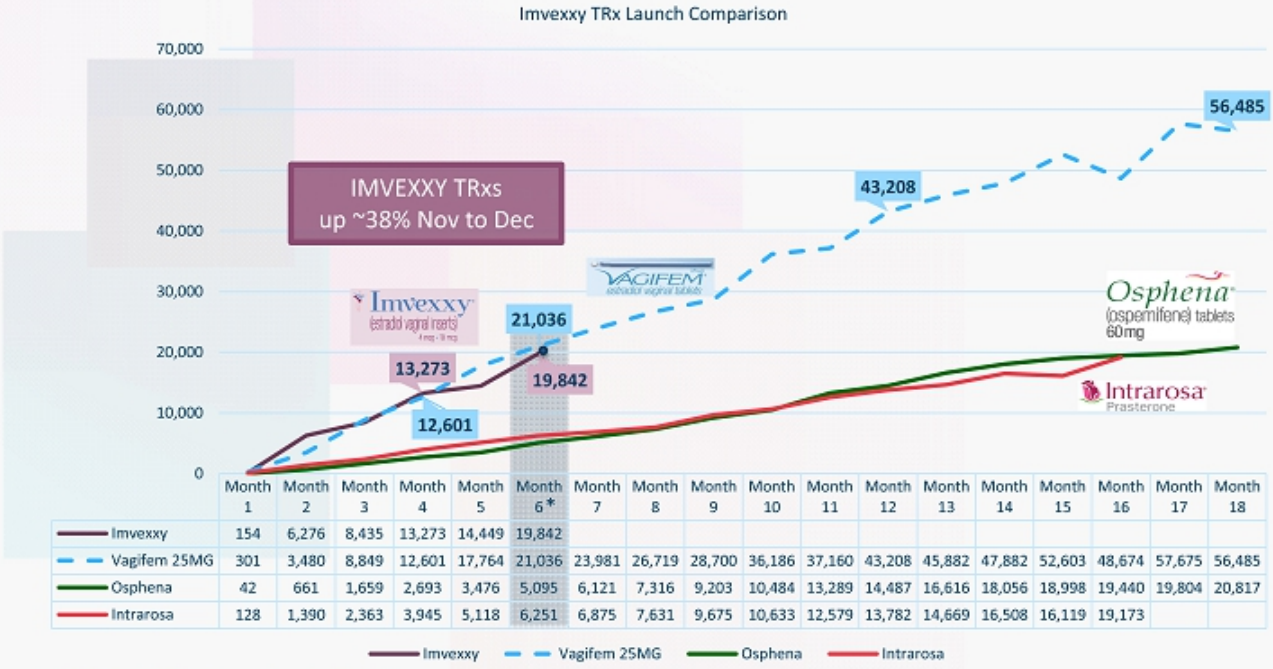
through December 31st, 2018

- Total units since launch ~62,400 paid scripts[1] dispensed to ~21,200 patients
  - Dec. 1st – Dec. 31st total units of ~19,800 paid scripts[1] (increase of ~38% Nov/Dec)
- Week ending December 21st ~6,100 total paid scripts[1,2]
- ~7,300 prescribers had a filled prescription (increase of 13% Nov/Dec)
- Refills continues to exceed VVA treatment averages
  - 62% of eligible IMVEXXY patients have filled their 4th script
  - 2.3 average IMVEXXY fills per patient, which is 82% of the maximum possible fills for those patients[3]
    - Previous two dyspareunia products averaged 1.7 fills per patient[4] during the first year of launch

[1]Units are based on IQVIA and copay redemption data based on utilization of our affordability programs. Cash pay or covered by insurance. Retail data for one week estimated on launch trends.
[2]December 21, 2018 was the last full week before the holiday period.
[3]Imvexxy fill data is based on IQVIA and copay redemption data.
[4]Previous two launches is based on Symphony total script data divided by the patient count data from IQVIA total patient tracker info from the 12 months of launch.

TherapeuticsMD®
For Her. For Life.

Monthly VVA TRx Launch Comparison Demonstrates Successful Launch Execution



	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6*	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18
Imvexxy	154	6,276	8,435	13,273	14,449	19,842												
Vagifem 25MG	301	3,480	8,849	12,601	17,764	21,036	23,981	26,719	28,700	36,186	37,160	43,208	45,882	47,882	52,603	48,674	57,675	56,485
Osphena	42	661	1,659	2,693	3,476	5,095	6,121	7,316	9,203	10,484	13,289	14,487	16,616	18,056	18,998	19,440	19,804	20,817
Intrarosa	128	1,390	2,363	3,945	5,118	6,251	6,875	7,631	9,675	10,633	12,579	13,782	14,669	16,508	16,119	19,173		

Imvexxy — Vagifem 25MG — Osphena — Intrarosa

*Month 6 of launch for IMVEXXY is December 2018

References:
Imvexxy is IQVIA and copay redemption data. IQVIA data for two weeks estimated on launch trends.
Osphena and Intrarosa is SHA PHAST data.
Vagifem is from IQVIA.

TherapeuticsMD®
For Her. For Life.

What is Leading to Rapid Uptake?

TherapeuticsMD®

For Her. For Life.

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

TherapeuticsMD®
For Her. For Life.

Effective IMVEXXY Detailing

The messaging by TXMD sales reps **is proving effective**, both at increasing the importance of treating VVA and educating Prescribers about IMVEXXY

Prescribers detailed[1]:

- Are more comfortable with estrogen
- Regard VVA and dyspareunia as more serious
- Are more favorable towards IMVEXXY
- Associate IMVEXXY more strongly with top attributes
- Plan to prescribe more IMVEXXY

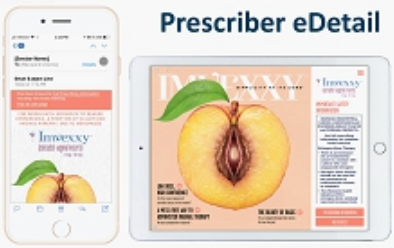
Direct Mail

Unbranded Direct to Consumer

American Association of Nurse Practitioners

Journal Ad

Prescriber eDetail



[1]TXMD sales force effectiveness research

TherapeuticsMD®
For Her. For Life.

New Levers and Messaging Planned to Support Driving NRx Trends in 2019

1Q-2Q19 New Tools

- Continued rollout of speaker programs

- Tools to support differentiation vs. other products

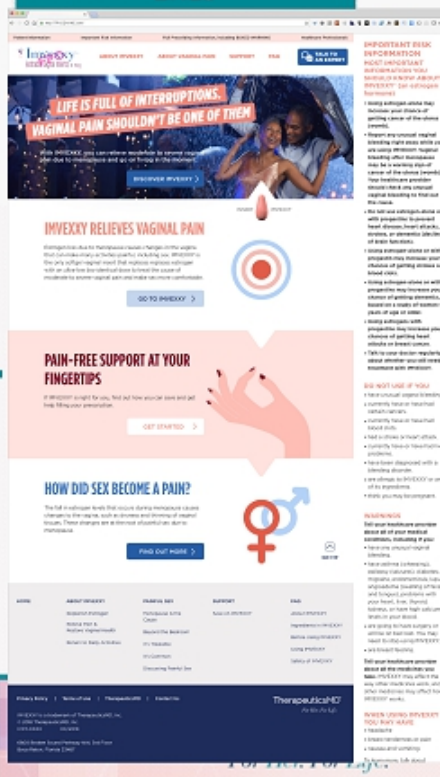
- Multichannel to segmented core targets
- Jump Start program for new writers

[1]TXMD research

2Q19 Evolved E-Detail & Tools

- Streamlined based on research results and salesforce input
- Additional leave behind tools

2H19



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 menopause[1] 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 prescription[2]
  - 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 1.0 mg/100 mg

Imvexxy (estradiol vaginal inserts) 4 mcg • 10 mcg

Same etiology – estrogen deficiency

Similar population[1]

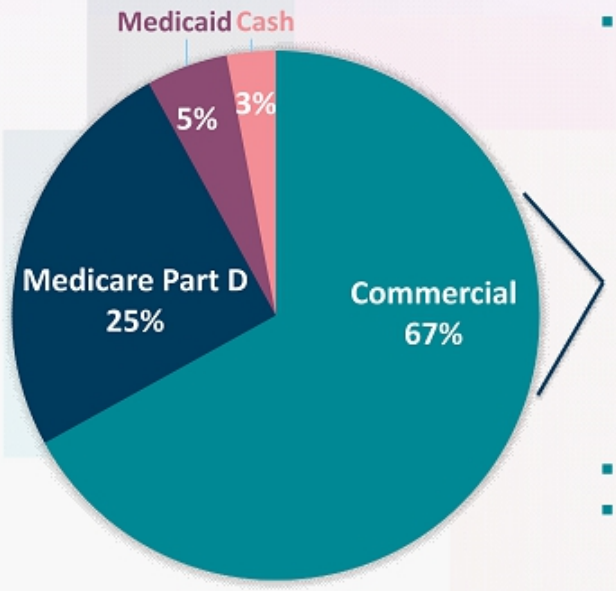
Same prescriber base

[1]The American Journal of Medicine (2005) Vol 118 (12B), 37S-46S.
[2]Notelovitz M. Urogenital aging: solutions in clinical practice. Int J Gynaecol Obstet 1997;59(suppl 1):S35-S39.

TherapeuticsMD® *For Her. For Life.*

IMVEXXY Payer Update
Payer Adjudication Begins Throughout 1Q 2019

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



- Strong IMVEXXY commercial payer progress
- No major road blocks seen
- Most major covered plans listed below begin adjudication at various points in 1Q19

Plan	Lives (M)	Status
ESI	28.9	Covered[2]
Prime	11.9	
Anthem	13.8	
OptumRx	11.4	
Cigna	7.5	
EnvisionRx	3.4	

- Medicare 2020 bids have been submitted
- If accepted, adjudication expected to begin October 1, 2019

[1]IMS Data April 2018
[2]MMIT January 2019

TherapeuticsMD®
For Her. For Life.

Key Drivers for IMVEXXY in 2019

Products

- First new differentiated estrogen treatment for VVA in over 12 years
- Launch of BIJUVA and ANNOVERA increase exposure in prescriber offices

Promotion

- Elevate the importance of the company with the prescriber with dual detail
  - Leverage full year of provider speaker programs across the US
  - Planned launch of consumer marketing programs 2H19
  - Increasing Bio-Ignite pharmacies
  - Improve access to menopausal women through BIJUVA
- Expand sales organization with a total of 200 sales reps planned by the end of 1Q19

Pull Through

- Patient adherence continues to exceed industry average and confirms target product profile is meeting a significant void in the market
- Major commercial payers will begin adjudicating throughout 1Q19
- Only a few major payers left to contract
- Medicare Part D contracting underway


Bijuva™
(estradiol and progesterone) capsules
1.0 mg/100 mg
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.
TherapeuticsMD®
For Her. For Life.
15

BIJUVA Market Opportunity

Expanded women's health/menopause footprint that allows us to connect with prescribers and women throughout the menopausal journey

- First and only FDA approved Bio-identical combination product*
- Little to no promotion in FDA approved hot flash category creates an opportunity to be the only new voice in the space
- Improvement in Quality of Life (MENQOL) and Sleep without somnolence
- Favorable tolerability with an improved bleeding profile
- Unique lipid, metabolic and clotting profiles for an oral estrogen
- Second product (IMVEXXY and BIJUVA) in the menopausal space increases provider and patient access
- Most women who experience hot flashes due to menopause will experience some level of VVA during their lifetime, which creates an opportunity to introduce IMVEXXY

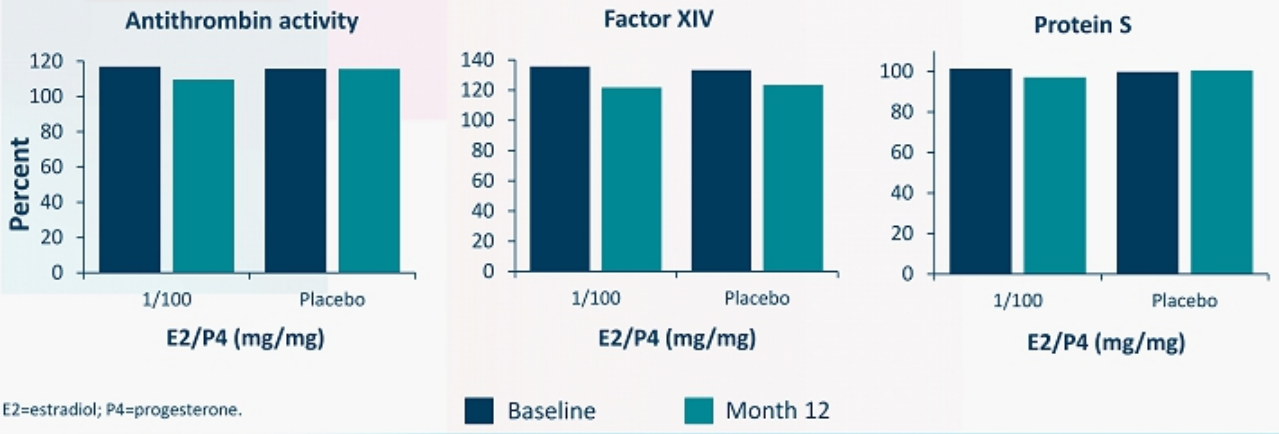
*"Bio-identical" refers to estradiol and progesterone that are molecularly identical to the hormones produced naturally in the woman's body. There is no evidence that bio-identical hormones are safer or more effective than synthetic hormones.

TherapeuticsMD®
For Her. For Life.


BIJUVA's
Phase 3
Clinical Attributes
TherapeuticsMD
For Her. For Life.
17

No Clinically Significant Changes in Coagulation Parameters were Observed with BIJUVA

- BIJUVA Phase 3 results supports unique lipid, metabolic and clotting profiles for an oral estrogen
- Benefits are likely due in part to BIJUVA's fully solubilized estrogens
- BIJUVA is the only hot flash product leveraging a lipid based technology system



E2=estradiol; P4=progesterone.

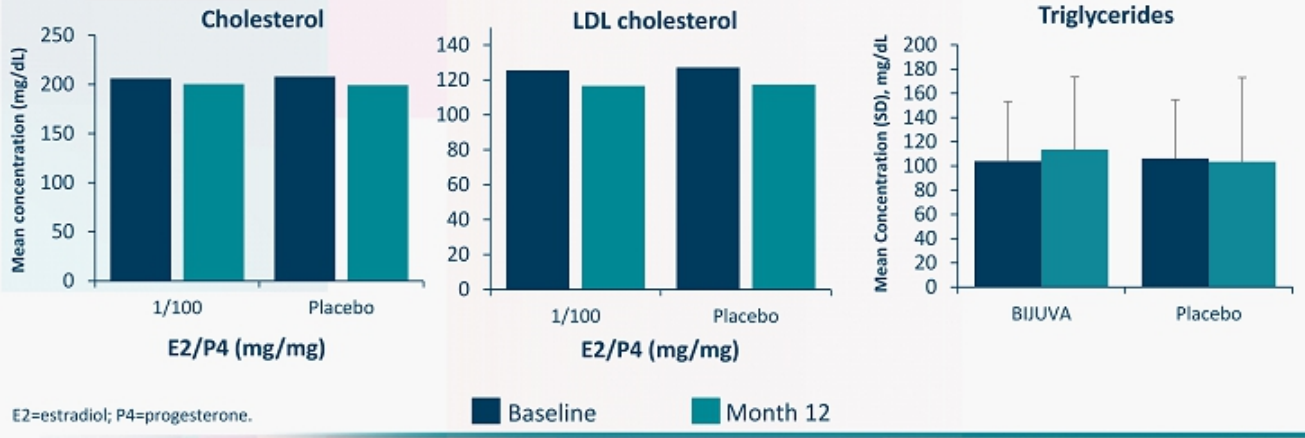
Reference
Data on file, TherapeuticsMD.

Bijuva
estradiol and progesterone capsules

No Clinically Significant Changes in Lipid Parameters were Observed with BIJUVA

- BIJUVA Phase 3 results supports unique lipid, metabolic and clotting profiles for an oral estrogen
- Benefits are likely due in part to BIJUVA's use of fully solubilized estrogens in a lipid based technology system
- No significant changes in Total Cholesterol, LDL or Triglycerides

Few women had cholesterol increases (≥50 mg/dL or above normal levels) at 12 months with BIJUVA vs placebo



E2=estradiol; P4=progesterone.

Reference
Data on file, TherapeuticsMD.

Bijuva
estradiol and progesterone capsules

Confirmed BIJUVA Efficacy: With a Consistency of Effect on Primary and Secondary Endpoints

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

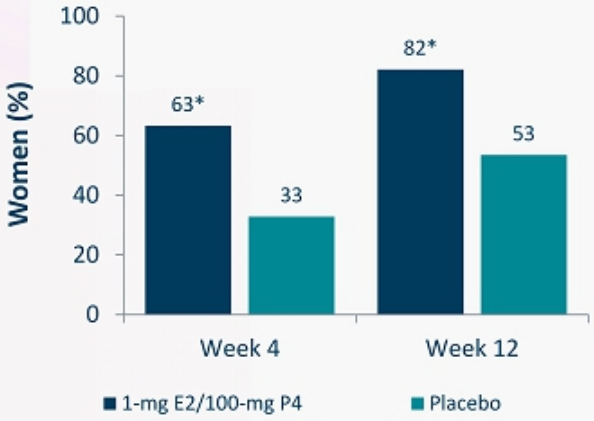
Menopause-Specific Quality of Life Questionnaire (MENQOL)

- 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[†]

CGI Response:
Clinically meaningful improvement



*$P<0.001$ vs placebo.
[†]Mean change from baseline at Month 12 was not significant.
E2=estradiol; P4=progesterone.

Reference
Data on file, TherapeuticsMD.

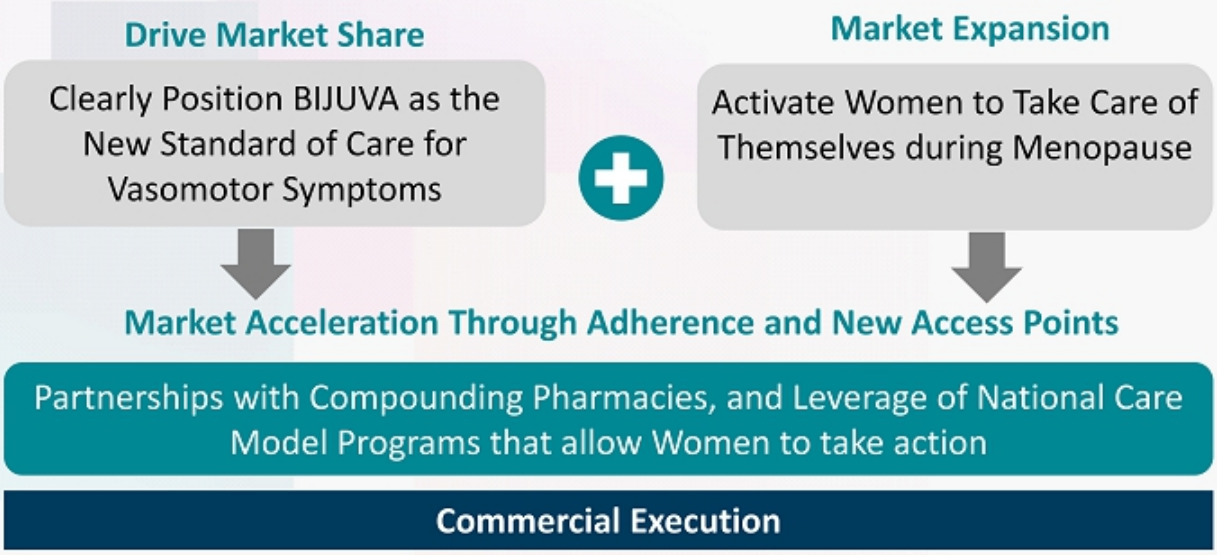
Bijuva
estradiol and progesterone capsules
1.0 mg/100 mg

BIJUVA Launch Strategy

TherapeuticsMD®

For Her. For Life.

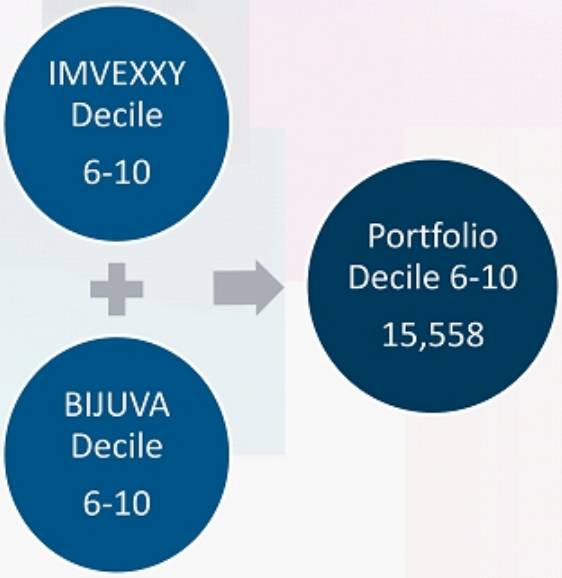
Focus on Three Main Fundamental Levers to Drive BIJUVA Launch



TherapeuticsMD®
For Her. For Life.

Salesforce Footprint Considers Distinct BIJUVA Market And IMVEXXY Overlap

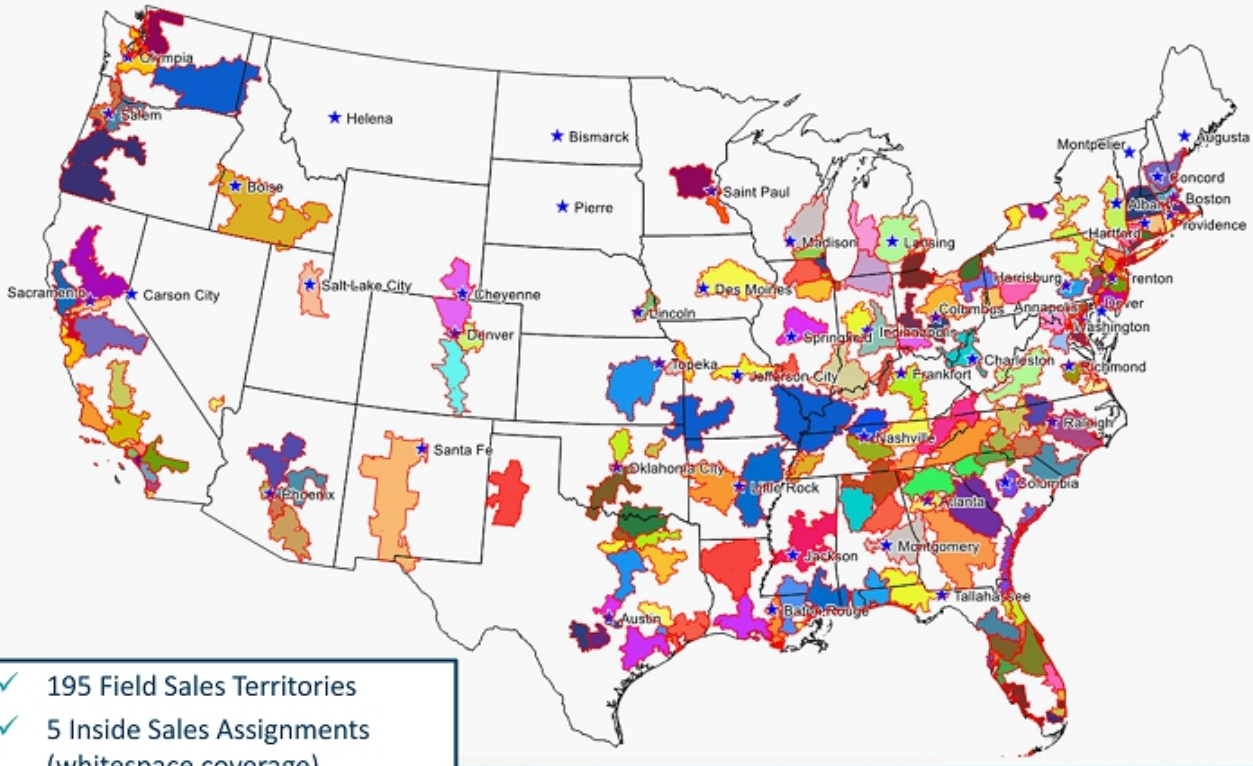
Portfolio Optimization Summary



Targeting Summary

- Writing behavior across all 3 market segments
- Ensured that any higher IMVEXXY writing stayed intact
  - 2019 Salesforce reaches 24,431 total Targets
  - 94% Coverage of Decile 6-10 Targets
  - 62% Coverage of total market TRx
- Geographic footprint
- Launch focus for BIJUVA will be selected high decile VMS customers and current IMVEXXY writers
- Portfolio targeting, messaging and bridging will be a focus on the launch meeting

2019 TXMD Salesforce Expansion



- ✓ 195 Field Sales Territories
- ✓ 5 Inside Sales Assignments (whitespace coverage)
- ✓ 8.5 to 1 Rep to Manager ratio
- ✓ 23 Sales Teams

TherapeuticsMD®

For Her. For Life.

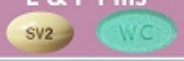
A Large Target Market for BIJUVA

Launch Expected: Early 2Q19

Phase 1: Initial focus 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] 	
	~3.8 million TRx (each)[1]	~3 million TRx[2]	12 – 18 million TRx[3]
>$25B[4,5] TAM	$760M-$950M[4] TAM	$600M-$750M[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 2017
2) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Bijuvia®
3) Consensus estimate based on Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31, 2017 and Fisher, J. Quintiles IMS, White Paper: A Profile of the US Compounding Pharmacy Market
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.

TherapeuticsMD®

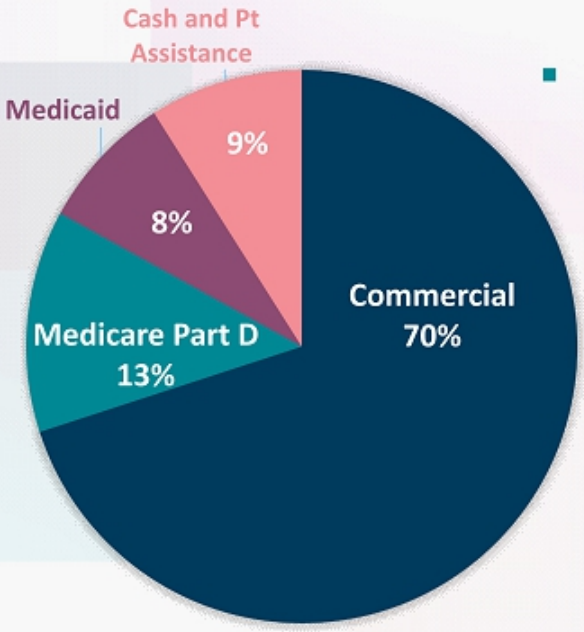
For Her. For Life.

BIO-IGNITE™
Provides Economic and Regulatory Benefits

Compounding Pharmacy Partnership Strategy

- **BIO-IGNITE™ Program:** Strategic partnership to work jointly with compounding pharmacies -- the largest and most influential channel for physicians and patients in bio-identical hormone therapy
- **Securing partnerships with large pharmacy network and individual pharmacies**
  - Alliance formed with Artiria-- approximately 300 compounding pharmacies
  - Expect to onboard 400 individual pharmacies
- **Advantages for compounding pharmacies**
  - Meet patient and physician demand for bio-identical hormone therapy
  - Assuming third-party reimbursement, significantly improve net margin per script
  - Lower certain legal and regulatory costs and requirements to continue compounding hormones
- **Current Phase: Build relationships and trust with IMVEXXY**
  - Expected to be 50-100 well recognized women compounding pharmacies in initial 12 months
- **Next Phase: Integrate BIJUVA to expand reach to the largest segment of the market**
  - Goal to expand to ~900 compounding pharmacies over a 24 month period from launch
- **Goal: Ensuring that BIJUVA has the best national access and uptake possible**

Payer Breakdown of FDA-Approved VMS Products[1]



- Expect 6 month commercial payer block and similar payer onboarding timeline to IMVEXXY

[1] IMS Data 2018

TherapeuticsMD®
For Her. For Life.


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).
TherapeuticsMD®
For Her. For Life.
28

ANNOVERA - 1-Year Vaginal System

Segesterone Acetate [Nestorone®]/Ethinyl Estradiol

- The vaginal system is composed of a "squishy" silicone elastomer
  - 21/7 days cyclical dosing regimen for one year (13 cycles)
  - 89% overall patient satisfaction in clinical trials[1]
- Average daily release over one year of use:
  - 0.15 mg/day segesterone acetate
  - 0.013 mg/day ethinyl estradiol
- Nestorone: progesterone derived unique progestin[2]
  - High progestational potency and anti-ovulatory activity
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Strong safety and efficacy data
- High patient satisfaction and acceptability

TherapeuticsMD®
For Her. For Life.

[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.

Phase 3 Acceptability Study

Demonstrated 1-Year Contraceptive Vaginal System High User Satisfaction

Acceptability Data[1]

- 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 CVR insertion (N=905)	Ease of remembering CVR 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)

[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.

TherapeuticsMD®
For Her. For Life.

Annovera Key Attributes

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 complete control of their fertility and menstruation
  - Annovera is the only user-directed single 12-month birth control product
- 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

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[3]
- "Vaginal System" – Potentially 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 prescriber

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

TherapeuticsMD®
For Her. For Life.

ANNOVERA Commercialization Strategy

Attractive Market Segments

- Long acting reversible contraceptives, such as IUDs and implants are experiencing significant growth as the market shifts to long-acting solutions growing at a CAGR of 15.3%[1]
  - Requires a procedure for insertion and removal
- Daily oral contraceptives are shrinking at a CAGR of 4.2%[1]
- Unmet need of a long-acting reversible contraception that is patient-controlled and procedure-free
- NuvaRing users (past 12 month gross sales ~$988M[2]) – leveraging the physical and clinical strengths of ANNOVERA
  - No additional sales representatives needed
  - ~80% of total prescribers within current 150 TXMD territories (197 after sales force expansion)[3]

Target Female Profile

- Women who want long-acting reversible contraception but don't want a procedure
- Providers who do not want to purchase and manage inventory of IUDs and implants
- Women who haven't had a child (nulliparous) or are not in a monogamous relationship and want long-term contraceptive options

[1]IQVIA 2017, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family,Paragard and Liletta. Net sales as reported in company filings.
[2]PHAST TRx MSB dollars.
[3]IQUVIA Data.

TherapeuticsMD®
For Her. For Life.

Looking Ahead:
Key Expected Events in 2019

- **1Q-** IMVEXXY 6 month payer block ends and payer adjudication starts at various points throughout 1Q
- **1Q-** Sales Force increase for IMVEXXY and BIJUVA
- **2H**- Begin direct-to-consumer marketing for IMVEXXY
- **2Q**- Expansion of Bio-Ignite program with BIJUVA launch
- **Early 2Q**- BIJUVA Launch and second $75 million debt tranche
- **2Q/3Q**- IMVEXXY Medicare Part D contracts to close
- **2H-** ANNOVERA launch (company working to accelerate original launch date)
- **Late 4Q-** BIJUVA 6 month payer block expected to end

TherapeuticsMD, *A Premier Women's Health Company*

TherapeuticsMD®

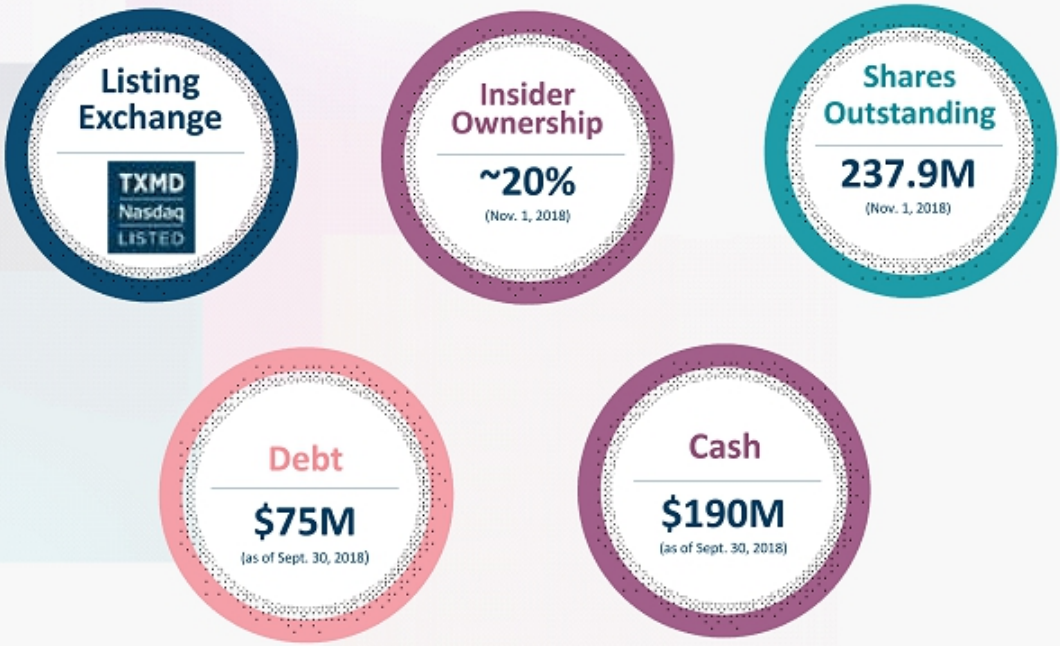
For Her. For Life.

Appendix

TherapeuticsMD®

For Her. For Life.

TXMD: Financial Snapshot



TherapeuticsMD®
For Her. For Life.

Expected Net Revenue Ramp for IMVEXXY

Net Revenue Ramp for Commercially Insured Patient

Starter Pack

- WAC $405
- 60% net = $243 average net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

Maintenance Pack

- WAC $180
- 60% net = $108 average net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

Blended Starter/Maintenance

- Current average WAC $225 (through October; will fluctuate based on mix and insurance coverage)
- 60% net = $135 net revenue per unit (script)
  - Company expects to net on average 60% of WAC when commercial insurance coverage is fully established
- Remaining 40% includes other costs (distribution, rebates and copay assistance programs)

Net Revenue Ramp for Medicare Part D to be determined

TherapeuticsMD®

For Her. For Life.

IMVEXXY Product Characteristics Compare Favorably [1-9]

	Estrogens				Non-estrogens	
Product	Estrace® Cream (estradiol vaginal cream, USP, 0.01%)[1]	Premarin® (conjugated estrogens) Vaginal Cream[2]	Vagifem® (estradiol vaginal inserts)[4]	IMVEXXY® (estradiol vaginal inserts)[5,6]	Intrarosa® (prasterone) vaginal inserts[7]	Osphena® (ospemifene) tablets, for oral use[8]
						
	Allergan	Pfizer	TEVA WOMEN'S HEALTH	TherapeuticsMD For Her. For Life.	amag	DUCHESNAY USA
FDA approval	1984	1978	1999	2018	2016	2013
TRx MSB Dollars 2017[9]	$504,804,770	$463,264,428	$446,044,670	-	$3,597,519	$66,904,883
Method of administration	Vaginal cream	Vaginal cream	Vaginal insert	Vaginal insert	Vaginal insert	Oral tablet
Application	Reusable vaginal applicator- cream	Reusable vaginal applicator- cream	Disposable vaginal applicator- tablet	No applicator needed- softgel vaginal insert	Disposable vaginal applicator- bullet insert	Oral daily tablet
Active ingredient	100 mcg estradiol	625 mcg/g conjugated equine estrogens	10 mcg estradiol	4 mcg or 10 mcg estradiol	6,500 mcg prasterone	60,000 mcg ospemifene
Average maintenance dose	100 mcg 2x/week	312.5 mcg 2x/week	10 mcg 2x/week	4 mcg or 10 mcg 2x/week	6,500 mcg daily	60,000 mcg daily
WAC package price (2018)[10]	$314.87 (42.5-g tube)	$355.77 (30-g tube)	$170.16 (8 tablets)	$180.00 (8 softgel capsules)	$185.50 (28 inserts)	$611.39 (90 tablets)
WAC 30-day supply (2018)[10]	$104.96	$118.59	$170.16	$180.00	$198.75	$203.80

There have been no head-to-head trials between IMVEXXY and any of the products listed above.
All trademarks are the property of their respective owners.
Abbreviations: WAC, wholesale acquisition cost.

References: 1. Estrace Vaginal Cream [package insert]. Irvine, CA: Allergan USA, Inc.; 2017. **2.** Premarin Vaginal Cream [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.; 2017. **3.** Estring [package insert]. New York, NY: Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc.; 2017. **4.** Vagifem [package insert] Plainsboro, NJ: Novo Nordisk Inc.; 2017. **5.** IMVEXXY [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2018. **6.** Constantine GD et al. The REJOICE trial: a phase 3 randomized, controlled trial evaluating the safety and efficacy of a novel vaginal estradiol soft-gel capsule for symptomatic vulvar and vaginal atrophy. *Menopause*. 2017;24(4):409-416. **7.** Intrarosa [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2017. **8.** Osphena [package insert]. Florham Park, NJ: Shionogi Inc.; 2015. **9.** Symphony Health Solutions PHAST Data powered by IDV; Annual 2017 [a. [2017 Estrace and generics (Teva, Mylan, Impax & Alvogen) and 2017 Vagifem, Yuvafem (authorized generic of Vagifem), and Teva generic] **10.** AnalySource. June 2018.

TherapeuticsMD®
For Her. For Life.

The First and Only FDA-Approved Bio-Identical Combination Hormone Replacement Therapy (HRT)

- Combination of bio-identical* estradiol and progesterone
- Strong efficacy and safety data
- Statistically significant reduction in both the frequency and severity of moderate to severe hot flashes
- Clinically meaningful improvements in quality of life and sleep disturbance data
- Low incidence of bleeding and somnolence
- Favorable lipid, coagulation and metabolic profiles, compared to the profiles separately established for synthetic progestins and synthetic estrogens

*"Bio-identical" refers to estradiol and progesterone that are molecularly identical to the hormones produced naturally in the woman's body. There is no evidence that bio-identical hormones are safer or more effective than synthetic hormones.

TherapeuticsMD®
For Her. For Life.

BIO-IGNITE Progress and Results

Partnerships with Large Pharmacy Network and Individual Pharmacies

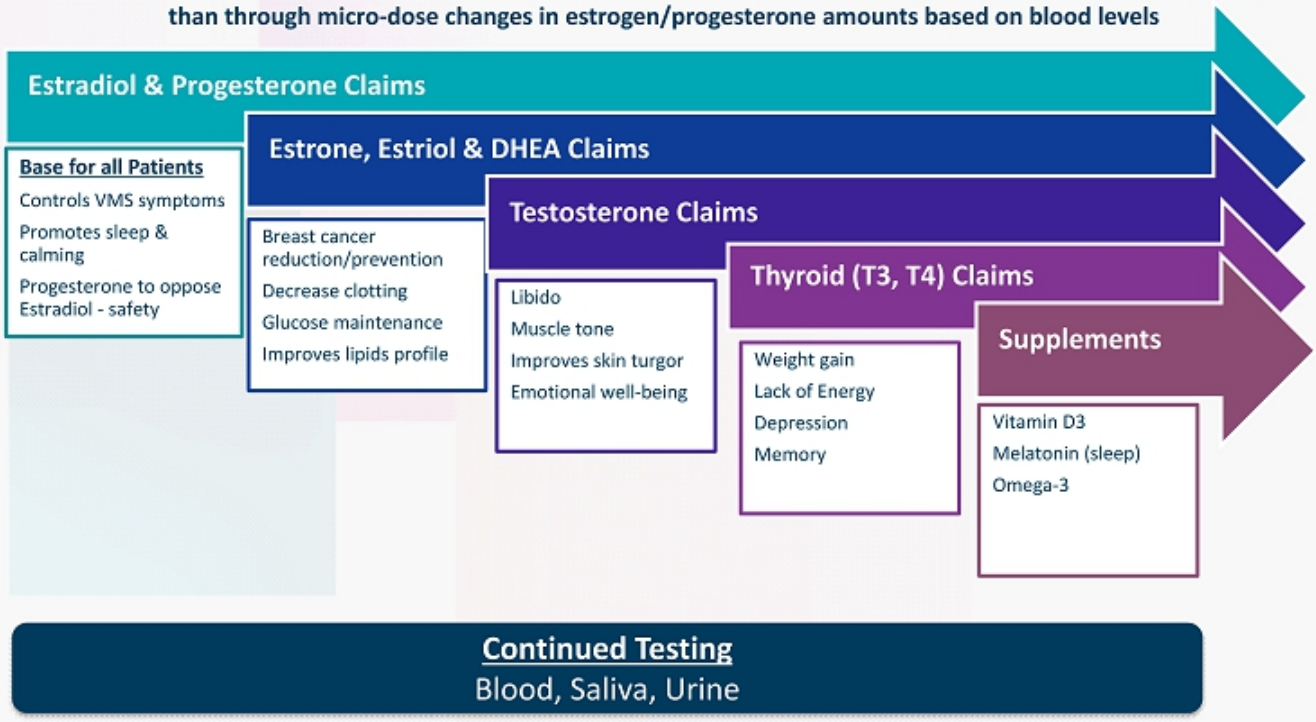
Pharmacy Network and Individual Pharmacy Partners	# of Pharmacies	Combination Bio-Identical E+P Scripts
Artiria*	>300 Pharmacies In Network	~1,500,000 prescriptions annually
TXMD Outreach to Individual Pharmacies	>400 Pharmacies with Prescription Data	>500,000 prescriptions annually

*Formerly known as Premier Value Pharmacy Compounding Network

TherapeuticsMD®
For Her. For Life.

Bio-Identical Customization

Customization of therapy at compounding pharmacies refers to addressing the overall patient condition including menopausal symptoms, adrenal function, libido, energy levels, thyroid function and nutrition, rather than through micro-dose changes in estrogen/progesterone amounts based on blood levels



Continued Testing
Blood, Saliva, Urine

TherapeuticsMD®
For Her. For Life.

1-Year Vaginal Contraceptive System Serves an Unmet Need in the U.S. Contraceptive Market

	ANNOVERA™	NuvaRing®	IUD's	Oral Contraceptives
Duration of Action	✓ 1 year (21/7 regimen)	× 1 month (21/ 7 regimen)	✓ 3-10 years	× Daily pill intake
Patient Control	✓ Removable at any time	✓ Removable at any time	× Procedure required	✓ Stop at any time
Nulliparous Women	✓ Yes	✓ Yes	× Not universally acceptable	✓ Yes
Product Administration	✓ Patient administered pliable ring	✓ Patient administered Semi-rigid ring	× Physician in-office procedure	✓ Oral intake
Patient Convenience	✓ 1 doctor's visit, 1 pharmacy visit per year	× Monthly pharmacy visit	× Physician in-office procedure prescriber stocking required	× Daily pill presents compliance/adherence risks; potential increase in unplanned pregnancies
Healthcare Provider Convenience	✓ Filled at pharmacy; No refrigeration; No inventory or capital outlay	✓ Filled at pharmacy; Refrigeration required prior to being dispensed	× Prescriber required to hold inventory	✓ Filled at pharmacy
Cost	✓ $1,400 WAC	× $154.89/28 days, or 1 year cost of $2013.57 (13 rings/year)	✓ $909 WAC + insertion and removal costs (good for 5 years)	× Lo Loestrin® Fe $128.51/28 days, or 1 year cost of $1,670.63 (13/year)
Contraceptive Class	Vaginal System	Vaginal Ring	IUD	Oral

- ✓ 89% overall patient satisfaction in clinical trials, 94% adherence rate, 78% continuation rate
- ✓ "Vaginal System"- potential for a new class of contraception with $0 co-pay
- ✓ Segesterone acetate component of Annovera classified as NCE with 5 year exclusivity

Chart comparisons for product characteristics only and are not intended to imply safety or efficacy comparisons

TherapeuticsMD®
For Her. For Life.