

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): November 7, 2018

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(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

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 2.02 Results of Operations and Financial Condition.

On November 7, 2018, TherapeuticsMD, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2018. In addition, the Company will be using a slide presentation during its earnings conference call. A copy of the press release and slide presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K (including the exhibits) are 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 Item 2.02 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in its expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

Item 7.01 Regulation FD Disclosure.

On November 7, 2018, the Company issued a press release announcing the Company’s financial results for its third quarter ended September 30, 2018. In addition, the Company will be using a slide presentation during its earnings conference call. 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 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, 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 November 7, 2018, entitled TherapeuticsMD Announces Third Quarter 2018 Financial Results.
99.2	TherapeuticsMD, Inc. Presentation dated November 7, 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: November 7, 2018

THERAPEUTICSMD, INC.

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



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2018 Financial Results

- Strong early launch indicators for IMVEXXY™-
- BIJUVA™ commercial launch planned for 2Q 2019-
- ANNOVERA™ commercial launch planned for 4Q 2019-
- Conference call scheduled for 4:30 p.m. ET today-

BOCA RATON, Fla. – November 7, 2018 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women’s healthcare company, today announced its clinical and corporate update for the quarter ended September 30, 2018.

“We are extremely pleased with the momentum of the IMVEXXY launch, including our progress with negotiating commercial payer coverage,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. “We are also pleased with the recent approvals of both BIJUVA and ANNOVERA. Over a short period of five months, we achieved three product approvals, which creates the solid foundation for our goal of becoming the leading women’s healthcare pharmaceutical company. We are focused on successfully commercializing all three of these highly differentiated products covering important stages in the lifespan of a woman from family planning to contraception through menopause.”

Third Quarter and Recent Developments

- On October 28, 2018, the company received U.S. Food and Drug Administration (FDA) approval of BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg. BIJUVA is the first and only FDA-approved bio-identical¹ 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 company commenced the U.S. commercial launch of IMVEXXY™ (estradiol vaginal inserts) 10 mcg dose in August 2018 and 4 mcg dose in September 2018 with 150 sales representatives. IMVEXXY is available in major pharmacy chains in the U.S. as well as through our BIO-IGNITE™ compounding pharmacy partners.
 - From launch through October 31, 2018, approximately 28,200 prescriptions of IMVEXXY were dispensed to approximately 12,800 patients.
 - During the third quarter, approximately 14,900 prescriptions of IMVEXXY were dispensed to approximately 8,400 patients.
 - Executed a branded multichannel awareness campaign for healthcare practitioners leveraging digital, non-personal promotion and journal advertising.
- On August 10, 2018, the company received FDA approval of ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first long-acting prescription birth control that is patient-controlled, procedure-free and reversible, to prevent ovulation for an entire year (administered in repeated four-week cycles for 13 cycles), after in-licensing the U.S. exclusive commercialization rights from the Population Council.
- Presented ten oral presentations and posters related to IMVEXXY and BIJUVA at the Annual Meeting of the North American Menopause Society.
- On July 30, 2018, the company licensed to Knight Therapeutics, Inc. (TSX: GUD) the exclusive rights to commercialize TX-004HR (branded as IMVEXXY in the U.S.) and TX-001HR (branded as BIJUVA in the U.S.) in Canada and Israel.
- During July 2018, completed underwritten public offering of common stock and concurrent registered direct offering and received net proceeds of approximately \$89.9 million.

- Net revenue was approximately \$3.5 million for the third quarter of 2018, compared with approximately \$4.4 million for the third quarter of 2017.
- Net loss was approximately \$35.6 million for the third quarter of 2018, compared with approximately \$14.7 million for the third quarter of 2017.
- Ended the quarter with approximately \$190 million in cash and approximately \$75 million in outstanding debt.
- As of September 30, 2018, the company has filed 241 global patent applications intellectual property portfolio with 22 issued foreign patents and 20 issued U.S. patents.

Summary of Third Quarter 2018 Financial Results

Net revenue was approximately \$3.5 million for the third quarter of 2018, compared with approximately \$4.4 million for the third quarter of 2017. Net revenue decreased primarily due to a decrease in prenatal vitamin sales partially offset by an increase in sales of IMVEXXY.

Net revenue from the company's prescription prenatal vitamin business was approximately \$3.3 million for the third quarter of 2018, compared with approximately \$4.4 million for the third quarter of 2017. The decrease was primarily related to the number of prenatal vitamin units sold and higher utilization of coupons offered to customers as compared to the third quarter of 2017. The company launched the IMVEXXY 10 mcg dose on August 6, 2018 followed by the 4 mcg dose on September 13, 2018. Net revenue for IMVEXXY was approximately \$0.2 million for the third quarter of 2018 and were greatly affected by our co-pay assistance program, which is a maximum \$35 out-of-pocket copay assistance program that allows patients to access the product for a reasonable cost. The company expects the net revenue for IMVEXXY to improve as commercial payer coverage for IMVEXXY increases and insurance plans complete the process needed to adjudicate IMVEXXY prescriptions at pharmacies.

Total operating expenses for the third quarter of 2018 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses for the third quarter of 2018 were approximately \$6.7 million compared with approximately \$6.4 million for the prior year's quarter. SG&A expenses for the third quarter of 2018 were approximately \$30.4 million compared with approximately \$12.1 million for the prior year's quarter, primarily due to higher sales, marketing, and personnel costs to support commercialization of IMVEXXY and pre-commercialization activities for BIJUVA.

Net loss for the third quarter of 2018 was approximately \$35.6 million, or \$0.16 per basic and diluted share, compared with approximately \$14.7 million, or \$0.07 per basic and diluted share, for the third quarter of 2017.

Balance Sheet

As of September 30, 2018, the company's cash on hand totaled approximately \$190 million, compared with approximately \$127.1 million at December 31, 2017. Total outstanding debt, net of issuance costs, was approximately \$73.3 million as of September 30, 2018.

Conference Call and Webcast Details

TherapeuticsMD will host a conference call and audio webcast today, at 4:30 p.m. ET to present third quarter 2018 results and provide a business update.

Date:	Wednesday, November 7, 2018
Time:	4:30 p.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	9651828

A live webcast and audio archive for the event may be accessed on the home page 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: 9651828.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current Assets:		
Cash	\$ 189,999,293	\$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of \$612,056 and \$380,580, respectively	12,802,652	4,328,802
Inventory	2,378,221	1,485,358
Other current assets	6,509,646	6,604,284
Total current assets	<u>211,689,812</u>	<u>139,554,072</u>
Fixed assets, net	<u>381,928</u>	<u>437,055</u>
Other Assets:		
Intangible assets, net	3,771,530	3,099,747
License rights	20,000,000	—
Long term deferred financing fees	759,229	—
Security deposit	150,522	139,036
Total other assets	<u>24,681,281</u>	<u>3,238,783</u>
Total assets	<u>\$ 236,753,021</u>	<u>\$ 143,229,910</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 11,382,093	\$ 4,097,600
Accrued expenses and other current liabilities	17,894,582	9,223,595
Total current liabilities	<u>29,276,675</u>	<u>13,321,195</u>
Long-term Liabilities:		
Long-term debt	73,261,065	—
Total long-term liabilities	<u>73,261,065</u>	<u>—</u>
Total liabilities	<u>102,537,740</u>	<u>13,321,195</u>
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - par value \$0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value \$0.001; 350,000,000 shares authorized: 236,464,789 and 216,429,642 issued and outstanding, respectively	236,465	216,430
Additional paid-in capital	613,864,115	516,351,405
Accumulated deficit	<u>(479,885,299)</u>	<u>(386,659,120)</u>
Total stockholders' equity	<u>134,215,281</u>	<u>129,908,715</u>
Total liabilities and stockholders' equity	<u>\$ 236,753,021</u>	<u>\$ 143,229,910</u>

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues, net	\$ 3,473,535	\$ 4,417,598	\$ 11,009,937	\$ 12,653,495
Cost of goods sold	699,118	700,814	1,786,902	2,042,174
Gross profit	<u>2,774,417</u>	<u>3,716,784</u>	<u>9,223,035</u>	<u>10,611,321</u>
Operating expenses:				
Sales, general, and administration	30,354,072	12,057,868	80,578,079	43,524,412
Research and development	6,708,271	6,436,802	20,545,948	22,878,037
Depreciation and amortization	73,321	54,055	198,545	156,943
Total operating expense	<u>37,135,664</u>	<u>18,548,725</u>	<u>101,322,572</u>	<u>66,559,392</u>
Operating loss	<u>(34,361,247)</u>	<u>(14,831,941)</u>	<u>(92,099,537)</u>	<u>(55,948,071)</u>
Other income (expense):				
Miscellaneous income	809,022	167,300	1,457,817	442,322
Accreted interest	—	—	—	7,699
Interest expense	<u>(2,053,077)</u>	<u>—</u>	<u>(2,584,459)</u>	<u>—</u>
Total other (expense) income	<u>(1,244,055)</u>	<u>167,300</u>	<u>(1,126,642)</u>	<u>450,021</u>
Loss before taxes	<u>(35,605,302)</u>	<u>(14,664,641)</u>	<u>(93,226,179)</u>	<u>(55,498,050)</u>
Provision for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$ (35,605,302)</u>	<u>\$ (14,664,641)</u>	<u>\$ (93,226,179)</u>	<u>\$ (55,498,050)</u>
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.07)</u>	<u>\$ (0.42)</u>	<u>\$ (0.27)</u>
Weighted average number of common shares outstanding	<u>228,107,240</u>	<u>207,938,338</u>	<u>220,466,673</u>	<u>203,282,335</u>

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (93,226,179)	\$ (55,498,050)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	121,423	104,622
Amortization of intangible assets	77,123	52,321
Provision for doubtful accounts	231,475	1,555
Share-based compensation	6,388,635	5,037,783
Amortization of deferred financing costs	149,909	—
Changes in operating assets and liabilities:		
Accounts receivable	(8,705,325)	106,509
Inventory	(892,863)	(217,196)
Other current assets	1,233,482	(831,623)
Accounts payable	7,284,493	(3,159,145)
Accrued interest	59,375	—
Accrued expenses and other current liabilities	8,611,611	(946,853)
Net cash used in operating activities	<u>(78,666,841)</u>	<u>(55,350,077)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Payment for intellectual property license	(20,000,000)	—
Patent costs	(748,906)	(439,770)
Purchase of fixed assets	(66,295)	(35,849)
Payment of security deposit	(11,485)	—
Net cash used in investing activities	<u>(20,826,686)</u>	<u>(475,619)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	89,907,797	68,572,635
Proceeds from term loan	75,000,000	—
Payment of deferred financing fees	(3,786,918)	—
Proceeds from exercise of options	1,236,313	212,615
Proceeds from exercise of warrants	—	3,798,999
Net cash provided by financing activities	<u>162,357,192</u>	<u>72,584,249</u>
Increase in cash	62,863,665	16,758,553
Cash, beginning of period	127,135,628	131,534,101
Cash, end of period	<u>\$ 189,999,293</u>	<u>\$ 148,292,654</u>
Supplemental disclosure of cash flow information		
Interest paid	\$ 1,759,316	\$ —

About IMVEXXY

IMVEXXY (estradiol vaginal inserts) is approved in the U.S. for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. IMVEXXY is the only product in its therapeutic class to offer a 4 mcg and 10 mcg dose, the 4 mcg dose representing the lowest approved dose of vaginal estradiol available.

IMPORTANT SAFETY INFORMATION FOR IMVEXXY

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

See full prescribing information for complete boxed warning.

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 Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Estrogen Plus Progestin Therapy

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

CONTRAINDICATIONS

- IMVEXXY™ is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease or a history of these conditions; known anaphylactic reaction or angioedema to IMVEXXY; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS

- IMVEXXY is intended only for vaginal administration. Systemic absorption may occur with the use of IMVEXXY.
 - The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
 - 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.
 - Other warnings include: gallbladder disease; severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice.
 - Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.
 - Women on thyroid replacement therapy should have their thyroid function monitored.
-

ADVERSE REACTIONS

- The most common adverse reaction with IMVEXXY (incidence \geq 3 percent) and greater than placebo was headache.

Please note that this information is not comprehensive. Please visit www.Imvexxy.com for the Full Prescribing Information, including the Boxed WARNING, for IMVEXXY at <https://imvexxy.com/pi.pdf>.

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.ⁱⁱ

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 or 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.
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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 and 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 ($\geq 3\%$) 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, for BIJUVA at <https://www.bijuva.com/pi.pdf>.

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 vaginal 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/m²).

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.

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 IMVEXXYTM, ANNOVERATM, 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 ability of licensees of the company's products to commercialize such licensed products; 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.

ⁱ "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.

ⁱⁱ 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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3Q 2018 Financial Results

November 7, 2018

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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.

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

TherapeuticsMD, A Premier Women's Health Company

Annovera™

vitaMedMD®

Annovera™

Bijuva™ 1mg/100mg
(estradiol and progesterone) capsules

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



CONTRACEPTION

PRENATAL CARE

CONTRACEPTION/
FAMILY PLANNING -
PERIMENOPAUSE

VASOMOTOR
SYMPTOMS

DYSPAREUNIA
(Vulvar &
Vaginal Atrophy)



REPRODUCTIVE HEALTH



MENOPAUSE MANAGEMENT

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IMVEXXY Launch Update



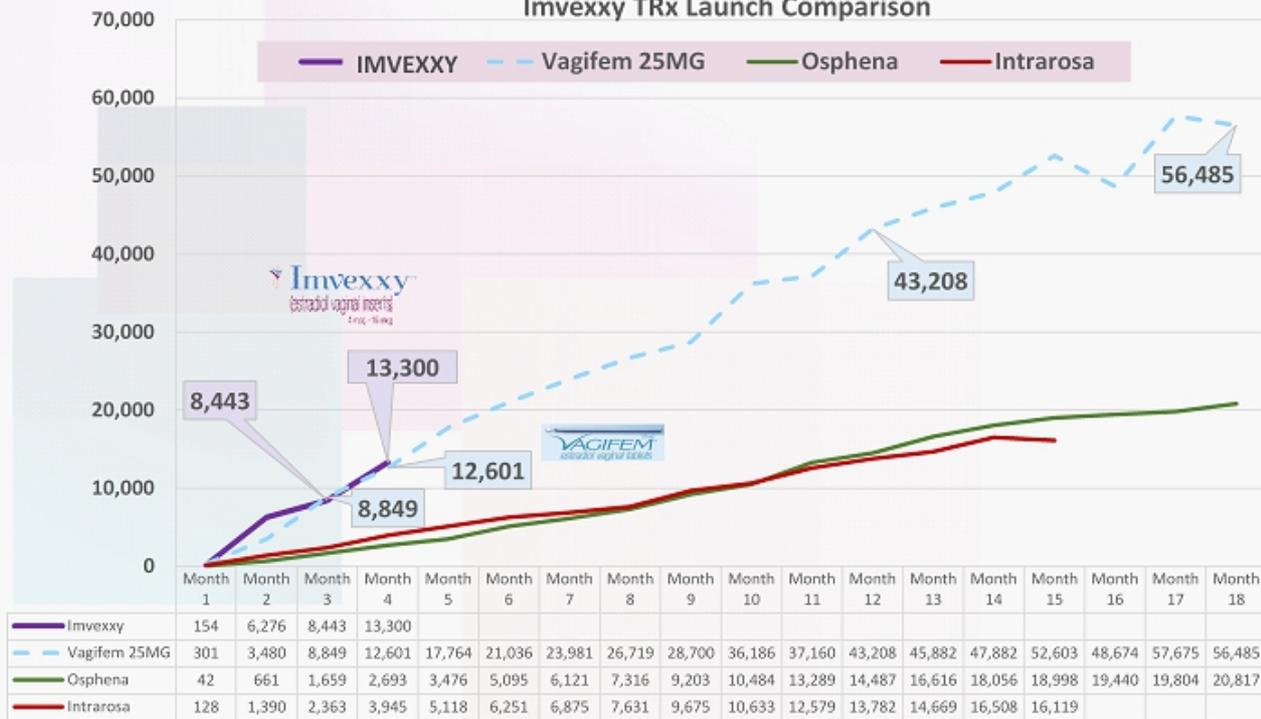
- Total units since launch ~28,200 paid scripts* dispensed to ~12,800 patients
- October total units of ~13,300 paid scripts*
- Refills for October of ~8,100 paid scripts
- New RXs for October of ~5,200 paid scripts
- 58% month over month growth (Sept/Oct)
- Blended starter and maintenance average WAC Q3 ~\$230
- Blended starter and maintenance average WAC for October ~\$225
- 37% commercial unrestricted coverage**
 - 11% adjudication rate
- 2.2 fills per patient (in the first 4 months)

*Units are based on IQVIA and copay redemption data based on utilization of our affordability programs. Cash pay or covered by insurance.

**MMIT

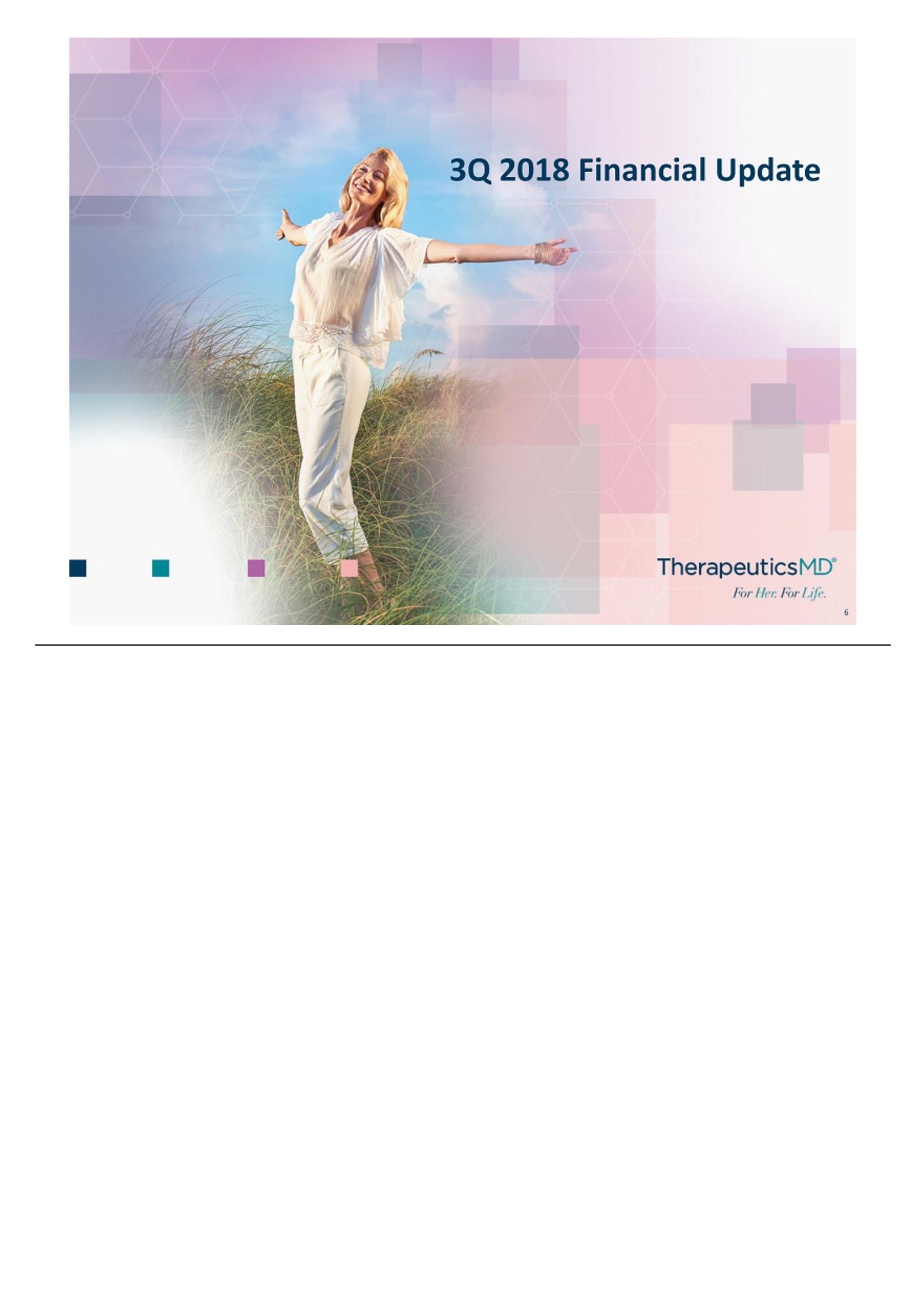
VVA TRx Launch Comparison

Imvexxy TRx Launch Comparison



References:
 Imvexxy is QVIA and copay redemption data.
 Ospheña and Intrarosa is SHA PHAST data.
 Vagifem is from IQVIA.

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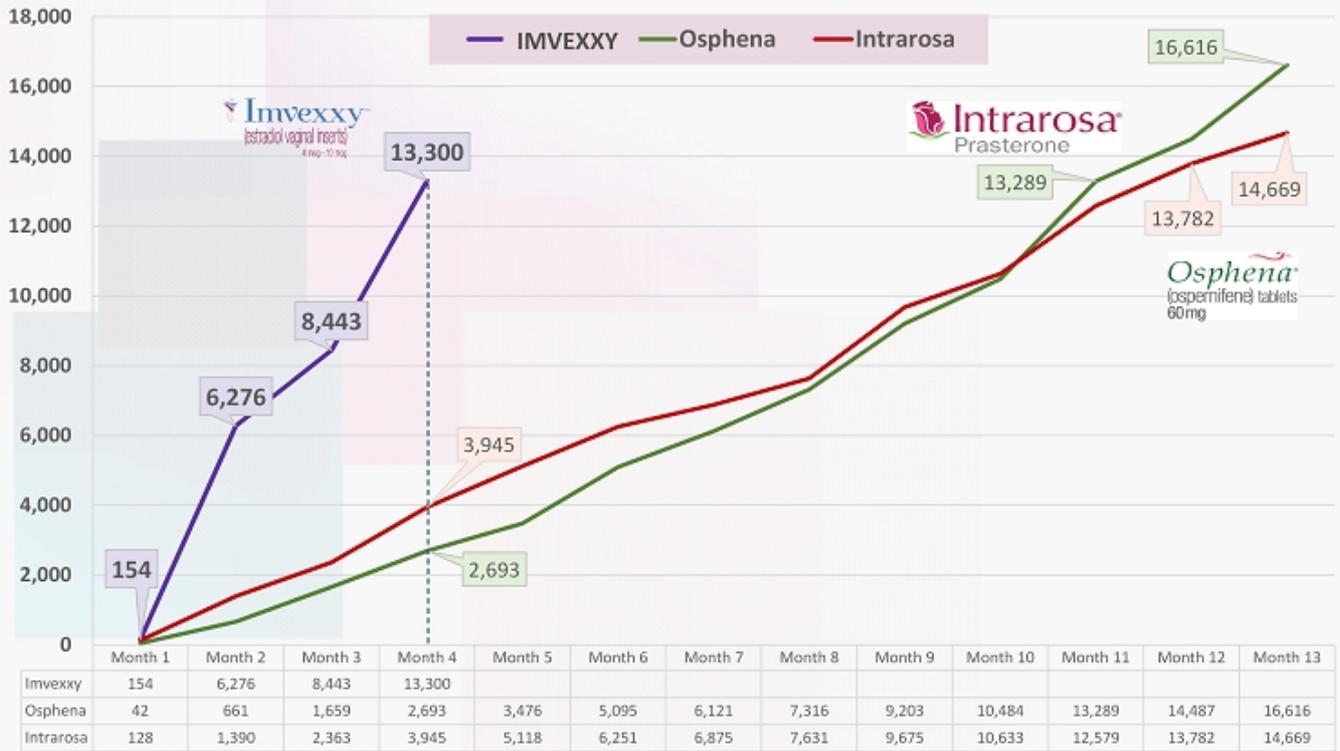
3Q 2018 Financial Update

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Commercial Update

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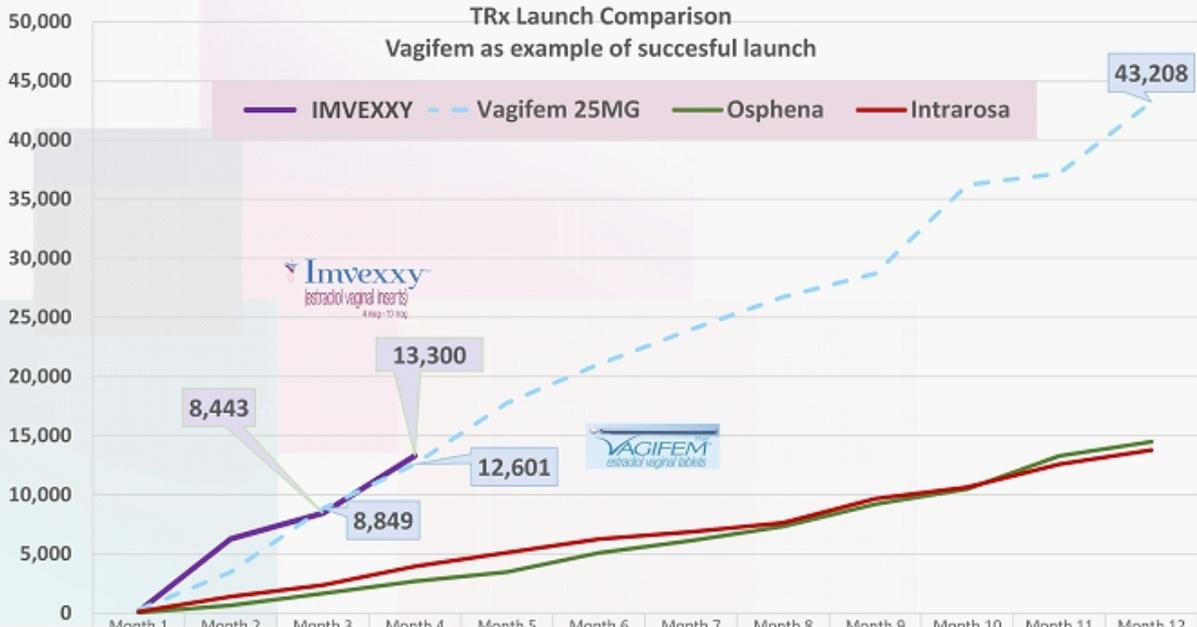
VVA TRx Launch Comparison



References:
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VVA TRx Launch Comparison



	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Imvexxy	154	6,276	8,443	13,300								
Vagifem 25MG	301	3,480	8,849	12,601	17,764	21,036	23,981	26,719	28,700	36,186	37,160	43,208
Ospheha	42	661	1,659	2,693	3,476	5,095	6,121	7,316	9,203	10,484	13,289	14,487
Intrarosa	128	1,390	2,363	3,945	5,118	6,251	6,875	7,631	9,675	10,633	12,579	13,782

References:
 Imvexxy is QVIA and copay redemption data.
 Ospheha and Intrarosa is SHA PHAST data.
 Vagifem is from IQVIA.

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Market Growth Through Treatment Compliance



■ As of October 31, 2018

- 2.2 IMVEXXY fills per patient in the first 4 months*
- Previous two dyspareunia product launches during the first year of launch averaged 1.7 fills per patient**
- IMVEXXY average refill rate ~74%
- Last week of October, over ~2,000 new patients received an IMVEXXY prescription

References:

*Imvexxy fill data is based on IQVIA and copay redemption data.

**Previous two launches is based on Symphony total script data divided by the patient count data from IQVIA total patient tracker info from the 12 months of launch

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Next Phase of Growth

- Launched speaker programs across the US
- Adding additional sales reps to increase IMVEXXY market share and launch BIJUVA
- Launching consumer marketing effort Q1 of 2019
- Increasing Bio-Ignite pharmacies with IMVEXXY
- Launch BIJUVA in the 2Q of 2019
- Launch ANNOVERA as early as the 4Q of 2019

IMVEXXY Payer Update

- Goal to close last remaining large commercial payers contracts in 2018
- We are near the end of the expected 6-month payer block
- Anticipate strong commercial adjudication will start in Q1 of 2019

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BIJUVA Substitutable Market

	Column 1	Column 2	Column 3
 BIJUVA <u>Substitutable</u> <u>Market</u>	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: Activalle®, FemMIRT®, Angele®, Generic 17β + Progesterone, Prempro®, Premphase®, Duavee®, Bristelle®

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

4) Assume WAC pricing between \$200-250

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Bijuva[™] 1mg/100mg
(estradiol and progesterone) capsules

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 Approval

▪ Post-Marketing Commitment

- To further develop and validate in-vitro dissolution to show manufacturing consistency between drug batches of how the drug is released from the capsule in an in-vitro setting for quality control assessments
 - Expect to submit the final report in December to enable Q2 launch

▪ One dose approved by the FDA

- Given the safety and efficacy demonstrated of the higher dose of 1mg estradiol/100 mg progesterone – there was no reason for the lower dose
- Represents the lowest approved dose of bio-identical estradiol in combination with bio-identical progesterone
- Represents over a \$1 billion opportunity as the dose HCPs, compounding pharmacists and women prefer

▪ Label statement of a clinically meaningful reduction of 14 hot flashes per week occurring at week 5

- Consistent with the data from other products on the market today
- Same methodology of clinical meaningfulness that established the approval of other products used to treat vasomotor symptoms achieved at Week 4 and sustained through Week 12

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BIJUVA Advantages For Stakeholders

Patients

- Satisfy demand for bio-identical hormone therapy with a product approved by FDA on safety and efficacy
- Reduce of out-of-pocket costs via insurance coverage
- Convenience of one combination product
- Widely acceptable at pharmacies and not just compounding pharmacies

Healthcare Providers

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

Pharmacies

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

FDA/Regulatory Bodies

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

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ANNOVERA Key Clinical Attributes

Clinical Attributes

- Only FDA approved long-acting reversible birth control that doesn't require a procedure or repeat doctor's visit
 - Empowers women to be in 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 trials¹ (89% overall satisfaction)
- Low daily release of ethinyl estradiol (13 mcg)
- Only product with new novel progestin - segesterone acetate²
 - No androgenic, estrogenic or glucocorticoid effects at contraceptive doses
- Favorable side effect profile including low rates of discontinuation related to irregular bleeding (1.7%)
- Safety profile generally consistent with other CHC products, including boxed warning

¹ Merkatz, Ruth B., Mariena 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

ANNOVERA Key Physical Attributes

Physical Attributes

- Softer and more pliable than NuvaRing
- Acceptable for women who haven't had a child (nulliparous) or are not in a monogamous relationship¹
- "Vaginal System" – the only product in a new class of contraception with potential for \$0 co-pay
- Cost and convenience (pharmacy and doc visits)
- Does not require refrigeration by HCP

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

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