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): October 29, 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:

☐ 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 October 29, 2018, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), issued a press release announcing that the United States Food and Drug Administration (FDA) has approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus. 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 BIJUVA™ on Monday, October 29, 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 October 29, 2018 and at subsequent meetings with investors or analysts.

The information included in this Item 7.01 and in Exhibits 99.1 and 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated October 29, 2018.
99.2	TherapeuticsMD, Inc. presentation dated October 29, 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: October 29, 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 TX-001HR: BIJUVA™ (Estradiol and Progesterone) Capsules for the Treatment of Moderate to Severe Vasomotor Symptoms Due to Menopause

- BIJUVA is the first and only FDA-approved hormone therapy of bio-identical estradiol in combination with bio-identical progesterone –

- BIJUVA is expected to be available in pharmacies in the second quarter of 2019 –

- TherapeuticsMD will host a conference call on Monday, October 29th at 8:30 A.M. ET-

BOCA RATON, Fla. — October 29, 2018 — TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced that the United States Food and Drug Administration (FDA) has approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical* hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.

"The approval of BIJUVA represents an important and new opportunity for menopausal women suffering from moderate to severe vasomotor symptoms. Menopausal women and their healthcare providers have been seeking bio-identical combination therapies for many years without an FDA-approved option," said Dr. Brian Bernick, Co-Founder and Director of TherapeuticsMD. "BIJUVA is the first and only FDA-approved combination of bio-identical hormones, offering a proven balance of bio-identical estradiol to reduce moderate to severe hot flashes combined with bio-identical progesterone to reduce the risks to the endometrium."

"This is an important milestone for TherapeuticsMD as we continue to build towards offering a full portfolio of products to women at all stages of their lives," said Robert Finizio, TherapeuticsMD CEO and Co-Founder. "BIJUVA addresses a significant demand for bio-identical hormone therapy and provides women, their healthcare providers and pharmacists with a proven bio-identical combination product that can be covered by their insurance."

The approval is based on the BIJUVA clinical development program that included the pivotal Phase III Replenish Trial. This trial evaluated the safety and efficacy of BIJUVA in generally healthy, postmenopausal women with a uterus for the treatment of moderate to severe hot flashes. Consistent with FDA guidance, the co-primary efficacy endpoints in the Replenish Trial were the change from baseline in the number and severity of hot flashes at weeks 4 and 12 as compared to placebo.[1] The primary safety endpoint was the incidence of endometrial hyperplasia with up to 12 months of treatment. BIJUVA demonstrated a statistically significant reduction from baseline in both the frequency and severity of hot flashes compared to placebo while reducing the risks to the endometrium. The most common adverse reactions (≥3 percent) were breast tenderness, headache, vaginal bleeding, vaginal discharge and pelvic pain. Additionally, there were no clinically significant changes in lipid, coagulation or glucose parameters as compared to placebo. There were no unexpected safety signals. The results of the trial were published in the journal *Obstetrics & Gynecology*.[2] Important safety information, including the BOXED WARNING, for BIJUVA is provided below. The BIJUVA full prescribing information may be viewed by visiting www.BIJUVA.com.

“For the first time, we have a combination hormone therapy of bio-identical estradiol with bio-identical progesterone evaluated in a large, well-controlled, randomized clinical trial that has demonstrated both safety and efficacy for the treatment of moderate to severe hot flashes due to menopause,” said Dr. James Liu, M.D., President of the North American Menopause Society and Chairman of the Department of Obstetrics and Gynecology, UH Cleveland Medical Center. “The approval of BIJUVA represents an important, novel and effective treatment option for women and their healthcare providers to manage the vasomotor symptoms of menopause.”

“The approval of BIJUVA finally supports the science of combination bio-identical estradiol and progesterone,” said Kelly S. Selby, R.Ph., FIACP, pharmacist and compounding pharmacy owner. “Compounding pharmacists have been supporting women and their healthcare providers who request bio-identical hormone therapy for years and look forward to having BIJUVA as a commercially available option that is covered by insurance.”

TherapeuticsMD expects that BIJUVA will be available in the U.S. in the second quarter of 2019.

Conference Call and Webcast Information

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

Date: Monday, October 29, 2018
Time: 8:30 A.M. ET
Telephone Access (US): 866-665-9531
Telephone Access (International): 724-987-6977
Access Code for All Callers: 5669703

Additionally, a live webcast and audio archive for the event may be accessed on the homepage or from the “Investors & Media” section of the TherapeuticsMD website at www.therapeuticsmd.com. Please connect to the website prior to the start of the presentation to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for at least 30 days. In addition, a digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in 855-859-2056 or international 404-537-3406 and Conference ID: 5669703.

About Menopause and Vasomotor Symptoms (VMS)

Menopause is a natural life-stage transition for women that usually occurs at an average onset of 51 years of age.[3] According to the United States Census Bureau, approximately 43 million women in the U.S. are of menopausal age (45-64 years) and women will spend greater than a third of their life in menopause with its associated morbidities.[4]

As the ovaries stop producing hormones, levels of circulating estrogen decrease, often causing vasomotor symptoms (VMS) (commonly known as hot flashes or flushes), as well as sleep and mood disturbances and genitourinary problems. Hot flashes (including night sweats) are the most common symptoms, occurring in up to 80 percent of women, and can be debilitating and last years after menopause.[5] Despite living with these troublesome symptoms, many women do not seek treatment.

About BIJUVA

BIJUVA is a novel combination of bio-identical estradiol and bio-identical progesterone approved for the treatment of moderate to severe vasomotor symptoms associated with menopause in women with a uterus in a once daily softgel capsule taken orally. Bio-identical refers to estradiol and progesterone that are molecularly identical to the hormones circulating naturally in the woman's body. There is no evidence that bio-identical hormones are safer or more effective than synthetic hormones. BIJUVA is the first and only bio-identical estradiol and bio-identical progesterone product offering women an alternative to the available FDA-approved synthetic (non-bio-identical) hormones, the separate FDA-approved bio-identical estrogen and progesterone products that are used together but are not approved for combination use, and the unapproved compounded bio-identical hormone products. An estimated total of 15 to 20 million annual prescriptions of both the separate FDA-approved and compounded bio-identical estrogen and progesterone products are filled annually in the US.[6] The full prescribing information for BIJUVA may be viewed by visiting www.BIJUVA.com.

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

INDICATION

BIJUVA is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOVASCULAR DISORDERS, BREAST CANCER, ENDOMETRIAL CANCER, AND PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen Plus Progestin Therapy

- **Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of stroke, deep vein thrombosis (DVT), pulmonary embolism (PE), and myocardial infarction (MI)**
- **The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer**
- **The WHI Memory Study (WHIMS) estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age of older**

Estrogen-Alone Therapy

- **There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens**
- **Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The WHI estrogen-alone substudy reported increased risks of stroke and DVT**
- **The WHIMS estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age or older**

CONTRAINDICATIONS

- BIJUVA is contraindicated in women with any of the following conditions: Undiagnosed abnormal genital bleeding; Known, suspected, or history of cancer of the breast; Known or suspected estrogen-dependent neoplasia; Active DVT, PE, or history of these conditions; Active arterial thromboembolic disease (for example, stroke, MI), or a history of these conditions; Known anaphylactic reaction, angioedema, or hypersensitivity to BIJUVA or any of its ingredients; Known liver impairment or disease; Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS

- An increased risk of PE, DVT, stroke, and MI has been reported with estrogen plus progestin therapy. Should these occur or be suspected, therapy should be discontinued immediately. Risk factors for arterial vascular disease and/or venous thromboembolism (VTE) should be managed appropriately.
- The WHI substudy of daily estrogen plus progestin after a mean follow-up of 5.6 years reported an increased risk of invasive breast cancer. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy after several years of use. The risk increased with duration of use an appeared to return to baseline over about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). The use of estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- Endometrial hyperplasia (a possible precursor to endometrial cancer) has been reported to occur at a rate of approximately less than one percent with BIJUVA. Clinical surveillance of all women using estrogen plus progestin therapy is important. Adequate diagnostic measures should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
- In the WHIMS ancillary studies of postmenopausal women 65 to 79 years of age, there was an increased risk of developing probable dementia in women receiving estrogen plus progestin when compared to placebo. It is unknown whether these findings apply to younger postmenopausal women.
- Estrogens increase the risk of gallbladder disease.
- Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia, or cholestatic jaundice occurs.
- Monitor thyroid function in women on thyroid replacement hormone therapy.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) for BIJUVA are breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%), and pelvic pain (3.1%).

Please note that this information is not comprehensive. Please see the Full Prescribing Information including BOXED WARNING at www.BIJUVA.com.

About TherapeuticsMD, Inc.

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

Forward-Looking Statements

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

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[1]2003 FDA Draft Guidance for Industry Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Recommendations for Clinical Evaluation http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071643.pdf.

[2]Lobo RA, Archer DF, Kagan R, Kaunitz AM, Constantine GD, Pickar JH, Graham S, Bernick B, Mirkin S. A 17β-Estradiol-Progesterone Oral Capsule for Vasomotor Symptoms in Postmenopausal Women: A Randomized Controlled Trial. Obstet Gynecol 2018;132:161-170.

[3]NAMS “Overview of Menopause” 2010.

[4]US Census Bureau. Age and Sex Composition: 2010. 2011 May. Report No.: C2010BR-03.

[5]Woods NF, Mitchell ES. Symptoms during the perimenopause: prevalence, severity, trajectory, and significance in women’s lives. Am J Med. 2005;118(suppl 12B):14–24.

[6]Consensus estimate based on Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31, 2017 and Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market.

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Exhibit 99.2


Bijuva™
(estradiol and progesterone) capsules
1.0mg/100mg
FDA Approval
Conference Call
October 29, 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: our ability to maintain or increase sales of our products; our ability to develop and commercialize IMVEXXY™, ANNOVERA™, BIJUVA™ and our hormone therapy drug candidates and obtain additional financing necessary therefor; whether we will be able to comply with the covenants and conditions under our term loan agreement; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products or preclude the approval of our future drug candidates; the length, cost and uncertain results of future clinical trials; the ability of our licensees to commercialize and distribute our product and product candidates; our reliance on third parties to conduct our manufacturing, research and development and clinical trials; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of our common stock and the concentration of power in our stock ownership.

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

TherapeuticsMD, *A Premier Women's Health Company*

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Bijuva™

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
- Favorable lipid, coagulation and metabolic profiles, compared to the profiles separately established for synthetic progestins and synthetic estrogens
- Low incidence of bleeding and somnolence
- The most common adverse reactions (≥3%) are breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%), and pelvic pain (3.1%)

Key Physical Attributes

- Once-a-day single oral softgel capsule
- One prescription, one copay

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

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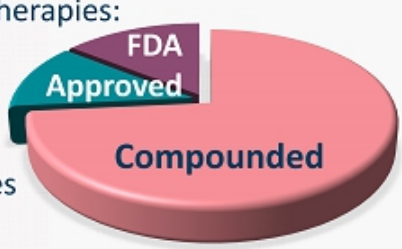
BIJUVA Product Development Rationale

- **2002 Post Women's Health Initiative,** women and healthcare providers shifted to compounded bio-identical hormone therapy containing estradiol and progesterone as an alternative despite being *unapproved* drugs that are *not covered by insurance*
  - Over 90M+ scripts of synthetic hormone therapy prescribed annually before 2002, declining to ~26M in 2015[1]
    - Until BIJUVA, patients had a choice between three therapies:
      - FDA-approved, **synthetic** combination hormones
      - FDA-approved, **separate** bio-identical hormone products not approved to be used together
      - Unapproved, **compounded** bio-identical hormones that have not been proven safe and effective and are not covered by insurance



- **Compounding filled the need for bio-identical hormone replacement therapy**
  - 30M scripts (3M women) of compounded bio-identical hormone therapy prescribed annually in the U.S. currently[2,3]

1) Symphony Health Solutions PHAST Data powered by IDV; Annual 2015
2) The reported number of annual custom compounded hormone therapy prescription of oral and transdermal estradiol and progesterones taken combined and in combination (26MM to 33MM)
3) Pinkerton, J.V. 2015. Menopause, Vol.22, No.9, pp 0-11.

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BIJUVA Fulfills the Therapeutic Gap For Stakeholders

Patients

- Meets demand for bio-identical hormone therapy with a FDA approved product with established safety and efficacy profile
- One prescription, one copay, one pill daily reduces out-of-pocket costs via insurance coverage
- Eliminates the risks of compounded hormone therapy and risks associated with off label use of separate pills
- Widely acceptable at pharmacies and also at compounding pharmacies

Healthcare Providers

- First and only FDA-approved bio-identical combination hormone therapy
- Clinically validated dose regimen
- Eliminates risks of compounded hormone therapy
- Meets patient demands and reduces patient out-of-pocket costs via insurance coverage
- Follows medical standards of care and society guidelines while reducing liability

Pharmacies

- Meets patient and physician demand for bio-identical hormone therapy
- Assuming third-party reimbursement, significantly improves net margin per script
- Lowers certain legal and regulatory costs and risks

FDA/Regulatory Bodies

- Reduces need for and use of compounded hormone products
- Full enforcement of regulations regarding compounded hormones

BIJUVA Substitutable Market

	Column 1	Column 2	Column 3
BIJUVA Substitutable Market	**FDA-Approved**		**Compounded Combination Bio-Identical E+P** 
	Off Label Separate Bio-Identical E & P Pills 	**Combination Synthetic E+P[1]** 	
TRx US:	**~3.8 million[1]**	**~3 million[2]**	**12 – 18 million[3]**
BIJUVA Potential Substitutable Market	**$760M-$950M[4]**	**$600M-$750M[4]**	**$2.4B-$4.5B[4]**

1) Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31 2017
2) Includes the following drugs: Activella®, FemHRT® , Angeliq®, Generic 17b + Progestins, Prempro®, Premphase®, Duavee®, Brisdelle®
3) Consensus estimate based on Symphony Health Solutions PHAST Data powered by IDV; 12 months as of December 31, 2017 and Fisher, J. QuintilesIMS, White Paper: A Profile of the US Compounding Pharmacy Market
4) Assume WAC pricing between $200-250

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BIO-IGNITE™

Compounding Pharmacy Partnership Strategy

BIO-IGNITE™ started as an outreach program to quantify the number of compounded bio-identical estradiol and progesterone prescriptions currently dispensed by the 3,000 high-volume compounding pharmacies, and qualify their interests in distributing our hormone product candidates, if approved.

WHAT IT HAS BECOME:

A four-phase strategic initiative to activate all current stakeholders involved in the bio-identical hormone therapy community. Ensuring that BIJUVA has the best national access and uptake possible.

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Executing Our Strategy

- **Track record of successful execution with 3 products approved by the FDA since May of this year for ~ $500 million in equity**
  - Developed two products, IMVEXXY and BIJUVA, from Phase 1 through approval
  - Licensed-in 1 New Chemical Entity - ANNOVERA
- **Primary focus now on commercializing IMVEXXY, BIJUVA and ANNOVERA**
  - Large, growing multi-billion dollar markets
  - Little to no promotional competition
  - Strong regulatory tailwinds
  - Positive demographic changes
  - Product characteristics and responsible price that should lead to good payer coverage


Thank You
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