

**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 6, 2021

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 2.02 Results of Operations and Financial Condition.

On May 6, 2021, TherapeuticsMD, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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) is furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information in Item 2.02 of this Current Report on Form 8-K (including the exhibits) 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 May 6, 2021, the Company issued a press release announcing the Company’s financial results for its first quarter ended March 31, 2021. 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 Index**

Exhibit Number	Description
99.1	Press Release from TherapeuticsMD, Inc., dated May 6, 2021, entitled “TherapeuticsMD Announces First Quarter 2021 Financial Results.”
99.2	TherapeuticsMD, Inc. Presentation dated May 6, 2021.
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 6, 2021

THERAPEUTICSMD, INC.

By: /s/ James C. D'Arecca
Name : James C. D'Arecca
Title: Chief Financial Officer

TherapeuticsMD®

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces First Quarter 2021 Financial Results

- 1Q21 total net revenue increased to \$19.9 million -
- 1Q21 total net product revenue increased 60% to \$19.6 million compared to 1Q20 -
- ANNOVERA prescriptions continue to grow with increasing consumer support and acceptance -
- Further strengthened ANNOVERA® patent family through June 2039 -
- Significantly improved average net revenue per unit for IMVEXXY® to \$61 and BIJUVA® to \$69 -
- vitaCare's divestiture process continues in an effort to unlock shareholder value-
- Conference call scheduled for 8:30 a.m. ET today -

BOCA RATON, Fla. – May 6, 2021 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women's healthcare Company, today reported financial results for the first quarter ended March 31, 2021.

"I am pleased with our ongoing execution across the organization, which is in-line with our 2021 operating plan led by ANNOVERA, which performed well in a challenging environment. Our financial performance continues to improve year-over-year. Both menopausal products, IMVEXXY and BIJUVA, had record net revenue per unit. We are also pleased to report that three new ANNOVERA patents were obtained, strengthening durability and extending exclusivity through June 2039. The Company won its appeal for the new low-dose BIJUVA 0.5/100 with the FDA. We are confident that these milestones, together with our existing and new commercial strategies, will continue to deliver strong growth throughout 2021," said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD.

First Quarter Review

Total net product revenue for the first quarter of 2021 increased 60% to \$19.6 million compared to the first quarter of 2020. When compared to the fourth quarter of 2020, total net product revenue decreased by 13% for the first quarter of 2021.

ANNOVERA (segestrone acetate and ethinyl estradiol vaginal system)

- ANNOVERA net product revenue increased by \$6.5 million to \$8.8 million for the first quarter of 2021 as compared to \$2.3 million for the first quarter of 2020.
- Net revenue per unit, calculated from sales to wholesalers and pharmacies, was \$1,071 for the first quarter of 2021. The Company expects net revenue per unit for ANNOVERA to average approximately \$1,100 for the year.
- Approximately 6,240 ANNOVERA prescriptions were dispensed to patients during the first quarter of 2021. ANNOVERA total prescription volume increased 164% for the first quarter of 2021 as compared to the first quarter of 2020. ANNOVERA total prescription volume increased 5% for the first quarter of 2021 as compared to the fourth quarter of 2020. Strong refill rates continued with eligible patients.
- During the first quarter the United States Patent and Trademark Office (USPTO) issued three new ANNOVERA patents, which are now listed in the U.S. Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). With these additional patents, the Orange Book lists a total of six patents for ANNOVERA. These newly issued patents protect key properties of ANNOVERA and extend patent protection for ANNOVERA from February 2039 to June 2039.

IMVEXXY® (estradiol vaginal inserts)

- IMVEXXY net product revenue increased by 10% to \$7.0 million for the first quarter of 2021 as compared to \$6.4 million for the first quarter of 2020.

- Net revenue per unit, calculated from sales to wholesalers and pharmacies, was approximately \$61 for the first quarter of 2021 reflecting a 39% improvement in net price compared to the first quarter of 2020.
- The impact of the Company's increase in cash pay price for IMVEXXY on January 1, 2021, had a positive impact on net revenue per unit and a short-term impact on volume. Approximately 108,200 prescriptions were dispensed to patients during the first quarter of 2021. As expected, IMVEXXY total prescription volume declined 14% for the first quarter of 2021 as compared to the first quarter of 2020. IMVEXXY fill rates remained at an average of approximately 6 fills per patient annually.
- The Company recently launched Long May She Reign, a new consumer campaign for IMVEXXY, designed to educate menopausal women about vaginal health during menopause.

BIJUVA® (estradiol and progesterone)

- BIJUVA net product revenue increased 120% to \$2.5 million for the first quarter of 2021 as compared to \$1.1 million for the first quarter of 2020.
- Net revenue per unit, calculated from sales to wholesalers and pharmacies, was approximately \$69 for the first quarter of 2020 reflecting an 85% improvement in net price as compared to the first quarter of 2020.
- The Company increased the cash pay price for BIJUVA on January 1, 2021, which was expected to have a short-term impact on volume. Approximately 30,800 BIJUVA prescriptions were dispensed to patients in the first quarter of 2021.
- The Company won its appeal for the new low-dose BIJUVA 0.5 mg/100 mg with the FDA. The Company has been granted a meeting with the FDA in May to discuss next steps.
- Theramex, the Company's licensee, was granted additional European approvals of BIJUVA (1 mg/100 mg).

Cost of Goods Sold/Gross Margin

- Cost of goods was \$4.7 million with gross margin of 76% for the first quarter of 2021 as compared to \$5.6 million with gross margin of 75% for the fourth quarter of 2020 and \$2.7 million with gross margin of 78% for the first quarter of 2020. The Company's gross margin of 76% for the first quarter of 2021 was adversely affected by production related write-offs for ANNOVERA of \$0.9 million.

Expense, Net Loss and Related Information

- Total operating expenses for the first quarter of 2021 decreased by \$16 million from \$60.5 million to \$44.5 million for the first quarter of 2020. Total operating expenses for the first quarter of 2021 decreased by \$7.1 million from \$51.6 million for the fourth quarter of 2020.
 - The decrease in operating expenses was primarily a result of measures initiated by the Company to reduce overall operating expenses.
- Net loss continues to improve. The first quarter of 2021 was \$39.4 million, or \$0.11 per basic and diluted share, compared with net loss for the first quarter of 2020 of \$56.8 million, or \$0.21 per basic and diluted share and net loss for the fourth quarter of 2020 of \$42.1 million, or \$0.15 per basic and diluted share.

Balance Sheet

- As of March 31, 2021, the Company's cash on hand totaled \$137.6 million, compared with \$80.5 million as of December 31, 2020.
- The Company received \$150.9 million in net proceeds from its at-the-market and underwritten equity offerings and repaid \$50 million of principal under its Financing Agreement. The remaining outstanding principal amount under the Financing Agreement is \$200 million.

vitaCare Update

The Company continues the vitaCare divestiture process to unlock shareholder value. The Company believes vitaCare is creating a significant revenue opportunity with two new live customers, a third scheduled to launch in the fourth quarter, and a pipeline with approximately twenty potential new deals. vitaCare continues to build its foundation to become a free-standing entity in a rapidly growing sector with no established leader.

Conference Call and Webcast Details

TherapeuticsMD will host a conference call and live audio webcast today at 8:30 a.m. ET to discuss these financial results and provide a business update.

Date:	Thursday, May 6, 2021
Time:	8:30 a.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977

Access Code for All Callers:

5683435

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: 5683435.

Please see the Full Prescribing Information, including indication and Boxed WARNING, for each TherapeuticsMD product as follows:

- IMVEXXY (estradiol vaginal inserts) at <https://imvexxy.com/pi.pdf>
- BIJUVA (estradiol and progesterone) capsules at <https://www.bijuva.com/pi.pdf>
- ANNOVERA (segesteron acetate and ethynodiol dienoate vaginal system) at www.annovera.com/pi.pdf

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 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®, and BIJUVA® and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan facility; whether the company will be able to successfully divest its vitaCare business and how the proceeds that may be generated by any such divestiture will be utilized; 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 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.

- Financial Statements to Follow -

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except per share data)

	March 31, 2021 (Unaudited)	December 31, 2020
Assets:		
Current assets:		
Cash	\$ 137,617	\$ 80,486
Accounts receivable, net of allowance for credit losses of \$1,231 and \$1,118 as of March 31, 2021 and December 31, 2020, respectively	33,719	32,382
Inventory	7,346	7,993
Prepaid and other current assets	8,360	7,543
Total current assets	187,042	128,404
Fixed assets, net	1,812	1,942
License rights and other intangible assets, net	40,994	41,445
Right of use assets	9,205	9,566
Other non-current assets	253	253
Total assets	\$ 239,306	\$ 181,610
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	\$ 5,000	\$ —
Accounts payable	10,310	21,068
Accrued expenses and other current liabilities	45,974	38,170
Total current liabilities	61,284	59,238
Long-term debt, net	178,970	237,698
Operating lease liabilities	8,530	8,675
Total liabilities	248,784	305,611
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value \$0.001; 600,000 shares authorized, 393,190 and 299,765 issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	393	300
Additional paid-in capital	908,457	754,644
Accumulated deficit	(918,328)	(878,945)
Total stockholders' deficit	(9,478)	(124,001)
Total liabilities and stockholders' equity (deficit)	\$ 239,306	\$ 181,610

TherapeuticsMD, Inc.
Consolidated Statements of Operations
(Uunaudited - in thousands, except per share data)

	Three Months Ended		
	March 31, 2021	2020	December 31, 2020
Product revenue, net	\$ 19,632	\$ 12,251	\$ 22,577
License revenue	234	—	—
Total revenue, net	19,866	12,251	22,577
Cost of goods sold	4,687	2,715	5,581
Gross profit	15,179	9,536	16,996
Operating expenses:			
Selling, general and administrative	42,407	57,189	49,210
Research and development	2,050	3,269	2,394
Total operating expenses	44,457	60,458	51,604
Loss from operations	(29,278)	(50,922)	(34,608)
Other (expense) income:			
Interest expense and other financing costs	(10,227)	(6,262)	(7,613)
Other income, net	122	335	133
Other (expense), net	(10,105)	(5,927)	(7,480)
Loss before income taxes	(39,383)	(56,849)	(42,088)
Provision for income taxes	—	—	—
Net loss	\$ (39,383)	\$ (56,849)	\$ (42,088)
Loss per common share, basic and diluted	\$ (0.11)	\$ (0.21)	\$ (0.15)
Weighted average common shares, basic and diluted	347,219	271,460	286,607

TherapeuticsMD, Inc.
Consolidated Statements of Cash Flows
(Uunaudited - in thousands, except per share data)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (39,383)	\$ (56,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,019	1,008
Charges (credits) to provision for doubtful accounts	230	(123)
Inventory charge	502	136
Debt financing fees	1,272	320
Non-cash operating lease expense	216	352
Share-based compensation	2,957	2,366
Impairment of other intangible assets and operating lease	—	—
Changes in operating assets and liabilities		
Accounts receivable	(1,567)	3,855
Inventory	145	(2,883)
Prepaid and other current assets	(817)	4,436
Other assets	—	—
Accounts payable	(10,758)	9,533
Accrued expenses and other current liabilities	7,804	(1,262)
Total adjustments	1,003	17,738
Net cash used in operating activities	<u>(38,380)</u>	<u>(39,111)</u>
Cash flows from investing activities:		
Payment of patent related costs	(375)	(422)
Purchase of fixed assets	(63)	(21)
Net cash used in investing activities	<u>(438)</u>	<u>(443)</u>
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	150,899	—
Proceeds from exercise of options and warrants	50	72
Repayments of debt	(50,000)	—
Borrowings of debt	—	50,000
Payment of debt financing fees	(5,000)	(1,250)
Net cash provided by financing activities	<u>95,949</u>	<u>48,822</u>
Net increase in cash	57,131	9,268
Cash, beginning of period	80,486	160,830
Cash, end of period	\$137,617	\$170,098
Supplemental disclosure of cash flow information Interest paid	<u>\$ 8,955</u>	<u>\$ 5,893</u>

Investor Contacts

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TherapeuticsMD®

For Her. For Life.

Building the Premier Women's Health Company

1Q 2021 Earnings

May 6, 2021



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 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®, and BIJUVA® 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 minimum net revenue and minimum cash covenants; whether the company will be able to successfully divest its vitaCare business and how the proceeds that may be generated by such divestiture will be used; 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 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 ability to grow the company's vitaCare business; 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.

Summary of Q1 Performance

Strong execution in the first quarter aligned with operating plan to drive shareholder value

ANNOVERA

- Remains #1 priority in portfolio
- Refined commercial strategies to address both short and long-term impacts from COVID-19
- New patents improve durability and exclusivity to June 2039

MENOPAUSE FRANCHISE

- Highest net revenue per unit for both IMVEXXY and BIJUVA
- Won appeal with FDA for low dose 0.5/100 BIJUVA

vitaCare Prescription Services

- Divestiture process continues to unlock shareholder value
- 2 new customers go live plus strong pipeline with approximately 20 potential customers
- Continue to build foundation to become free-standing entity in a rapidly growing sector with no clear market leader

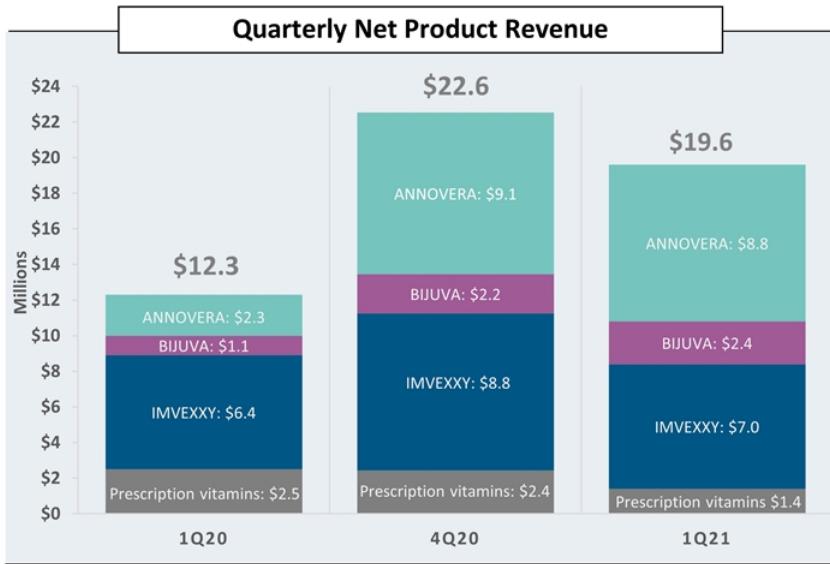


1Q21 Financial Overview

FOR INVESTOR PRESENTATION PURPOSES ONLY.

4

Quarterly Net Revenue Trends



Total net product revenue may not add due to rounding.

(1) Average net revenue per unit calculated based on units sold to wholesalers and pharmacies divided into net revenue for the quarter.

1Q21 Highlights

- Total net product revenue increased 60% 1Q21 vs 1Q20
- ANNOVERA net revenue increased 285%
 - Average net revenue per unit \$1,071⁽¹⁾
- IMVEXXY net revenue increased 10%
 - Average net revenue per unit \$61⁽¹⁾
- BIJUVA net revenue increased 120%
 - Average net revenue per unit \$69⁽¹⁾
- Improved net revenue per unit 13% for IMVEXXY and 33% for BIJUVA in 1Q21 versus 4Q20
- Menopausal franchise has historically retracted in 1Q versus 4Q due to high deductible and copay resets

Financial Results: Comparison 1Q 2021 to 4Q 2020 and 1Q 2020

Comparison of Key Financial Statement Items [in 1,000's]

	1Q21	4Q20	1Q20
<u>Balance Sheet⁽¹⁾</u>			
Cash	\$137,617	\$80,486	\$170,098
Debt	\$183,970	\$237,698	\$243,429
<u>Income Statement</u>			
Net Product Revenue	\$19,632	\$22,577	\$12,251
Gross Profit from Products	\$14,945	\$16,996	\$9,536
Gross Margin %	76%	75%	78%
Total Operating Expenses	\$44,457	\$51,604	\$60,458
Net loss	(\$39,383)	(\$42,088)	(\$56,849)
<u>Statement of Cash Flow</u>			
Net Cash Used In Operating Activities	(\$38,380)	(\$30,357)	(\$39,111)

- Reduced debt to \$184M by a \$50M cash payment
- Gross Margin of 76%
 - Impacted by write-offs of production related costs for ANNOVERA of \$0.9M
- Reduced operating expenses by \$16M to \$44.5M as compared to 1Q20
- Net cash used in operating activities decreased to \$38.4M

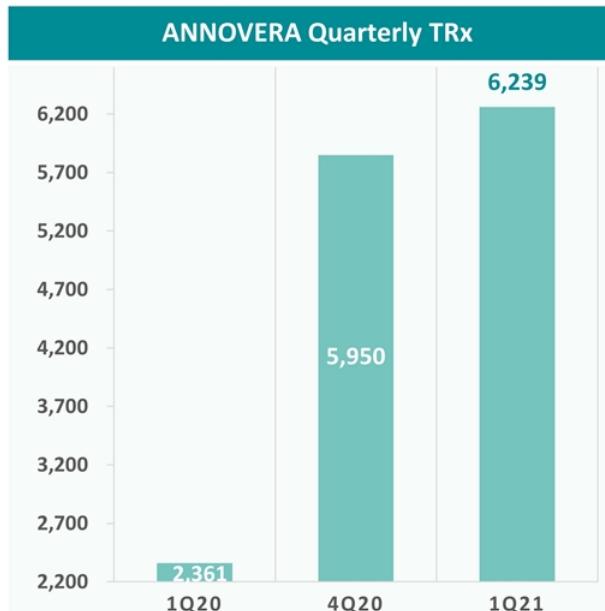
(1) Balance Sheet as of quarter end.



ANNOVERA: Unique Opportunity to Create a New Segment within Birth Control

FOR INVESTOR PRESENTATION PURPOSES ONLY.

ANNOVERA TRX: Continued Growth Through COVID-19



Source: Prescription data per Symphony Health PHAST Data.

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1Q21 Key Metrics

- 164% YOY and 5% QOQ TRx growth
- Net revenue per unit at \$1,071
 - Expect annual net revenue per unit to average ~\$1,100 for the year
- ~17% increase in prescribers with a prescription in 1Q21 compared to 4Q20 (~3,160 vs ~2,700)
- Refill rates remain at ~50%

FOR INVESTOR PRESENTATION PURPOSES ONLY.

ANNOVERA Creating a New Procedure Free Long-Acting Segment

New messaging focuses on long-acting procedure free alternative to IUD is attracting previous IUD users

	Q4 2020	Q1 2021
Oral Contraception	22%	22%
NuvaRing & Generics	53%  43%	
Injection/Patch	13%	11%
IUD/Implant	8%  18%	
New to Birth Control	5%	6%

The majority of ANNOVERA patients are new to rings

Source: vitaCare patient survey data.

TherapeuticsMD®

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Payor Update: Progress In Spite of Express Scripts (ESI) Formulary Removal

		Coverage April 21, 2021
	Commercial	57% UR, 66% ⁽¹⁾
	Medicaid	56% ⁽²⁾
	Department of Defense	On Formulary
	Commercial	75%
	Part D	37%+ ⁽³⁾
	Commercial	78%

Recent changes to access:

- Effective April 1st, 2021, ESI replaced branded contraceptives with generics on formulary and placed branded contraceptives on the drug exclusion list. This included ANNOVERA.
- ESI patients continue to receive ANNOVERA when their prescribers submit Letters of Medical Necessity (LMN) through the protection of the Affordable Care Act (ACA)

Source: MMIT as of April 2021.

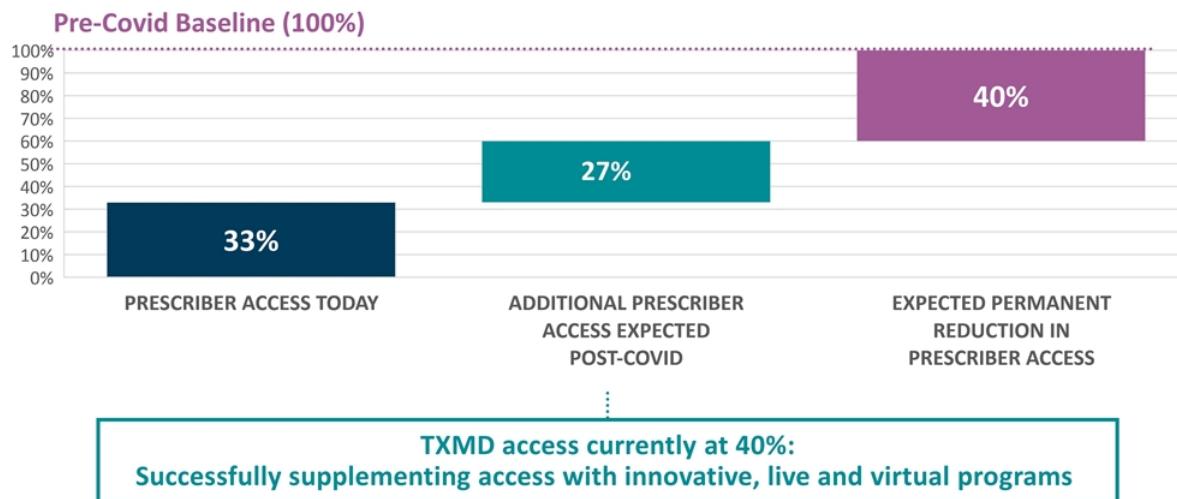
Note: (1) 66% covered with prior authorization (PA) / step edit; UR=unrestricted. (2) ANNOVERA Medicaid Note: estimated coverage will increase from 40% in April to ~56% on when MediCal controls all the Medicaid Managed Care formularies in California. (3) Includes lives with PA to indication only. (4) https://www.express-scripts.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf, Accessed 4/29/2021.

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Prescriber Access Still an Ongoing Challenge, but COVID-19 Headwinds Beginning to Recede

HCPs believe in-person visit volume may double from current levels within a year, but a sizeable gap to pre-COVID levels will continue



NRx Trend of Recently Launched Mass Market Product Volumes

COVID's impact on recently launched brands

Brand Name	Indication	Mar-21	Feb-21	Jan-21	Dec-20
ANNOVERA	Contraception - TXMD	2,145	1,724	1,770	1,728
Phexxi	Contraception	4,282	2,446	1,819	1,612
Twirla	Contraception	623	430	270	104
Slynd	Contraception	14,726	12,077	12,388	11,923
Orilissa	Endometriosis	5,918	5,125	5,420	5,668
Solosec	Bacterial Vaginosis	2,867	2,461	2,817	3,378
Aklief	Acne	15,000	11,668	12,631	14,332
Winlevi	Acne	14	15	5	
Klisyri	Actinic Keratosis	733	48		
Dayvigo	Insomnia	8,772	6,892	6,396	6,332
Nexletol	Cholesterol	3,829	3,112	2,963	2,947
Nurtec ODT	Migraine	36,644	30,904	30,460	32,413
Reyvow	Migraine	1,837	1,539	1,430	1,620
Vyepti	Migraine	78	48	28	55
Ubrelvy	Migraine	44,480	35,690	35,350	38,850
Rhopressa	Elevated Eye Pressure	14,841	12,020	13,226	14,020
Rocklatan	Elevated Eye Pressure	9,378	7,812	8,358	8,714

Symphony Health National Level Data.
All trademarks are property of their respective owners.

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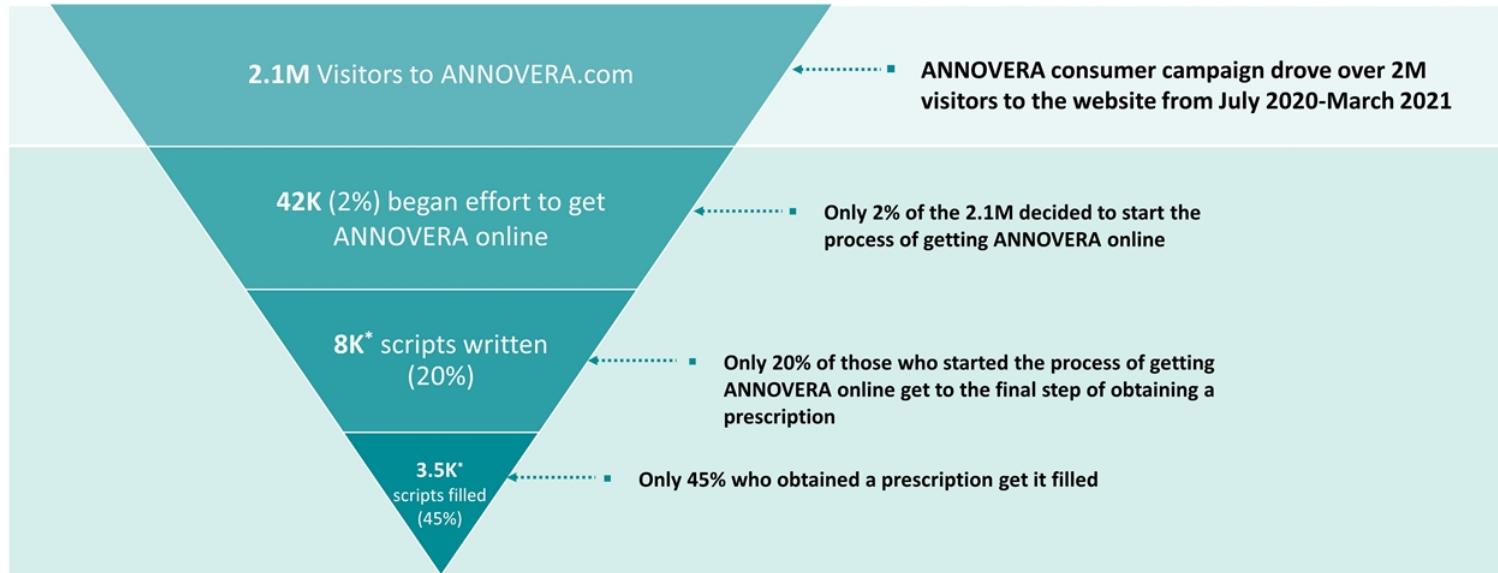
COVID-19 Constraints Accelerated New Ways to Engage with Consumers

- COVID-19 challenges have created a faster shift to technology solutions
 - Increasing breadth of telemedicine solutions and services for patients
- Digital allows for fast data, learning and adaptation
- Capability built across organization in change management
 - "Fast" pilot, pivot, production

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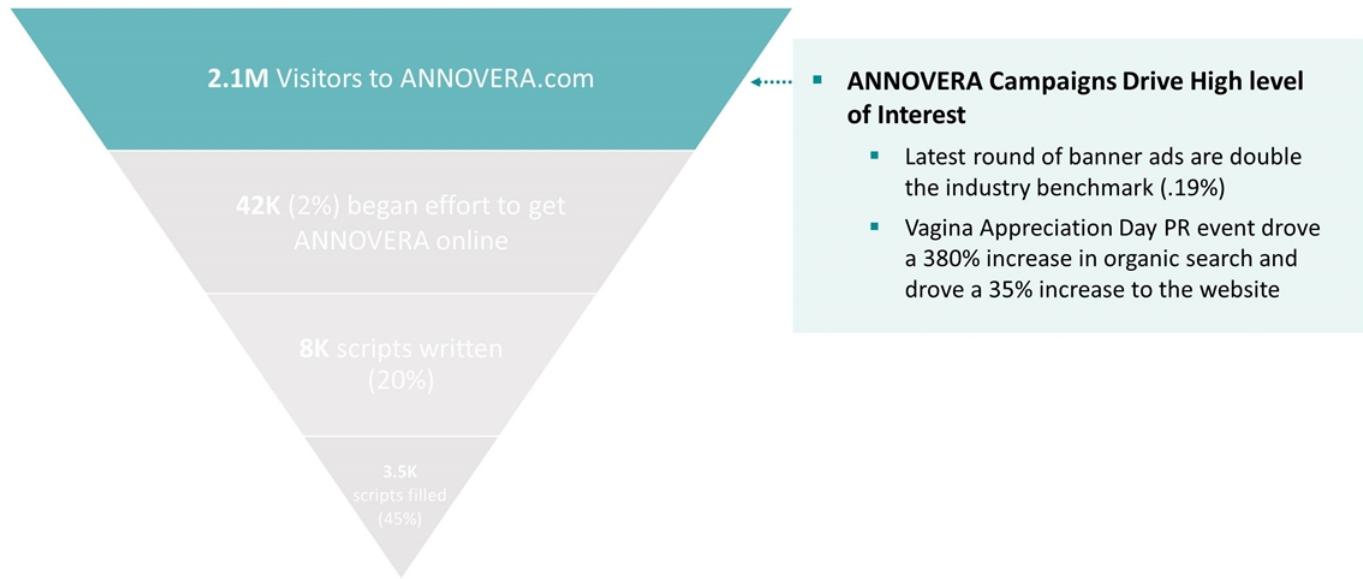
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ANNOVERA's Attributes Create Significant Interest with Consumers, but Access to Patients Remains Difficult

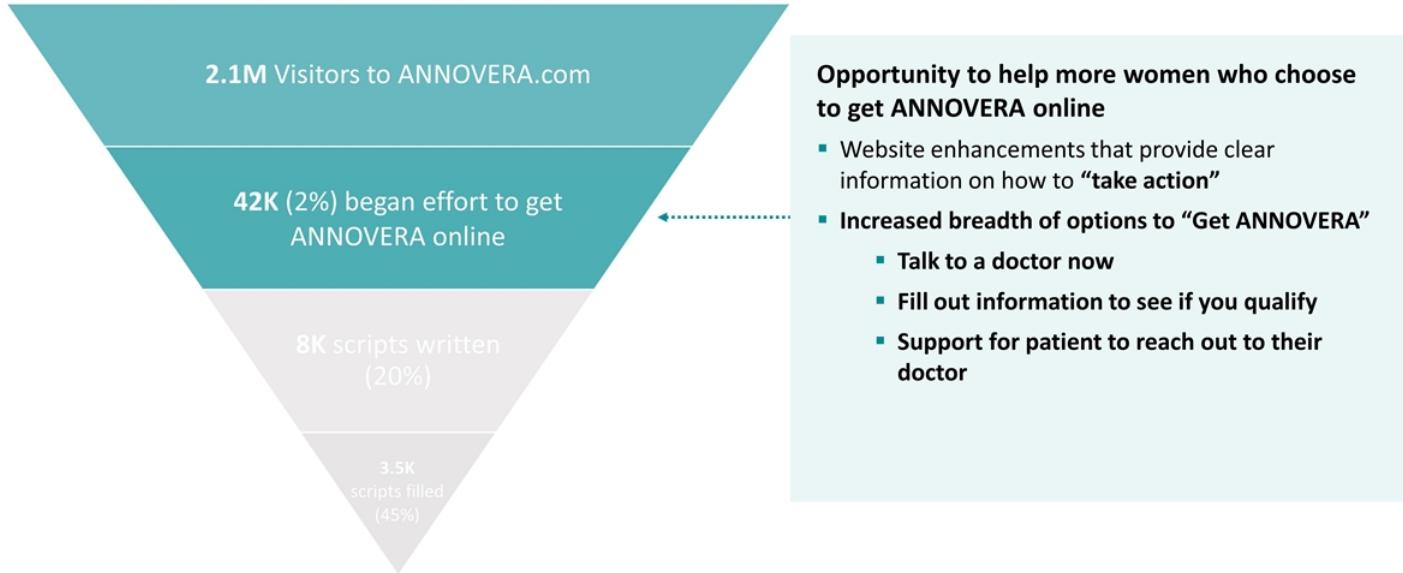


*Reflects single-source data transformed to reflect full digital business from July 2020 to March 2021

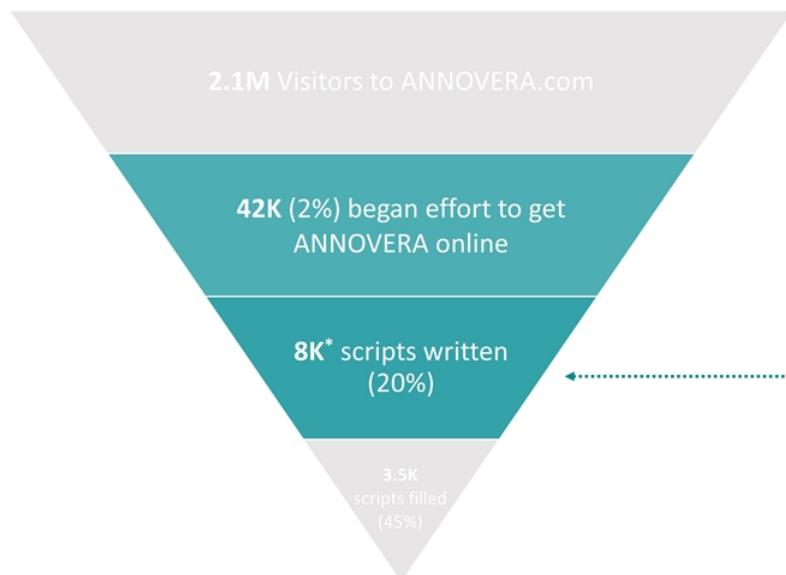
Goal: Translate Significant Interest into Increased Consumers that can Access ANNOVERA



Goal: Increase Breadth of Options for Consumers to Access ANNOVERA



Goal: Improve Rate of those that Receive a Prescription

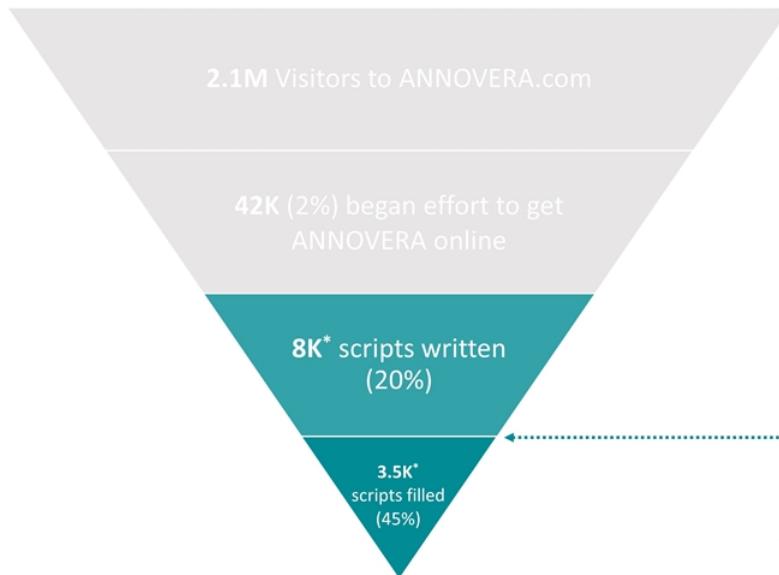


Opportunity to help more women who want ANNOVERA actually receive a prescription

- Telehealth improving each quarter: 30% increase in prescriptions from telehealth quarter over quarter, the fastest growing channel for ANNOVERA
- Increase dependent on breadth of options and efficiency of the process
- In Q1, pilot programs demonstrated ability to help more women who wanted ANNOVERA receive a prescription; program is now being expanded

*Reflects single-source data transformed to reflect full digital business from July 2020 to March 2021

Goal: Increase the Fill Rate Once a Prescription is Written



Opportunity to increase from ~45%

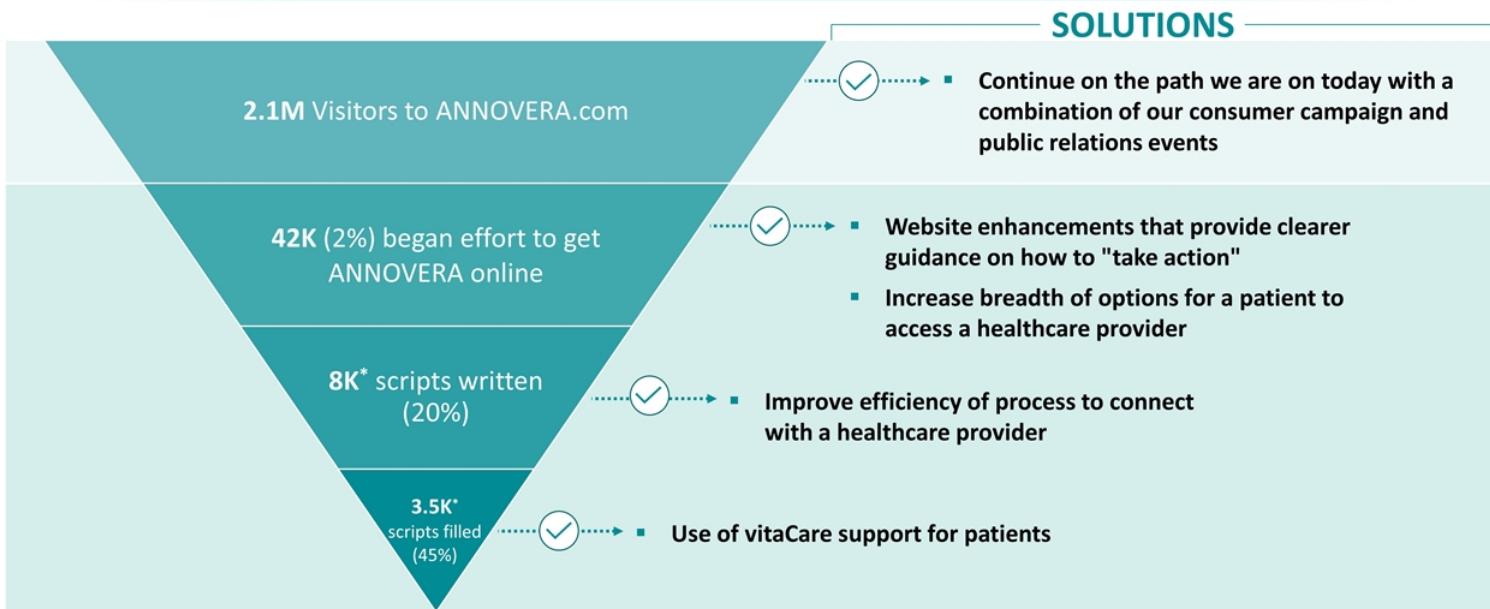
- Reasons for drop off are cost/coverage issues
- Industry fill rate average is ~50%
- With vitaCare support, before sending to a retail/mail order pharmacy, the fill rate is ~70% for IMVEXXY/BIJUVA

Solution: Use of vitaCare to support patients receiving an ANNOVERA Prescription

- Launched April 13th

*Reflects single-source data transformed to reflect full digital business from July 2020 to March 2021

ANNOVERA Solutions to Grow Access to Patients



*Reflects single-source data transformed to reflect full digital business from July 2020 to March 2021

ANNOVERA Intellectual Property

ANNOVERA's exclusivity position has significantly improved over the last 12 months

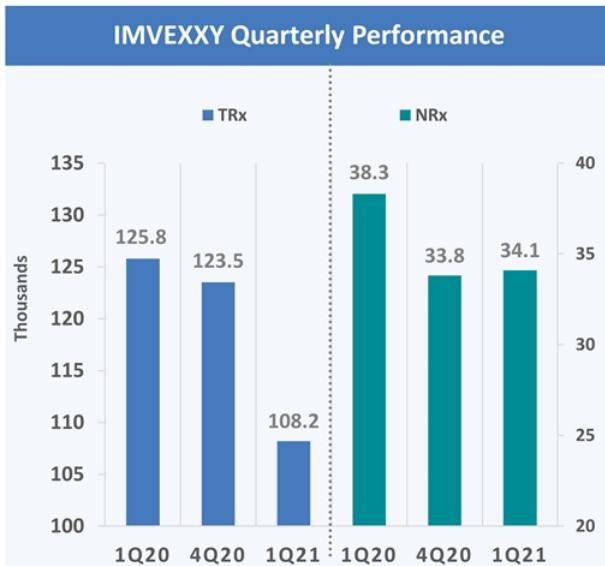
- Three new patent issuances in 2021 that offer improved strategic value and durability
- Further patent work is on-going
- Six patents listed in the Orange Book
- Most recent patents extend patent exclusivity from February of 2039 to June 2039



IMVEXXY: Fastest Growing Branded Product in Vulvar and Vaginal Atrophy Category

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IMVEXXY Performance Drivers



Source: Prescription data per Symphony Health PHAST Data.

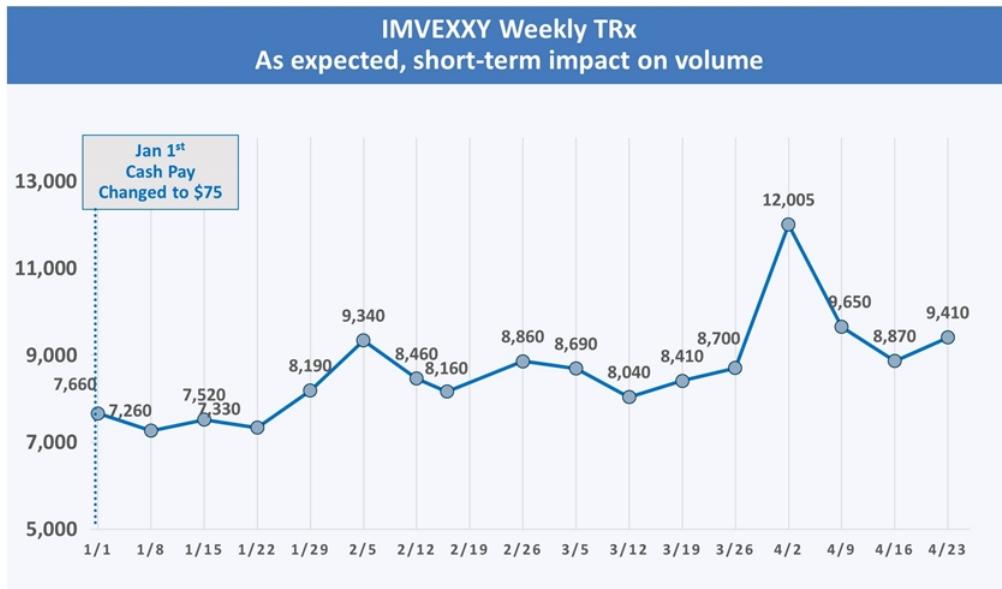
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IMVEXXY 1Q21 Performance

- IMVEXXY volume trends across the past year aligned with VVA market
- Loss of TRx Q1 vs. Q4 due to cash pay shift
 - 1Q historically lower than 4Q due to the impact of high deductible insurance plans resetting
- Net revenue per unit improved to \$61 offsetting volume losses
 - Expect annual blended net price to be in a range of ~\$65 to ~\$75 average for 2021
- ~2% increase in prescribers writing a prescription in 1Q21 compared to 4Q20 (~13,745 vs ~13,500)
- Average of ~6 fills per patient annually

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2021 IMVEXXY Strategic Initiatives: Status Update



Data Source: Prescription data per Symphony Health PHAST Data.



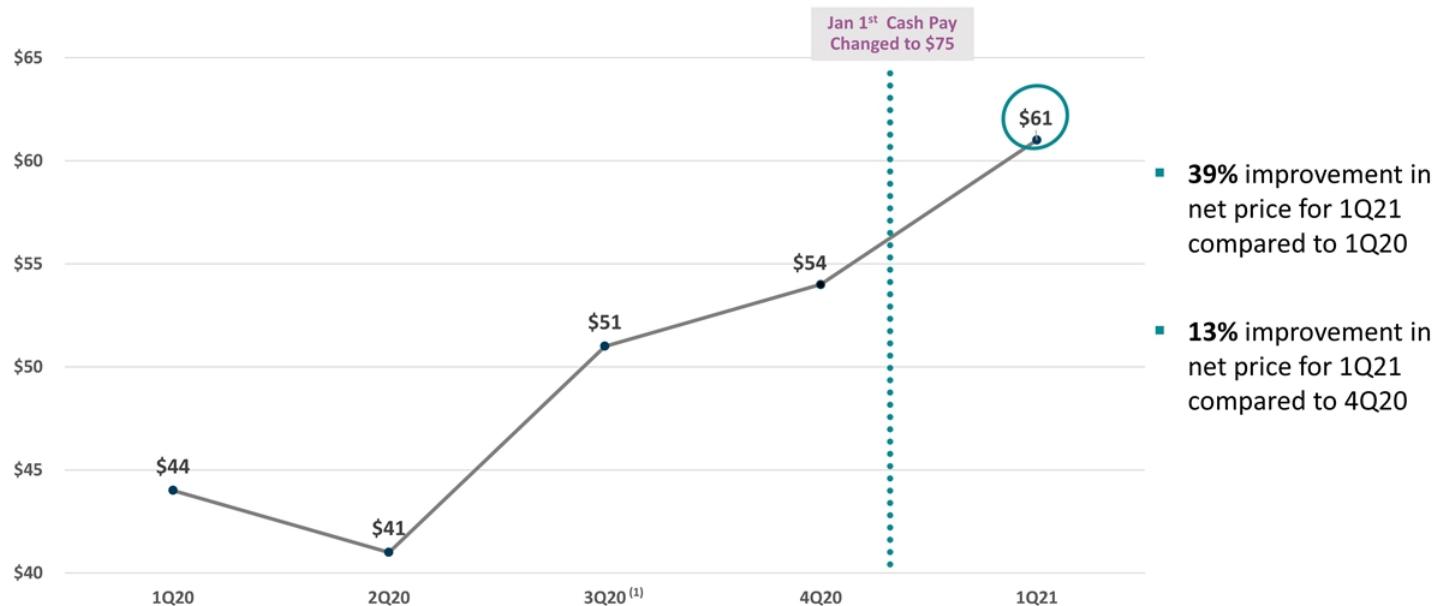
Realize Higher Net Pricing

- IMVEXXY back to strong growth post cash pay change

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IMVEXXY Net Price Build Shows Improvement

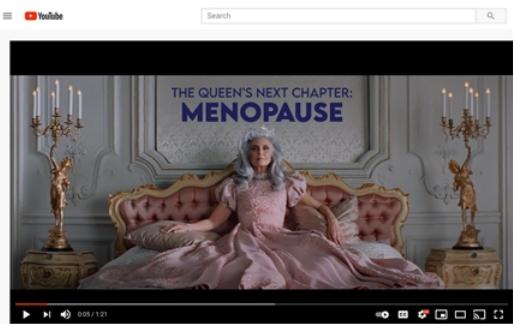


¹ Average net revenue per unit calculated based on units sold to wholesalers and pharmacies divided into net revenue for the quarter. Effective 1Q20, this reflects a change in methodology from previous "calculated net revenue per unit" which used units sold to patients in the quarter.

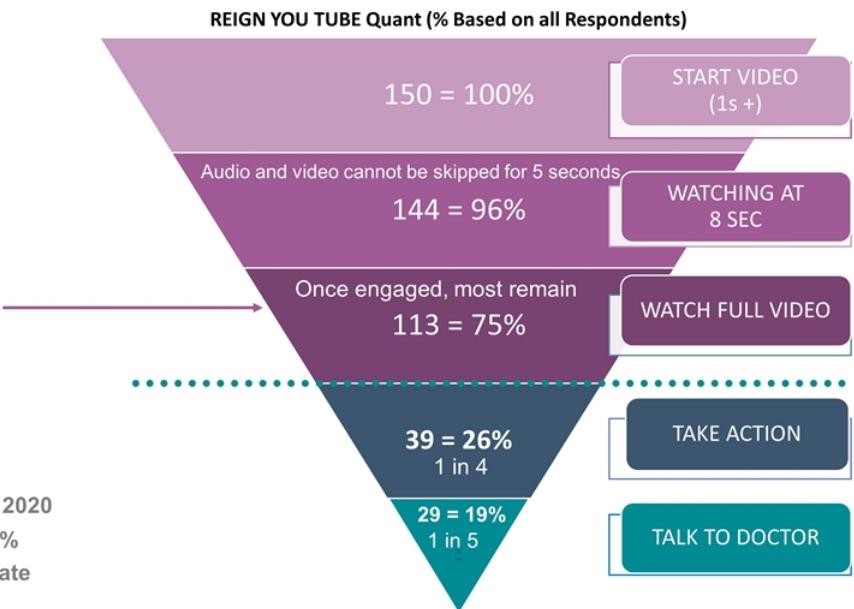
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Consumer Campaign, Reign Launched April 26th



IMVEXXY Campaign Quantitative Test, N=150, Oct. 2020
August-September 2020 Results. Display CTR 0.08%
CTR: Click through rate. VCR: Video Completion Rate

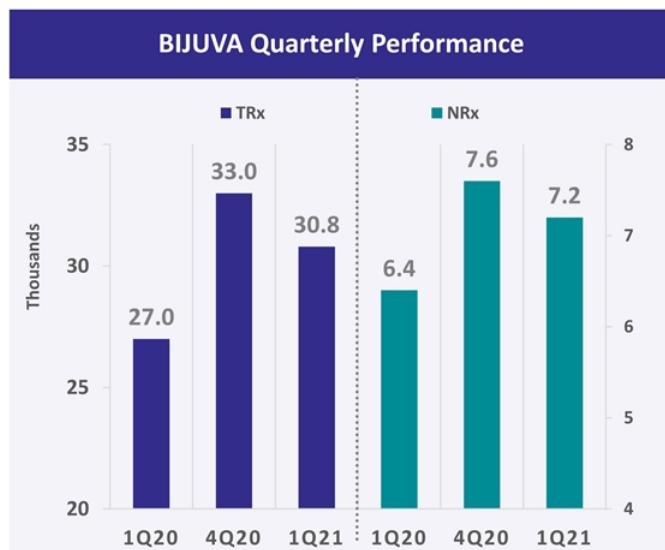




BIJUVA: First and Only FDA-Approved Bio-Identical Solution in Vasomotor Symptoms (VMS) Market

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BIJUVA Volume Increased YoY with Limited Focus



Data Source: Prescription data per Symphony Health PHAST Data.

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BIJUVA 1Q21 Trends

- Loss of TRx due to copay shift that is now rebounding
- ~3% increase in prescribers writing a prescription in 1Q21 compared to 4Q20 (~4,900 vs ~4,750)
 - 1Q historically lower than 4Q due to the impact of high deductible insurance plans resetting
- Net revenue per unit improved to \$69
- Targeted approach with supporting Bio-Ignite to maintain brand loyalists with 7 sales representatives

- Formal Dispute Resolution Request granted by FDA

- **APPEAL GRANTED**

- “Study TXC12-05 has provided sufficient data for approval of the 0.5 mg/100 mg dose of Bijuva”
 - “Sufficient evidence from other data provided in your original NDA”

- Type B meeting scheduled on 05/12/2021 to discuss:

- Resubmission and label discussions

Key Takeaways

- Improved cash position
- Lowered debt by \$50M
- Increased revenue growth while significantly lowering operating expenses by \$16.0M YOY
- Record nets per unit for menopausal products
- vitaCare process continues and strong execution enhances divestiture value
- TXMD performance aligned with 2021 operating plan
- Goal of achieving EBITDA breakeven on a quarterly basis in 1H22

Q&A



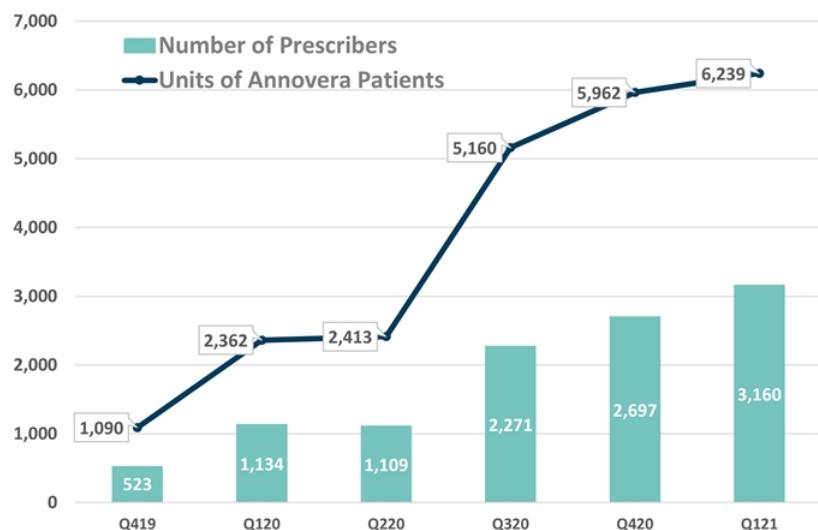
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Appendix



Leading Indicator of Potential Future Growth: ANNOVERA Writers Continue to Grow

Annovera®
(segesterone acetate and
ethynodiol dienoate vaginal system)
Delivers 0.15 mg/0.013 mg per day



Key Takeaways

- Growth across all categories of targets that are sales force driven
- Growth across non-targets that are marketing driven

ANNOVERA Goal: Become a New Segment in Birth Control

Short-Acting Decline

-4.2% CAGR⁽¹⁾



Daily



Weekly



Monthly



3 mo. injection



Annovera®
 (segesterone acetate and
 ethinyl estradiol vaginal system)
 Delivers 0.15 mg/0.013 mg per day

Annual,
 Procedure Free

1 Year



Long-Acting Growth

+15% CAGR⁽¹⁾



3-10 Years



SHORT-ACTING

Market Void

LONG-ACTING

Note: (1) Based on company filings.

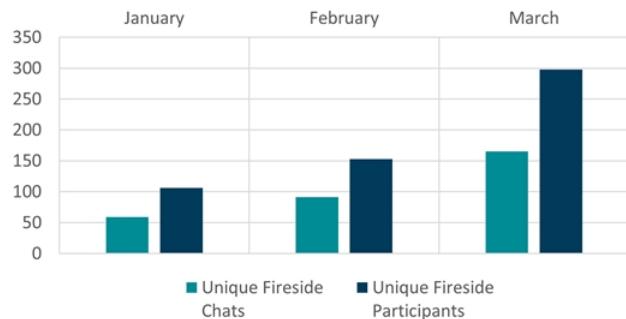
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Goal: Supplement Reach and Frequency of Salesforce to Providers through Innovative Programs

Fireside Chats: Deep Dives on ANNOVERA by qualified Healthcare Providers in conjunction with a sales representative

- Since inception in Q4, ~500 events conducted
- 845 unique HCP attendees
 - 14 self-scheduled events without a representative
- 99 events scheduled for May



Results
<ul style="list-style-type: none">▪ Activation of new prescribers (167)▪ Reactivation of lapsed writers