

**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 16, 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 May 16, 2022, the Company issued a press release announcing its financial results for the first quarter ended March 31, 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

<u>Exhibit No.</u>	<u>Description</u>	<u>Exhibit Index</u>
99.1	Press Release from TherapeuticsMD, Inc., dated May 16, 2022, entitled "TherapeuticsMD Announces First Quarter 2022 Financial Results."	
99.2	TherapeuticsMD, Inc. Presentation dated May 16, 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: May 16, 2022

THERAPEUTICSMD, INC.

/s/ Michael C. Donegan

Michael C. Donegan

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

TherapeuticsMD Announces First Quarter 2022 Financial Results

- Quarterly total net product revenue of \$19.3 million -
- ANNOVERA[®] TRx of 8,014, an increase of 27% over Q1 2021 -
- Announced and completed vitaCare divestiture in five weeks -
- Conference call scheduled for 4:30 p.m. ET today -

BOCA RATON, Fla. – May 16, 2022 – TherapeuticsMD, Inc. (“TXMD” or the “Company”) (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today reported financial results for the first quarter ended March 31, 2022.

“Our revenue performance during the quarter was impacted by ANNOVERA manufacturing challenges as anticipated, but we believe these obstacles peaked in the first quarter of 2022 and expect incremental improvement as the year progresses. I’m also pleased to report that the \$150 million divestiture of vitaCare that we announced during the quarter was driven to a successful conclusion, closing just five weeks following the announcement,” said Hugh O’Dowd, CEO of TherapeuticsMD.

“With our increased focus and optimized sales organization, we believe that we will now be able to properly leverage all three of our assets and are confident these products can play a significant role in the marketplace,” concluded O’Dowd.

First Quarter 2022 Financial Results and Business Highlights

	Three Months Ended March 31,	
	2022	2021
Product revenue:		
ANNOVERA	\$ 8,510	\$ 8,750
IMVEXXY	6,969	7,012
BIJUVA	2,560	2,445
Prescription vitamin	875	1,425
Product revenue, net	18,914	19,632
License and service revenue	419	234
Total revenue, net	\$ 19,333	\$ 19,866

ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system)

- ANNOVERA net product revenue of \$8.5 million for the first quarter of 2022 decreased by approximately \$0.3 million compared to \$8.8 million for the first quarter of 2021.
- Approximately 8,014 ANNOVERA prescriptions were dispensed to patients during the first quarter of 2022.
- Over 3,601 healthcare providers (HCPs) prescribed ANNOVERA during the first quarter, of which 1,274 were new writers.
 - Growth in prescribers of approximately 16% over first quarter of 2021.

IMVEXXY[®] (estradiol vaginal inserts)

- IMVEXXY net product revenue of \$7.0 million for the first quarter of 2022 decreased by less than \$0.1 million compared to \$7.0 million for the first quarter of 2021.
- Approximately 99,743 IMVEXXY prescriptions were dispensed to patients during the first quarter of 2022.

BIJUVA[®] (estradiol and progesterone) capsules

- BIJUVA net product revenue of \$2.6 million for the first quarter of 2022 increased by approximately \$0.2 million compared to \$2.4 million for the first quarter of 2021.
- BIJUVA net product revenue for the first quarter of 2022 includes \$0.7 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 \$4.9 million with product gross margin of 74% for the first quarter of 2022 compared to \$4.7 million with product gross margin of 76% for the first quarter of 2021. The lower product gross margin for the first quarter of 2022 reflects the impact of \$0.7 million of BIJUVA export sales, which were sold at cost.

Operating Expense, Net Loss and Related Information

- Total operating expense of \$40.7 million for the first quarter of 2022 decreased by \$3.8 million compared to \$44.5 million for the first quarter of 2021.
- Net loss for the first quarter of 2022 was \$49.0 million, or \$5.69 per basic and diluted share, compared to net loss for the first quarter of 2021 of \$39.4 million, or \$5.67 per basic and diluted share. Included in net loss for the first quarter of 2022 was a loss on extinguishment of debt of \$8.4 million. Without this non-recurring non-operating expense item, net loss for the first quarter of 2022 would have been \$40.6 million, or \$4.72 per basic and diluted share.

Balance Sheet

- As of March 31, 2022, the Company's cash on hand totaled \$30.4 million, compared with \$65.1 million as of December 31, 2021.
- As of March 31, 2022, the remaining outstanding principal amount under the Company's Financing Agreement was \$225.0 million, which reflects a repayment of \$5.0 million of principal during 2022 and an increase in debt related to a paid in kind ("PIK") debt financing fee of \$30.0 million. On April 14, 2022, the Company utilized \$120.0 million of net proceeds from the divestiture of the vitaCare Prescription Services, Inc. business to paydown a portion of the debt, and \$16.0 million of the PIK financing fee was waived.

Conference Call and Webcast Details

TherapeuticsMD will host a conference call and live audio webcast today at 4:30 p.m. ET to discuss these financial results and provide a business update.

Date:	Monday, May 16, 2022
Time:	4:30 p.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	3179996

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: 3179996.

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: 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.

- Financial Statements to Follow -

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

	March 31, 2022	December 31, 2021
Assets:		
Current assets:		
Cash	\$ 30,384	\$ 65,122
Accounts receivable, net of allowance for credit losses of \$1,334 as of March 31, 2022 and December 31, 2021	35,413	36,176
Inventory	8,967	7,622
Prepaid and other current assets	9,660	10,548
Total current assets	84,424	119,468
Fixed assets, net	1,082	1,199
License rights and other intangible assets, net	39,547	40,318
Right of use assets	8,075	8,234
Other non-current assets	253	253
Total assets	\$ 133,381	\$ 169,472
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	\$ 202,857	\$ 188,269
Accounts payable	20,753	20,318
Accrued expenses and other current liabilities	41,225	44,304
Total current liabilities	264,835	252,891
Operating lease liabilities	7,897	8,063
Other non-current liabilities	1,229	2,139
Total liabilities	273,961	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, 8,669 and 8,598 (each) adjusted for the 50-for-1 reverse stock split) issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9	9
Additional paid-in capital	959,792	957,730
Accumulated deficit	(1,100,381)	(1,051,360)
Total stockholders' deficit	(140,580)	(93,621)
Total liabilities and stockholders' deficit	\$ 133,381	\$ 169,472

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

	Three Months Ended March 31,	
	2022	2021
Revenue, net:		
Product	\$ 18,914	\$ 19,632
License and service	419	234
Total revenue, net	19,333	19,866
Cost of goods sold	4,860	4,687
Total gross profit	14,473	15,179
Operating expenses:		
Selling and marketing	18,895	24,024
General and administrative	20,407	18,383
Research and development	1,400	2,050
Total operating expenses	40,702	44,457
Loss from operations	(26,229)	(29,278)
Other expense:		
Loss on extinguishment of debt	(8,380)	—
Interest expense and other financing costs	(14,412)	(10,227)
Other income, net	—	122
Total other expense, net	(22,792)	(10,105)
Loss before income taxes	(49,021)	(39,383)
Provision for income taxes	—	—
Net loss	\$ (49,021)	\$ (39,383)
Loss per common share, basic and diluted	\$ (5.69)	\$ (5.67)
Weighted average common shares, basic and diluted	8,614	6,945

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (49,021)	\$ (39,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,100	1,019
Charges to provision for doubtful accounts	274	230
Inventory charge	73	502
Debt financing fees	9,048	1,272
Loss on extinguishment of debt	8,380	—
Share-based compensation	2,062	2,957
Other	(7)	216
Changes in operating assets and liabilities:		
Accounts receivable	489	(1,567)
Inventory	(1,418)	145
Prepaid and other current assets	888	(817)
Accounts payable	435	(10,758)
Accrued expenses and other current liabilities	(1,829)	7,804
Total adjustments	19,495	1,003
Net cash used in operating activities	(29,526)	(38,380)
Cash flows from investing activities:		
Payment of patent related costs	(170)	(375)
Purchase of fixed assets	(42)	(63)
Net cash used in investing activities	(212)	(438)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	—	150,899
Proceeds from exercise of options and warrants	—	50
Repayments of debt	(5,000)	(50,000)
Payment of debt financing fees	—	(5,000)
Net cash (used in) provided by financing activities	(5,000)	95,949
Net (decrease) increase in cash	(34,738)	57,131
Cash, beginning of period	65,122	80,486
Cash, end of period	\$ 30,384	\$ 137,617
Supplemental disclosure of cash flow information:		
Interest paid	\$ 5,364	\$ 8,955
Supplemental disclosure of noncash financing activities:		
Paid in kind ("PIK") debt financing fees with corresponding increase in debt	\$ 30,000	\$ —

CONTACT:

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Interim Chief Financial Officer,
Chief Accounting Officer and
Vice President Finance
561-961-1900

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TherapeuticsMD®

For Her. For Life.

**Building the Premier
Women's Health Company**
Q1 2022 Earnings
May 16, 2022



FOR INVESTOR PRESENTATION PURPOSES ONLY.

Forward-Looking Statements

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For Her. For Life.



Hugh O'Dowd
CEO

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Q1 2022 Financial Overview

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Quarterly Revenue Trends



Q1-22 Highlights

- § Total net revenue decreased 3% in Q1-22 vs Q1-21, but increased 4% vs Q4-21
- § Total net product revenue decreased 4% in Q1-22 vs Q1-21, but increased 1% vs Q4-21
- § ANNOVERA net revenue decreased 3% in Q1-22 vs Q1-21 and was impacted by production and supply issues, but increased 9% vs Q4-21
- § BIJUVA net revenue increased 5% in Q1-22 vs Q1-21, but decreased 5% vs Q4-21
- § IMVEXXY net revenue was flat in Q1-22 vs Q1-21, but increased 5% vs Q4-21

Financial Results: Comparison Q1 2022 to Q1 2022 to Q4 2021

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

	Q1-22	Q1-21	Q4-21
Balance Sheet⁽¹⁾			
Cash	\$ 30,384	\$ 137,617	\$ 65,122
Debt	\$ 225,000	\$ 200,000	\$ 200,000
Income Statement			
Net Revenue	\$ 19,333	\$ 19,866	\$ 18,678
Gross Profit	\$ 14,473	\$ 15,179	\$ 13,941
Gross Margin %	75%	76%	75%
Total Operating Expenses	\$ 40,702	\$ 44,457	\$ 49,333
Net Loss	\$ (49,021)	\$ (39,383)	\$ (42,960)
Cash Flow			
Net Cash Used In Operating Activities	\$ (29,526)	\$ (38,380)	\$ (39,558)

(1) Balance Sheet as of quarter end.

- In April, certain proceeds from the vitaCare divestiture were used to paydown the debt; April 30th debt balance was \$89M.
- Gross margin of 75% in Q1-22 relatively consistent Q1-21 and Q4-21.
- Operating expenses in Q1-22 decreased \$3.8M from Q1-21 and \$8.6M from Q4-21.
- Net loss in Q1-22 increased \$9.6M from Q1-21 and \$6.1M from Q4-21. Net loss in Q1-22 included a \$8.4 million loss on extinguishment of debt and higher financing fees amortization as compared to Q1-21 and Q4-21.
- Net cash used in operating activities in Q1-22 decreased \$8.9M from Q1-21 and \$10.0M from Q4-21.



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Q1 2022 Commercial Overview

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Call Activity Highlights



9.2 calls per day



6,271 targets reached (87%)



10,868 calls to targets (84%)

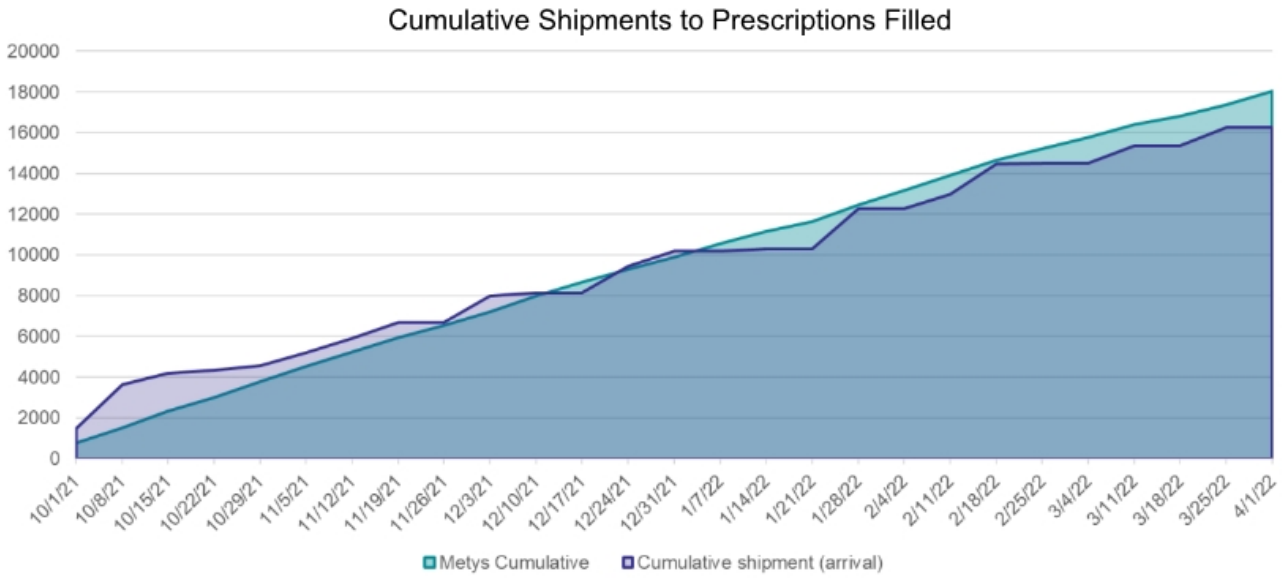
*Source: Veeva; reflects Mar22 call activity, excluding vacancies and new hires in training

TherapeuticsMD

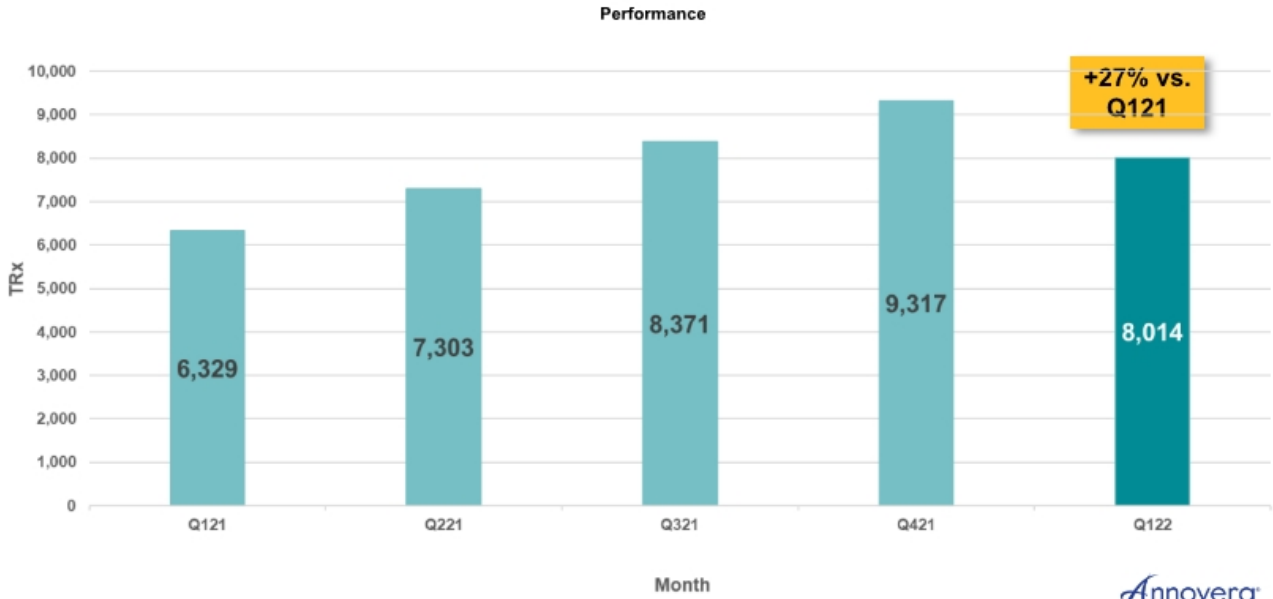
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Available ANNOVERA vs. Prescriptions



ANNOVERA Quarterly TRx

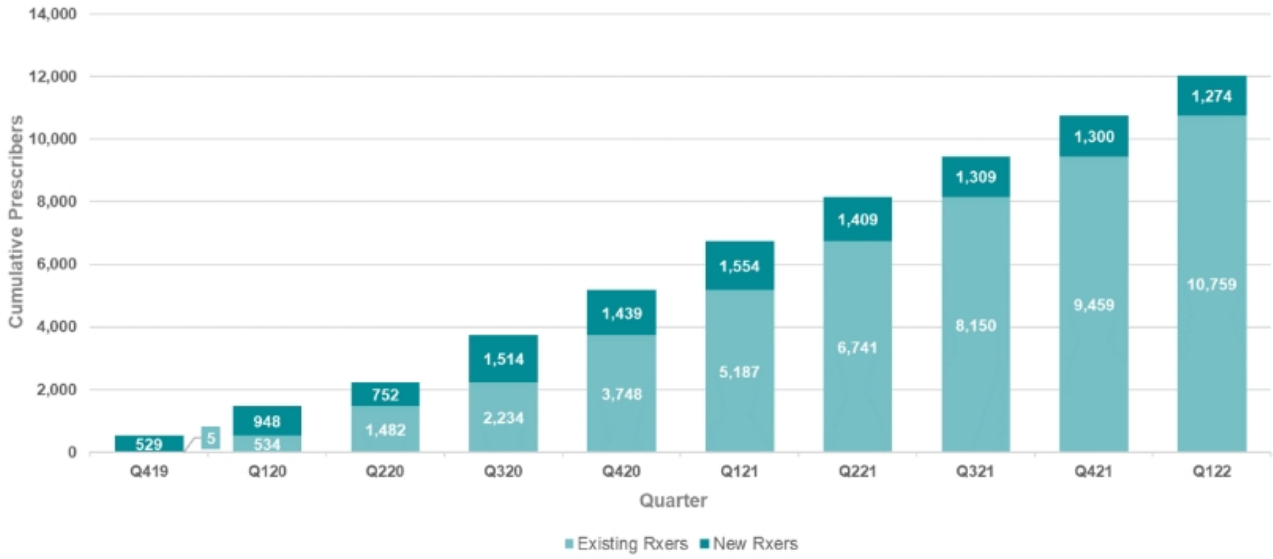


TherapeuticsMD[®]

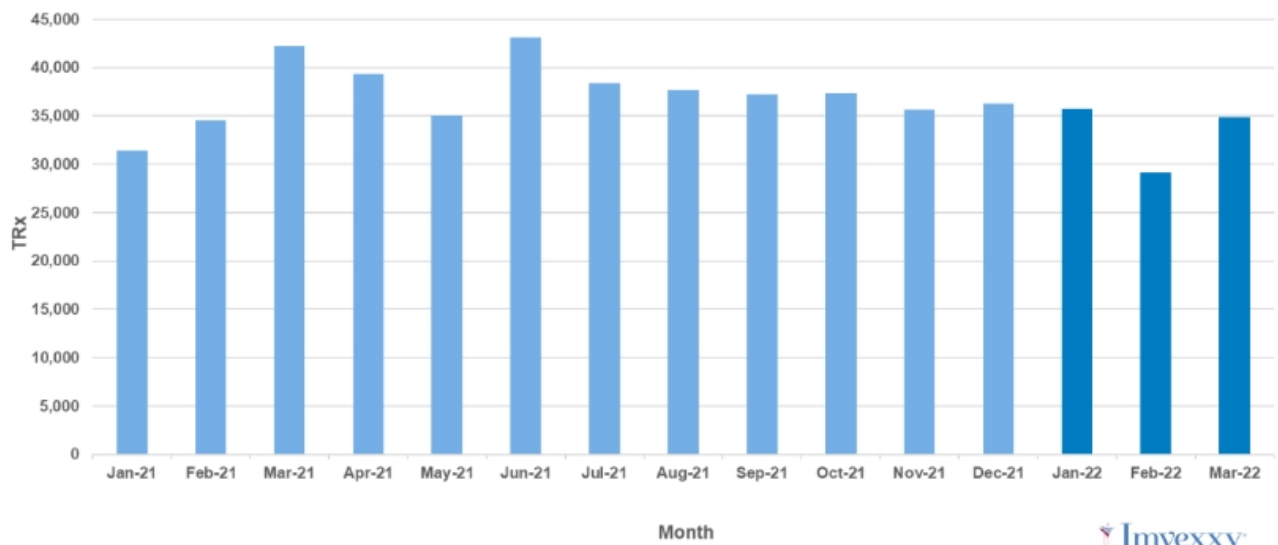
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Source: Symphony Metys - December 2021

ANNOVERA Prescribers: Launch to Date



IMVEXXY Monthly TRx



BIJUVA Quarterly TRx

