

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): November 11, 2021**

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.

See information provided in Item 7.01.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 11, 2021, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), announced that Mr. Hugh O'Dowd, the Company's current President, will succeed Mr. Robert G. Finizio, the Company's Co-founder and current Chief Executive Officer, as the Company's Chief Executive Officer effective on or before December 31, 2021. Mr. O'Dowd will also be appointed to the Company's Board of Directors. Mr. Finizio will continue with the Company and has been appointed Vice Chair of the Board of Directors.

Except pursuant to Mr. O'Dowd's existing employment Agreement, dated August 3, 2021, which was filed as an exhibit to the Company's Current Report on Form 8-K on August 9, 2021 and is incorporated herein by reference, there are no arrangements or understandings between Mr. O'Dowd and any other person pursuant to which he was appointed as Chief Executive Officer of the Company and no family relationship between Mr. O'Dowd and any director or executive officer of the Company. Other than as described in this Current Report on Form 8-K, since the beginning of the Company's last fiscal year, the Company has not engaged in any transactions, and there are no proposed transactions, or series of similar transactions, in which the Company was or is to be a participant and in which Mr. O'Dowd had a direct or indirect material interest in which the amount involved exceeds or exceeded \$120,000.

Item 7.01 Regulation FD Disclosure.

On November 11, 2021, the Company issued a press release announcing the leadership changes described in Item 5.02 of this Current Report on Form 8-K. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The following information is provided pursuant to Item 7.01 of Form 8-K, "Regulation FD Disclosure," and Item 2.02 of Form 8-K, "Results of Operations and Financial Condition."

On November 11, 2021, the Company issued a press release and held a webcast and conference call announcing its financial results for the third quarter ended September 30, 2021. In addition, the Company provided a slide presentation during its earnings conference call. Copies of the press release and slide presentation are furnished as Exhibits 99.2 and 99.3, respectively, to this Current Report on Form 8-K and are incorporated herein by reference. The Company intends to amend this Current Report on Form 8-K to provide a transcript of the webcast and conference call.

The information in this Item 7.01 and the information contained in Exhibits 99.1, 99.2 and 99.3 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 November 11, 2021, entitled "TherapeuticsMD Announces Leadership Changes: Appointment of Industry Veteran, Hugh O'Dowd, as Chief Executive Officer."
99.2	Press Release from TherapeuticsMD, Inc., dated November 11, 2021, entitled "TherapeuticsMD Announces Third Quarter 2021 Financial Results."
99.3	TherapeuticsMD, Inc. Presentation dated November 11, 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: November 12, 2021

THERAPEUTICSMD, INC.

/s/ James C. D'Arecca
James C. D'Arecca
Chief Financial Officer

FOR IMMEDIATE RELEASE**TherapeuticsMD Announces Leadership Changes; Appointment of Industry Veteran, Hugh O'Dowd, as Chief Executive Officer**

- Mr. O'Dowd to succeed Robert G. Finizio, effective on or before December 31, 2021 -
- Mr. Finizio appointed Vice Chair of the Board -

BOCA RATON, Fla. – November 11, 2021 – TherapeuticsMD, Inc. (NASDAQ: TXMD) (TXMD or the Company), an innovative, leading women's healthcare company, today announced key leadership changes, including the appointment of Hugh O'Dowd, the Company's current President, as the Company's Chief Executive Officer and member of the board of directors. Mr. O'Dowd will succeed Robert G. Finizio, the Company's Co-founder and current Chief Executive Officer, effective on or before December 31, 2021. Mr. Finizio will continue with the Company and has been appointed Vice Chair of the Board of Directors.

"I want to thank Rob for his strong leadership and vision over the past 13 years," said Honorable Tommy Thompson, Chairman of the Board of TherapeuticsMD. "Rob is an innovator who has made an indelible mark not only on this company, but on the women's healthcare industry as a whole."

"Founding TherapeuticsMD has been one of the highlights of my career. Hugh is an experienced leader with a strong track record of delivering results, and in the few short months since joining the company, he has already made invaluable contributions. I am confident that he is the right person to bring TherapeuticsMD to the next level of growth," said Mr. Finizio.

"TherapeuticsMD is an innovator in women's healthcare, and I welcome the opportunity to drive operating performance and craft our long-term strategy," stated Mr. O'Dowd. "Rob has created a dynamic company and established TXMD's foundation for growth and I will build upon our mission of empowering women of all ages through better healthcare."

Mr. O'Dowd previously served as President, Chief Executive Officer, and member of the Board of Directors of Neon Therapeutics, Inc., a clinical-stage immuno-oncology company until its acquisition by BioNTech SE in May 2020. Prior to Neon Therapeutics, Mr. O'Dowd spent more than 20 years in a variety of senior leadership roles at Novartis Pharmaceuticals Corporation, where he served as Country President and General Manager of the United Kingdom and Ireland, Senior Vice President and Chief Commercial Officer of Novartis Oncology, and Vice President, Latin America Region Head for the Oncology business unit. During his time as Chief Commercial Officer Oncology, Mr. O'Dowd was responsible for the oncology portfolio strategy for the world's then second-largest oncology/hematology organization, including global brand leadership, business development/licensing, and commercialization. Mr. O'Dowd currently serves as Director and Non-executive Chairman of ONK Therapeutics Ltd, an innovative natural killer cell therapy company, and as a Director of Polyphor AG, a clinical-stage biopharmaceutical company focused on the discovery and development of antibiotics and immuno-oncology compounds. Mr. O'Dowd received an MBA from the Kellstadt Graduate School of Business at DePaul University in Chicago and a B.A. from Loyola University Chicago.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is an innovative, leading healthcare company, focused on developing and commercializing novel products exclusively for women. Our products are designed to address the unique changes and challenges women experience through the various stages of their lives with a therapeutic focus in family planning.

reproductive health, and menopause management. The company is committed to advancing the health of women and championing awareness of their healthcare issues. To learn more about TherapeuticsMD, please visit therapeuticsmd.com or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

Forward-Looking Statements

This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: the 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, or obtain an investment in, its vitaCare business and how the proceeds that may be generated by any such divestiture or investment will be utilized; 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 lower dose of BIJUVA and 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 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 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.

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

FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Third Quarter 2021 Financial Results

- Quarterly total net product revenue of \$24.5 million, an increase of 41.1% over Q3 2020 -
- ANNOVERA[®] TRx of 8,351, an increase of 62.7% over Q3 2020 -
- Cost savings initiative to reduce SG&A by \$40 million in 2022; anticipated additional savings of approximately \$20 million annualized tied to the divestiture of vitaCare -
- Hugh O'Dowd, President, to become Chief Executive Officer; Robert Finizio appointed Vice Chair of the Board -
- Conference call scheduled for 8:30 a.m. ET today -

BOCA RATON, Fla. – November 11, 2021 – TherapeuticsMD, Inc. (“TXMD” or the “Company”) (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today reported financial results for the third quarter ended September 30, 2021. In addition, today the Company announced a significant cost savings initiative designed to reduce its annual costs in 2022 by at least \$40 million. This figure does not include savings from, or the costs associated with, the divestiture of vitaCare, which are estimated at approximately \$20 million annually.

“We have made significant changes to our business strategy, which we believe will help us achieve our goal of EBITDA breakeven in the second half of 2022. Specifically, we put a cost savings plan in place and we have implemented a more concerted focus on healthcare professionals. These refinements are already yielding results, as evidenced by the steady progress made during the third quarter, notably the strong year-over-year growth in ANNOVERA prescriptions, said Hugh O’Dowd, President of TherapeuticsMD.

“I would like to thank Rob for his leadership and vision in creating an innovative healthcare company with products that benefit women across their lifecycles. I would also like to formally welcome Mark Glickman as our Chief Commercial Officer. His commercial acumen is already having a positive impact on our day-to-day operations. Looking ahead, I am confident that we can reduce our annual expenses significantly, deliver value to shareholders, and most importantly, bring our high-quality products to the women who need them,” concluded O’Dowd.

Third Quarter 2021 Financial Results and Business Highlights**Net Product Revenue (in thousands)**

	Three Months Ended	
	September 30,	
	2021	2020
Product revenue:		
ANNOVERA	\$ 11,807	\$ 6,419
IMVEXXY	8,016	6,841
BIJUVA	3,298	1,646
Prescription vitamin	1,348	2,436
Product revenue, net	24,469	17,342
License revenue	937	2,000
Total revenue, net	\$ 25,406	\$ 19,342

ANNOVERA (segesteronone acetate and ethinyl estradiol vaginal system)

- ANNOVERA net product revenue of \$11.8 million for the third quarter of 2021 increased by \$5.4 million compared to \$6.4 million for the third quarter of 2020.
- Approximately 8,350 ANNOVERA prescriptions were dispensed to patients during the third quarter of 2021. Prescriptions increased 62.7% compared to the third quarter of 2020.
- Over 4,500 health care providers (HCPs) prescribed ANNOVERA during the third quarter, of which nearly 29% were new writers.

- o Growth in prescribers of approximately 1,600 over third quarter of 2020.
- o Cumulatively over 9,450 HCPs have prescribed ANNOVERA.

IMVEXXY® (estradiol vaginal inserts)

- IMVEXXY net product revenue of \$8.0 million for the third quarter of 2021 increased by \$1.2 million compared to \$6.8 million for the third quarter of 2020.
- Approximately 113,000 IMVEXXY prescriptions were dispensed to patients during the third quarter of 2021.
- Full re-targeting initiative taking place in the fourth quarter of 2021, with implementation in the first quarter of 2022.
 - o Plan to rejuvenate growth and optimize HCP focus.

BIJUVA® (estradiol and progesterone)

- BIJUVA net product revenue of \$3.3 million for the third quarter of 2021 increased by \$1.7 million compared to \$1.6 million for the third quarter of 2020.
- BIJUVA net product revenue for the third quarter of 2021 includes \$0.7 million of export sales through our international licensing and supply agreement with Theramex HQ UK Limited.
- Re-targeting initiative taking place, similar to the process with IMVEXXY.

Cost of Goods Sold and Gross Margin

- Cost of goods was \$5.3 million with product gross margin of 78% for the third quarter of 2021 compared to \$3.3 million with product gross margin of 81% for the third quarter of 2020. The lower product gross margin for the third quarter of 2021 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 \$60.0 million for the third quarter of 2021 increased by \$19.0 million compared to \$41.0 million for the third quarter of 2020. Included in total operating expense for the third quarter of 2021 was \$7.3 million of severance related expenses recorded for certain former senior executives.
- Net loss for the third quarter of 2021 was \$47.4 million, or \$0.11 per basic and diluted share, compared to net loss for the third quarter of 2020 of \$32.6 million, or \$0.12 per basic and diluted share.

Balance Sheet

- As of September 30, 2021, the Company's cash on hand totaled \$104.8 million, compared with \$80.5 million as of December 31, 2020.
- For the first nine months of 2021, the Company received \$182.9 million in net proceeds from its at-the-market and underwritten equity offerings.
- As of September 30, 2021, the remaining outstanding principal amount under the Company's Financing Agreement was \$200.0 million, which reflects a repayment of \$50.0 million of principal during the first nine months of 2021.

The contract manufacturing organization that manufactures ANNOVERA has recently experienced an increase in difficulties with the manufacturing process for ANNOVERA resulting in batch failures. The Company filed a supplemental NDA with the FDA to modify the manufacturing (testing) specification for ANNOVERA to allow for normal manufacturing variation that would increase the consistency of manufacturing and supply of ANNOVERA. The Company expects that the FDA will act on the supplemental NDA by the Prescription Drug User Fee Act ("PDUFA") date of December 12, 2021. If the FDA does not approve the supplemental NDA by the PDUFA date, the Company may not be able to meet the revenue covenants under its Financing Agreement in the near term. The manufacturing difficulties relate only to our ability to meet the release specification, and any ANNOVERA rings currently being sold meet the exacting quality specifications. For more information regarding the covenants under the Financing Agreement, please see the Company's filings with the SEC.

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, November 11, 2021
Time:	8:30 a.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	6341637

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: 6341637.

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; 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, or obtain an investment in, its vitaCare business and how the proceeds that may be generated by any such divestiture or investment will be utilized; 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 lower dose of BIJUVA and 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 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 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
(In thousands, except per share data)

	September 30, 2021	December 31, 2020
	(Unaudited)	
Assets:		
Current assets:		
Cash	\$ 104,841	\$ 80,486
Accounts receivable, net of allowance for credit losses of \$1,351 and \$1,118 as of September 30, 2021 and December 31, 2020, respectively	37,402	32,382
Inventory	7,362	7,993
Prepaid and other current assets	10,374	7,543
Total current assets	159,979	128,404
Fixed assets, net	1,388	1,942
License rights and other intangible assets, net	39,617	41,445
Right of use assets	8,391	9,566
Other non-current assets	253	253
Total assets	\$ 209,628	\$ 181,610
Liabilities and stockholders' equity (deficit):		
Current liabilities:		
Current maturities of long-term debt	\$ 15,000	\$ —
Accounts payable	19,592	21,068
Accrued expenses and other current liabilities	51,674	38,170
Total current liabilities	86,266	59,238
Long-term debt, net	171,738	237,698
Operating lease liabilities	8,226	8,675
Other non-current liabilities	758	—
Total liabilities	266,988	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, 424,879 and 299,765 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	425	300
Additional paid-in capital	950,615	754,644
Accumulated deficit	(1,008,400)	(878,945)
Total stockholders' deficit	(57,360)	(124,001)
Total liabilities and stockholders' equity (deficit)	\$ 209,628	\$ 181,610

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Product revenue, net	\$ 24,469	\$ 17,342	\$ 67,102	\$ 40,294
License revenue	937	2,000	1,171	2,000
Total revenue, net	25,406	19,342	68,273	42,294
Cost of goods sold	5,282	3,279	14,101	10,394
Gross profit	20,124	16,063	54,172	31,900
Operating expenses:				
Selling and marketing	30,005	22,373	86,193	91,056
General and administrative	28,435	16,637	66,691	53,740
Research and development	1,605	2,027	5,666	8,038
Total operating expenses	60,045	41,037	158,550	152,834
Loss from operations	(39,921)	(24,974)	(104,378)	(120,934)
Other (expense) income:				
Interest expense and other financing costs	(7,518)	(7,680)	(25,341)	(20,969)
Other income, net	19	42	264	466
Total other (expense), net	(7,499)	(7,638)	(25,077)	(20,503)
Loss before income taxes	(47,420)	(32,612)	(129,455)	(141,437)
Provision for income taxes	—	—	—	—
Net loss	\$ (47,420)	\$ (32,612)	\$ (129,455)	\$ (141,437)
Loss per common share, basic and diluted	\$ (0.11)	\$ (0.12)	\$ (0.33)	\$ (0.52)
Weighted average common shares, basic and diluted	422,216	272,565	388,111	271,969

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (129,455)	\$ (141,437)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,091	3,039
Charges (credits) to provision for doubtful accounts	540	(47)
Inventory charge	1,082	5,744
Debt financing fees	4,158	1,645
Share-based compensation	12,779	8,502
Other	726	1,719
Changes in operating assets and liabilities:		
Accounts receivable	(5,560)	384
Inventory	(451)	(3,816)
Prepaid and other current assets	(2,831)	2,038
Accounts payable	(1,476)	(3,072)
Accrued expenses and other current liabilities	13,504	(3,813)
Other non-current liabilities	758	—
Total adjustments	26,320	12,323
Net cash used in operating activities	(103,135)	(129,114)
Cash flows from investing activities:		
Payment of patent related costs	(675)	(1,065)
Purchase of fixed assets	(34)	(39)
Net cash used in investing activities	(709)	(1,104)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	182,881	—
Proceeds from exercise of options and warrants	302	272
Proceeds from sale of common stock related to employee stock purchase plan	134	—
Repayments of debt	(50,000)	—
Borrowings of debt	—	50,000
Payment of debt financing fees	(5,118)	(1,250)
Net cash provided by financing activities	128,199	49,022
Net increase in cash	24,355	(81,196)
Cash, beginning of period	80,486	160,830
Cash, end of period	\$ 104,841	\$ 79,634
Supplemental disclosure of noncash financing activities:		
Warrants issued in relation to debt financing agreement	—	7,428
Supplemental disclosure of cash flow information:		
Interest paid	\$ 19,675	\$ 12,032

CONTACT:

James D'Arecca
Chief Financial Officer
561-961-1900

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

TherapeuticsMD®

For Her. For Life.

**Building the Premier
Women's Health Company**
Q3 2021 Earnings
November 11, 2021



FOR INVESTOR PRESENTATION PURPOSES ONLY.

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, or obtain an investment in, its vitaCare business and how the proceeds that may be generated by such divestiture or investment 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; and the revised manufacturing specifications for ANNOVERA; the effects of supply chain and manufacturing issues related to ANNOVERA; 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.



TherapeuticsMD[®]



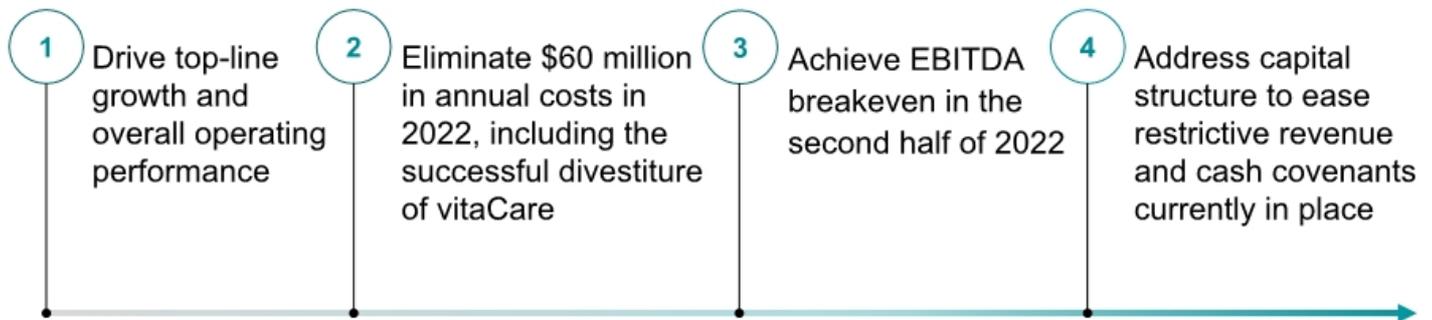
Announcing:

Hugh O'Dowd

FOR INVESTOR PRESENTATION PURPOSES ONLY.

3

Immediate Priorities

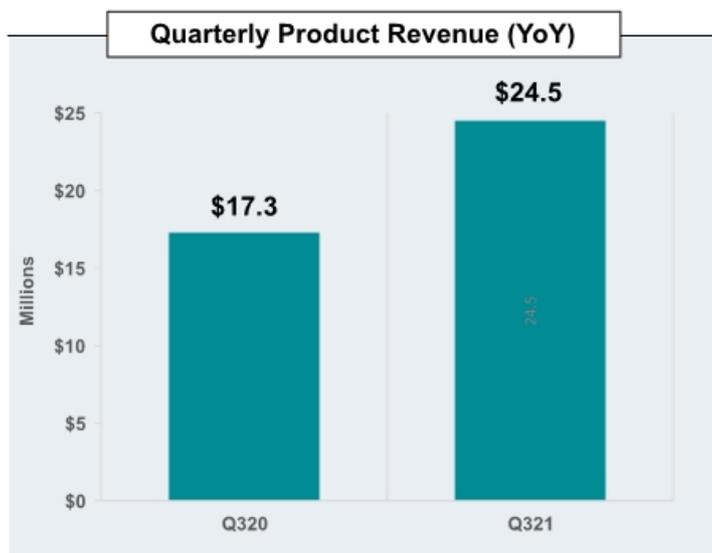




3Q21 Financial Overview

FOR INVESTOR PRESENTATION PURPOSES ONLY.

Quarterly Product Revenue Trends



3Q21 Highlights

- Total net product revenue increased 41% Q321 vs Q320
- ANNOVERA sales increased by 84% on strong volume growth Q321 vs Q320
- IMVEXXY net revenue increased by 17% Q321 vs 3Q20 driven by higher net pricing, partially offset by a moderate decrease in sales volumes

Financial Results: Comparison 3Q 2021 to 2Q 2021 and 3Q 2020

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

	Q321	Q221	Q320
<u>Balance Sheet⁽¹⁾</u>			
➔ Cash	\$104,841	\$111,424	\$79,634
Debt	\$186,738	\$185,261	\$237,051
<u>Income Statement</u>			
Net Revenue	\$25,406	\$23,001	\$19,343
Gross Profit	\$20,124	\$18,869	\$16,064
Gross Margin %	79%	82%	83%
➔ Total Operating Expenses	\$60,045	\$54,048	\$41,037
Net Loss	(\$47,420)	(\$42,652)	(\$32,612)
<u>Statement of Cash Flow</u>			
➔ Net Cash Used In Operating Activities	(\$38,223)	(\$26,532)	(\$34,049)

(1) Balance Sheet as of quarter end.

- Net revenue of \$25.4M was an increase of \$6.1M compared to Q320
- Gross margin of 79% decreased from 83% in Q320
 - Mainly attributable to Q321 margins being negatively impacted by export sales
- Higher operating expenses in Q321 reflect increase from employee termination cost
- Net loss increased by \$14.8M from Q320 to \$47.4M
- Net cash used in operating activities increased to \$38.2M



Q3 2021 Commercial Overview

FOR INVESTOR PRESENTATION PURPOSES ONLY.

Career Highlights

- Started with Baxter Healthcare
- MBA Finance and International Management NYU Stern School of Business

Bristol Myers Squibb

- Lead team on Plavix marketing
- Launched pivotal CURE Trial
- Multi-billion dollar product

Kos Pharmaceutical

- Launched company's second product
- Promoted to Executive Level after 2 years
- Sold to Abbott

Auxilium

- Came in with former Kos management team to turn around the company
- 3 years turned around 2 products and launched 2 products
- Sold company to Endo within 3 years

Esperion

- CCO
- Built entire commercial structure and transitioned the company from clinical to commercial
- Product approved 2/21/2020 and launched directly into COVID
- Signed two large out license deals for EU and Japan

Commercial Vision



Focus on our Patients and Physicians



Environment of Accountability



Create a Performance Based Organization
that will Execute with Excellence



Become the Premier Women's Healthcare
Commercial Organization

Opportunities



Initial Assessment



**Marketing programs
overweighted to consumer**



Complex solution orientation



**Managed care was good,
albeit in need of optimization**

Areas of Immediate Focus

Retarget and redistribute activity to highest decile physicians for all products

- Significant overhaul of effort
- Roll out occurring in stages
- Clear direction and evaluation regarding call and all field activity

Focus representatives on solution selling

- Build confidence around positive outcomes for prescribing
- Highlight the many solutions to ensure successful patient acquisition of TXMD products



Accountability message delivered throughout TXMD

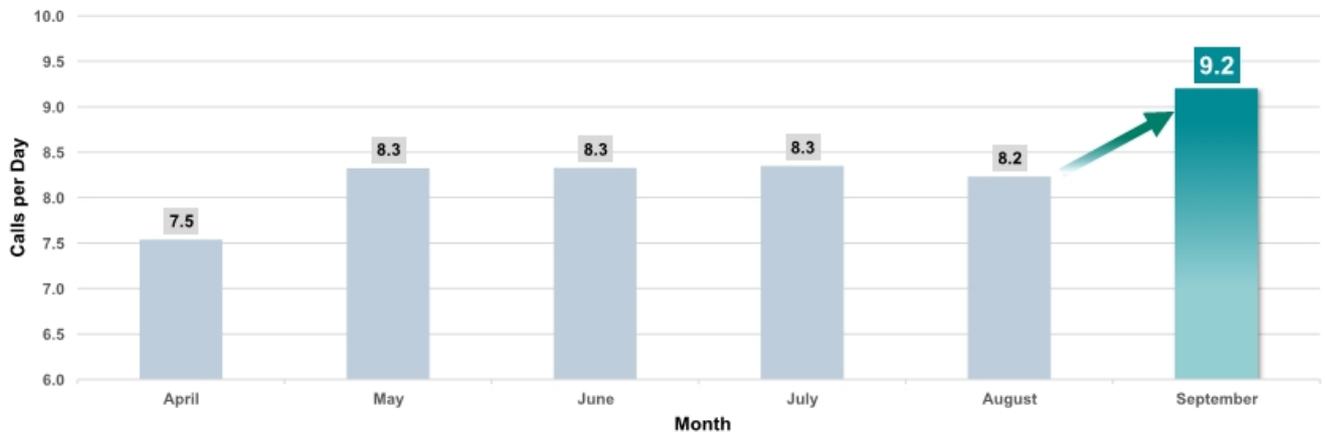
Provide direction, tools and evaluations to create sustainable, consistent growth



Results

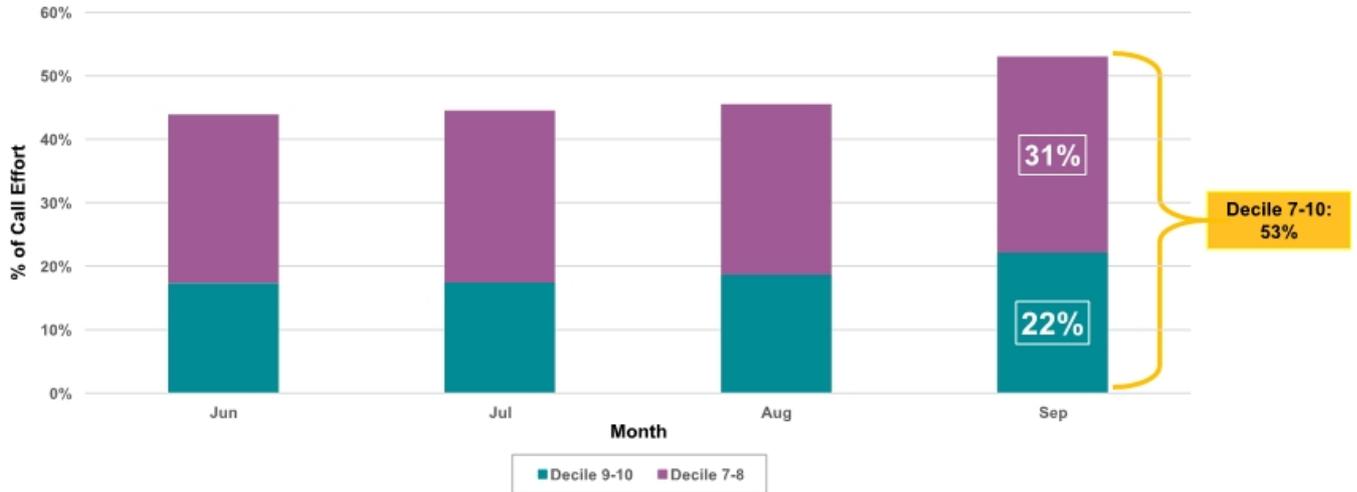
Calls per Day

September's **9.2** average calls per day reflects an 11% increase versus August and the **highest level in the past 6 months**

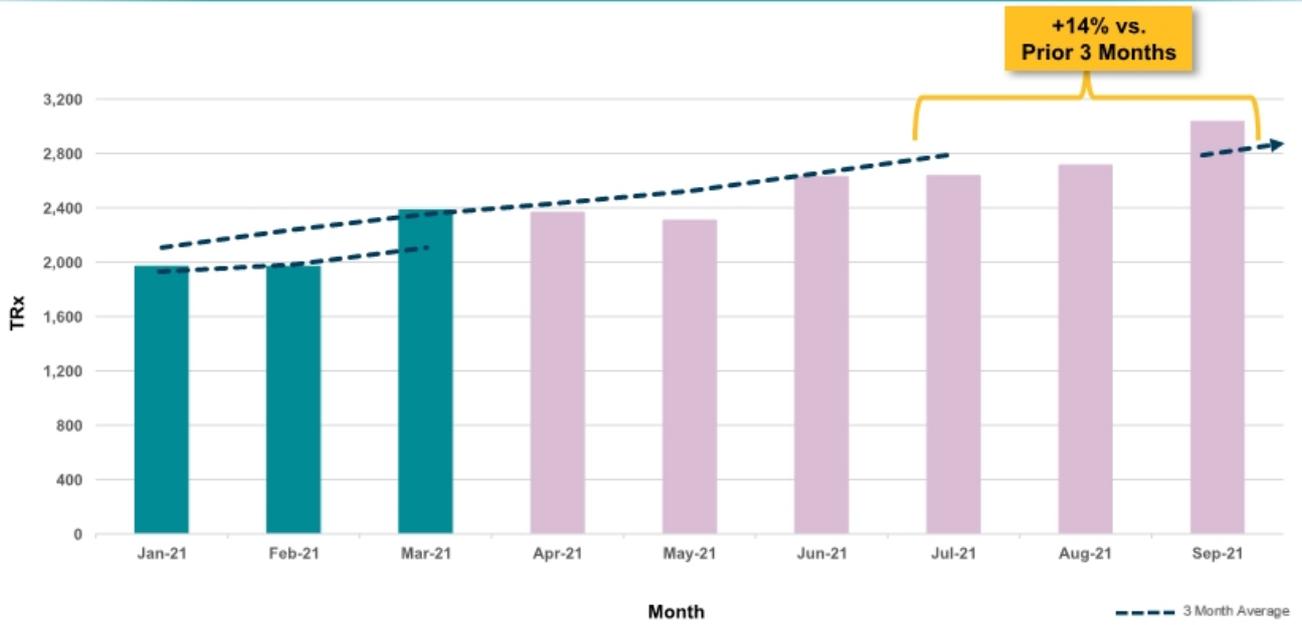


% of Call Effort to Top Decile HCPs

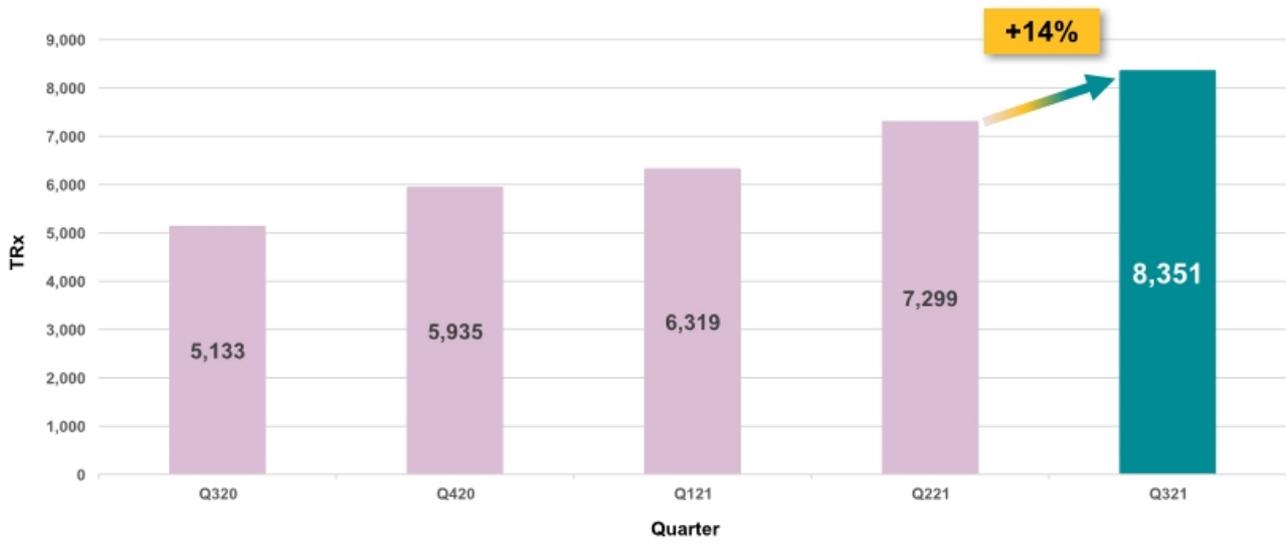
Decile 7-10 HCPs represented greater than 50% of all call efforts in September, aligning with rollout of a smaller, yet higher opportunity, target audience receiving increased frequency



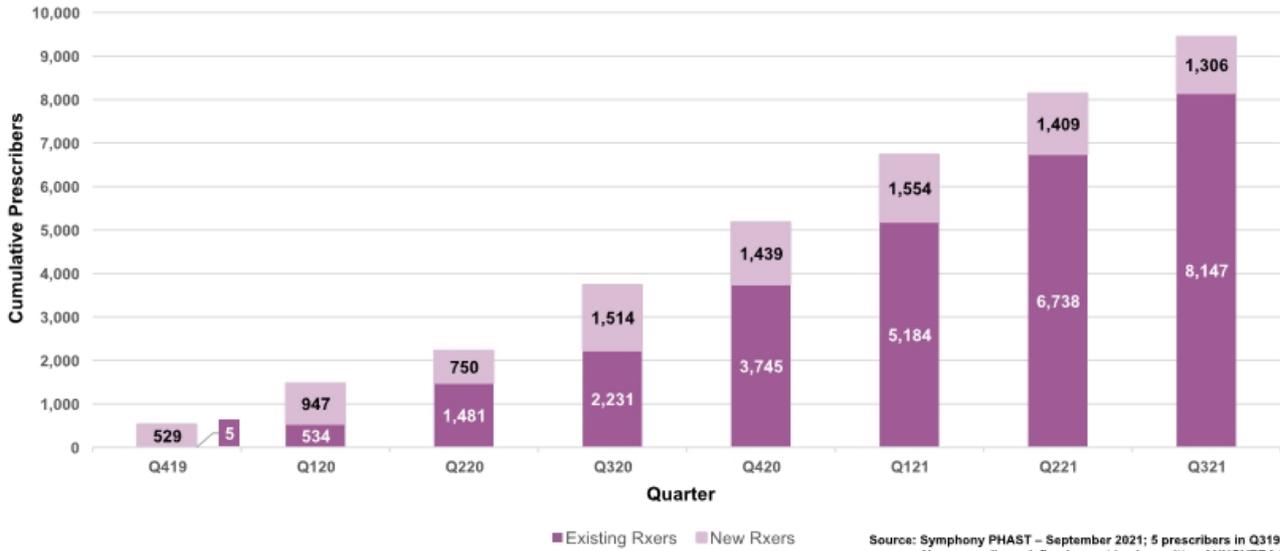
ANNOVERA Monthly TRx



ANNOVERA Quarterly TRx



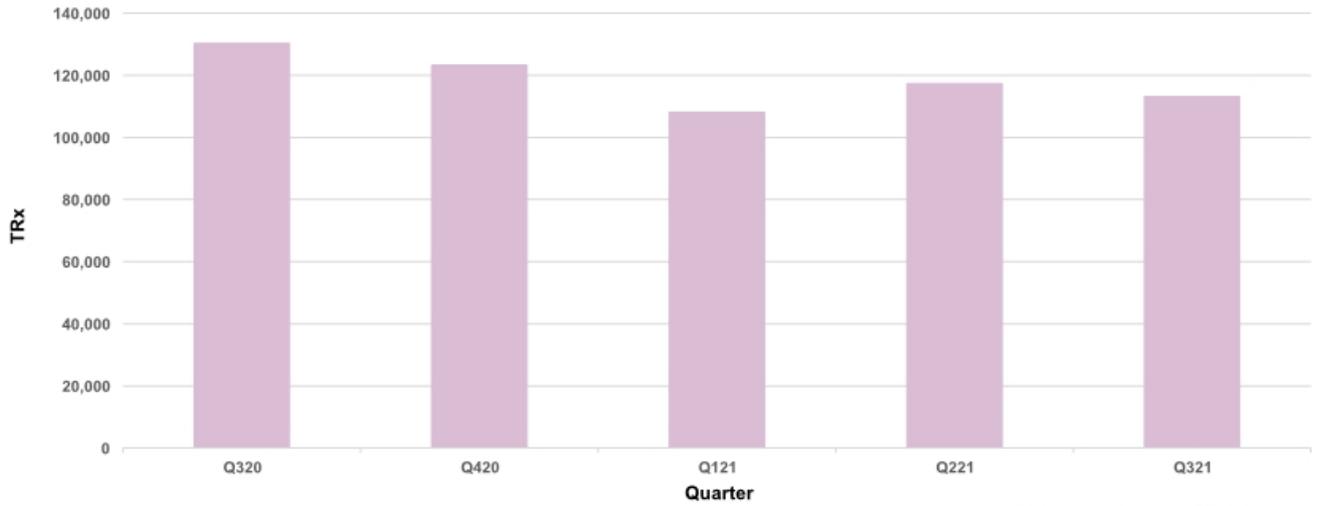
ANNOVERA Prescribers: Launch to Date



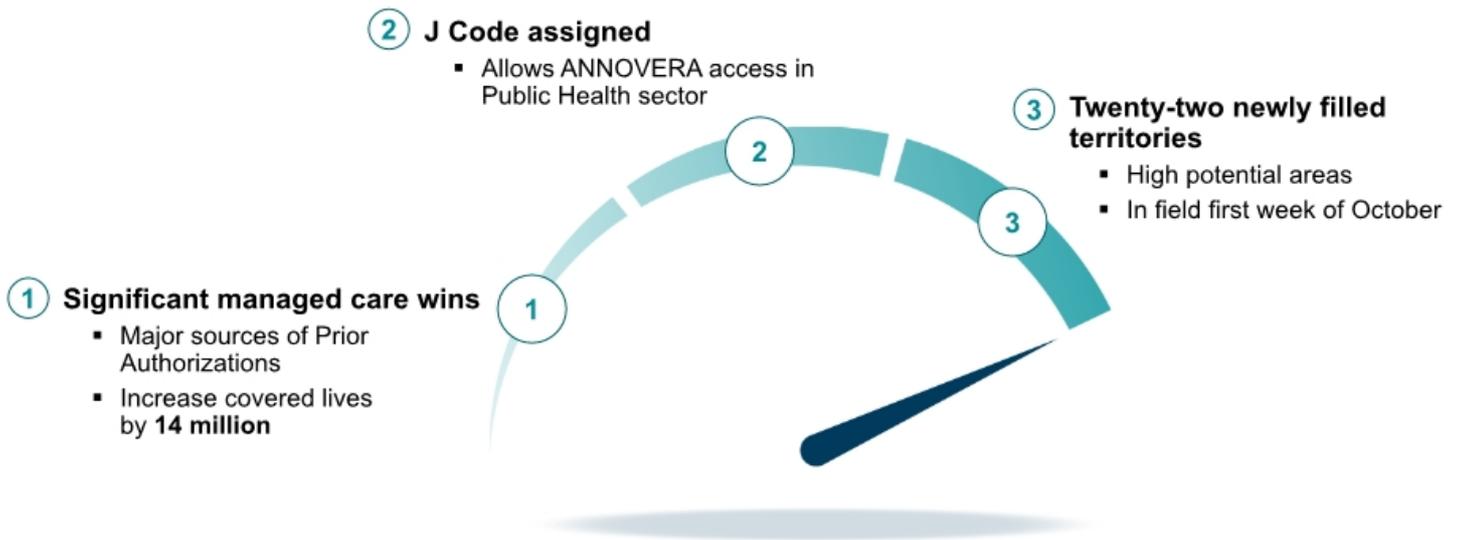
Source: Symphony PHAST – September 2021; 5 prescribers in Q319
 New prescribers defined as not having written ANNOVERA in prior periods

IMVEXXY Quarterly TRx

- Held up well considering prioritization on ANNOVERA in Q3
- Full targeting and mix assessment to be completed Q4 2021



Accelerators for Q4 and Beyond





TherapeuticsMD®
For Her. For Life.



Q&A

FOR INVESTOR PRESENTATION PURPOSES ONLY.
