#### 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): June 10, 2019

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

001-00100

Nevada (State or Other Jurisdiction of Incorporation)

(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

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

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

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  $\Box$ 

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 that was used at its Investor Day on June 10, 2019 and may be used, in whole or in part, and subject to modification, 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 <u>Number</u>	Description
	<u>99.1</u>	TherapeuticsMD, Inc. presentation dated June 10, 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: June 10, 2019

#### THERAPEUTICSMD, INC.

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



### **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®, ANNOVERATM, BIJUVATM and our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our products; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock and the concentration of power in our stock ownership.

This non-promotional presentation is intended for investor audiences only.

TherapeuticsMD<sup>\*</sup> For Her. For Life.



**WELCOME** 8 Imvexxy (estradiol vaginal inserts) 4 mog · 10 mog **Robert Finizio** Chief Executive Officer Bijuva<sup>\*</sup>ing/100mg (estractiol and progesterone) capsules **ANNOVERA**<sup>™</sup> (segesterone acetate and ethinyl estradiol vaginal system) TXMD Nasdaq Listed 

Therapeutics MD\* For Her. For Life.

	TXMD Investor Day Agenda	
11:00-11:10 AM	OVERVIEW AND INTRODUCTIONS	
	Welcome – Robert Finizio	
	Introductions – Brian Bernick, M.D.	
11:10-11:50 AM	KEY OPINION LEADERS – IMVEXXY, BIJUVA AND ANNOVERA	
	IMVEXXY – Risa Kagan, M.D.	
	BIJUVA – James Simon, M.D.	
	ANNOVERA – James Liu, M.D.	
	Portfolio View – Jay Cohen, M.D.	
11:50-12:00 PM	Q&A PANEL	
12:00-1:00 PM	PORTFOLIO COMMERCIAL LAUNCH STRATEGY	
12.00-1.00 PW	IMVEXXY Launch Strategy & Performance Metrics – Dawn Halkuff	
	BIJUVA Launch Strategy & Performance Metrics – Dawn Halkuff	
	ANNOVERA Launch Strategy - Dawn Halkuff	
	BIO-IGNITE Update - Dedra Lyden	
	Compounding Pharmacist Perspective - Donnie Calhoun	
	Compounding Pharmacist Perspective - Scott Mazza	
1:00-1:10 PM	Q&A PANEL	
1:10-1:40 PM	PAYER OVERVIEW	
	Payer Environment – Robert Lahman	
	Payer Update – Mike Steelman	
	ANNOVERA – Ambrose Carrejo	
1:40-2:15 PM	CLOSING – PORTFOLIO OF 3 PRODUCTS AND FINANCIAL GUIDANCE	
1.40-2.10 1 10	How strategy, plan and model come together – Mitch Krassan	
	Financial Guidance - Rob Finizio	/
2:15-2:30 PM	Q&A PANEL	1

TherapeuticsMD\* TXMD For Her. For Life. Nasdaq Listed <section-header>



### Portfolio Approach to Women's Heath Sum of the Parts



- Innovative products, chronic conditions, large markets
- Single call point
- Products transition from one to the next through the various stages of life
  - contraception → prenatal vitamins → contraception → vasomotor symptoms → vulvar and vaginal atrophy
- Patient cost conscious portfolio
  - Products with patient out-of-pocket costs of \$35 or less with copay programs
  - Possibility of no out-of-pocket costs for Annovera

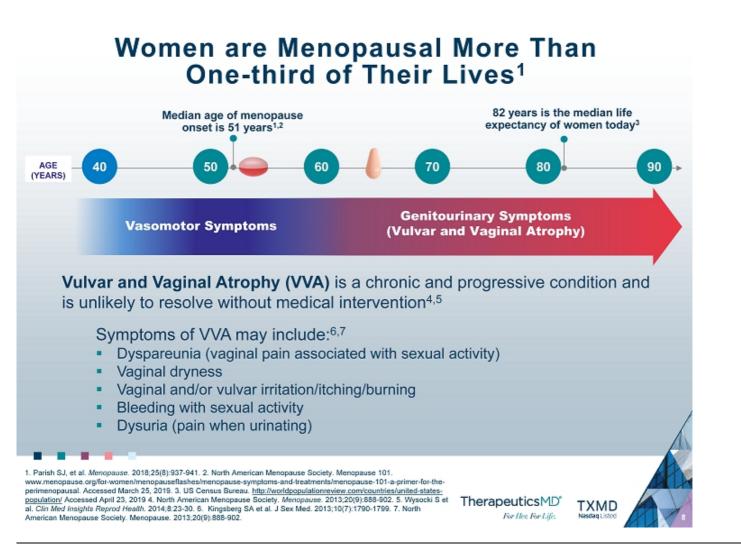
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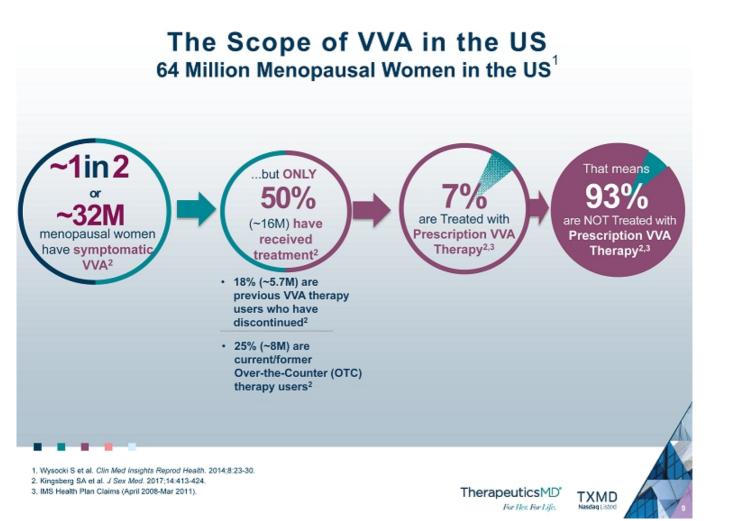


# Risa Kagan, MD, FACOG, CCD, NCMP

- Clinical Professor in the Department of OB/GYN and Reproductive Sciences at UCSF
- Gynecologist and Clinical Research with Sutter East Bay Medical Foundation
- Past Trustee of NAMS
- Leading expert in sexual medicine and menopause
- Lead author for the pivotal peer reviewed publications on female sexual disorders, menopause and bone health
- Principal investigator for over 100 clinical trials of sexual disorders, menopause and bone health







#### IMVEXXY is "Redefining Relief" A highly effective patient experience supported by strong clinical attributes Small, digitally inserted, vaginal softgel insert that dissolves completely **\* I**mvexxy Easy to use without the need for an applicator (estradiol vaginal inserts) •Mess-free administration Use any-time of day New lowest approved doses of estradiol 4 mcg and 10 mcg ·Efficacy demonstrated as early as 2 weeks (secondary endpoint) and maintained through week 12 •PK data - No increase in systemic hormone levels beyond the normal postmenopausal range\* Mechanism of action and dosing that are familiar and comfortable \* Invexxy 0000000 00000008 10 mea lestado No patient education required for dose preparation or applicators 001 ODE Dose packaging to optimize compliance and convenience \* Invexxy 0000 10 mog lestadol vagiral inserts) → High patient satisfaction resulting in high refill rates 0000 \*The clinical relevance of systemic absorption rates for vaginal estrogen therapies is not known.

TherapeuticsMD<sup>®</sup> For Her, For Life.

Bijuva 1mg/100mg (estradiol and progesterone) capsules Therapeutics MD\* For Her. For Life.

# James A. Simon, MD, CCD, NCMP, IF

- Clinical Professor Division of Reproductive Endocrinology and Infertility Department of The George Washington University School of Medicine Washington, D.C.
- President, International Society for the Study of Women's Sexual Health (ISSWSH)
- Past President, The North American Menopause Society (NAMS)
- Leading expert in sexual medicine and menopause
- Lead author for the pivotal peer reviewed publications on female sexual disorders and menopause
- Over 400 publications
- Principal investigator for more than 350 clinical trials



## Menopause Overview



Menopause represents the natural life-stage transition when women stop having periods as the production of estrogen and progesterone decreases

- May result in physical and emotional symptoms1
  - Symptoms include vasomotor symptoms (hot flashes and night sweats), mood changes and vaginal dryness
  - Prolonged lack of estrogen can affect the bones and cardiovascular system
- Estrogen is given to reduce symptoms and other long-term conditions
  - Increased risk for endometrial hyperplasia/endometrial cancer if estrogen unopposed<sup>2</sup>
- Progesterone is given to prevent thickening of the uterine wall when estrogen is used<sup>2</sup>



Vasomotor symptoms are experienced by the majority of women during the menopausal transition<sup>3</sup>

- As many as 74% of menopausal women<sup>4</sup>
- Up to 88% of perimenopausal women<sup>4</sup>



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<sup>5,6</sup>



National Institutes of Health, National Institute on Aging, https://www.nia.nih.gov/health/publication/menopause, last accessed November 3, 2015.
 International Journal on Women's Health, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3897322/
 Thurston RC et al. Obstat Gynecol Clin North Am.

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### **BIJUVA Product Development Rationale**

- 2002 Women's Health Initiative (WHI) study showed that the long-term use of certain synthetic hormones (a combination of medroxyprogesterone acetate and conjugated equine estrogens) increased the risk of breast cancer, stroke, heart attack and blood clots
  - Prior to BIJUVA, all FDA-approved combination hormonal products contain a synthetic progestin and not a bio-identical progesterone
- After WHI, women and healthcare providers shifted to bio-identical hormone therapy as an alternative despite estradiol and progesterone combinations being *unapproved* drugs for use together
- Compounding filled the need for bio-identical hormone therapy
- All the major medical societies and the FDA discourage the prescribing of compounded hormones
- NEED FOR AN FDA-APPROVED COMBINATION BIO-IDENTICAL HORMONE THEREAPY

1) Symphony Health Solutions PHAST Data powered by IDV; Annual 2015

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### Current Hormone Therapy Options for Vasomotor Symptoms

After WHI (2002), a majority of women and clinicians shifted to bio-identical hormone therapy<sup>1,2</sup>

FDA-APPROVED		NOT FDA-APPROVED				
Combination <u>Synthetic</u> Estrogens + Progestins*	Separate <u>Bio-identical</u> Estradiol & Progesterone	Compounded <u>Bio-identical</u> Estradiol + Progesterone				
~ 2.5 million total annual prescriptions <sup>1</sup>	~ 3.9 million total annual prescriptions (each) <sup>2</sup>	12 - 18 million total annual prescriptions <sup>3</sup>				
Prempro <sup>®</sup> , Activella <sup>®</sup> , Angeliq <sup>®</sup> , Femhrt <sup>®</sup> , Climara Pro <sup>®</sup> , Combipatch <sup>®</sup>	Oral or transdermal estradiol & Prometrium®	Compounded estradiol + progesterone				
FDA-approved	Not FDA-approved to be used together	Not FDA-approved				
1 copay	2 copays	Often not covered by insurance				
Insurance coverage	Insurance coverage	Almost 100% out of pocket				
NEED FOR AN FDA-APPROVED COMBINATION BIO-IDENTICAL HORMONE THERAPY						
2) Includes the following drugs: Activella@, FemHRT@, Angeliq@, Generic 17b + Progestins, Prempro@, Premphase@, Dusvee@, Brisdelle@ 3) Composite of Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market, internal surveying of compounding pharmacies & NAMS publications All trademarks are the property of their respective owners.  TherapeuticsMD® For Her, For Life, For Life, Internal Surveying						



BIJUVA is indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause

#### KEY CLINICAL ATTRIBUTES

- First and only bio-identical combination of estradiol to reduce moderate to severe hot flashes combined with progesterone to help reduce the risk to the endometrium
- Strong efficacy and safety data
- Sustained steady state of estradiol
- No clinically meaningful changes in weight or blood pressure
- No clinically meaningful changes in coagulation or lipid parameters
- No clinically meaningful changes in mammograms
- Clinically meaningful improvements in quality of life and sleep disturbance data
- High desired amenorrhea rates (no bleeding)

### OTHER KEY ATTRIBUTES

- Once-a-day single oral softgel capsule only approved continuous combined progesterone product
- No peanut allergen (as in other FDA-approved progesterone products)
- One prescription, one copay
- BIJUVA is available in blister packages containing 30 capsules



BIJUVA [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2019. Lobo RA, et al. Obstet Gynecol. 2018;132(1):161-170. Lobo RA, et al. North American Menopause Society Annual Meeting, October 3 – 6, 2018, San Diego, CA, USA, abstract number S-2.

TherapeuticsMD<sup>\*</sup> For Hen. For Life. Nasdaq Listed



(segesterone acetate and ethinyl estradiol vaginal system) Therapeutics MD\* For Her. For Life.

### James Liu, MD

- President, North American Menopause Society (NAMS)
- Chairman, Department of Obstetrics and Gynecology, University Hospitals Health System, MacDonald Women's Hospital, Cleveland, Ohio
- Chair, Department of Reproductive Biology, Case Western Reserve University
- Obstetrician-Gynecologist in Chief, University Hospitals Health System
- Leading expert in fertility, contraception, sexual medicine and menopause
- Lead author for over 114 pivotal peer reviewed publications on women's health
- Principal investigator for multiple clinical trials including NIH Contraceptive Clinical Trials Network
- Holds five patents on vaginal drug delivery



# **ANNOVERA - 1-Year Vaginal System**

Segesterone Acetate [Nestorone®]/Ethinyl Estradiol

# First and only patient-controlled, procedure-free, long-lasting, reversible birth control

- ANNOVERA approved on August 10, 2018
  - Segesterone acetate component of ANNOVERA classified as NCE with 5 year exclusivity
- Developed by the Population Council creator of the best selling long- acting contraceptive products
  - ParaGard<sup>®</sup> and Mirena<sup>®</sup> IUDs; Norplant<sup>®</sup> and Jadelle<sup>®</sup> implants<sup>®</sup>
- Motivation was for a long-acting product that doesn't require a procedure for insertion or removal

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# **U.S. Contraceptive Market**

- Contraception is most notably used for family planning, but also to control symptoms associated with menstruation, endometriosis, fibroids, acne and perimenopause
- Nearly all women (99%) have used contraceptives at some point in their lives<sup>1</sup>
- Long-acting methods of contraception (IUDs and Implants) are experiencing the greatest growth (CAGR 15.3% from 2012 to 2017), while daily oral contraceptive use has declined (CAGR -4.2% from 2012 to 2017)<sup>2</sup>
- Yet, these long-acting methods are not offered routinely by a large segment of women's health providers
  - According to research, only 56% of office-based obstetricians/gynecologists, family practitioners, and adolescent medicine specialists offered on-site IUDs; only 32% offered implants<sup>3</sup>
    - ~45% of preventive care visits among reproductive-age women are made to family practitioners, nurse practitioners, or internists<sup>3</sup>
      - Less than a quarter of family practitioners report providing any form of longacting reversible contraception<sup>4</sup>
- Women and healthcare providers want a long-lasting, reversible, patient controlled and procedure-free birth control

 CDC. Current Contraceptive Status Among Women Aged 15–49: United States, 2015–2017, <a href="https://www.edc.gov/nchs/products/databriefs/db327.htm">https://www.edc.gov/nchs/products/databriefs/db327.htm</a> 2. QuintilesIMS MIDAS, QuintilesIMS Analysis, Company filings. 3. Pace, Lydia E. et al., Incorporating Long-acting Reversible Contraception Into Primary Care: A Training and Practice Innovation. Women's Health Issues, Volume 26, Issue 2, 131 – 134 4. Chelvakumar, M, et al., Long-acting Reversible Contraception (LARC) Provision by Family Physicians: Low But on the Rise, The Journal of the American Board of Family Medicine January 2019, 32 (1) 10-12. LARC market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.

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# **ANNOVERA Key Attributes**

#### ACCESS ATTRIBUTES

- Market shift to long-acting
- Offer women a long-term birth control option without requiring a procedure for insertion and removal like IUDs or Implants
- Available to all prescribers no special training, equipment, or inventory
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship<sup>1</sup>
- "Vaginal System" the only product in a potential new category of contraception with potential for \$0 co-pay
- Does not require refrigeration



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# **ANNOVERA Key Attributes**

#### CLINICAL ATTRIBUTES

- Only FDA-approved long-lasting reversible birth control that doesn't require a procedure or repeat 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 (phase 3 acceptability study of 905 women)<sup>1</sup>
  - -89% overall satisfaction, adherence (94.3%) and continuation (78%)
- Softer and more pliable than NuvaRing<sup>®</sup>
- Only product with new novel progestin segesterone acetate<sup>2</sup>
   No androgenic or glucocorticoid effects at contraceptive doses\*
- Low rates of discontinuation related to irregular bleeding (1.7%)

 <sup>1</sup> 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.
 <sup>2</sup> Narender Kumar, Samuel S. Kolde, Yun-Yen Tsong, and Kalyan Sundaram. 2000. "*Nestorone: a Progestin with a Unique Pharmacological Profile*," Steroids 55: 629-636

\*Based on pharmacological studies in animals and in vitro receptor binding studies. All trademarks are the property of their respective owners. TherapeuticsMD<sup>\*</sup> For Her. For Life. Nasdaq Used



# **ANNOVERA** Patient Types

- Broad-based product a single contraceptive product for most patient and prescriber types
- Supports patient preference
- Amenable to women of all reproductive ages and demographics
- Highly effective
- Self-administered, long-lasting product that is reversible
- Nulliparous women (never had a child before)
- Between children birth spacing
- Women not in monogamous relationships
- Ideal for adolescents of reproductive age who don't want to take a product everyday, but don't want a procedure or nulliparous or non-monogamous
- College women no need for monthly refills
- Women in the military control fertility for 1 year



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# Jay Cohen, MD

- Medical Director of all Women's Healthcare of West Broward, Clinical Research, and Discovery Clinical Research, divisions of Envision Women's Healthcare
- Board certified OB/GYN at all Women's Healthcare of West Broward, a division of Envision Women's Healthcare
- Author for multiple peer reviewed publications on women's health
- Past of Board Member with the William Little OB/GYN Society, American Cancer Society (Breast Task Force), West Broward Unit of the American Cancer Society
- Principal Investigator of over 110 clinical trials on women's healthcare



### What Impact of TXMD Portfolio has on Typical Practice

- TXMD portfolio is important when covers critical stages of a woman's life cycle
   Leads to trust with Women
  - Very much like Wyeth, Ortho, Warner Chilcott market is wide open
- Women are more apt to discuss sexual health with their doctors today
  - Women are staying healthier and active longer
  - Often question products and safety more
- Modern products supported by strong clinical data that enable a provider to meet patient demands for bio-identical therapy
- Cost point is the most important
  - Consumer focused company
  - Menopause products have \$35 commercial co-pay with card; ~\$40 for preferred Medicare Part D co-pay
  - ANNOVERA potential for no-copay due to potential new method of contraceptive

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# Why Do IMVEXXY and BIJUVA Matter to Typical Clinicians

- Addresses the real life discussions between patients and physicians
- IMVEXXY is a unique product with the lowest approved dose
  - Key issue today systemic vs local estrogen
- BIJUVA is the only FDA-approved systemic therapy that is bio-identical, meets demand of patients
  - Do not need to compound
  - Can replace use of two separate FDA-approved products, which are not approved in combination and are not supported by endometrial safety data
- One co-pay per product affordability is key and creates compliance

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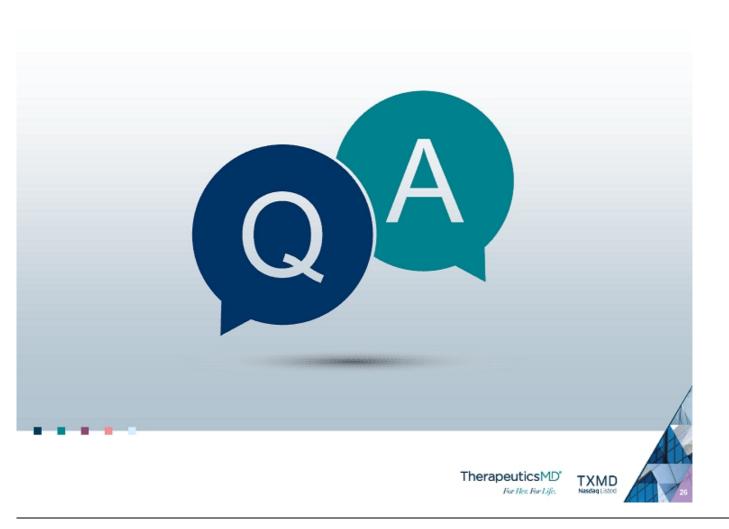
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### How Can ANNOVERA Change Things

- Only one visit to the doctor and pharmacy
- Addresses important reasons women discontinue daily and/or monthly contraceptives
  - Access, insurance coverage
  - Adverse events such as bleeding, weight gain, and nausea
- Long lasting ring (cyclical dosing for 13 cycles)
- State mandated coverage and potential 19<sup>th</sup> contraceptive method

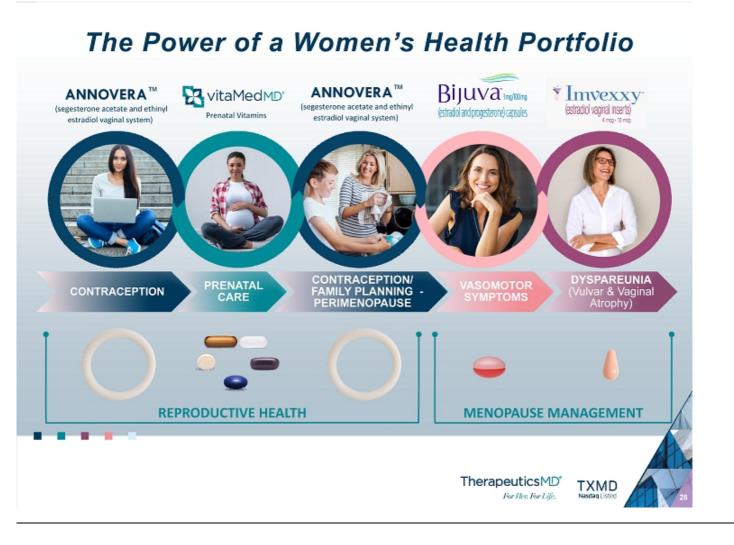
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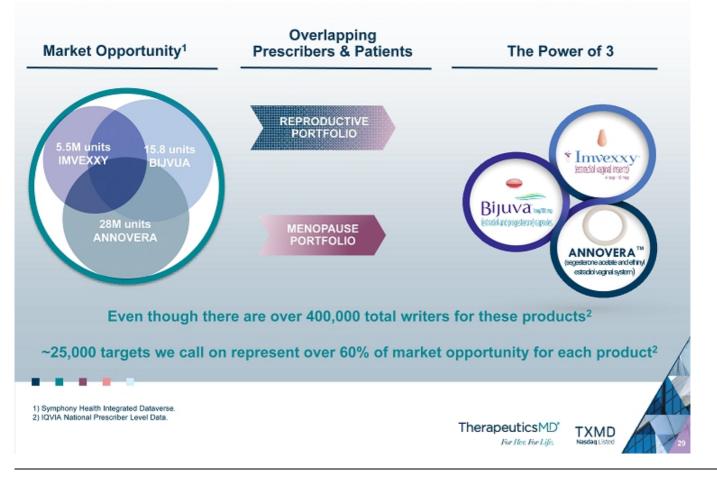


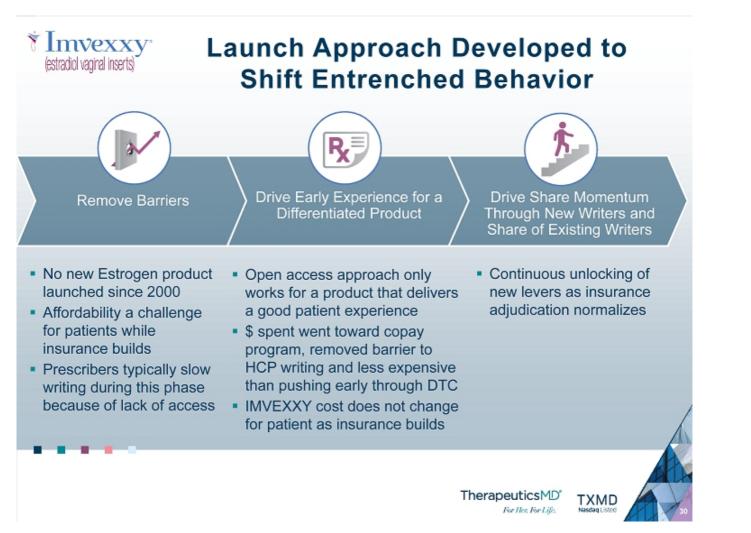
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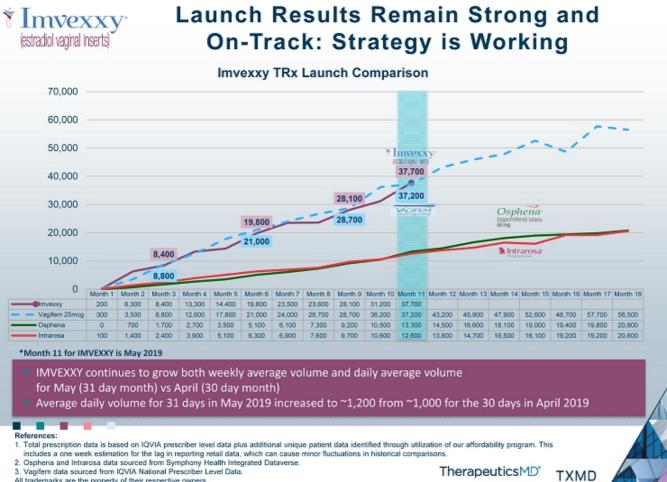
#### **COMMERCIAL UPDATE** Building a Premier Women's Health Portfolio 8 Invexxy (estradiol vaginal inserts) 4 mog • 10 mog **Dawn Halkuff** Bijuva Ing/100mg Chief Commercial Officer (estraction and progesterone) capsules ANNOVER A<sup>TM</sup> (segesterone acetate and ethinyl , estradiol vaginal system) TXMD Nasdaq Listed



### The Power of A Women's Health Portfolio







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### Strong Patient Adherence = Women are Staying on IMVEXXY

#### IMVEXXY Patient Adherence<sup>1,2</sup> Maximum Allowable Fills Average # Fills for those Month Initial Prescription Given the Month of Initial Filled Patients Fill May 2019 1 Fills 1 Fills 1.8 Fills 2 Fills Apr 2019 3 Fills Mar 2019 2.4 Fills Feb 2019 3.0 Fills 4 Fills Jan 2019 3.6 Fills 5 Fills Dec 2018 4.0 Fills 6 Fills Nov 2018 4.7 Fills 7 Fills Oct 2018 5.0 Fills 8 Fills Sep 2018 5.6 Fills 9 Fills Aug 2018 7.0 Fills 10 Fills

Example of calculation: For patients who filled their initial prescription in November 2018, each of those patients averaged 4.7 fills from November 2018 through May 2019

Average fills for all patients through May 31, 2019 = 3.34<sup>3</sup>

 Average number of fills per patient is the average number of fills per patient grouped by their initial month on therapy.
 Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program.

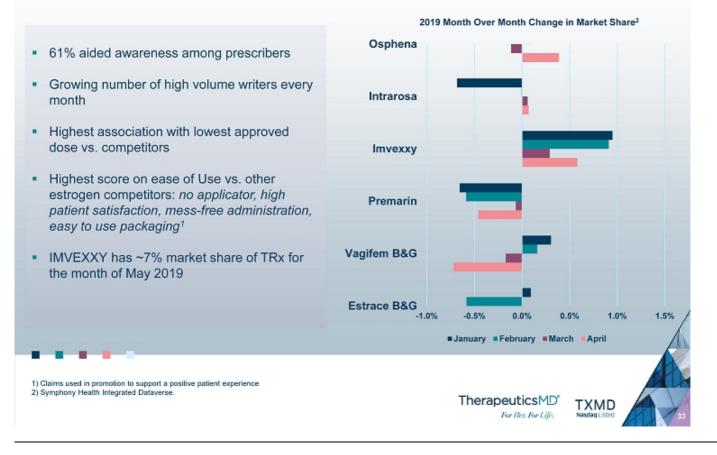
3) Average number of fills for all patients is calculated as Total Rx / Total Patients.

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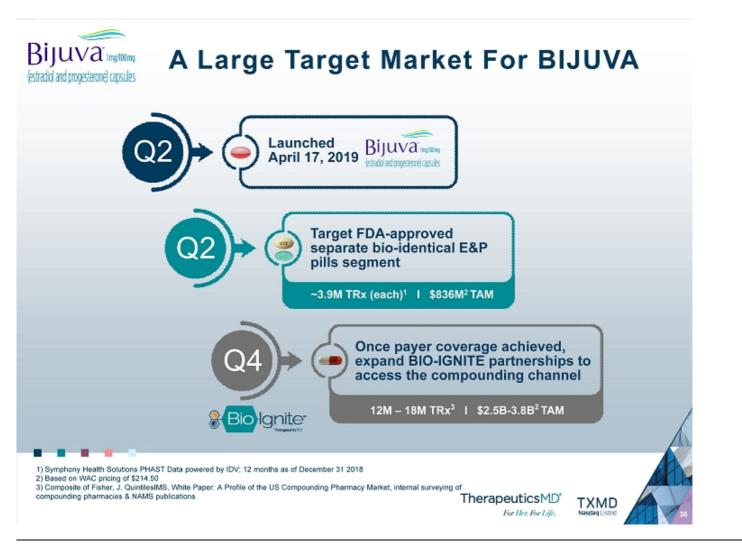
#### \*Invexxy **IMVEXXY Momentum Driven by** Increased Experience With the Product

(estradiol vaginal inserts)











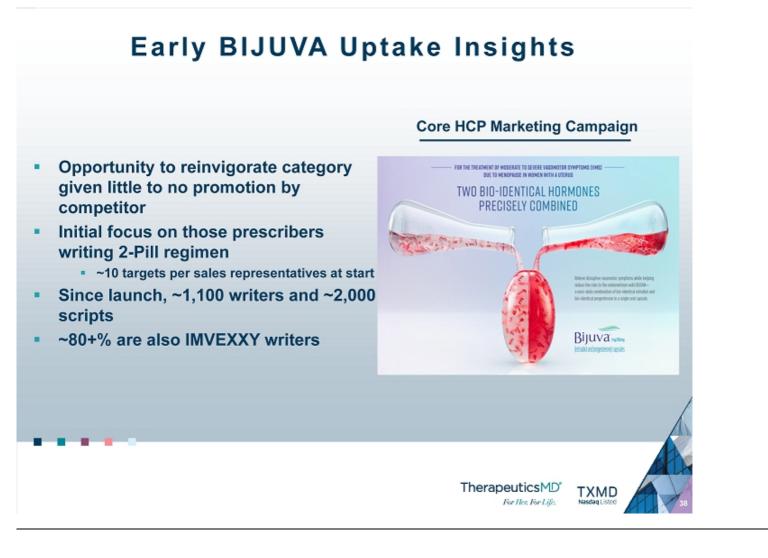
#### Launch Plan Mirrors IMVEXXY Focused on Driving Early Behavior Change that Leads to Long Term Adoption



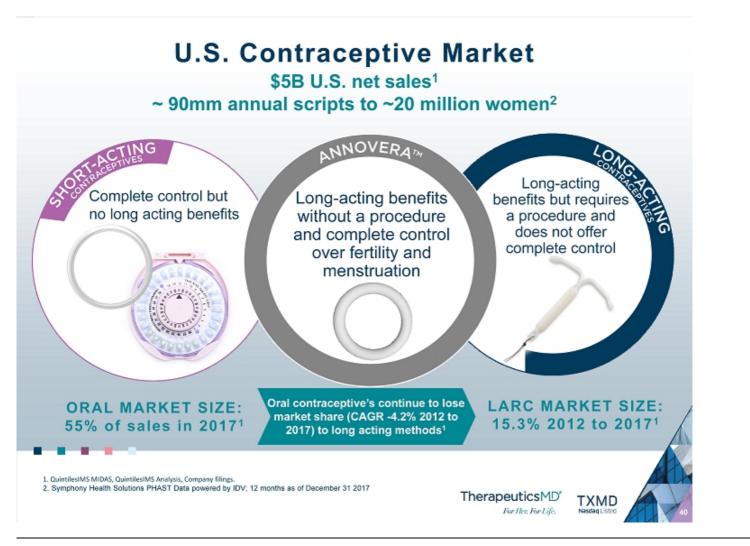
- \$35 or less out-of-pocket cost\*
- Addresses the cost and coverage concerns which are often barriers to early adoption
- "Keep Cool" Early Experience Program drives appropriate patient and prescriber education
- Positive early clinical experience has the potential to drive momentum

\*For commercial patients

TherapeuticsMD<sup>®</sup> For Her. For Life. Nasdaq Listed







# Prescribers and Consumers are<br/>DependenceHigh level of acceptance from prescribers with 89% of prescribers<br/>very or somewhat likely to prescribe1Providers report that they would expect to use ANNOVERA for 18%<br/>of their patients using birth control22 consumer segments accounting for almost 50% of the population<br/>have a high openness to ANNOVERA and openness to switching<br/>their current birth control product3Features that resonate for both prescribers and patients around long-<br/>acting/long-lasting and "patient-controlled"

 Internal Concept Evaluation, n=100 HCPs, SurveyGizmo, Nov, 2018
 Annovera HCP Concept/Positioning Study, n=300 HCPs, Phoenix, June 2019
 Women in their Reproductive Years Segmentation, n=1000, SMI Alcott/Brado, May, 2019
 Internal Concept Evaluation, n=100 HCPs, n=300 women, SurveyGizmo, Nov, 2018. Annovera HCP and Consumer positioning Study, n=300 HCPs, n= 450 consumers, Phoenix, June 2019.

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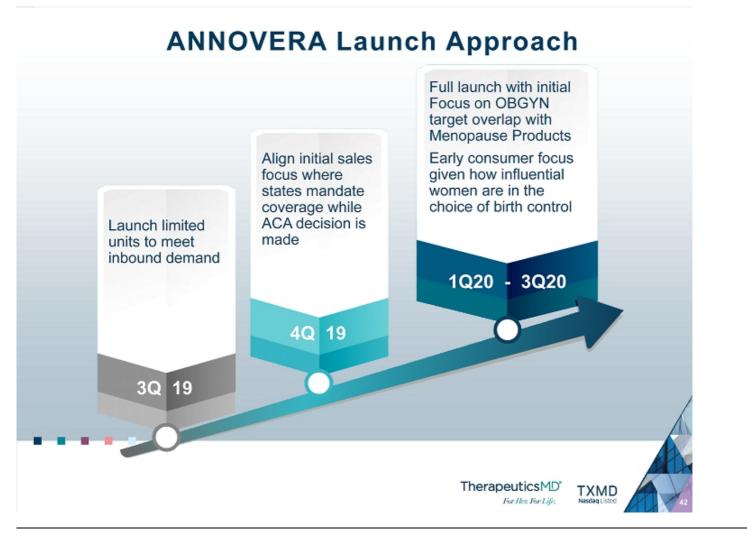
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# The Power of a Women's Health Portfolio



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# **BIO-IGNITE Introduction**

**Dedra Reiger Lyden** 

Vice President, Strategic Partnerships & Initiatives





# Bio-Ignite = Innovative Collaborative Approach

#### Large, Untapped Market

- Over 3,000 physicians are currently writing high volumes of bio-identical hormones
- Over 700 pharmacies are currently dispensing high volumes of bio-identical hormones
  - With marketing reps
- HYBRID pharmacy model (filling FDA approved and compounded products)
- Changing commercial and regulatory dynamics ultimately driving change in this market
- Compounding channel opportunity is ignored by pharmaceutical companies
- We want to be where our competition is not

#### **Regulatory Environment**

- Drug Quality and Security Act
- Loss of Third-Party Reimbursement
- USP <800> Hazardous Drugs



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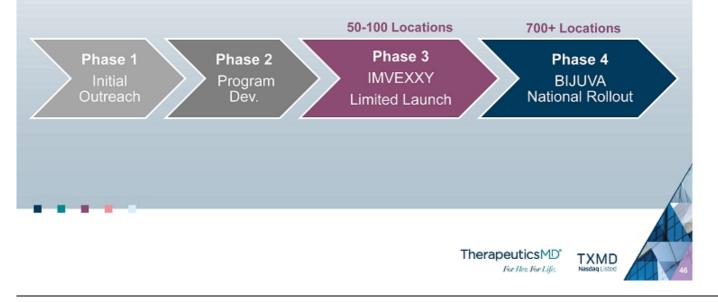


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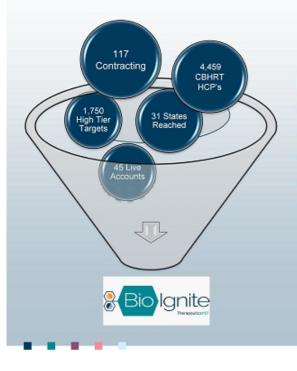


## **A Four-Phase Strategic Initiative**

Goal to activate all current stakeholders involved in the Bio-identical Hormone Replacement Therapy (BHRT) community, ensuring that TherapeuticsMD's portfolio has the best national access and uptake possible







## **Pharmacy Targeting:**

Over 1,750 are high tier targets

 These locations produce the highest volume of compounded bio-identical hormone replacement therapy (CBHRT) scripts

#### **Program Stats:**

- Live Accounts: 45
- States Reached: 31
- In Vetting Process: 89
- In Contracting Process: 117
- Unique CBHRT Prescribers Identified not in IMS: 4,459
  - 1,202 are identified as high-value CBHRT HCP's targeted by KAM's

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## Donnie Calhoun, BPharm, RPh.

- Licensed pharmacist in Alabama and owner of Calhoun Compounding Pharmacy in Anniston, Alabama
- Past President of the National Community Pharmacists Association, Past President of the Alabama Board of Pharmacy, Past Executive Director of the Specialty Sterile Pharmaceutical Society
- Has held many positions with the Alabama Pharmacy Association
- Former CEO/Executive Vice President for the American College of Apothecaries, CEO/Executive Vice President for the American College of Veterinary Pharmacists and CEO/Executive Vice President for the American College of Apothecaries Research and Education Foundation
- Elected to the Pharmacist Mutual Board of Directors in 2005



# Scott Mazza PharmD, MS, R.Ph.

- Over 30 years of clinical pharmacy experience in a variety of practice settings
- Currently oversees the Therapeutic Interchange Program for Polaris Pharmacy Services
- Served as Pharmacy Manager for a regional specialty and compounding pharmacy specializing in oncology and women's health compounding services
- Former National Director of Regulatory Compliance and Professional Practice for CVS Caremark
- Served on both national and state Medicaid Pharmacy & Therapeutics Committees and currently maintains 27 pharmacist licenses





## USP <800> Compliance Deadline December 2019

The practice of pharmacy as we know it today will be changing

The U.S. Pharmacopeial Convention (USP) has issued <u>USP General Chapter</u> <<u>800> Hazardous Drug Handling in Healthcare Settings</u> describing practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection

Key Points:

- To protect patients, personnel, and the environment from hazardous drug contamination
- Estradiol and progesterone are considered hazardous drugs
- Upgrades to be compliant are timely and costly
- OSHA has adopted the standards for enforcement

Community compounding pharmacies had hoped this would go away, but it did not Deadline for compliance now very close

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# **Partnership Types**

#### Pharmacy Profiles

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1. Will not be USP <800> Compliant

- No longer plans to compound BHRT
  - Bio-Ignite provides access to the greatest subset of BHRT patients and prescribing HCPs
- 2. Will be USP 800 Compliant
  - Will still be capable of compounding forms of BHRT
    - Bio-Ignite provides another option for their location to fill all patient and prescriber needs (not just a compounder)

#### Pharmacy Size and Reach

- Single pharmacy location (with/without wholesaler purchasing requirements)
- · Multi pharmacy location, multi state, not self-distributing model
- Self-distributing pharmacy, 10-100's of pharmacy locations

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# What is the opportunity for IMVEXXY and BIJUVA and why

#### Headwinds

- Community Pharmacies that compound are going through a significant market shift
  - Loss of reimbursement for many areas for compounded drugs including hormones
  - Significant increase in cost and regulation associated with compounding hormones and other "hazardous" drugs (USP800)

#### Solutions

- Pharmacy can continue to provide BHRT through FDA-approved product without increasing costs
- Decrease patient out-of-pocket through patient support program
- Respond to patient and provider requests for commercially available BHRT product
- Expand the tool chest with FDA-approved products
- Encourage pharmacy engagement with the medical community and patient community

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## Why are Community Pharmacies Right for this Opportunity

- Compounding pharmacies offer a concierge experience with patients
  - Available 24/7 and offer cell phone contact
  - Pharmacy business model has changed significantly over the past few years and will continue to change
  - Lower reimbursement, increasing costs of compliance
  - Need to find innovative solutions
- Compounding pharmacies opportunities
  - Increased prescriber access/relationships with HCPs who are not listed as prescribers in IMS
  - Large female patient demographic
  - Separate sales force to promote pharmacy offerings
  - Meet patient demands for FDA-approved BHRT products

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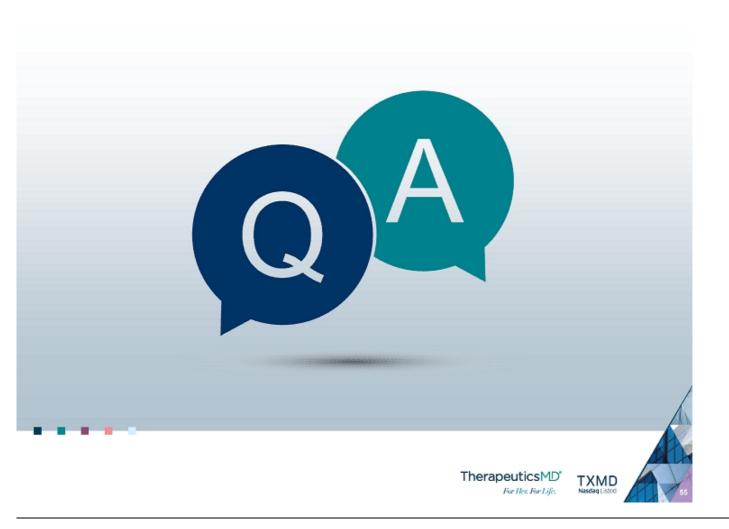


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# Bio Ignite Hybrid Pharmacy Based Rx Model

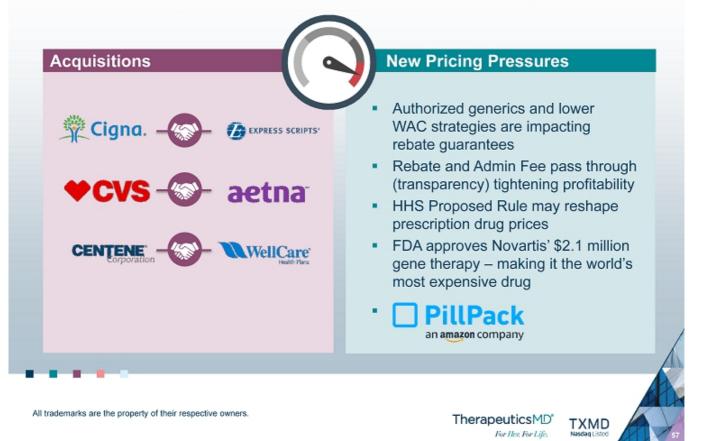
- The "Hybrid" pharmacy- compounding, specialty care and traditional Rxs
- Compounders are local community pharmacy providers and have key relationships with physicians and other community based health care providers
- Engage regularly with the prescriber community
- Pharmacies with a large female demographic
- Patient-centric approach establishes patient trust with their pharmacist
- Offer services not available with other delivery systems, such as charge accounts, free delivery, consultation services, and a host of others
- Ability to readily obtain refills for their patients, perform prior authorizations and other insurance services for their patients
- Medication Therapy Management Approach

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# 2019 US Payer Environment is Rapidly Evolving



# **Commercial Payer Update**

- Commercial Average Non Preferred Copay is \$59
- IMVEXXY co-pay card offering can bring this down to \$35

Among Covered Workers With Prescription Drug Coverage, Average Copayments and Coinsurance, 2018

	Average Copayment	Average Coinsurance
With Three or More Tiers		
t Tier	\$11	19%
ond Tier	\$33	26%
d Tier	\$59	36%
rth Tier	\$105	31%
With Two Tiers		
t Tier	\$11	NSD
cond Tier	\$31	28%
With the Same Cost Sharing I Covered Drugs		
t Tier	NSD	20%
Num ber of tiers refers to the num ber of tiers ex Not Sufficient Data	, cluding those specifically for specialty d	irugs.
Tier Num ber of tiers refers to the num ber of tiers ex	1	irugs.

Source: 2018 Employer Health Benefits Survey, Section 9: Prescription Drug Benefits (KFF, Oct. 3, 2018), https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-9-prescription-drug-benefits/ (accessed June 5, 2019). TherapeuticsMD\*

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# Medicare Part D Payer Update

#### Medicare Part D Median Preferred Copay is \$40

	Preferred generics		Generics		Preferred brands*		Non-preferred drugs		Specialty drugs	
Name of PDP	2018	2019	2018	2019	2018	2019	2018	2019	2018	2019
Median for all PDPs	\$1	\$1	\$6	\$5	\$37/21%	\$40/20%	4096	4096	26%	26%
Top 10 PDPs										
SilverScript Choice	\$3	\$3	\$14	\$13	\$42	\$42	4696	45%	33%	33%
AARP MedicareRx Preferred	\$5	\$5	\$12	\$10	\$37	\$40	40%	4096	33%	3396
Humana Walmart Rx	\$1	\$1	\$4	\$4	23%	2096	35%	35%	25%	25%
Humana Preferred Rx	\$0	\$0	\$1	\$1	2096	2596	3596	3796	25%	25%
AARP MedicareRx Saver Plus	\$1	\$1	\$3	\$6	\$33	\$25	3096	3396	25%	25%
Aetna Medicare Rx Saver	\$1	\$1	\$2	\$2	\$30	\$30	3596	35%	26%	27%
WellCare Classic	\$0	\$0	\$1	\$2	\$35	\$37	4296	4196	25%	25%
Humana Enhanced	\$3	\$5	\$7	\$10	\$42	\$47	4496	50%	33%	33%
AARP MedicareRx Walgreens	\$0	\$0	\$6	\$5	\$31	\$30	3296	3296	25%	25%
Aetna Medicare Rx Value Plus	\$1	\$1	\$2	\$2	\$47	\$47	50%	4796	3396	33%

NOTE: PDP is prescription drug plan. Estimates are weighted medians for those plans that vary cost sharing by region (weighted by September 2018 enrollees are in plans with a preferred brand copay and 23% are in plans with a preferred brand coinsurance.

SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2018-2019 Part D plan files.

Source: Juliette Cubanski, Anthony Damico, and Tricia Neuman, Medicare Part D: A First Look at Precription Drug Plans in 2019 (Kff, Oct. 16, 2018), https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019tables/\_ (accessed June 5, 2019).

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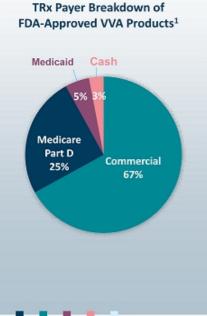
# The Power of 3 in the Payer World

Expected widespread insurance coverage across the portfolio in 1 <sup>st</sup> Half, 2020 ANNOVERA <sup>™</sup> (segesterore acetate and ethinvi estradiolvaginal system) + Establishes TXMD as a Women's Health company with products across the life stages - Back again with the same payer contacts - Largest Women's Health Category with no Medicare Part D - ACA and State mandates exist in birth control category	Target Timeline for         Insurance Coverage         from Launch         • 1-3 Quarters         from launch.         • ACA / 19 <sup>th</sup> Category         Designation         decision by FDA         will impact
• Establishes TXMD as key Women's Health product leader • Back negotiating with the same Women's Health contacts at the payers • Contract amendments in larger category with little Medicare Part D overall	<ul> <li>3-4 Quarters Commercial</li> <li>Part D not viewed as material at this point</li> </ul>
<ul> <li>Introduced TXMD to the Women's Health contacts in the payer community</li> <li>Started base contracts from scratch in Commercial and Medicare</li> <li>Smallest category of the portfolio with highest Medicare Part D patient population and longest time lag to access</li> </ul>	<ul> <li>4 Quarters Commercial</li> <li>6 Quarters for Part D</li> </ul>
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# **IMVEXXY** Payer Update

~102M Commercial Lives are Unrestricted<sup>2</sup>



Commercial Payer Update<sup>2, 3</sup>

- Strategy: Continue to seek unrestricted access in a fiscally responsible manner
- ~102 million lives are unrestricted with the majority being adjudicated at a Non Preferred copay\*
- 21 states have greater than 60% unrestricted Commercial access
- IMVEXXY has secured access with the majority of the largest Commercial payers
- CVS and Aetna continue to not cover for the majority of their plan designs
  - Access available with a Non Preferred copay on open plan designs which is ~12% of CVS (~3.5M lives) and ~24% of Aetna (~1.8M lives)
  - Negotiations for all other plans with CVS / Aetna are ongoing seeking financially responsible opportunities to increase access

<sup>1</sup>IMS Data April 2018 <sup>2</sup>Plan numbers as of May 2019 from MMIT <sup>3</sup>MMIT May 2019 and Account Insights

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

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~12M Medicare Lives are Unrestricted<sup>2</sup>

#### Medicare Part D Update<sup>1, 2</sup>

Invexy (estradiol vacinal inserts)

- Strategy: Continue to seek Preferred unrestricted access in a fiscally responsible manner
- IMVEXXY launched in July 2018, after the 2019 bid cycle was completed.
- ~12 million lives are unrestricted with a majority adjudicating at a Preferred copay (~\$40)\*
  - Pull through underway with key United Healthcare HCP targets
  - 2020 bids submitted for other Medicare Part D plans
    - Plan to finalize these contracts in Q4, 2019 for adjudication in Q1, 2020



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

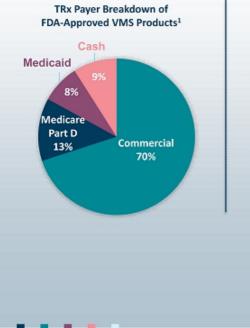
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# BIJUVA Payer Update

~77M Commercial Lives are Unrestricted<sup>2</sup>



#### Commercial Payer Update<sup>2,3</sup>

- Strategy: Seek unrestricted access in a fiscally responsible manner
- BIJUVA clinical and financial reviews are underway with payers
- ~77 million Commercial lives are unrestricted with the majority adjudicating at a Non Preferred copay
- 2 of the top 10 already adjudicating\*
- Most additional commercial plans will make a decision in Q3-Q4, 2019 with coverage the following quarter. Any plan we miss could take an additional 6-12 months to secure coverage

<sup>1</sup>IMS Data April 2018 <sup>2</sup>Plan numbers as of May 2019 from MMIT <sup>3</sup>MMIT May 2019 and Account Insights \*Adjudication of claim by payer: BUUVA is on payer formulary as covered product and is being submitted to insurance company for payment by payer to pharmacy.

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# **Access to Contraception**

- In 2012, the Affordable Care Act (ACA) required all health insurances to cover, without cost-sharing, the full range of contraceptive methods and services approved by the FDA as prescribed for women
  - 18 methods of birth control at least one product in each method must be covered with no patient out-of-pocket costs
  - If a provider recommends a specific option or product, plans must cover it at no cost as well
  - Expectation that ANNOVERA would become the 19<sup>th</sup> method 1-year contraceptive vaginal system
- Irrespective of ACA mandate, 19 states require insurance plans to cover all contraceptives without a generic equivalent

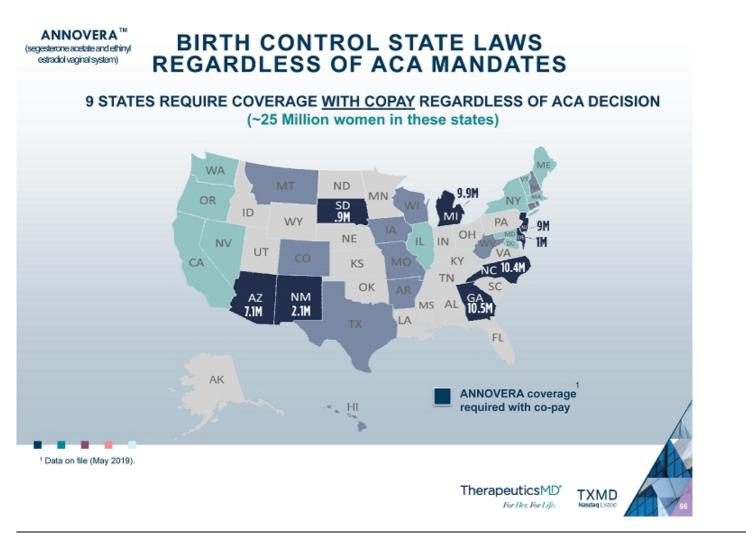




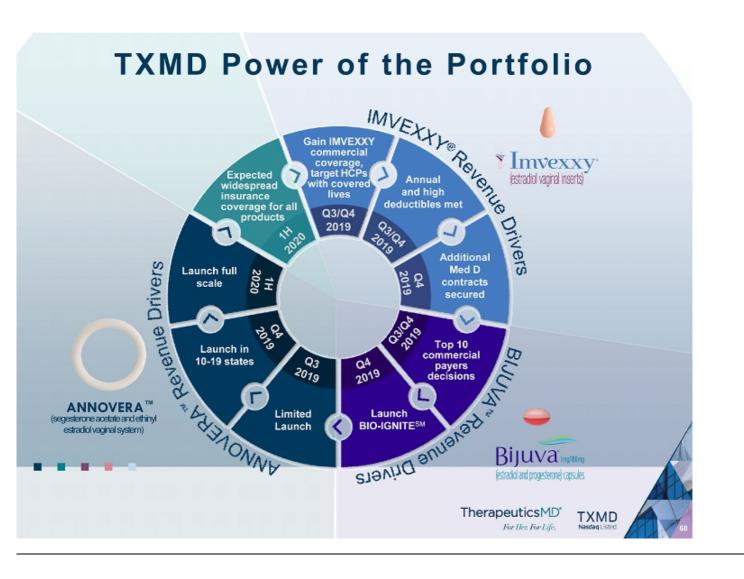
### BIRTH CONTROL STATE LAWS REGARDLESS OF ACA MANDATES

#### 10 STATES REQUIRE COVERAGE WITH <u>NO COPAY</u> REGARDLESS OF ACA DECISION (~42 Million women in these states)





ANNOVERA <sup>™</sup> (segesterone acetate and ethinyl estradiol vaginal system)		SIGHT ON BIRTH OL COVERAGE	
		from Market Rese	arch <sup>1</sup>
a female millen last thing I war	nnial with a smartphone and	nt scares the living hell out of I a Twitter and Facebook acco ff. The quickest way I could to her birth control.	ount. The
aboutWe're i	mandated to cover it at zero	ist leave broad open, don't ev co-payNone of us was goin th control. And so they're jus	ng to be the
<ul> <li>The ACA mand And then pricit</li> </ul>		decision making within the p	process.
<ul> <li>I think the poin options for pat</li> </ul>	nt in the contraceptive class ients and providers.	is to provide a number of dif	ferent
<sup>1</sup> Milliman Pricing Research on ANNo	OVERA May 2019	TherapeuticsMD <sup>*</sup> For Her. For Life.	TXMD Nasdaq Listed



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# HOW STRATEGY, PLAN, AND MODEL COME TOGETHER

Mitch Krassan

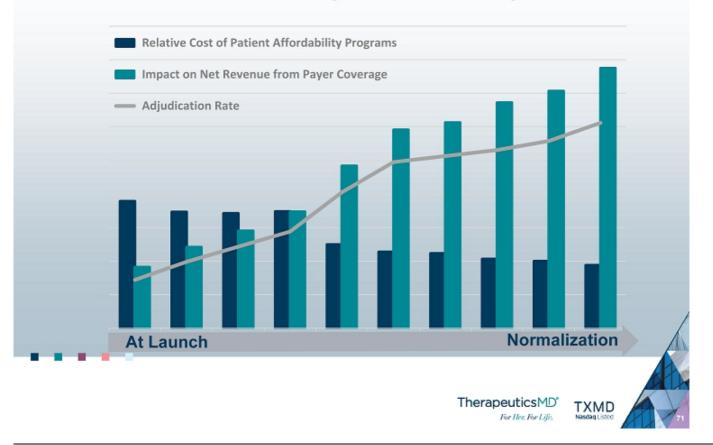
Chief Strategy and Performance Officer



# IMVEXXY Model Different Than Typical Pharmaceutical Launch

Patient Copay Assistance	Where We Focused
Wholesale Costs	-
Pharmacy Discounts	
Payer Rebates	
Returns, Allowances & Other Accruals	
Net Revenue	
Cost of Sales	
Gross Margin	
Sales & Marketing Cost	Copay Assistance substituted for Marketing Cost
	Therapeutics <sup>MD'</sup> TXME

#### Example: Relationship of Cost of Copay Card vs Net Revenue Driven by Insurance Adjudication



## Example: How a Prescription is Paid & the Impact on Manufacturer

	Column A Patient's Insurance Doesn't Cover Product Yet	Column B Commercial Insurance Used w/ Patient Deductible Not Yet Met & High Deductible Plans	Column C Commercial Insurance Used w/ Average Copay	Column D Medicare Part D Insurance Used w/ Average Copay
Payment from Copay Card (cost to Manufacturer)	\$200	\$215	\$40	\$0
Payment from Insurance Company	\$0	\$0	\$175	\$205
Payment from Patient	\$ 35	\$ 35	_\$ 35	<u>\$ 40</u>
Total Amount Received by Pharmacy	\$235	\$250	\$250	\$245

- For columns A and B, the copay card covers most of the cost of the product for the patient
- For columns C and D, the insurance company pays most of the cost of the product for the patient

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# How Adjudication Rate Will Change Over Time: NOW



Cha	art are based o	n May Actuals	
	Column A	Column B	Column C
IMVEXXY	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	5%	61%	35%
% Adjudicated	0%	47%	7%
Contribution to Overall Adjudication Rate	0%	29%	2%
Overall Adjudication Rate		31%	
	Column A	Column B	Column C

BIJUVA	No Insurance	Commercial Insurance	Medicare Eligible Patients
% of Business	8%	82%	9%
% Adjudicated	0%	30%	0%
Contribution to Overall Adjudication Rate	0%	25%	0%
Overall Adjudication Rate		25%	

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## **Target Adjudication Rate at** Fully Established Insurance Coverage

		Column A	Column B	Column C
	IMVEXXY	No Insurance	Commercial Insurance	Medicare Eligible Patients
	% of Business	8%	68%	24%
% of siness	% Adjudicated	0%	75%	65%
less	Contribution to Overall Adjudication Rate	0%	51%	17%
	Overall Adjudication Rate		68%	
Overall Adjudication				
Rate		Column A	Column B	Column C
	BIJUVA	No Insurance	Commercial Insurance	Medicare Eligible Patients
	% of Business	8%	82%	10%
	% Adjudicated	0%	75%	65%
	Contribution to Overall Adjudication Rate	0%	62%	7%
	Overall Adjudication Rate		69%	
		Therapeut For II	icsMD" TXN 77. For Life. Nasdaq	



# \$300M Non-Dilutive Term Loan Financing Secured

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

	Amount (\$)	TXMD Company Milestone <sup>1</sup>	Anticipated Timing
Tranche 1	\$200 million	Closing of the facility	Completed in April 2019
Tranche 2	\$50 million	Designation of ANNOVERA as a new category of birth control by the U.S. Food and Drug Administration on or prior to December 31, 2019	Second Half of 2019
Tranche 3	\$50 million	Achieving \$11 million in net revenues from IMVEXXY, BIJUVA and ANNOVERA for the fourth quarter of 2019	First Quarter of 2020
only and are no Ability to draw a	t affirmative covena	draw triggers for additional tranches of fund nts that the company must otherwise meet. s also subject to satisfaction (or waiver) of o	

# The Power of the Portfolio at Peak Sales \$1B

	Р	ercent	of Market Based	on l	Patient Count of	f 2.3N	I and 4 fills pe	r yea	ir 👘
Ave	rage Net								
Reve	nue / Unit		20%		30%		40%		50%
\$	60	\$	110,400,000	\$	165,600,000	\$	220,800,000	\$	276,000,000
\$	80	\$	147,200,000	\$	220,800,000	\$	294,400,000	\$	368,000,000
\$	100	\$	184,000,000	\$	276,000,000	\$	368,000,000	\$	460,000,000

		Total Addressable	FD	A Market	3,800	,000		
Total	Add	dressable Compour	ndin	ng Market 1	2,000	,000		
		Perce	nt c	of Addressable M	larke	t in the second second		
Average Net Revenue / Unit		20%		25%		35%		40%
\$ 60	\$	189,600,000	\$	237,000,000	\$	331,800,000	\$	379,200,000
\$ 80	\$	252,800,000	\$	316,000,000	\$	442,400,000	\$	505,600,000
\$ 100	¢	316.000.000	¢	395,000,000	¢	553,000,000	e .	632.000.000

		e Birth Control				000,000 200,000		
Percer	t of Ov	erall Market for I	Birtl	h Control / Perce	ent	of NuvaRing Mar	rke	t of NRx
Average Net Revenue / Unit	1	1.0% / 23%		1.5% / 35%		2.0% / 47%		2.5% / 58%
\$ 1,000	s	280,000,000	\$	420,000,000	\$	560,000,000	\$	700,000,000
\$ 1,500	\$	420,000,000	\$	630,000,000	\$	840,000,000	\$	1,050,000,000
\$ 1,750	s	490,000,000	\$	735,000,000	\$	980,000,000	\$	1,225,000,000

 50%

 276,000,000

 368,000,000

 40,000,000

 379,200,000

 505,600,000

 622,000,000

 NRx

 % 1 58%

 700,000,0000

 255,000,000

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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®, ANNOVERATM, BIJUVATM and our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan facility; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our products; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock and the concentration of power in our stock ownership.

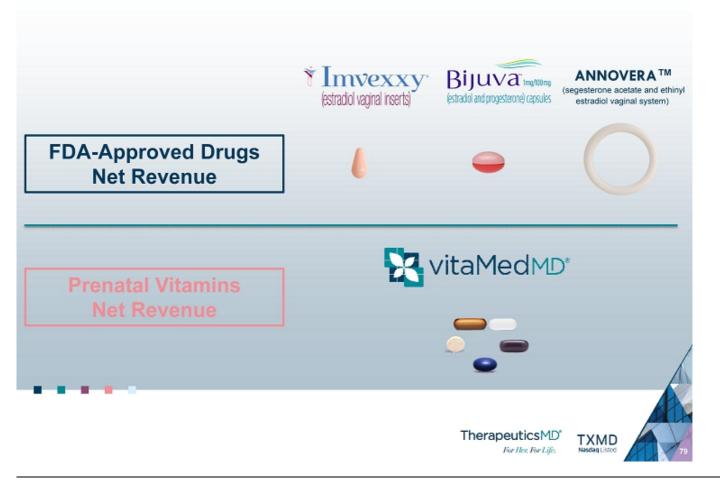
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# **TXMD** Financial Guidance Overview



# 2019 TXMD Quarterly Financial Guidance

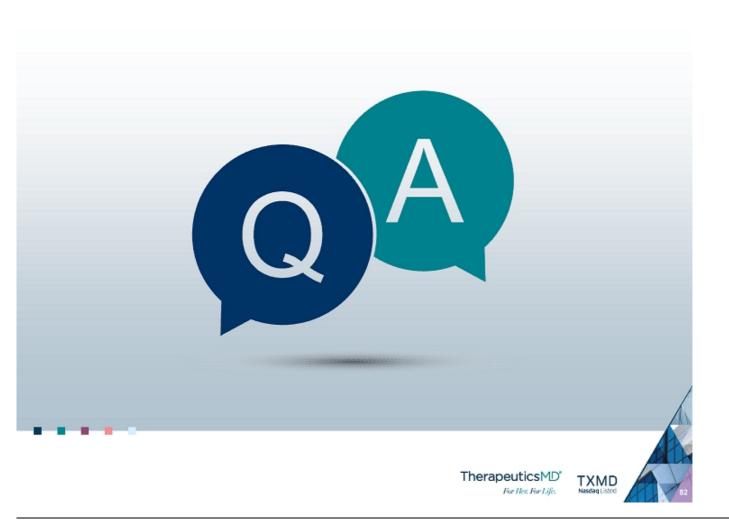
	1Q2019 Actual	2Q2019 Expectation	3Q2019 Expectation	4Q2019 Expectation	FY2019 Expectation
	6	6	1 -	0	0
FDA-Approved Drugs Net Revenue	\$2.0M	\$2.5-3.0M	\$4.5-6.5M	\$11-13M	\$20-24.5M
Prenatal Vitamins Net Revenue	\$1.9M	\$2.0-2.5M	\$1.75-2.25M	\$1.5-2.0M	\$7.15-8.65M
Total TXMD Net Revenue	\$3.9M	\$4.5-5.5M	\$6.25-8.75M	\$12.5-15M	\$27.1-33.1M
			The	rapeuticsMD" For Her, For Life,	TXMD Pastag Lord

# 2019 TXMD Annual Financial Guidance

FY2018 Actual	FY2019 Expectation	y/y growth <sup>1</sup>
\$1.0M	\$20-24.5M	i 2,125%
i		
\$15M	\$7.15-8.65M	(47%)
\$16M	\$27.1-33.1M	~88%
ease for prenatal vitamir	ns, we anticipate prenat	al vitamins will
	\$1.0M \$15M \$16M Notes: De focus shifts to our FE ease for prenatal vitamin	Expectation           \$1.0M         \$20-24.5M           \$15M         \$7.15-8.65M           \$16M         \$27.1-33.1M

1. y/y growth calculated at midpoint of guidance

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# \* Invexy (estradiol vaginal inserts) Strong IMVEXXY Launch

	Y Launch Metrics			
Total paid scripts dispensed (since launch through May 31,	~206,500			
Total paid scripts (May 1-31, 2019)				
Total patients (since launch through May 31,	otal patients since launch through May 31, 2019)			
Total prescribers <sup>2</sup> (since launch through May 31,	2019)	~12,000		
Comparison of Average (Average Weekly Volume: 1				
	For 30 Days in Apr. 2019	For 31 Days in May. 2019		
	- 7 200	~8,500		
Average weekly volume	~7,300	0,000		

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

Therapeutics MD\* TXMD Nasdaq Listed For Her. For Life.





# Model To Change Behavior Is Working

Scripts are accelerating while adjudication is increasing and adherence (staying on therapy) is growing

IMVEXXY Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through May 31, 2019)	~206,500
Total paid scripts (May 1-31, 2019)	~37,700
Total patients (since launch through May 31, 2019)	~61,800
Total prescribers <sup>2</sup> (since launch through May 31, 2019)	~12,000

<sup>1</sup> 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. <sup>2</sup> Total Unique Prescribers that have sent a prescription to a pharmacy for at least 1 patient for IMVEXXY. Therease.

TherapeuticsMD<sup>\*</sup> For Her. For Life.



### **IMVEXXY Product Characteristics Compare Favorably**<sup>1-9</sup>

Estrogens				Non-estrogens		
	Estrace® Cream (estradiol vaginal cream, USP, 0.01%) <sup>1</sup>	Premarin® (conjugated estrogens) Vaginal Cream <sup>2</sup>	Vagifem® (estradiol vaginal inserts) <sup>4</sup>	IMVEXXY® (estradiol vaginal inserts) <sup>s</sup>	Intrarosa® (prasterone) vaginal inserts <sup>7</sup>	Osphena® (ospemifene) tablets, for oral use <sup>s</sup>
Product	NUMBER OF	Roman B		* Inverse	Section and Sectio	Destants
	📢 Allergan	Pfizer	new Vierosu	TherapeuticsMD <sup>*</sup> For the ArcT <sub>2</sub> P.	🙈 amag	DUCHESNAY USA
FDA approval	1984	1978	1999	2018	2016	2013
TRx MSB Dollars of Brand & Generic 2018 <sup>9</sup>	\$540,000,000	\$462,226,000	\$420,030,000	\$44,000,000	\$35,001,000	\$73,908,000
2018 Total Units <sup>9</sup>	1,902,000	1,220,000	1,500,000	205,500 (10 months)	169,000	218,000
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) <sup>10</sup>	\$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) <sup>10</sup>	\$104.96	\$118.59	\$170.16	\$180.00	\$198.75	\$203.80

References: 1. Estrace Vaginal Cream [package insert]. Invine, CA: Allergan USA, Inc.; 2017. 2. Premarin Vaginal Cream [package insert]. Philadelphia, PA: Wydet Pharmaceuticals Inc., a subsidiary of Plizer 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: Navo Nardisk Inc.; 2017. 5. IMVEXXY [package insert]. Boca Raton, FL: TherapeuticaMD, Inc; 2019. 7. Intrarosa [package insert] Walthem, MA: ANAG PharmaceuticaB, Inc.; 2017. 8. Cosphera [package insert]. Floriham Park, NJ: Shionogilinc; 2015. 9. Symphory Health Solutions PH/AST Data pawered by IDY; Annual 2018 and Invexxy is 10 months data through May 2019 [a. [2017 Estrace and generics [Teva, Mylan, Impax & Alvegen] and 2017 Vagifem, Yuxafem (authorized generic of Vagifem), and Teva generic] 10. AnalySource. June 2018.

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. TherapeuticsMD' For Her, For Life.



## **BIJUVA Launch Metrics**

BIJUVA Launch Metrics	
Total paid scripts dispensed to patients <sup>1</sup> (since launch through May 31, 2019)	~2,000
Total paid scripts (May 1-31, 2019)	~1,600
Total patients (since launch through May 31, 2019)	~1,500
Total prescribers <sup>2</sup> (since launch through May 31, 2019)	~1,100

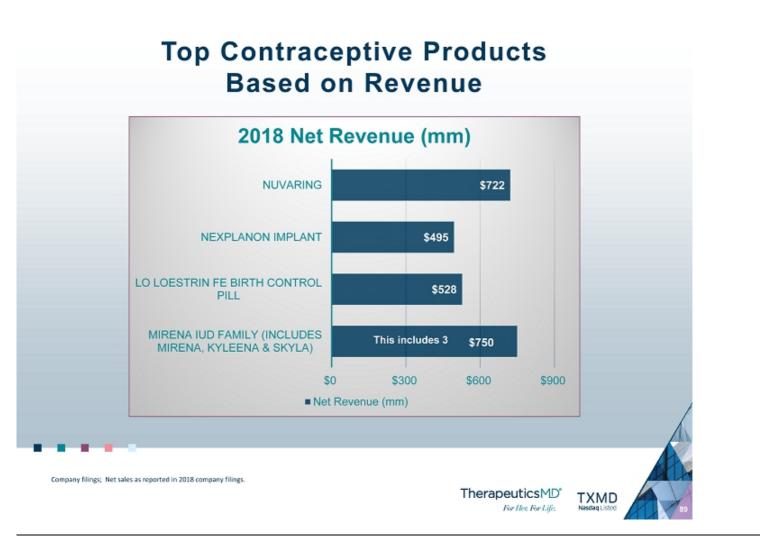
<sup>1</sup> Total prescription data is based on IQVIA prescriber level data plus additional unique patients identified through utilization of our affordability program. This includes a two week estimation for the lag in reporting retail data, which can cause minor fluctuations in historical comparisons.
 <sup>2</sup> Total Unique Prescribers that have sent a prescription to a pharmacy for at least 1 patient for BUUVA.

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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 Administrati on	Oral intake	Patient administered flexible ring	Physician in-office injection every 3 months	Patient administered Soft and pliable vaginal system	Physician in-office procedure for insertion and removal
Patient Convenience	Daily pill presents compliance and 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-\$2,100	Liletta® \$749.40 + \$425.25 for insertion/removal Plus office visits and screenings
All trademarks are the pr	operty of their respective own	ers.	Т		



## **Overview of TXMD's Patents**

- As of June 7, 2019, TherapeuticsMD's patent portfolio includes:
  - 293 patent applications:
    - 24 issued U.S. patents •
      - 12 U.S. patents have been listed in the Orange Book for BIJUVA •
      - 3 U.S. patents have been listed in the Orange Book for IMVEXXY
    - 27 issued international patents
- TXMD currently has international patents or patent applications in:
  - Argentina
    - Australia ٠
      - •

Israel

- Canada
- China

Brazil

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- Hong Kong
- South Korea



TXMD

- Europe

- Russia •
- - South Africa
- Japan Mexico New Zealand

#### **Overview of TXMD's Patents for BIJUVA and IMVEXXY**

BIJUVA Patent Summary		IMVEXXY Patent Summary		
Formulation and Method Claims		Formulation and Method Claims; Design Patent		
US Issued / Allowed	12* / 0	US Issued / Allowed	4/3	
Expiration	2032	Expiration	No earlier than 2032	
US Patents Pending	8	US Patents Pending	11	
International Patents Granted	5	International Patents Granted	13	
International Patents Pending	52	International Patents Pending	33	
International Coverage	AR, AU, BR, CA, CN, EU, IL, MX, NZ, JP, KR, RU, ZA	International Coverage	AR, AU, BR, CA, EU, HK, IL, MX, NZ, JP, KR, RU, ZA	
Expiration	No earlier than 2032	Expiration	No earlier than 2033	
* This number does not include the 3 issued U.S. patents that cover the 0.25/50, 0.5/50, and 0.5/100 E+P dosage strengths				
Therapeutics MD For Hear For Life. TXMD Hasting Listed				