

**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): August 15, 2022**

TherapeuticsMD

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.

The information provided in Item 7.01 of this Current Report on Form 8-K is incorporated in this Item 2.02 by reference.

Item 7.01 Regulation FD Disclosure.

On August 15, 2022, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2022. In addition, the Company provided a slide presentation for use during its earnings conference call. Copies 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 this Item 7.01 and the information contained in Exhibits 99.1 and 99.2 is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in any such filing, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release from TherapeuticsMD, Inc., dated August 15, 2022, entitled "TherapeuticsMD Announces Second Quarter 2022 Financial Results."
99.2	TherapeuticsMD, Inc. Presentation dated August 15, 2022.
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: August 15, 2022

THERAPEUTICSMD, INC.

/s/ Michael C. Donegan

Michael C. Donegan

Interim Chief Financial Officer, Chief Accounting Officer and Vice President
Finance

TherapeuticsMD Announces Second Quarter 2022 Financial Results

- Quarterly total net revenue of \$28.6 million -
- ANNOVERA® TRx of 9,329, an increase of 28% over Q2 2021 -
- Conference call scheduled for 8:30 a.m. ET today -

BOCA RATON, Fla. – August 15, 2022 – TherapeuticsMD, Inc. (“TXMD” or the “Company”) (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today reported financial results for the Second Quarter ended June 30, 2022.

“We saw solid revenue growth during the quarter, with an increase of 24% over the prior year period, while also experiencing a 21% decrease in operating expenses. The U.S. Food and Drug Administration’s recent approval of our supplemental new drug application for ANNOVERA has significantly enhanced our ability to meet demand for the product. We were also able to repay \$120 million dollars of debt with the proceeds of our successful divestiture of our vitaCare unit,” said Hugh O’Dowd, CEO of TherapeuticsMD.

“With these initiatives and accomplishments behind us, the Company can better focus on our mission of advancing the healthcare of women throughout all stages of life,” concluded O’Dowd.

Second Quarter 2022 Financial Results and Business Highlights

	Three Months Ended June 30,			
	2022		2021	
Product revenue:				
ANNOVERA	\$	18,271	\$	9,555
IMVEXXY		6,667		9,838
BIJUVA		2,654		2,156
Prescription vitamin		904		1,402
Product revenue, net		28,496		22,951
License and service		65		50
Total revenue, net	\$	28,561	\$	23,001

ANNOVERA® (segesteron acetate and ethinyl estradiol vaginal system)

- ANNOVERA net product revenue of \$18.3 million for the Second Quarter of 2022 increased by approximately \$8.7 million compared to \$9.6 million for the Second Quarter of 2021.
- 9,329 ANNOVERA prescriptions were dispensed to patients during the Second Quarter of 2022.
- Over 13,000 healthcare providers (HCPs) prescribed ANNOVERA during the Second Quarter, of which 1,487 were new writers.
 - o Growth in total prescribers of approximately 65% over Second Quarter of 2021.

IMVEXXY® (estradiol vaginal inserts)

- IMVEXXY net product revenue of \$6.7 million for the Second Quarter of 2022 decreased by \$3.2 million compared to \$9.8 million for the Second Quarter of 2021.
- Approximately 97,881 IMVEXXY prescriptions were dispensed to patients during the Second Quarter of 2022.

BIJUVA® (estradiol and progesterone) capsules

- BIJUVA net product revenue of \$2.7 million for the Second Quarter of 2022 increased by approximately \$0.5 million compared to \$2.2 million for the Second Quarter of 2021.
- BIJUVA net product revenue for the Second Quarter of 2022 includes \$0.3 million of export sales through our international licensing and supply agreement with Theramex HQ UK Limited.

Cost of Goods Sold and Gross Margin

- Cost of goods was \$4.7 million with product gross margin of 83% for the Second Quarter of 2022 compared to \$4.1 million with product gross margin of 82% for the Second Quarter of 2021. The increase in product gross margins was mainly due to changes in product sales mix, including increased sales volumes for ANNOVERA and BIJUVA, and a decrease in sales volume of IMVEXXY.

Operating Expense, Net Loss and Related Information

- Total operating expense of \$42.7 million for the Second Quarter of 2022 decreased by \$11.4 million compared to \$54.1 million for the Second Quarter of 2021.
- Net income for the Second Quarter of 2022 was \$112.3 million, or \$12.83 per basic and \$12.39 per diluted share, compared to net loss for the Second Quarter of 2021 of \$42.7 million, or \$5.41 per basic and diluted share. Included in the net income for the Second Quarter of 2022 was a \$143.4 million gain recognized from the sale of vitaCare and other non-operating expenses of \$11.7 million, an increase of \$4.2 million, or 56.7%, compared to non-operating expenses of \$7.5 million for the second quarter of 2021. This increase was a result of higher amortization of deferred financing costs, offset by lower interest expense due to lower average debt balance, and lower interest prepayment fees due to the March 2022 amendment to our financing agreement.

Balance Sheet

- As of June 30, 2022, the Company's cash on hand totaled \$26.3 million, compared with \$65.1 million as of December 31, 2021. The Company also had \$11.3 million in restricted cash related to customary holdbacks as part of the vitaCare divestiture.
- As of June 30, 2022, the remaining outstanding principal amount under the Company's Financing Agreement was \$90.8 million, which reflects a repayment of \$125.0 million of principal during 2022.

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:	Monday, August 15, 2022
Time:	8:30 a.m. ET
Audio Conference Line	https://register.vevent.com/register/B17d111b66df2f4e8f849bb6048c1fa4d1
Webcast Link:	https://edge.media-server.com/mmc/p/trnoknyx

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 in the "Investors & Media" section of the TherapeuticsMD website at www.therapeuticsmd.com.

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 (segesterone acetate and ethinyl estradiol 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: whether the company will be able to refinance the indebtedness under its term loan facility, and, if not, whether the company will be able to continue as a going concern; whether the company will be able to raise capital to fund its operations; whether and how the executive order on contraception is implemented; 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; the effects of supply chain issues on the supply of the company's products; 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 company's ability to protect its intellectual property; 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 impact of leadership transitions; and the volatility of the trading price of the company's common stock.

- Financial Statements to Follow -

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

	June 30, 2022	December 31, 2021
Assets:		
Current assets:		
Cash	\$ 26,303	\$ 65,122
Restricted cash	11,250	—
Accounts receivable, net of allowance for credit losses of \$1,587 and \$1,334 as of June 30, 2022 and December 31, 2021, respectively	45,804	36,176
Inventory	6,150	7,622
Prepaid and other current assets	9,096	10,548
Total current assets	98,603	119,468
Fixed assets, net	710	1,199
License rights and other intangible assets, net	38,721	40,318
Right of use assets	7,914	8,234
Other non-current assets	254	253
Total assets	\$ 146,202	\$ 169,472
Liabilities and stockholders' deficit:		
Current liabilities:		
Current maturities of long-term debt	\$ 90,780	\$ 188,269
Accounts payable	13,978	20,318
Accrued expenses and other current liabilities	59,228	44,304
Total current liabilities	163,986	252,891
Operating lease liabilities	7,728	8,063
Other non-current liabilities	554	2,139
Total liabilities	172,268	263,093
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, par value \$0.001; 10,000 shares authorized, none issued	—	—
Common stock, par value \$0.001; 12,000 shares authorized, 8,860 and 8,598 (adjusted for the 50-for-1 reverse stock split) shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	9	9
Additional paid-in capital	962,025	957,730
Accumulated deficit	(988,100)	(1,051,360)
Total stockholders' deficit	(26,066)	(93,621)
Total liabilities and stockholders' deficit	\$ 146,202	\$ 169,472

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue, net:				
Product	\$ 28,496	\$ 22,951	\$ 47,410	\$ 42,583
License and service	65	50	484	284
Total revenue, net	28,561	23,001	47,894	42,867
Cost of goods sold	4,740	4,132	9,600	8,819
Total gross profit	23,821	18,869	38,294	34,048
Operating expenses:				
Selling and marketing	23,679	32,164	42,574	56,188
General and administrative	17,403	19,873	37,810	38,256
Research and development	1,580	2,011	2,980	4,061
Total operating expenses	42,662	54,048	83,364	98,505
Loss from operations	(18,841)	(35,179)	(45,070)	(64,457)
Other income (expense):				
Gain on sale of business	143,384	—	143,384	—
Loss on extinguishment of debt	—	—	(8,380)	—
Interest expense and other financing costs	(11,696)	(7,596)	(26,108)	(17,823)
Other income, net	(16)	123	(16)	245
Total other income (expense), net	131,672	(7,473)	108,880	(17,578)
Income (loss) before income taxes	112,831	(42,652)	63,810	(82,035)
Provision for income taxes	550	—	550	—
Net income (loss)	\$ 112,281	\$ (42,652)	\$ 63,260	\$ (82,035)
Earnings (loss) per common share, basic	\$ 12.83	\$ (5.41)	\$ 7.29	\$ (11.06)
Weighted average common shares, basic	8,750	7,881	8,682	7,416
Earnings (loss) per common share, diluted	\$ 12.39	\$ (5.41)	\$ 7.05	\$ (11.06)
Weighted average common shares, diluted	9,059	7,881	8,971	7,416

TherapeuticsMD, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(Unaudited - in thousands)

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net income (loss)	\$ 63,260	\$ (82,035)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	2,146	2,061
Charges (credits) to provision for doubtful accounts	542	445
Inventory charge	73	502
Debt financing fees	16,971	2,681
Share-based compensation	4,281	5,467
Gain on sale of business	(143,384)	—
Loss on extinguishment of debt	8,380	—
Other	(15)	434
Changes in operating assets and liabilities:		
Accounts receivable	(10,603)	(1,544)
Inventory	1,399	(83)
Prepaid and other current assets	1,373	365
Accounts payable	(5,591)	(6,503)
Accrued expenses and other current liabilities	16,913	12,940
Other non-current liabilities	(675)	358
Total adjustments	(108,190)	17,123
Net cash used in operating activities	(44,930)	(64,912)
Cash flows from investing activities:		
Proceeds from sale of business, net of transaction costs	142,634	—
Payment of patent related costs	(267)	(423)
Purchase of fixed assets	(20)	(104)
Net cash provided by (used in) investing activities	142,347	(527)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	—	151,062
Proceeds from exercise of options and warrants	—	299
Proceeds from sale of common stock related to employee stock purchase plan	14	134
Repayments of debt	(125,000)	(50,000)
Payment of debt financing fees	—	(5,118)
Net cash (used in) provided by financing activities	(124,986)	96,377
Net (decrease) increase in cash and restricted cash	(27,569)	30,938
Cash and restricted cash, beginning of period	65,122	80,486
Cash and restricted cash, end of period	\$ 37,553	\$ 111,424
Supplemental disclosure of cash flow information:		
Interest paid	\$ 9,137	\$ 14,284
Supplemental disclosure of noncash financing activities:		
Paid in kind ("PIK") debt financing fees with corresponding increase in debt	\$ 15,780	\$ —

CONTACT:

Michael C. Donegan
Interim Chief Financial Officer,
Chief Accounting Officer and
Vice President Finance
561-961-1900

Lisa M. Wilson
In-Site Communications, Inc.
212-452-2793
lwilson@insitecony.com

TherapeuticsMD®



Building the Premier Women's Health Company

Q2 2022 Earnings

August 15, 2022



FOR INVESTOR PRESENTATION PURPOSES ONLY.

Forward-Looking Statements

This presentation 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; how the proceeds from the divestiture of the company's vitaCare business will be utilized; 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 and the company's ability to refinance such facility; the effects of supply chain issues on the supply of the company's products; 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 manufacturing supplement for ANNOVERA; the company's ability to protect its intellectual property, including with respect to the Paragraph IV notice letters the company received regarding IMVEXXY; 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 impact of leadership transitions; the volatility of the trading price of the company's common stock and the concentration of power in its stock ownership.



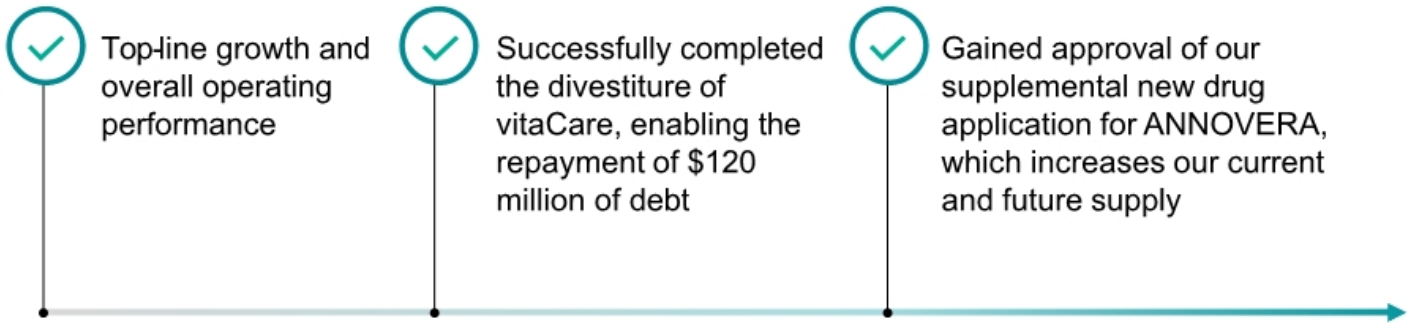
TherapeuticsMD®



Hugh O'Dowd
CEO

FOR INVESTOR PRESENTATION PURPOSES ONLY.

Q2 Accomplishments

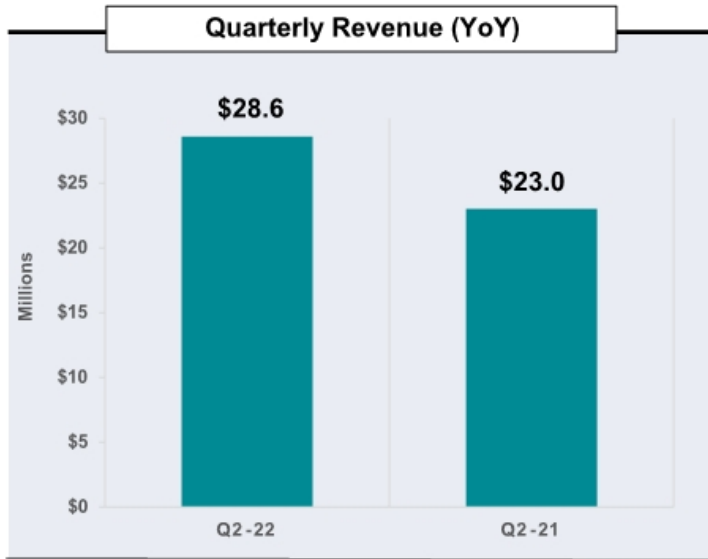




Q2 2022 Financial Overview

FOR INVESTOR PRESENTATION PURPOSES ONLY.

Quarterly Revenue Trends



Q2-22 Highlights

- Total net revenue increased 24% in Q2-22 vs Q2-21
- Total net product revenue increased 24% in Q2-22 vs Q2-21
- ANNOVERA net revenue increased 91% in Q2-22 vs Q2-21 as supply and demand improved
- BIJUVA net revenue increased 23% in Q2-22 vs Q2-21
- IMVEXXY net revenue decreased 32% Q2-22 vs Q2-21

Financial Results: Comparison Q2 2022 to Q2 2021 to Q1 2022

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

	Q2-22	Q2-21
Balance Sheet⁽¹⁾		
Cash	\$ 26,303	\$ 111,424
Debt	\$ 90,780	\$ 185,300
Income Statement		
Net Revenue	\$ 28,561	\$ 23,001
Gross Profit	\$ 23,821	\$ 18,869
Gross Margin %	83%	82%
Total Operating Expenses	\$ 42,662	\$ 54,048
Net Profit / (Loss)	\$ 112,281	\$ (42,652)
Cash Flow		
Net Cash Used In Operating Activities	\$ (15,404)	\$ (26,532)

- In April, \$120M in proceeds from the vitaCare divestiture were used to paydown the debt.
- Gross margin of 83% in Q2-22 is relatively consistent to Q2-21.
- Operating expenses in Q2-22 decreased \$11.4M from Q2-21.
- Net Profit in Q2-22 resulted from the sale of vitaCare. Net Operating Loss;
 - \$18.8M Q2-2022
 - \$35.2M Q2-2021
- Net cash used in operating activities in Q2-22 decreased \$11.1M from Q2-21.

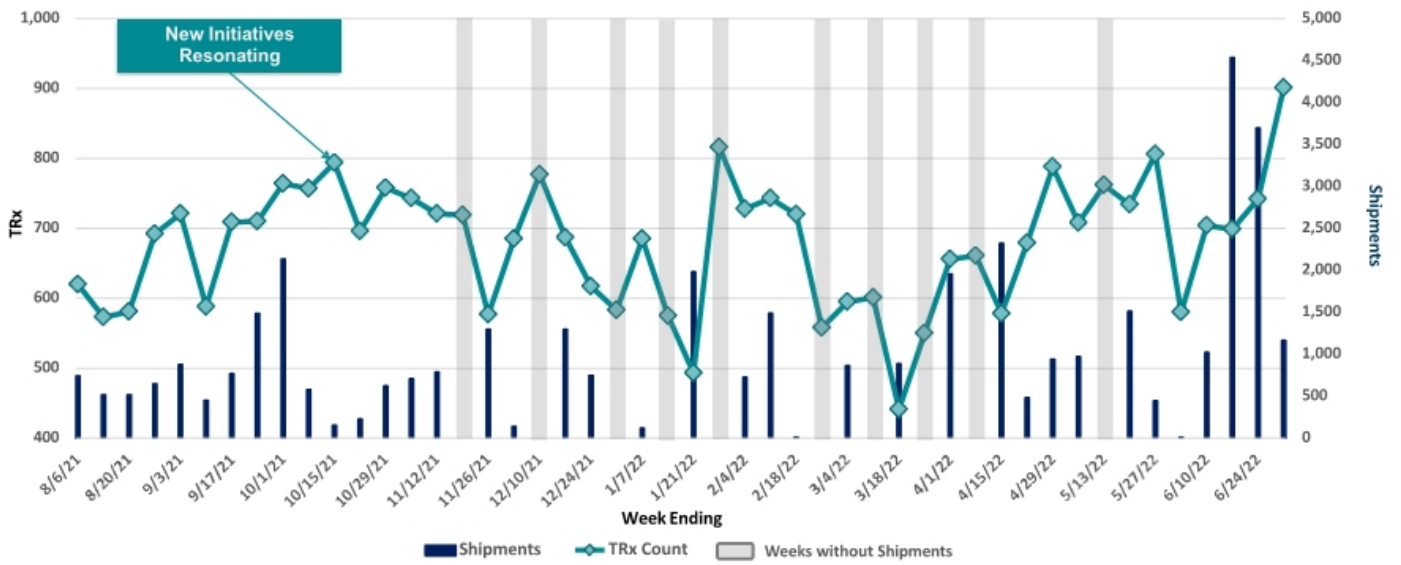
(1) Balance Sheet as of quarter end.



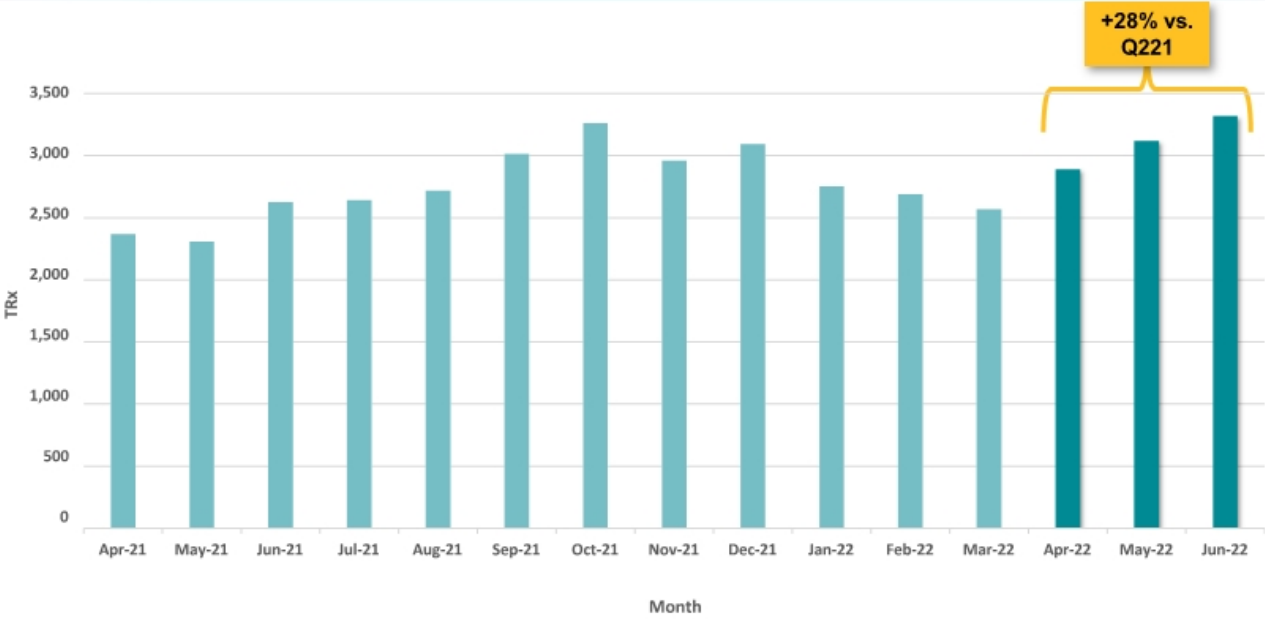
Q2 2022 Commercial Overview

FOR INVESTOR PRESENTATION PURPOSES ONLY.

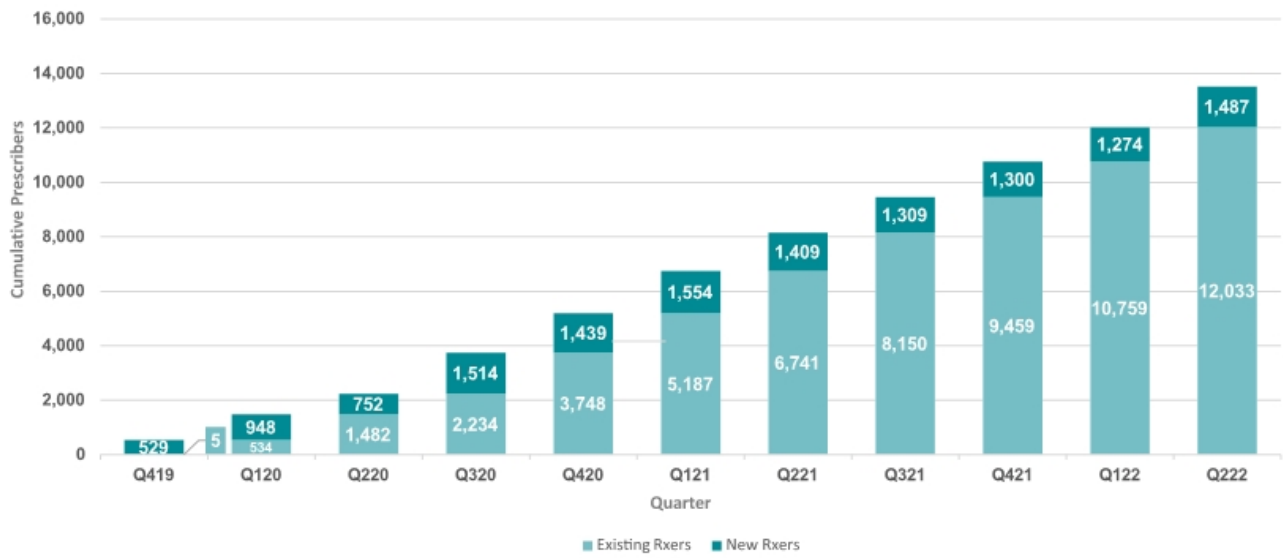
Inventory Impact



ANNOVERA Monthly TRx



ANNOVERA Prescribers: Launch to Date

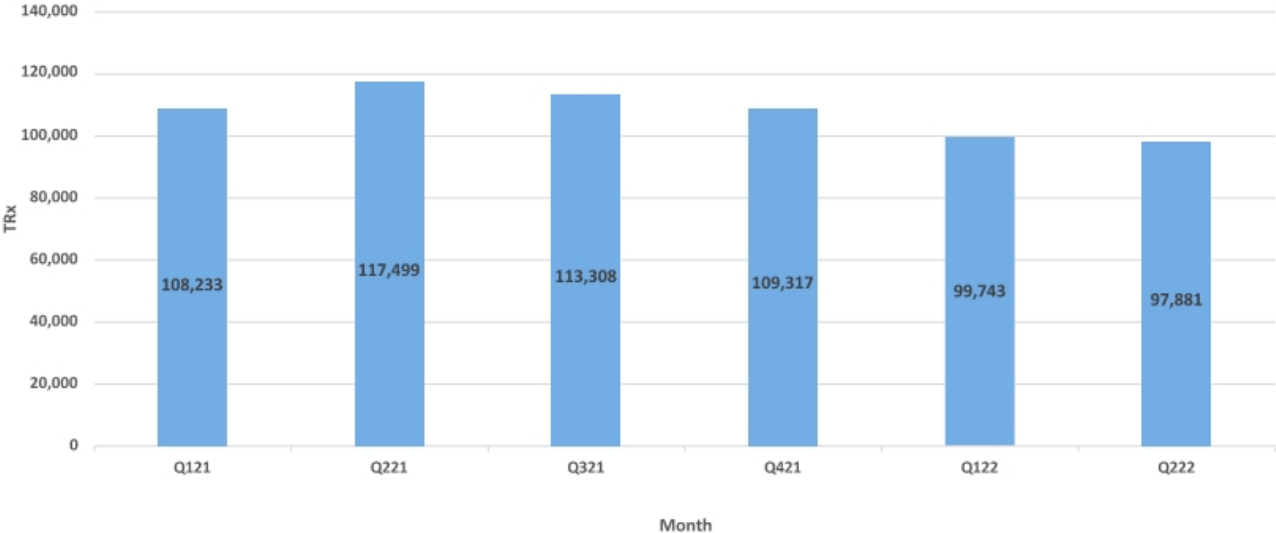


Requests for Administration/Tri-Agencies & Impact for TXMD

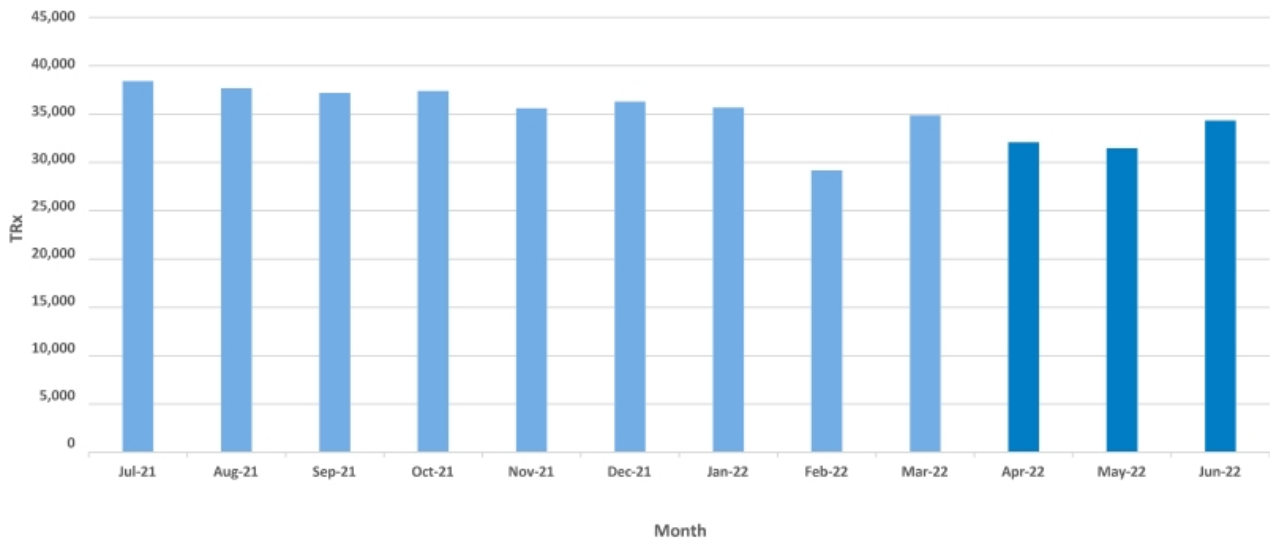
REQUEST	POTENTIAL IMPACT
1 Standardize the forms for the exceptions process	Vast majority of exceptions (LMNs) approved instantaneously <ul style="list-style-type: none">– <i>LMN denials are the greatest burden to Rx fulfillment for ANNOVERA</i>– <i>A standard form and process would almost eliminate denials</i>
2 Greater enforcement is needed <i>Enforce existing requirements and penalties</i>	Enforcement of current legislative language would ensure more Rx fulfillment. <ul style="list-style-type: none">– <i>Payors react to penalties and risk; if they fall in-line, coverage and barriers to fulfillment would immediately decrease</i>
3 Remove reference to FDA-approved methods in HRSA guidelines <i>(after the exceptions process and enforcement are addressed)</i>	If all brands without generic substitution were required to be covered at a \$0 cost share. ANNOVERA would be covered 100% of the time. <ul style="list-style-type: none">– <i>With exception to the religious beliefs clause</i>

IMVEXXY Quarterly TRx

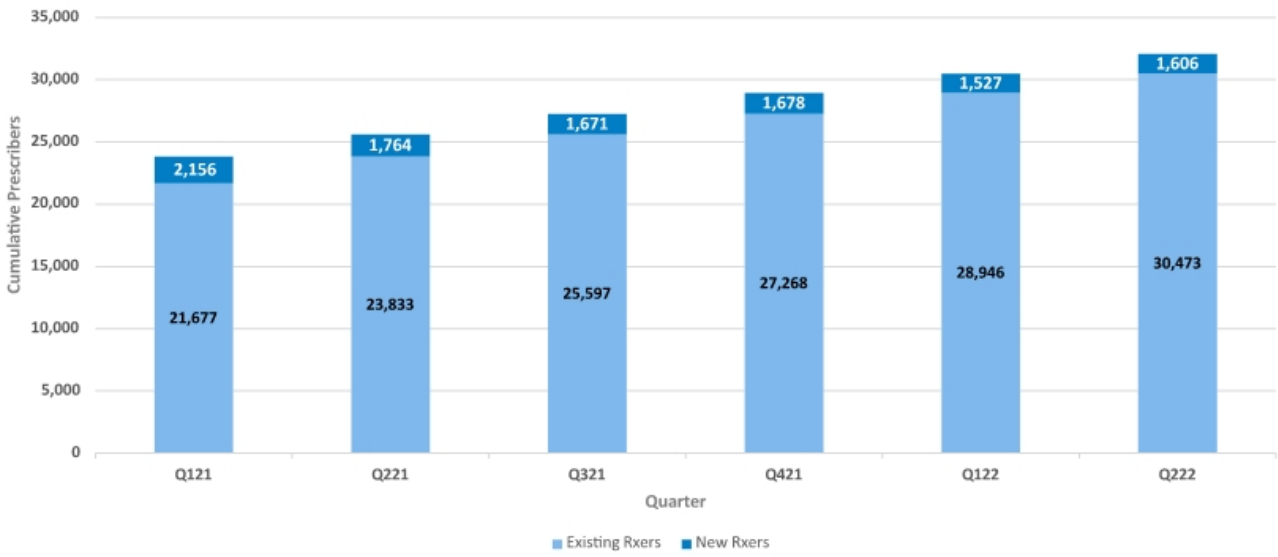
- Held up well considering prioritization on Anovera beginning Q321



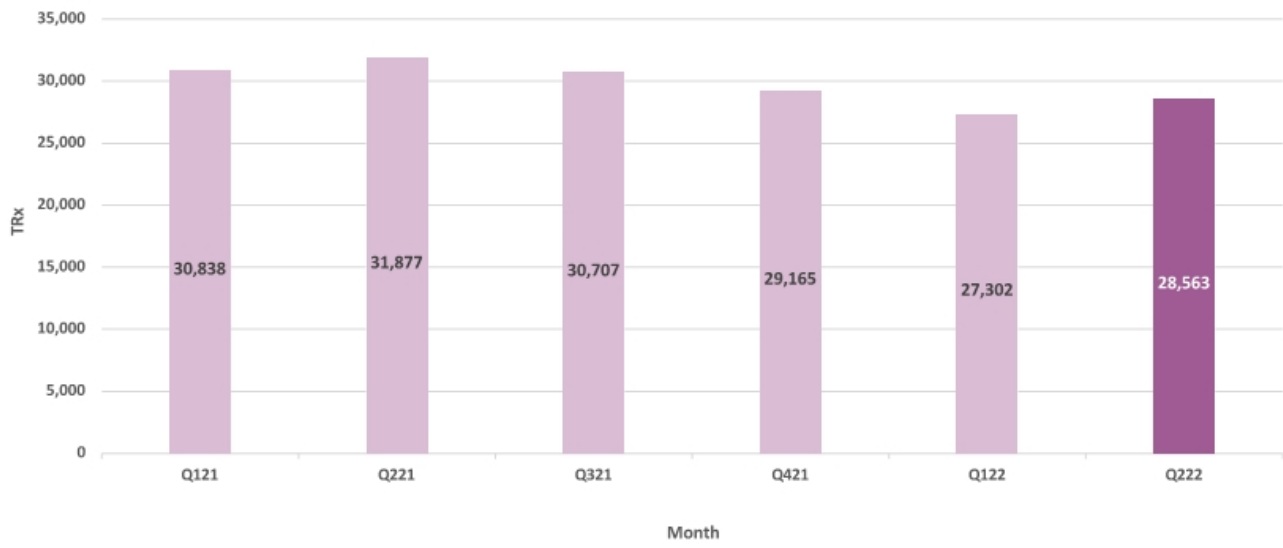
IMVEXXY Monthly TRx



IMVEXXY Prescribers: Launch to Date

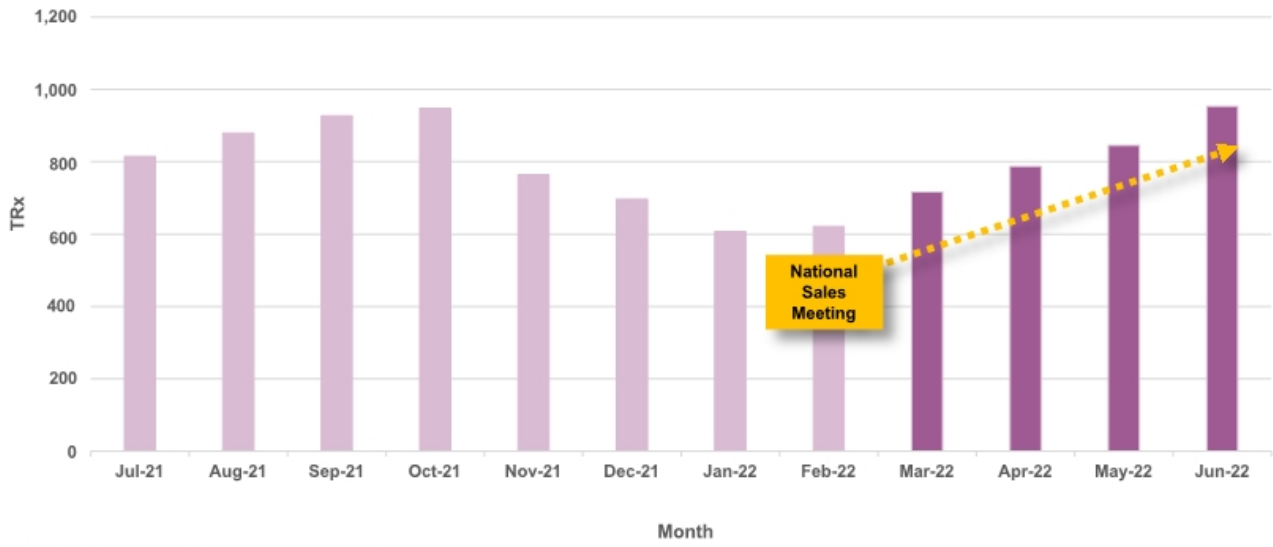


BIJUVA Quarterly TRx



BIJUVA New-to-Brand TRx*

- Growth coincides with targeting strategy change initiated post-NSM



* New to brand includes patient switches/adds and new to market patients



Q&A

