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): August 10, 2018

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 (*see* General Instruction A.2 below):

☐ 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.

On August 10, 2018, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), issued a press release announcing that that the United States (U.S.) Food and Drug Administration (FDA) has approved ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system) for birth control. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated in this Item 7.01 by reference. The Company intends to host a conference call to discuss the approval of ANNOVERA™ on Monday, August 13, 2018, at 8:30 a.m. EDT, and is furnishing as Exhibit 99.2 to this Current Report on Form 8-K a presentation which will be used, in whole or in part, and subject to modification, on August 13, 2018 and at subsequent meetings with investors or analysts.

The information in Items 7.01 and 9.01 of this Current Report on Form 8-K (including the exhibits) is furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in Items 7.01 and 9.01 of this Current Report shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press release dated August 10, 2018 entitled "TherapeuticsMD Announces FDA Approval of ANNOVERA™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) for Birth Control."
99.2	TherapeuticsMD, Inc. presentation dated August 13, 2018.

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: August 13, 2018

THERAPEUTICSMD, INC.

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces FDA Approval of ANNOVERA ™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) for Birth Control

- The first and only birth control approved as a vaginal system -
- The first and only patient-controlled, procedure-free, long-acting, reversible prescription birth control product to provide a full year of protection from pregnancy -

-TherapeuticsMD will host a conference call on Monday, August 13th at 8:30 a.m. EDT-

BOCA RATON, Fla.—August 10, 2018—TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first long-acting prescription birth control that is patient-controlled, procedure-free and reversible. The ANNOVERA contraceptive vaginal system is a small, soft flexible ring that prevents ovulation for an entire year (13 cycles) and can be inserted and removed by a woman at her discretion in repeated four-week cycles (remaining in place continuously for three weeks followed by removal for one week).

The segesterone acetate component of the ANNOVERA contraceptive vaginal system is expected to be classified as a "new chemical entity," or NCE, by the FDA and thus will likely be entitled to five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. This unique contraceptive vaginal system technology combines low doses of a novel progestin, Nestorone® (segesterone acetate), with a widely used estrogen (ethinyl estradiol). The contraceptive vaginal system works by releasing an average continuous daily dose of 0.15 mg/day of segesterone acetate and 0.013 mg/day of ethinyl estradiol to prevent pregnancy.

"The U.S. contraceptive market is shifting toward long-acting solutions and we believe ANNOVERA represents an exciting new entrant for women and healthcare providers by providing the first woman-controlled, procedure-free, long-acting, reversible birth control product putting the woman in control of both her fertility and menstruation," said Dr. Brian Bernick, Co-Founder of TherapeuticsMD. "We believe ANNOVERA can help meet the needs of women who are looking for long-acting solutions, including women who have never given birth and women who are not in a monogamous relationship, who are often counseled not to use many of the currently available long-acting contraceptive products."

ANNOVERA was developed by the global non-profit research organization, Population Council, a leading developer of long-acting, reversible contraceptives. The FDA approval of ANNOVERA is based in part on data from 17 clinical trials, including safety and efficacy data from three open-label trials that included 2,308 healthy women in total. The data showed that ANNOVERA was 97.3% effective in preventing pregnancy when used as directed – making it among the most effective women-controlled methods of contraception. Based on pooled data from the two trials of 2,111 females ≤35 years of age, the primary endpoint Pearl Index (PI) was 2.98 per 100 woman-years of ANNOVERA use. Results from the Phase 3 acceptability sub-study of 905 women support an overall satisfaction rate of 89%, which was related to ease of use, side effects, expulsions/feeling the product and effects during sexual activity. The trials also demonstrated high rates of adherence and continuation for a full year.[i] The most common adverse reactions leading to discontinuation by ≥ 1% of ANNOVERA-treated women included irregular bleeding (metrorrhagia/menorrhagia) (1.7%), headache/migraine (1.3%), vaginal discharge/vulvovaginal mycotic infections (1.3%), and nausea/vomiting (1.2%). Consistent with other combination hormonal contraceptives (CHCs), cigarette smoking increases the risk of serious cardiovascular events from CHC use. Women over 35 years old who smoke should not use ANNOVERA. Also consistent with other CHCs, women are at increased risk for a venous thrombotic event (VTE) when using the one-year contraceptive vaginal system. Limited data are available in women with a Body Mass Index (BMI) greater than 29 kg/m^2 because this population was excluded from the clinical trials after VTEs were reported. A post-approval observational study will be performed to measure the risk of venous thromboembolism. Important safety information for ANNOVERA, including the boxed warning, is provided below.

“ANNOVERA’s approval and designation as a ‘vaginal system’ potentially creates a new class of contraception that private health plans will be required to cover with no patient out-of-pocket costs under the Affordable Care Act (ACA),” said Robert Finizio, TherapeuticsMD CEO and Co-Founder. “TherapeuticsMD intends to leverage its existing infrastructure to commercialize ANNOVERA. Together with our prescription menopausal hormone products and prenatal vitamins, TherapeuticsMD aims to become the premier women’s healthcare company, offering a full portfolio of products across the woman’s lifespan from contraception and pregnancy through menopause.”

The U.S. market for prescription contraceptives generated more than $5 billion in net sales in 2017.[ii] An estimated 43 million women in the U.S. are at risk of unintended pregnancy of which 18 million women want to avoid pregnancy and nearly half of all pregnancies that occur each year in the U.S. are unintended.[iii,iv] According to the National Center for Health and Statistics, use of long-acting reversible contraceptives increased nearly 5-fold in the last decade among women aged 15 to 44.[v]

TherapeuticsMD intends to leverage the Population Council’s existing relationships with the supplier of segesterone acetate and the manufacturer of the clinical trial supply of the one-year contraceptive vaginal system to scale-up commercial manufacturing of ANNOVERA. TherapeuticsMD currently estimates that ANNOVERA will be commercially available as early as the third quarter of 2019 with the commercial launch as early as the fourth quarter of 2019 or first quarter of 2020. The ACA mandates that private health plans provide coverage with no out-of-pocket costs for one treatment per class of in each of the classes identified by the FDA for women in its Birth Control Guide. As part of its license agreement with the Population Council, TherapeuticsMD has agreed to provide significantly reduced pricing to federally designated Title X family planning clinics serving lower-income women.

Conference Call Information

TherapeuticsMD will host a conference call to discuss the ANNOVERA approval. Details for the call are:

Date:	Monday, August 13, 2018
Time:	8:30 a.m. EDT
Telephone Access (US):	(866) 665-9531
Telephone Access (International):	(724) 987-6977
Access Code for All Callers:	5239706

Additionally, a live webcast can be accessed on the company’s website, www.therapeuticsmd.com, on the Home Page or under the “Investors & Media” section. A digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in (855) 859-2056 or international (404) 537-3406 and Conference ID: 5239706.

About ANNOVERA

The ANNOVERA one-year contraceptive vaginal system combines a widely used estrogen (ethinyl estradiol) with a new progestin segesterone acetate (Nestorone®) into a single ring to prevent ovulation for an entire year (13 cycles; used in repeated four-week cycles (remaining in place continuously for three weeks followed by removal for one week)). Designed to empower women to be in complete control of their fertility and menstruation, ANNOVERA represents the first and only long-acting birth control product that is reversible and does not require a medical procedure for insertion or removal. The soft, flexible ring can be inserted and removed by the woman herself and without the help of a healthcare professional. The one-year vaginal system represents a new option for women, including nulliparous women (women who have not given birth) desiring long-acting reversible contraception. The one-year contraceptive vaginal system does not require refrigeration.

Indication

ANNOVERA is a progestin/estrogen CHC indicated for use by females of reproductive potential to prevent pregnancy. (Limitation of use: Not adequately evaluated in females with a BMI of > 29 kg/m^2).

Important Safety Information

Cigarette smoking increases the risk of cardiovascular events from CHC use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. CHCs should not be used by females who are over 35 years of age and smoke.

Due to increased risks of serious side effects, ANNOVERA should not be used in females with certain medical conditions, including females who have a high risk of arterial or venous thrombotic diseases; who have or have had breast cancer or other estrogen- or progestin-sensitive cancer; who have liver tumors, acute hepatitis, severe cirrhosis, undiagnosed abnormal uterine bleeding, or hypersensitivity to any ingredients in ANNOVERA; who use certain Hepatitis C drug combinations; or who are pregnant or breastfeeding.

Risks from use of a CHC, like ANNOVERA, particularly in females with any condition listed above, include venous thrombotic events; cardiovascular events and cerebrovascular events such as stroke and myocardial infarction; liver disease; elevated liver enzymes with concomitant Hepatitis C treatment; hypertension; carbohydrate and lipid metabolic effects; headache; bleeding irregularities and amenorrhea.

ANNOVERA does not protect against HIV-infection (AIDS) and other sexually transmitted infections.

Please note that this information is not comprehensive. Please see the Full Prescribing Information, including the Boxed Warning, for ANNOVERA at www.annovera.com/pi.pdf.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing novel products exclusively for women. Our products are designed to address the unique changes and challenges women experience through the various stages of their lives with a therapeutic focus in family planning/reproductive health and menopause management. The company is committed to advancing the health of women and championing awareness of their healthcare issues. To learn more about TherapeuticsMD, please visit www.therapeuticsmd.com or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

About the Population Council

The Population Council (http://www.popcouncil.org) confronts critical health and development issues—from stopping the spread of HIV to improving reproductive health and ensuring that young people lead full and productive lives. Through biomedical, social science, and public health research in 50 countries, the Council works with partners to deliver solutions that lead to more effective policies, programs, and technologies that improve lives around the world. Established in 1952 and headquartered in New York, the Council is a nongovernmental, nonprofit organization governed by an international board of trustees.

Forward-Looking Statements

This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: whether the FDA will approve the NDA for the company's TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize IMVEXXY™, ANNOVERA and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan agreement; the length, cost and uncertain results of the company's clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of the company's hormone therapy drug candidates or adversely affect the commercialization of the company's current or future approved products; the company's reliance on third parties to conduct its clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the company's common stock and the concentration of power in its stock ownership. PDF copies of the company's historical press releases and financial tables can be viewed and downloaded at its website: www.therapeuticsmd.com/pressreleases.aspx.

---

i Merkatz, RB, Plagianos M, Hoskin E, et al, Acceptability of the nestorone®/ethinyl estradiol contraceptive vaginal ring: development of a model; implications for introduction" *Contraception*. 2014 November; 90(5): 514–521.

ii IQVIA 2017, Company filings.

iii Guttmacher Institute, Fact Sheet: Contraceptive Use in the United States, July 2018.

iv Finer LB and Zolna MR, Declines in unintended pregnancy in the United States, 2008–2011, *New England Journal of Medicine*, 2016, 374(9):843–852, http://nejm.org/doi/full/10.1056/NEJMsa1506575.

v Branum A and Jones J, Trends in Long-Acting Reversible Contraception Use Among U.S. Women Aged 15-44, NCHS Data Brief, Number 188, February 2015.

Investor Contact

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

Exhibit 99.2


Annovera™
FDA Approval
Conference Call
August 13, 2018
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: whether the FDA will approve the NDA for our TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; our ability to maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and one-year contraceptive vaginal system licensed product and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan agreement; the length, cost and uncertain results of our clinical trials; potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates or adversely affect the commercialization of our current or future approved products; the ability of our licensees to commercialize and distribute our product and product candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; 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.

TX-001HR, TX-005HR, and TX-006HR are investigational drugs and are not approved by the FDA. This non-promotional presentation is intended for investor audiences only.

Annovera - 1-Year Vaginal System

Segesterone Acetate [Nestorone® (NES)]/Ethinyl Estradiol (EE)

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

- Product fits into existing TXMD infrastructure
  - **Approved: August 10, 2018**
  - **Segesterone acetate component of Annovera expected to be classified as NCE with 5 year exclusivity**
- Developed by the Population Council – developer of multi-billion dollar products
  - ParaGard® and Mirena® IUDs; Norplant® and Jadelle® implants; and Progering®
  - Funded by several organizations, including: Bill & Melinda Gates Foundation, US National Institutes of Health, USAID and The Population Council
- The ring system is composed of a "squishy" silicone elastomer
  - 21/7 days cyclical dosing regimen
  - 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 antiovulatory activity
  - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses

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

Clinical Trial Experience

Efficacy & Safety[1,2]

- **Based on two pivotal Phase 3 clinical trials with 2,308 women**
  - Efficacy and safety consistent with other birth control pills, patches and hormonal rings
- **Efficacy**
  - 97.3% effective in preventing pregnancy when used as directed
    - Primary Endpoint Pearl Index was 2.98 per 100 woman-years
    - Consistent with all other combination hormone birth control pills, patches and other rings
- **Safety**
  - Class labeling for combination hormonal contraceptives (CHCs)
  - All CHCs carry the boxed warning about cigarette smoking and serious cardiovascular events, particularly for women over age 35
  - The risk profile is consistent with other CHCs
  - The most common adverse reactions include headache, nausea/vomiting, vulvovaginal mycotic infections, abdominal pain, dysmenorrhea, vaginal discharge, UTIs, among others
  - Consistent with other CHC products the most common adverse reactions leading to discontinuation were:
    - Irregular bleeding (1.7%), headache (1.3%), vaginal discharge (1.3%), and nausea/vomiting (1.2%)

[1] www.annovera.pi.pdf
[2] Data with respect to the Phase 3 clinical trials

TherapeuticsMD®
For Her. For Life.

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 and continuation

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.
[2]http://www.merck.com/product/usa/pi_circulars/n/nuvaring/nuvaring_ppi.pdf

TherapeuticsMD®
For Her. For Life.

Annovera Deal Terms

Milestone Payments

- Upon FDA approval: $20mm
- First commercial batch release: $20mm
- $200mm in cumulative net sales: $40mm
- $400mm in cumulative net sales: $40mm
- $1b in cumulative net sales: $40mm

Royalty %

Step structure:

- Annual net sales ≤ $50mm: 5%
- Annual net sales > $50mm and ≤ $150mm: 10%
- Annual net sales > $150mm: 15%

Additional Cost Considerations

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

*Costs exceeding $20mm to be shared with Population Council

TherapeuticsMD®
For Her. For Life.

NuvaRing – Large Established Ring Market

- NuvaRing Owner: Merck
- **$500mm+ net sales in US ring market with no other branded products in the space***
- NuvaRing monthly contraceptive ring (vs. Annovera 1-year ring)
  - Annual WAC Price of $2,013 (vs. $1,400)
  - Semi-rigid ring body (vs. pliable/squishy)
  - Monthly visit to pharmacy (vs. one annual visit)
- 2 NuvaRing generics expected in 2019

(Dollars in Millions)	Year End December 31,				
	2013A	2014A	2015A	2016A	2017A
NuvaRing Net Revenue*	$426	$461	$515	$576	$564
market growth		*8.2%*	*11.7%*	*11.8%*	*-2.1%*
NuvaRing Scripts*	4.7	4.6	4.4	4.5	4.3
script gowth		*-1.4%*	*-4.8%*	*1.1%*	*-3.6%*

*Symphony Health Solutions PHAST Data powered by IDV. Net sales as reported in company filings.

TherapeuticsMD®
For Her. For Life.

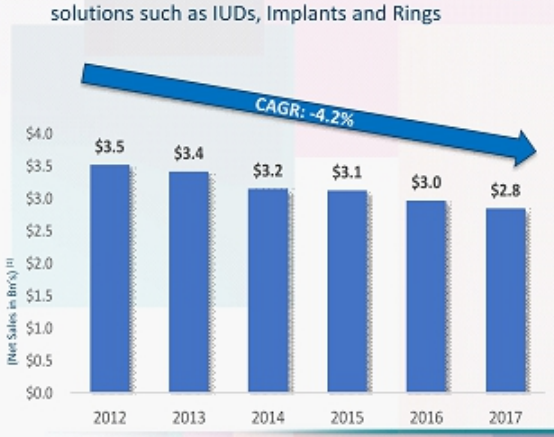
U.S. Prescription Contraceptive Market

U.S. Contraceptive Market

- One of the largest therapeutic categories by script count
- ~ 90mm scripts[1]
- ~ > $5B U.S. net sales[2]
- ~ 43 million women are at risk of unintended pregnancy of which ~ 18 million want to avoid pregnancy[3]

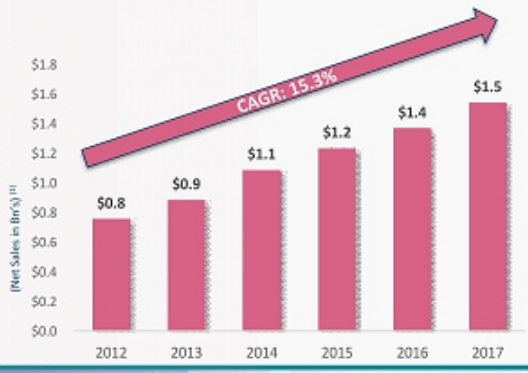
Daily Oral Contraceptives

- OC's continue to lose market share to longer acting solutions such as IUDs, Implants and Rings



Long Acting Reversible Contraceptives

- IUDs and Implants are experiencing significant growth as the market shifts towards long-acting solutions



[1] IQVIA Total Patient Tracker database; Annual 2017
[2] IQVIA 2017, Company filings. Long acting reversible contraceptive market includes: Nexplanon/Implanon, Mirena family, Paragard and Liletta. Net sales as reported in company filings.
[3] Contraceptive Use in the United States, Guttmacher, July 2018.

TherapeuticsMD®
For Her. For Life.

Expected Benefits of 1-Year Vaginal Contraceptive System

Patients

- Long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
- Softer and more pliable than NuvaRing and doesn't require refrigeration
- "Vaginal System"- a new class of contraception with potential for $0 co-pay
- Acceptable for all indicated women including nulliparous women and women who are not in a monogamous relationship*
- Empowers women to be in complete control of their fertility and menstruation
- Available with a single annual pharmacy visit

Healthcare Providers

- A long-acting reversible birth control option that doesn't require a procedure
- No requirement to buy, hold and manage inventory
- Acceptable for nulliparous women and women not in a monogamous relationship*
- Satisfies patients' desire to be in control of their fertility and menstruation

TherapeuticsMD®

For Her. For Life.

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

Unique Product Characteristics Should Lead to Good Payor Coverage

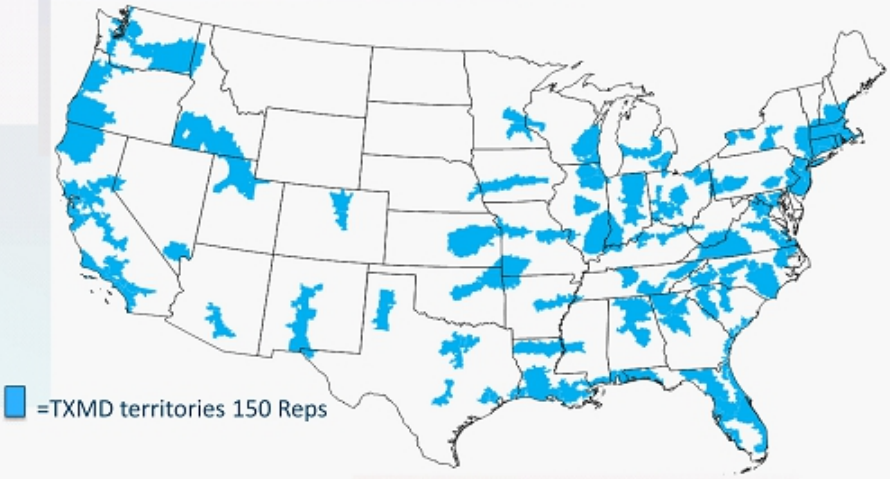
- Anticipate parity or discount pricing level ~$1400 annual WAC cost
  - 40% decrease to annual WAC of NuvaRing, reflects TXMD's responsible brand pricing
  - Allows for improved patient adherence and a potential decrease in unplanned pregnancies
  - Only one pharmacy fill fee per year (estimated savings of $33 annually)
  - No repeat office visit or procedure fees (several hundred dollars)
  - Contains ethinyl estradiol and Nestorone®, a new and unique progestin
  - "Vaginal System"- a new class of contraception with potential for $0 co-pay

The Affordable Care Act (ACA) mandates that private health plans provide coverage for one treatment per class of contraception used by women with no patient out-of-pocket costs

TXMD Sales Force Has Strong Overlap With NuvaRing Prescribers

NuvaRing Prescribers Overlap with TXMD Sales Force[1]

- 81% of total prescribers within current 150 TXMD territories
- No additional sales representatives needed



1. IQVIA Data

TherapeuticsMD®
For Her. For Life.

Commercialization Strategy & Timing

Focused Launch Strategy - Base Case Market Opportunity

- NuvaRing customers – monthly ring replaced by annual ring
- ~60K annual vitaMedMD prenatal customers who may proceed to contraception
- Patients who prefer long acting reversible contraception but fear procedures
- Healthcare providers who prefer long acting reversible contraception but forgo due to procedures and cost of procurement
- Nulliparous women and those who are not in a monogamous relationship who desire long acting reversible contraception but discouraged from IUDs[1]

Commercialization & Launch Timing

- Estimated to be commercially available as early as Q3'19 with commercial launch as early as Q4'19 to Q1'20
- Additional marketing team exclusively focused on Annovera anticipated
- TXMD to be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages, and any additional desired clinical studies (subject to oversight by the Joint Product Committee)

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

TherapeuticsMD®
For Her. For Life.

Contraceptive Pipeline

Exclusive rights to negotiate co-development and marketing rights[1]

- 3 month ring using NES plus bio-identical Estradiol (E2) (Phase 2)
- 1 Year ring (NES/EE) life cycle management

1. TXMD has the option to co-develop and market in the US, if approved

TherapeuticsMD®
For Her. For Life.

Complete Women's Healthcare Portfolio

vitaMedMD® | Annovera™ | TX-001HR® | Imvexxy® (estradiol vaginal inserts) 4 mcg • 10 mcg

~60,000 New Prenatal Patients *Many will go on contraception after breastfeeding*

Vasomotor symptoms affect up to 75% of perimenopausal women[1]

PRENATAL CARE → CONTRACEPTION/ FAMILY PLANNING -PERIMENOPAUSE → VASOMOTOR SYMPTOMS → DYSPAREUNIA (Vulvar & Vaginal Atrophy)

REPRODUCTIVE HEALTH

MENOPAUSE MANAGEMENT

*Investigational product, pending FDA approval

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4539866/

TherapeuticsMD®

For Her. For Life.


Q&A
TherapeuticsMD®
For Her. For Life.
15