

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): May 13, 2020

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.)

951 Yamato Road, Suite 220
Boca Raton, FL 33431

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

Not Applicable

(Former name or former address, if changed since last report)

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))

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

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

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) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2).

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.

TherapeuticsMD, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on May 13, 2020 and at subsequent meetings with investors or analysts.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
99.1	TherapeuticsMD, Inc. Presentation dated May 13, 2020.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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: May 13, 2020

THERAPEUTICSMD, INC.

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



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**BofA Securities
Conference**

May 13, 2020

*Building the Premier
Women's Health
Company*

Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as "we," "our," or "the Company") 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 (SEC), 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: the company's ability to protect the intellectual property related to its products; the effects of the COVID-19 pandemic; 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 facility, including the conditions to draw an additional tranche thereunder and whether the lender will make such tranche available; 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; whether the FDA will approve the efficacy supplement for the lower dose of BIJUVA; the company's ability to protect its intellectual property, including with respect to the Paragraph IV notice letters the company received regarding IMVEXXY and BIJUVA; 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 ability of the company's licensees to commercialize and distribute the company's products; the ability of the company's marketing contractors to market ANNOVERA; 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. This non-promotional presentation is intended for investor audiences only.



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1Q20 Highlights

Our approach is strategic, highly focused and achievable:

- Now that we have patient, provider and net revenue data on all 3 of our products, we have developed a path to reduce overall expenses and reallocate our resources that maintains our goal of achieving EBITDA breakeven in 2021
- We believe we are positioned to capitalize on emerging market trends that have been accelerated by COVID-19 with our retail and online distribution channels
- In the short-term, we have adjusted our strategy to be primarily focused on ANNOVERA and IMVEXXY

Portfolio Strategic Focus

- ANNOVERA will remain our primary focus because of the positive market reception and net revenue per unit results that are a full year ahead of our internal expectations
- IMVEXXY is our second priority as it has gained traction amongst the prescribing population and is now the fastest growing product in the category
- To fund these initiatives, we are pausing the majority of our BIJUVA related promotional activities
- We have been able to cut costs considerably by pausing BIJUVA, which supports our goal of EBITDA breakeven in 2021

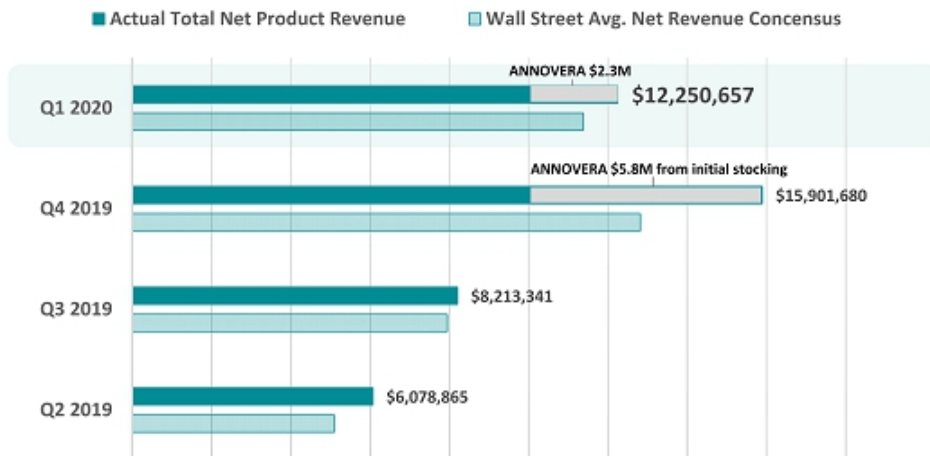
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1Q20 Accomplishments and Trends

TherapeuticsMD Met or Beat Wallstreet Net Revenue Consensus for the Last 4 Quarters



* Wall Street Consensus Estimate per "estimate"

- ANNOVERA: Patient demand doubled in Q1 from Q4 and outpaced restocking into the channel in Q1.

1Q 2020 Key Performance Metrics

ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system)



- 1Q20 net revenue: **~\$2.3M**
- 1Q20 total prescriptions (TRx) to patient¹: **2,361**
 - During February soft launch, Sales Reps promoted to 10 prescribers per territory and generated monthly TRx of **~970**
 - Paused launch due to COVID-19 in early March
- 1Q20 Average (avg.) net revenue per unit²: **~\$1,350**
 - Adjudication rate: **~100%**
- Expected avg. net revenue per unit during 2020: **~\$1,200 - \$1,400**
 - **~77%** of ANNOVERA patients are paying **\$0 copay**
- # Healthcare professionals (HCPs) with TRx: **~1,140**

IMVEXXY® (estradiol vaginal inserts)



- 1Q20 net revenue: **~\$6.4M**
- 1Q20 TRx to patient¹: **~134,000**
- 1Q20 net revenue per unit²: **~\$48**
 - Overall adjudication rate: **~44%**
- # HCPs with TRx: **17,000**
- Focus on fills allows for continued revenue growth
 - Avg. of 6 units per patient for those patients who started therapy over 12 months ago
 - Avg. of 4.2 units per patient in 2019

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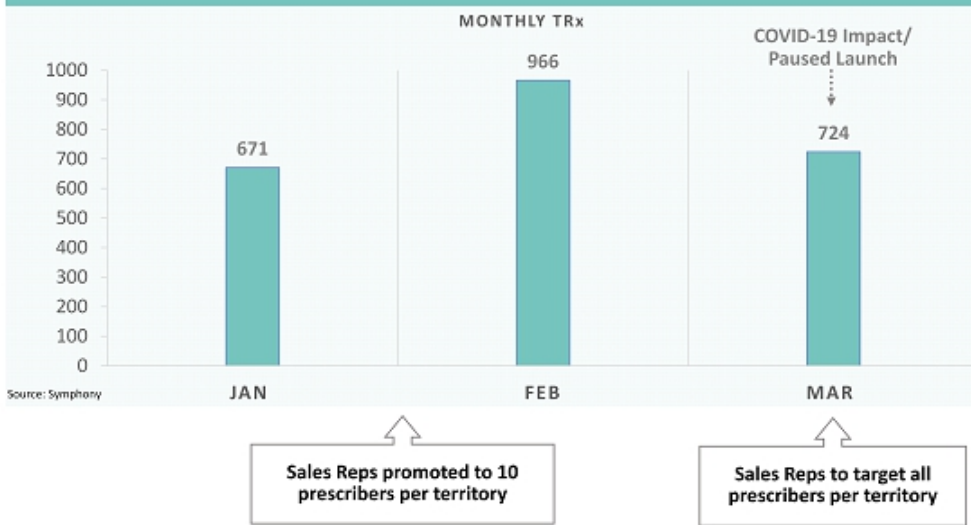
¹ Source: Symphony

² Average net revenue per unit calculated from sales to wholesalers and pharmacies [®]

1Q20 Key Metrics: ANNOVERA



ANNOVERA Full Launch Month Interrupted by COVID-19



1Q 2020 Key Performance Metrics

BIJUVA[®] (estradiol and progesterone) capsules



- 1Q20 net revenue: **~\$1.1M**
- 1Q TRx to patients¹: **~26,000**
- 1Q20 net revenue per unit²: **~\$43**
 - Overall adjudication rate: **~51%**
- # HCPs with TRx: **~5,000**

- Pausing BIJUVA promotional activities enhances funding for ANNOVERA and IMVEXXY post COVID-19

Continued Expansion of Payor Coverage Including Significant Gains in Public Health for ANNOVERA

	Coverage May 2020	Target Coverage Year-end 2020
ANNOVERA		
Commercial	76%*	80%*
Medicaid	37 of 50 states	
Department of Defense	On Formulary	On Formulary
IMVEXXY		
Commercial	72%	75%
Part D	26%+	70%
BIJUVA		
Commercial	54%	75%

- Earlier Unrestricted Medicaid access than expected for ANNOVERA in Ohio, Florida, Illinois, Kentucky, Texas, Massachusetts, South Carolina, Michigan, Nebraska, New Hampshire, North Carolina, North Dakota, South Dakota, Virginia, Alabama, Oregon, Idaho, Connecticut, Maryland, Alaska, Arkansas, Washington, Maine, Montana, Utah, Wyoming, Missouri, New York, New Jersey, DC, Colorado, Kansas, Indiana, Tennessee, Rhode Island, Nevada, Louisiana and Hawaii

*Annovera coverage includes unrestricted access and coverage with a step edit/prior authorization. +Includes PA to indication

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Source: MMIT 4_22_20¹¹



Finance Update

Financial Results: Comparison Q1 2020 to Q4 2019

Comparison of Key Financial Statement Items

	Q1 2020	Q4 2019
<u>Balance Sheet</u>		
→ Cash	\$170,100,000	\$160,830,000
→ Working Capital	\$150,349,000	\$153,354,000
→ Long-term Debt	\$243,429,000	\$194,635,000
<u>Income Statement</u>		
→ Product Revenue, Net	\$12,251,000	\$15,902,000
→ Total Operating Expenses	\$60,458,000	\$57,415,000
→ Net Loss	(\$56,849,000)	(\$49,436,000)
<u>Statement of Cash Flow</u>		
→ Net Cash Used In Operating Activities	(\$39,111,000)	(\$50,797,000)

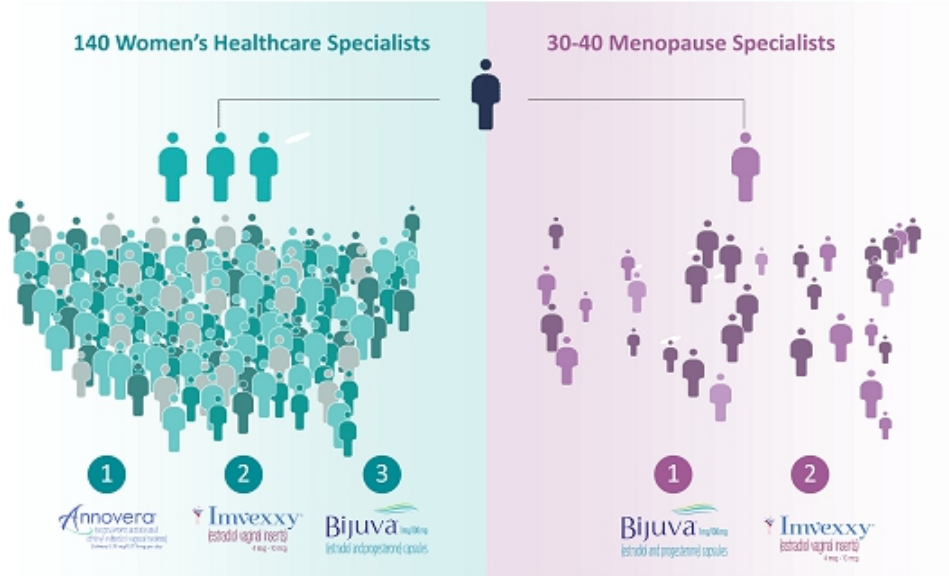
- * Cash balance for Q1 does not include a loan of \$6,477,094 pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration, which was received on April 27, 2020

Corporate Wide Cost Reductions in Total Operating Expenses



- Expect 2Q20 total operating expenses to be \$45.5M - \$47.5M
 - Defer \$10M in marketing spend primarily related to media
- Expect total operating expenses in 3Q20 and 4Q20 to be approximately \$40M or less¹
- We believe these actions will continue to position us to become EBITDA break even in 2021

Previous Sales Structure Supporting All Three Products



Current Sales Team and Distribution Channels

120-130 Women's
Healthcare Sales Reps



Distribution Channels

Puerto Rico
 WSI
 VA/Military
 PILL CLUB
 PlushCare

Medicaid
 afaxys
 Public Health
 Pill Park



1



2

- ANNOVERA is positioned as the lead product
- IMVEXXY is positioned as second detail
- BIJUVA promotional activities to be paused to create cost savings from the following:
 - Eliminating menopausal sales force
 - Reducing medical affairs support staff
 - Eliminating marketing spend
 - Advertising cost
 - Marketing agency costs
 - Social media cost
 - Brochures, marketing collateral, direct mail, etc.
 - Samples will continue to support current writers



Advantages to Pausing BIJUVA

- A laser-focused sales force to drive market adoption of ANNOVERA and IMVEXXY
- Pausing BIJUVA promotional activities enhances funding for ANNOVERA and IMVEXXY post COVID-19
- Reduces operating expense and will not delay goal of EBITDA break even in 2021
- Using partners to increase patient access for ANNOVERA into Government, Public Health and Online markets to increase access and reduce cost
- BIJUVA opportunity and revenue build is delayed but not lost

Update to TPG Sixth Street Loan Covenants



- Due to the uncertainty created by COVID-19 and its impact on our business, TXMD has been in discussions with Sixth Street Partners regarding the revenue covenants in the loan document
- We are working with Sixth Street to defer the scheduled start of the quarterly revenue covenant to reflect the impact of COVID-19
- Sixth Street has expressed preliminary support and while there is currently no final agreement or obligation, they understand the importance of flexibility for our company at this time



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**Product Overview and Plans to Drive
Revenue Inflection Point**

Our approach is strategic, highly focused and achievable:

- Now that we have patient, provider and net revenue data on all 3 of our products, we have developed a path to reduce overall expenses and reallocate our resources that maintains our goal of achieving EBITDA breakeven in 2021
- We believe we are positioned to capitalize on emerging market trends that have been accelerated by COVID-19 with our retail and online distribution channels
- In the short-term, we have adjusted our strategy to be primarily focused on ANNOVERA and IMVEXXY

ANNOVERA: Well Positioned for Fast Uptake When Full Plans Deployed



Contraception: Largest Women's Health Category at \$5B

- ~500,000 U.S. prescribers of contraception
- ~18M women on prescription birth control annually
- ~28M NRx in 2019

Full Sales Force Plans and Consumer Advertising will Quickly Accelerate Ramp

1Q20 Efforts and Results

- 1,140 Prescribers
- 10 Providers per sales representative
- Paused launch of consumer campaign and live field promotion halted in March due to COVID-19

3Q20 Efforts

- 125-150 sales force targets per representative
- Large scale consumer campaign to launch in early Q3

Broad Availability will Allow Growth Across Contraception Channels

Retail Pharmacies

Online Distribution Partners:

Public Health

- Universities, 340b including Title X (Planned Parenthood), Medicaid (37 states approved)





Military

- Available to 92 military bases

ANNOVERA Compelling Now and Post COVID-19

- One year's worth of protection
- Good substitute for elective procedures are not happening for women that want a long-lasting option or do not want a procedure

ANNOVERA is the only long-lasting contraceptive that is patient-controlled and procedure-free²

	 ANNOVERA	 IUDs	 IMPLANTS	 OTHER HORMONAL CONTRACEPTIVES
Patient-controlled	✓			✓
Procedure-free	✓			✓
Long-lasting	✓	✓	✓	

- Covers you for a year even if your insurance situation changes
- ~77% of patients have \$0 co-pay
- Available to be delivered to your door

IMVEXXY's Unique Product Attributes

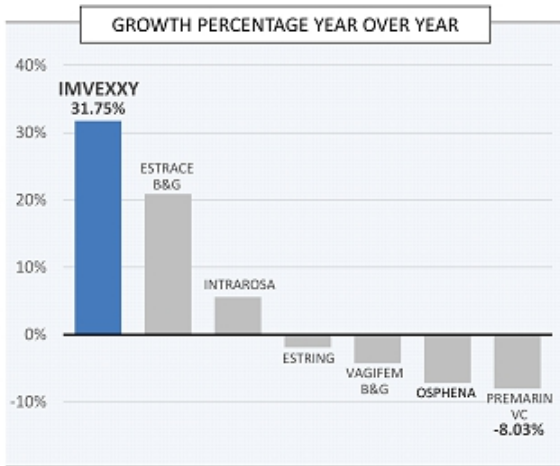
- Indicated for moderate to severe dyspareunia
- Small, digitally inserted, softgel vaginal insert that dissolves completely
- **Easy to use without the need for an applicator**
- **Mess-free** administration
- Use **any-time of day**
- **Lowest approved doses** of estradiol 4 mcg and 10 mcg
- **Efficacy demonstrated as early as 2 weeks** (secondary endpoint) and maintained through week 12 in clinical studies
- PK data - **No increase in systemic hormone levels** beyond the normal postmenopausal range*
- **Dose packaging to optimize compliance and convenience**



IMVEXXY Continues to Gain Momentum



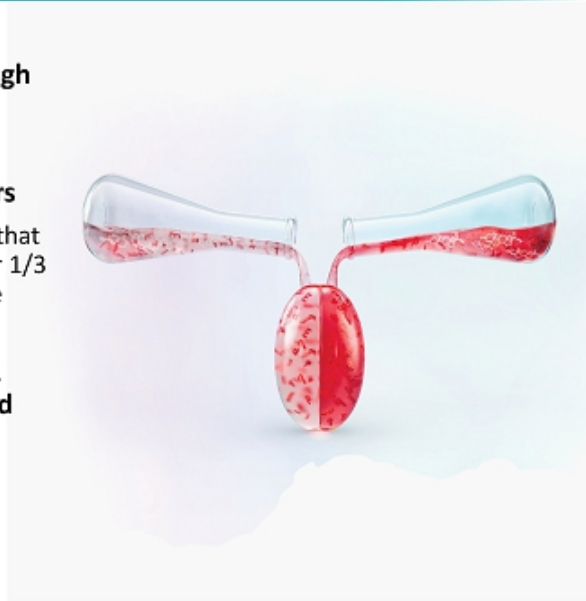
IMVEXXY is the fastest growing product in the VVA market and share gains vs. Premarin



- March 10.8% market share of TRx
- Support of high writer base and expansion of productive writers
 - New writers delivered 10% of 1Q NRx volume
- Consumer efforts are driving action
 - Intent to ask HCP about IMVEXXY continues to grow now at 66%
- Consumer media will expand to support continued share gain in back half of year

BIJUVA Targeted Focus Until 0.5/100 Launch is Funded

- **Focus on current writer base through remainder of 2020**
 - Non-personal promotion
- **Focus on current Bio-ignite partners**
 - Compounding pharmacists report that they would recommend BIJUVA for 1/3 of their estradiol and progesterone (E+P) patients
- **Prepare for 0.5/100 launch in 2021 with internal resources, if approved**
 - PDUFA date: November 16, 2020



2020 Post COVID-19 Outlook

- **Currently regaining access to doctors' offices in lock step as the states reopen**
 - Currently operating in a hybrid (face-to-face and remote) interaction model
 - We expect office access to expand and accelerate during 2Q and normalize during 3Q
 - 2Q20 revenue will be impacted due to COVID-19
- **We believe ANNOVERA and IMVEXXY are positioned to capitalize on trends accelerating due to COVID-19**
 - Expanded access through telehealth
 - Online and retail home delivery distribution
- **Cash runway extended due to saving from pausing BIJUVA commercial activities and other cost-saving measures**
- **We expect to reactivate the growth drivers in early 3Q20**
 - ANNOVERA full launch including launch of Consumer Campaign “Unapologetically ANNOVERA”
 - IMVEXXY acceleration of media and reengagement of in person sales efforts
- **TPG Sixth Street Partners discussions ongoing**

We believe we are well positioned to resume our growth trajectory in 3Q

Market Opportunity

Total Addressable Birth Control Market NRx: 28M				
Average Net Revenue / Unit	1.0%	1.5%	2.0%	2.5%
\$1,000	\$280M	\$420M	\$560M	\$700M
\$1,250	\$350M	\$525M	\$700M	\$875M
\$1,500	\$420M	\$630M	\$840M	\$1.05B
\$1,750	\$490M	\$735M	\$980M	\$1.2B

ANNOVERA Comparison to other Branded Products¹

- NuvaRing 2019 NRx of ~400K units from ~153K writers
- Lo Loestrin FE 2019 NRx of ~450K units from ~114K writers
- ANNOVERA NRx of ~400k units would @ \$1,250 a unit = ~\$500M annual revenue

Percent of Market Based on Patient Count of 2.3M and 4 fills per year				
Average Net Revenue / Unit	25%	35%	45%	55%
\$80	\$184M	\$257.6M	\$331.2M	\$404.8M
\$100	\$230M	\$322M	\$414M	\$506M



¹Symphony Health Metys Data

The Power of a Women's Health Portfolio

Annovera
 (bazedoxone acetate and
 ethinyl estradiol vaginal system)
 0.02 mg/0.01 mg per day

vitaMedMD
 Prenatal Vitamins

Annovera
 (bazedoxone acetate and
 ethinyl estradiol vaginal system)
 0.02 mg/0.01 mg per day

Bijuva
 (estradiol and progesterone) capsules

Imvexxy
 (estradiol vaginal inserts)
 4 mg - 11 mg



REPRODUCTIVE HEALTH

MENOPAUSE MANAGEMENT



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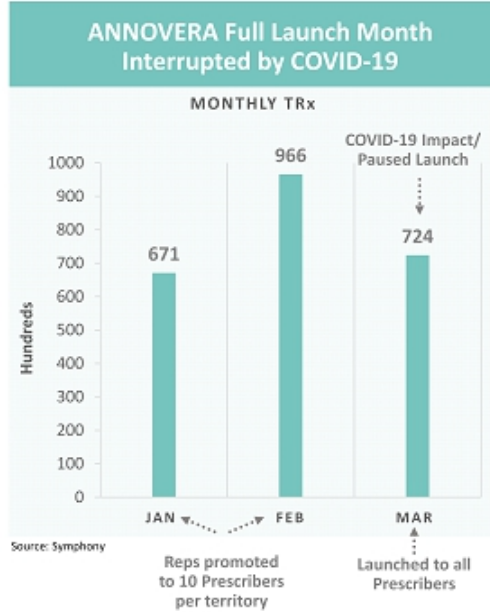


Appendix

1Q20 Key Metrics: ANNOVERA

	1Q 2020	4Q 2019
Net Revenue	~\$2.3M	~\$5.8M
TRx to patients	2,361	1,095
Average Net Revenue / Unit	\$1,350	\$1,350
# Prescribers w/ TRx	1,140	540

- Patient demand more than doubled 1Q20 over 4Q19 and outpaced unit sales into the channel
- Adjudication rate: ~100%
- ~77% of ANNOVERA patients are paying \$0 copay



*Average net revenue per unit calculated from sales to wholesalers and pharmacies

1Q Key Metrics: IMVEXXY

	1Q 2020	4Q 2019
Net Revenue	~\$6.4M	~\$6.35M
TRx to patients	134,000	123,300
Average Net Revenue / Unit	\$48	\$51
# Prescribers w/ TRx	17,000	16,500

- Patient demand increased Q over Q
- Not as heavily impacted by COVID-19
- Established base of business across writers and patients
- Overall adjudication rate (Q1): **~44%**



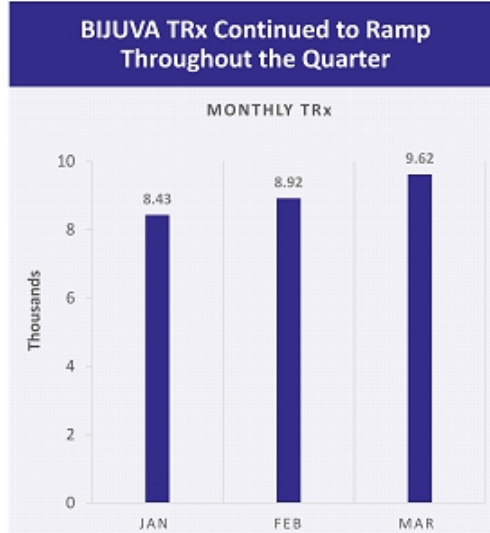
Source: Symphony

* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period

1Q Key Metrics: BIJUVA

	1Q 2020	4Q 2019
Net Revenue	~\$1.1M	~\$1.2M
TRx to patients	~26,000	~21,600
Average Net Revenue / Unit	\$43	\$56
# Prescribers w/ TRx	5,000	5,500

- Overall adjudication rate Q1: ~51%
- Continued growth in patient demand quarter over quarter



Source: Symphony

* Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period

- **Surpassed IMVEXXY and BIJUVA progress in January 2020 with payor coverage, adjudication, and net revenue per unit**
 - Public Health Expansion fast progress with our partners Afaxys and WSI
 - Added to formulary for Department of Defense and being sold to 92 military bases
 - Will be available for Title X entities (e.g. Planned Parenthood) in early May
 - Expect universities to adopt and prescribe ANNOVERA during Fall semester
 - Medicaid market is 15% of contraceptive volume
 - 37 states now unrestricted in Medicaid with average copays of \$5 or less
- **~76% coverage and ~77% patients paying \$0 copay even without the 19th category**
 - Positive engagement with FDA continues

1Q20 Payor Progress: Menopausal Products



- **IMVEXXY Commercial access remains solid at 72% unrestricted**
 - No additional major Medicare Part D adds in 1Q20; still expect to gain 2 of the 3 remaining major plans
 - COVID-19 has slowed down the payor review process for Part D
 - Since January 1st, IMVEXXY has added 21 states with unrestricted Medicaid access with average copays of \$5 or less

- **BIJUVA Commercial access remains at 54% unrestricted and discussions are ongoing**
 - We have achieved access with 7 of the top 10 commercial payors
 - Since January 1st, BIJUVA has added 21 states with unrestricted Medicaid access with average copays of \$5 or less

ANNOVERA Update of Patent Strategy

- **On April 28, 2020, the USPTO issued the first Orange Book listable patent for ANNOVERA**

- US Patent No 10,632,066 will expire February 2039
- On March 29, 2020, TherapeuticsMD filed FDA Form 3542 to have the '066 patent listed in the Orange Book
- The '066 patent claims elements of the ANNOVERA label, which a generic would need to copy as part of its Abbreviated New Drug Application (ANDA)

- **Currently on file with the USPTO are six additional utility patent applications for ANNOVERA and one design patent**

- These applications cover different aspects of ANNOVERA and if issued would strengthen ANNOVERA's exclusivity position