



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

Annovera™



Annovera™

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

Imvexxy™
(estradiol vaginal inserts)
4 mcg - 10 mcg



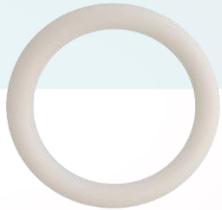
CONTRACEPTION

PRENATAL CARE

CONTRACEPTION/
FAMILY PLANNING -
PERIMENOPAUSE

VASOMOTOR
SYMPTOMS

DYSPAREUNIA
(Vulvar &
Vaginal Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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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 ($\geq 3\%$) 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 2015¹
 - 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.

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 |
|---|--|---|---|
|  <p>BIJUVA <u>Substitutable</u> <u>Market</u></p> | FDA-Approved | | Compounded Combination Bio-Identical E+P |
| | Off Label Separate Bio-Identical E & P Pills  | Combination Synthetic E+P¹  | |
| 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

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





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THANK YOU!

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