# 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, 2020

Name of Registrant as Specifie	d in its Charter)
	a in its charter)
001-00100	87-0233535
(Commission File Numb	
	Identification No.)
Boca Raton, FL 33431	<u> </u>
ess of Principal Executive Offi	ce) (Zip Code)
lephone number,including area	a code: (561) 961-1900
Not Applicable	
ne or former address, if chang	ed since last report)
e Exchange Act (17 CFR 240.	14a-12) Act (17 CFR 240.14d-2(b))
Trading Symbol	Name of Each Exchange on Which Registered
TXMD	The Nasdaq Stock Market LLC
the registrant has elected not t	ned in Rule 405 of the Securities Act of 1933 (§230-405) or Rule o use the extended transition period for complying with any new large Act. □
	(Commission File Numb  951 Yamato Road, Suite 2 Boca Raton, FL 33431 ess of Principal Executive Offi lephone number,including area  Not Applicable me or former address, if chang g is intended to simultaneousl r the Securities Act (17 CFR 2 ne Exchange Act (17 CFR 240. 14d-2(b) under the Exchange alle 13e-4(c) under the Exchange le 13e-4(c) under the Exchange Trading Symbol TXMD  ging growth company as defire).

#### Item 2.02 Results of Operations and Financial Condition.

On May 6, 2020, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020. 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, 2020, the Company issued a press release announcing the Company's financial results for its first quarter ended March 31, 2020. 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 <u>Number</u>	<u>Description</u>
99.1	Press Release from TherapeuticsMD, Inc., dated May 6, 2020, entitled "TherapeuticsMD Announces First Quarter 2020 Financial Results."
99.2	TherapeuticsMD, Inc. Presentation dated May 6, 2020.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2020 THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright
Title: Chief Financial Officer



#### FOR IMMEDIATE RELEASE

### TherapeuticsMD Announces First Quarter 2020 Financial Results

1Q20 total net product revenue of \$12.3 million exceeded Wall Street consensus Significantly reducing operating expenses, while maintaining goal of achieving EBITDA breakeven in 2021 In discussions with TPG Sixth Street Partners to defer the scheduled start of quarterly revenue covenants due to COVID-19-

-First Orange Book listed patent for ANNOVERA® issued providing potential extended exclusivity to 2039--Strengthened board of directors with diverse industry veterans-

- Conference call scheduled for 8:30 a.m. ET today -

**BOCA RATON, Fla.** – **May 6, 2020** – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women's healthcare Company, today reported financial results for the first quarter ended March 31, 2020.

"I would like to thank our team for delivering a successful quarter during a challenging time. We have made significant progress across the business," said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. "We delivered a solid quarter in revenue. Recently, we extended the value of our lead asset, ANNOVERA, with the first Orange Book listed patent, and revised our strategic priorities and significantly reduced our operating cost structure, bringing us closer to achieving EBITDA break even in 2021."

#### First Quarter & Recent Highlights

- The Company continued to evaluate its strategy and commercial infrastructure as the impact of COVID-19 persisted. Our strategy remains the same: to drive revenues by prioritizing ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system) as the lead product, IMVEXXY® (estradiol vaginal inserts) in the second position and BIJUVA® (estradiol and progesterone) in the third position. The Company's approach is straightforward, reallocate resources towards those products and initiatives that drive the fastest revenue growth, while reducing overall operating expenses. Total operating expenses excluding non-cash items for the first quarter of 2020 were approximately \$57.5 million. The Company has initiated measures to reduce its operating expenses for the second quarter by approximately \$10 million to \$12 million and plans to further reduce total operating expenses to approximately \$40 million or below for the third and fourth quarters of 2020. The Company's goal still remains to achieve EBITDA break even in 2021.
- Due to the uncertainty created by COIVD-19 and its impact, the Company has been in discussions with TPG Sixth Street Partners ("Sixth Street") regarding the revenue covenants in the loan document. The Company is working with Sixth Street to defer the scheduled start of the quarterly revenue covenant for two to three quarters to reflect the impact of COVID-19. Sixth Street has expressed preliminary support and while there is currently no final agreement or obligation, they understand the importance of flexibility for our Company at this time.
- Net product revenue for the first quarter of 2020 was \$12.3 million. The Company anticipated that net revenue would be lower in the first quarter of 2020 compared to fourth quarter of 2019 due to the impact of high deductible insurance plans resetting.
- The COVID-19 pandemic had an impact on all of the Company's product revenue with the sales force being out of the field for about four weeks of the quarter. In particular, the full commercial launch of ANNOVERA was paused on March 1, 2020 as the Company deferred sales and marketing initiatives due to lack of access to healthcare providers and a shift of patients' focus during the pandemic.
- ANNOVERA net revenue of \$2.3 million for the first quarter of 2020. Total prescriptions sold to patients doubled for the first quarter of 2020 over the fourth quarter of 2019. Patient demand was greater than the wholesale orders for the first quarter of 2020, reducing inventory with our distributors. Net revenue per unit, calculated from sales to wholesalers and pharmacies, for the first quarter 2020 was approximately \$1,350.

- For the long-term success of ANNOVERA, the Company is focusing on establishing the broad availability of ANNOVERA with retail
  pharmacies, mail order pharmacies, and online distributors, as well as public health and the military, which allows access where contraception is
  prescribed.
  - O Medicaid access is advancing with 37 states now covering ANNOVERA with average copays of \$5 or less. ANNOVERA will be available for Title X entities in early 2020 and expects universities to adopt and prescribe ANNOVERA during the fall 2020 semester. ANNOVERA was added to formulary for the Department of Defense and is currently selling at 92 bases.
- The United States Patent and Trademark Office (USPTO) recently issued a patent that covers the labeled indication for ANNOVERA that has been listed in the U.S. Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). In addition to this patent, which provides patent exclusivity through 2039, ANNOVERA contains segesterone acetate, which qualifies ANNOVERA for FDA regulatory exclusivity through August 2023 under the Hatch-Waxman Act as a "new chemical entity." Additional utility patent applications for ANNOVERA have been filed, including a design patent that, if issued, would strengthen the product's exclusivity position.
- IMVEXXY® first quarter 2020 net revenue was \$6.4 million. In the first quarter of 2020, approximately 134,000 IMVEXXY prescriptions were dispensed to patients. Average calculated net revenue per unit on these dispensed products was approximately \$48 for the first quarter of 2020. IMVEXXY is the fastest growing product in the vulvar and vaginal atrophy (VVA) market with 10.8% market share of total prescriptions in March 2020. Strong IMVEXXY refill rates continued with patients adhering to therapy. Patients on IMEXXY for one year average six fills.
- IMVEXXY has market access for the majority of lives under commercial plans with 72% unrestricted commercial coverage, including all of the top ten commercial payors of VVA products. Three of the top eight Medicare Part D payors of VVA products cover IMVEXXY. While COVID-19 has slowed down the payor review process, the Company will continue to seek profitable preferred level access in Medicare Part D to keep patient copay experience consistent across commercial and Part D. IMVEXXY Medicaid access is advancing with 21 states now unrestricted in Medicaid with average copays of \$5 or less.
- BIJUVA® capsules first quarter 2020 net revenue was \$1.1 million. In the first quarter of 2020, approximately 26,000 prescriptions were dispensed to patients. Average calculated net revenue per unit on these dispensed products was approximately \$43 for the first quarter of 2020.
- BIJUVA has market access for the majority of lives under commercial plans with 54% commercial coverage, including seven of the top ten
  commercial payors of vasomotor symptoms (VMS) products. BIJUVA Medicaid access is advancing with 21 states now unrestricted in Medicaid
  with average copays of \$5 or less.
- On behalf of the Board of Directors of TherapeuticsMD, Inc., Chairman Tommy G. Thompson recently strengthened the Board with the appointments of Paul Bisaro, Gail Naughton, Ph.D. and Karen Ling. These independent directors bring diversity, significant experience and a unique skillset to contribute to the Company's next stage of growth. As part of the Board of Directors' continued review of its composition and effectiveness, the Board has reduced its size from eleven directors to nine directors.

#### First Quarter 2020 Revenue Performance

For the quarter ended March 31, 2020, net product revenue was \$12.3 million compared to \$15.9 million for the prior quarter.

	 ee Months Ended Iarch 31, 2020	 Months Ended arch 31, 2019	 e Months Ended ember 31, 2019
Prenatal vitamins	\$ 2,473,691	\$ 1,935,971	\$ 2,576,319
IMVEXXY	6,392,601	2,010,680	6,347,301
BIJUVA	1,111,604	_	1,211,456
ANNOVERA	2,272,761	_	5,766,604
Net revenue	\$ 12,250,657	\$ 3,946,651	\$ 15,901,680

#### **Net Product Revenue**

Net product revenue for the quarter was significantly affected by the COVID-19 pandemic for all product sales. Though ANNOVERA was commercially launched in early March of 2020, the Company subsequently paused the launch due to the COVID-19 pandemic. Net product revenue of \$12.3 million for the quarter ended March 31, 2020 included a slight increase in IMVEXXY revenue offset by a decrease in net revenues for ANNOVERA, BIJUVA, and prenatal vitamins. This net product revenue was comprised of sales of IMVEXXY of \$6.4 million, BIJUVA of \$1.1 million, ANNOVERA of \$2.3 million, and prenatal vitamins of \$2.5 million. The decrease in ANNOVERA net revenue was due to the decline in unit sales, which was largely due to the paused launch in March 2020 as a result of the COVID-19 pandemic. The decrease in BIJUVA net revenue was due primarily to the decrease in revenue per unit while the decrease in net revenue related to the Company's prenatal vitamins was due to a decline in units sold when compared to the quarter ended December 31, 2019.

Net revenue for IMVEXXY and BIJUVA has been greatly affected by the Company's co-pay assistance programs introduced to provide products at a reasonable cost regardless of insurance coverage. The Company expects net product revenue to improve as commercial and Medicare payor coverage increases, and the plans complete the process needed to adjudicate IMVEXXY, BIJUVA, and ANNOVERA prescriptions at pharmacies.

#### **Expense, EPS and Related Information**

Research and Development (R&D) expenses for the first quarter of 2020 were \$3.3 million compared with \$4.4 million for the prior quarter. R&D expenditures have been reduced as the Company refocused resources towards launching its approved drugs. Though the Company continued to deploy adequate resources to develop its drug pipeline, continue stability testing and validation on its drugs, develop and validate secondary manufacturers, prepare regulatory submissions, and work with regulatory authorities on existing submissions, the Company is committed to refocusing resources to complete the launch of ANNOVERA and continue the commercialization of its other FDA approved products.

SG&A expenses increased to \$57.0 million for the first quarter of 2020 compared with \$52.7 million for the prior quarter. The increase in SG&A expenses for first quarter 2020 was primarily a result of higher expenses associated with sales and marketing efforts to support the significant initiatives related to the launch of ANNOVERA in March 2020, which was subsequently paused as a result of the COVID-19 pandemic. Additionally these higher expenses related to the continued commercialization of BIJUVA and IMVEXXY, which was also pre-empted by the COVID-19 pandemic. In the case of all products the increased costs related to advertising expenses and spend on consumer media while certain one-time launch expenses related to the paused launch of ANNOVERA were also incurred. Near the end of the quarter, the Company pulled back on a large portion of the marketing spend due to COVID-19, which will result in reduced costs in the second quarter that will continue to play out in subsequent quarters.

Human resources costs, including salaries, benefits and taxes, for the three months ended March 31, 2020 decreased compared to the quarter ended December 31, 2019. Other operating expenses for the three months ended March 31, 2020 remained flat, when compared to the three months ended December 31, 2019, due to the Company's effort to focus spend on commercialization of its products. The Company expects total operating costs to be significantly reduced for the remainder of the year.

Net loss for the first quarter of 2020 increased to \$56.8 million, or \$0.21 per basic and diluted share, compared with \$49.4 million, or \$0.19 per basic and diluted share, for the fourth quarter of 2019.

#### **Balance Sheet**

As of March 31, 2020, the Company's cash on hand totaled \$170.1 million, compared with approximately \$160.8 million at December 31, 2019.

Total outstanding debt, net of issuance costs, was approximately \$243.4 million as of March 31, 2020 compared to \$194.6 million as of December 31, 2019. The change is due to the drawdown of the \$50 million tranche for meeting the fourth quarter 2019 revenue draw trigger.

#### **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:** Wednesday, May 6, 2020

Time:8:30 a.m. ETTelephone Access (US):866-665-9531Telephone Access (International):724-987-6977Access Code for All Callers:5832796

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: 5832796.

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 Company's ability to protect the intellectual property related to its products; the effects of the COVID-19 pandemic; the Company's ability to maintain or increase sales of its products; the Company's ability to develop and commercialize IMVEXXY®, ANNOVERA®, BIJUVA® and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the Company will be able to comply with the covenants and conditions under its term loan facility, including the conditions to draw an additional tranche thereunder and whether the lender will make such tranche available; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of the Company's current or future approved products or preclude the approval of the Company's future drug candidates; whether the FDA will approve the efficacy supplement for the lower dose of BIJUVA; the Company's ability to protect its intellectual property, including with respect to the Paragraph IV notice letters the Company received regarding IMVEXXY and BIJUVA; the length, cost and uncertain results of future clinical trials; the Company's reliance on third parties to conduct its manufacturing, research and development and clinical trials; the ability of the Company's licensees to commercialize and distribute the Company's products; the ability of the Company's marketing contractors to market ANNOVERA; the availability of reimbursement from government authorities and health insurance companies for the Company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the Company's common stock and the concentration of power in its stock ownership. PDF Company's press financial copies of the historical releases and tables he viewed downloaded can and website: www.therapeuticsmd.com/pressreleases.aspx.

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#### **Investor Contact**

Nichol Ochsner Vice President, Investor Relations 561-961-1900, ext. 2088 Nochsner@TherapeuticsMD.com

# THERAPEUTICSMD, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	N	March 31, 2020	Dec	cember 31, 2019
ASSETS		(Unaudited)		
Current Assets:				
Cash	\$	170,097,813	\$	160,829,713
Accounts receivable, net of allowance for doubtful accounts of \$781,419 and \$904,040,	Ф	170,037,013	Ф	100,029,713
respectively		20,664,009		24,395,958
Inventory		14,607,453		11,860,716
Other current assets		6,618,367		11,329,793
Total current assets		211,987,642		208,416,180
				<u> </u>
Fixed assets, net		2,330,190		2,507,775
	_	_,	_	_,,
Other Assets:				
License rights, net		38,475,797		39,221,308
Intangible assets, net		5,616,832		5,258,211
Right of use assets		9,757,167		10,109,154
Other assets		473,009		473,009
Total other assets	_	54,322,805	_	55,061,682
Total assets	\$	268,640,637	\$	265,985,637
	Ť		<u> </u>	
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUI	TV			
Current Liabilities:				
Accounts payable	\$	28,714,327	\$	19,181,212
Other current liabilities	Ψ	32,924,485	Ψ	33,823,613
Total current liabilities	-	61,638,812		53,004,825
Total Carrent Informació		01,050,012		55,00 1,025
Long-Term Liabilities:				
Long-term debt		243,428,671		194,634,643
Operating lease liability		8,782,274		9,145,049
Total long term liabilities		252,210,945		203,779,692
Total liabilities		313,849,757		256,784,517
		313,0 13,7 37		200,701,017
Commitments and Contingencies				
Communicity and Contingencies				
Stockholders' (Deficit) Equity:				
Preferred stock - par value \$0.001; 10,000,000 shares authorized; no shares issued and				
outstanding		_		_
Common stock - par value \$0.001; 350,000,000 shares authorized: 271,677,742 and				
271,177,076 issued and outstanding, respectively		271,678		271,177
Additional paid-in capital		706,789,283		704,351,222
Accumulated deficit		(752,270,081)		(695,421,279)
Total stockholders' (deficit) equity		(45,209,120)		9,201,120
Total liabilities and stockholders' equity	\$	268,640,637	\$	265,985,637

# THERAPEUTICSMD, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended March 31,		Three Months Ended December 31,		
		2020	 2019		2019
Product revenue, net	\$	12,250,657	\$ 3,946,651	\$	15,901,680
Cost of goods sold		2,715,051	 762,827		2,878,590
Gross profit		9,535,606	 3,183,824		13,023,090
Operating expenses:					
Sales, general, and administrative		56,927,021	34,864,082		52,734,093
Research and development		3,268,829	6,317,882		4,432,224
Depreciation and amortization		261,994	106,938		248,830
Total operating expenses		60,457,844	41,288,902		57,415,147
Operating loss		(50,922,238)	(38,105,078)		(44,392,057)
Other income (expense)					
Miscellaneous income		335,482	688,721		621,126
Interest expense		(6,262,046)	 (2,090,018)		(5,664,583)
Total other expense		(5,926,564)	 (1,401,297)		(5,043,457)
Loss before income taxes		(56,848,802)	(39,506,375)		(49,435,514)
Provision for income taxes			 <u> </u>		
Net loss	\$	(56,848,802)	\$ (39,506,375)	\$	(49,435,514)
Loss per share, basic and diluted:					
Net loss per share, basic and diluted	\$	(0.21)	\$ (0.16)	\$	(0.19)
Weighted average number of common shares outstanding, basic and diluted		271,459,522	 241,006,032	_	261,752,076

# THERAPEUTICSMD, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

Three Months Ended

	March 31,			
		2020		2019
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	\$	(56,848,802)	\$	(39,506,375)
Adjustments to reconcile net loss to net cash used in operating activities:		,		
Depreciation of fixed assets		198,839		66,494
Amortization of intangible assets		63,155		40,444
Non-cash operating lease expense		351,987		219,765
(Recovery of) provision for doubtful accounts		(122,621)		82,284
Share-based compensation		2,366,453		2,586,948
Amortization of deferred financing fees		319,408		120,146
Amortization of license fee		745,511		_
Changes in operating assets and liabilities:				
Accounts receivable		3,854,569		(3,963,214)
Inventory		(2,746,737)		(1,688,045)
Other current assets		4,436,047		987,794
Accounts payable		9,533,115		2,621,402
Accrued expenses and other current liabilities		(1,261,904)		268,939
·				
Net cash used in operating activities		(39,110,980)		(38,163,418)
CASH FLOWS FROM INVESTING ACTIVITIES				
Patent costs		(421,775)		(403,496)
Purchase of fixed assets		(21,254)		(262,418)
Net cash used in investing activities		(443,029)		(665,914)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from exercise of options and warrants		72,109		100,107
Proceeds from Financing Agreement		50,000,000		_
Payment of deferred financing fees		(1,250,000)		_
Net cash provided by financing activities		48,822,109		100,107
Increase (decrease) in cash		9,268,100		(38,729,225)
Cash, beginning of period		160,829,713		161,613,077
Cash, end of period	\$	170,097,813	\$	122,883,852
Supplemental disclosure of cash flow information				
••				
Interest paid	\$	5,892,639	\$	1,913,956



## Forward-Looking Statements

This presentation by TherapeuticsMD, Inc. (referred to as "we," "our," or "the Company") may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believe," "hope," "may," "anticipate," "should," "intend," "plan," "will," "expect," "estimate," "project," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of our managerial experience and perception of historical trends, current conditions, expected future developments and other factors we believe to be appropriate.

Forward-looking statements in this presentation are made as of the date of this presentation, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise, Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which may be outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission (SEC), including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our current reports on Form 8-K, and include the following: the company's ability to protect the intellectual property related to its products; the effects of the COVID-19 pandemic; the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize IMVEXXY\*, ANNOVERA\*, BIJUVA\* and its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company will be able to comply with the covenants and conditions under its term loan facility, including the conditions to draw an additional tranche thereunder and whether the lender will make such tranche available; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of the company's current or future approved products or preclude the approval of the company's future drug candidates; whether the FDA will approve the efficacy supplement for the lower dose of BIJUVA; the 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 licensees to commercialize and d

Therapeutics MD'





## Our approach is strategic, highly focused and achievable:

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

## **Portfolio Strategic Focus**

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

## **COVID-19 Adaptation**

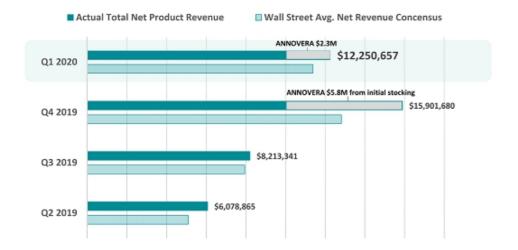


- TPG Sixth Street Partners discussions ongoing
- We believe ANNOVERA and IMVEXXY are positioned to capitalize on trends accelerating due to COVID-19
  - Expanded access through telehealth
  - Online and retail home delivery distribution
  - As a result of job losses due to COVID-19, we expect unemployment to grow the Medicaid population where we have recently established coverage

Therapeutics MD\*



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



\* Wallstreet Consensus Estimate per "estimize"

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

Therapeutics MD\*

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## 1Q20 Key Metrics: ANNOVERA

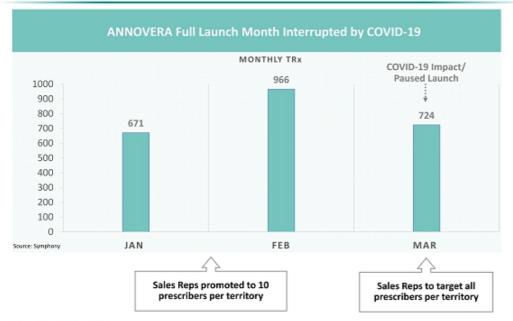


- 1Q20 net revenue: ~\$2.3M
- 1Q20 total prescriptions (TRx) to patient<sup>1</sup>: 2,361
- 1Q20 Average (avg.) net revenue per unit<sup>2</sup>: ~\$1,350
  - Adjudication rate: ~100%
- Expected avg. net revenue per unit during 2020: ~\$1,200 \$1,400
  - ~77% of ANNOVERA patients are paying \$0 copay
- # Healthcare professionals (HCPs) with TRx: ~1,140

<sup>&</sup>lt;sup>3</sup> Source: Symphony
<sup>3</sup> Average net revenue per unit calculated from sales to wholesalers and pharmacies



## 1Q20 Key Metrics: ANNOVERA



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## 1Q Key Metrics: IMVEXXY

1Q20 net revenue: ~\$6.4M

1Q20 TRx to patient<sup>1</sup>: ~134,000

1Q20 net revenue per unit<sup>2</sup>: ~\$48

Overall adjudication rate: ~44%

Not as heavily impacted by COVID-19

Established base of business across writers and patients

# HCPs with TRx: 17,000

Focus on fills allows for continued revenue growth

 Average of 6 units per patient for those patients who started therapy over 12 months ago

Average of 4.2 units per patient in 2019

<sup>3</sup> Source: Symphony
<sup>3</sup> Source: Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period

## 1Q Key Metrics: BIJUVA



■ 1Q20 net revenue: ~\$1.1M

■ 1Q TRx to patients1: ~26,000

1Q20 net revenue per unit<sup>2</sup>: ~\$43

■ Overall adjudication rate: ~51%

# HCPs with TRx: ~5,000

<sup>1</sup> Source: Symphony
<sup>2</sup> Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period



## 1Q20 Payor Progress: ANNOVERA



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

## **1Q20 Payor Progress: Menopausal Products**

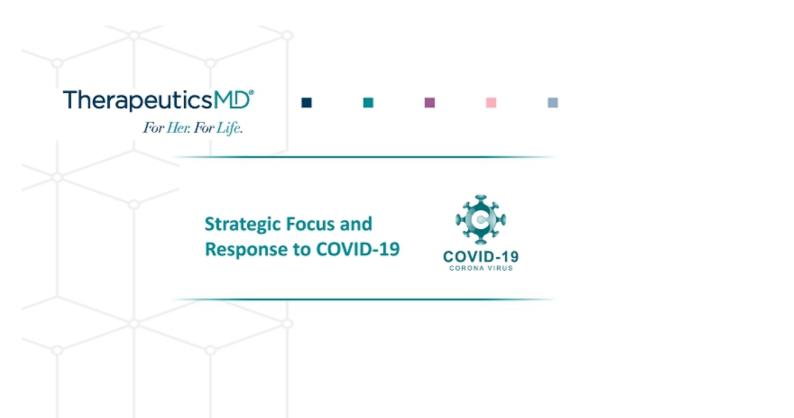


#### IMVEXXY Commercial access remains solid at 72% unrestricted

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

### BIJUVA Commercial access remains at 54% unrestricted and discussions are ongoing

- We have achieved access with 7 of the top 10 commercial payors
- Since January 1st, BIJUVA has added 21 states with unrestricted Medicaid access with average copays of \$5 or less



## Ç COVID-19

## **Strategic Changes Related to COVID-19**

Given the uncertainty around the impact and length of COVID-19, like most companies we are proactively reducing our expense structure

- Decreasing expenses related to BIJUVA and areas not contributing to near-term revenue
  - Decreasing the expense base related to BIJUVA enhances funding for ANNOVERA and IMVEXXY post COVID-19
- Changes lead to the following operational adjustments:
  - -Sales support primarily on ANNOVERA and IMVEXXY
  - -Reduction in medical support related to BIJUVA
  - -Slowing acquisition of BIO-IGNITE partners
  - -Reduction in agency related marketing spend
- Supports goal of EBITDA breakeven in 2021

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## **COVID-19 Strategic Changes Related to Revenue**

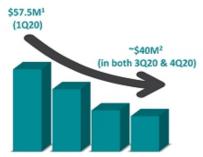
- We continue to believe in the long-term trajectory of our portfolio; however, due to COVID-19 we don't have complete visibility in the short-term
- Currently regaining access to doctors' offices in lock step as the states reopen
  - -Currently operating in a hybrid (face-to-face and remote) interaction model
  - -We expect office access to expand and accelerate during 2Q and normalize during 3Q
- We expect to reactivate the growth drivers in early 3Q20
  - —ANNOVERA full launch including launch of Consumer Campaign "Unapologetically ANNOVERA"
  - -IMVEXXY acceleration of media and reengagement of in person sales efforts

We expect a revenue impact in 2Q due to COVID-19 and believe we are well positioned to resume our growth trajectory in 3Q

## **Corporate Wide Cost Reductions in Total Operating Expenses**



- 1Q20 operating expense of \$57.5M<sup>1</sup>
  - One-time expenses of \$5M due to ANNOVERA training and launch
- Expect 2Q20 total operating expenses to be \$10-\$12M lower than 1Q20
  - Defer \$10M in marketing spend primarily related to media
- Expect average total operating expenses in 3Q20 and 4Q20 to be approximately \$40M or less<sup>2</sup>
- We believe these actions will continue to position us to become EBITDA break even in 2021



Therapeutics 1560.5M total operating expenses excluding \$3M non-cash items

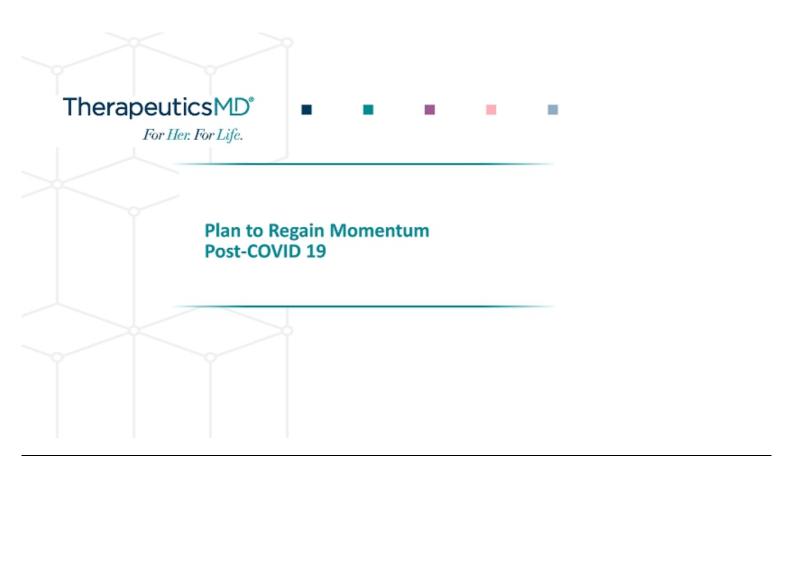
1560.5M total operating expenses excluding \$3M non-cash items

1560.5M total operating expenses excluding non-cash items



## **Update to TPG Sixth Street Loan Covenants**

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



## **ANNOVERA: Well Positioned for Fast Uptake When Full Plans Deployed**



**Contraception: Largest** Women's Health Category

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

will Quickly Accelerate at \$5B Ramp

#### 1Q20 Efforts and Results

**Full Sales Force Plans and** 

**Consumer Advertising** 

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

#### **3Q20 Efforts**

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

**Broad Availability will** Allow Growth Across **Contraception Channels** 

## **Retail Pharmacies**

Whitgreeks @ Bo Ignite



::PlustiCare PILL CLUB

SimpleHealth ☐ PillPack

#### **Public Health**

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

Available to 92 military bases

## **ANNOVERA Compelling Now and Post COVID-19**

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



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

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## **ANNOVERA Update of Patent Strategy**

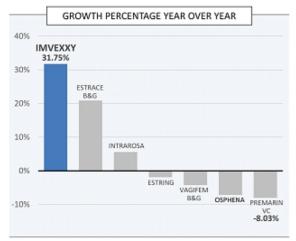
### On April 28, 2020, the USPTO issued the first Orange Book listable patent for ANNOVERA

- -US Patent No 10,632,066 will expire February 2039
- —On March 29, 2020, TherapeuticsMD filed FDA Form 3542 to have the '066 patent listed in the Orange Book
- -The '066 patent claims elements of the ANNOVERA label, which a generic would need to copy as part of its Abbreviated New Drug Application (ANDA)
- Currently on file with the USPTO are six additional utility patent applications for ANNOVERA and one design patent
  - These applications cover different aspects of ANNOVERA and if issued would strengthen ANNOVERA's exclusivity position

## **IMVEXXY Continues to Gain Momentum**



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



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

## BIJUVA Targeted Focus Until 0.5/100 Launch is Funded in 2021

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



# Q&A



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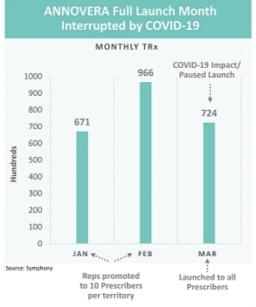


	1Q 2020	4Q 2019
Net Revenue	~\$2.3M	~\$5.8M
TRx to patients	2,361	1,095
Average Net Revenue / Unit	\$1,350	\$1,350
# Prescribers w/ TRx	1,140	540

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

<sup>\*</sup>Average net revenue per unit calculated from sales to wholesalers and pharmacies





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## 1Q Key Metrics: IMVEXXY

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

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



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

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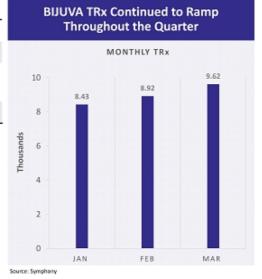


## 1Q Key Metrics: BIJUVA



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

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



<sup>\*</sup> Calculated Net Revenue per Unit = GAAP Net Revenue divided by number of prescriptions filled by patients in period

## **Strengthened Board with New Independent Directors**

### TXMD added 3 experienced, diverse, independent, health care industry veterans



Karen Ling

- Ms. Ling is an accomplished executive with 25 years experience leading the human resources functions at a variety of companies and has spent the majority of her career in women's health
- Experience in small and large pharmaceutical companies including, American International Group, Inc., Allergan plc, Actavis plc., Merck Global, Schering-Plough and Wyeth



Paul Bisaro

- Mr. Bisaro is an accomplished global business leader with more than 25 year of of generic and branded pharmaceutical experience, including in women's health with a track record of driving company growth through operational execution and corporate transformation
- Experience in small and large pharmaceutical companies including, Allergan, plc, Actavis, Watson Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc., Impax Laboratories, Inc. and Barr Pharmaceuticals, Inc.



Gail Naughton

- Dr. Naughton is an accomplished life sciences executive and researcher that founded two regenerative medicine companies and is the holder of more than 105 U.S. and foreign patents
- Dr. Naughton currently serves as Histogen's Chief Scientific Officer. She has brought several tissue engineered products to market including a product for severe burns (TransCyte), a dermal replacement for diabetic ulcers (Dermagraft), an aesthetic dermal filler (Cosmederm/Cosmeplast) and SkinMedica's TNS product for skin care
- Board members and insiders John Milligan (President), Brian Bernick MD (Co-Founder), independents, Nick Segal and Rob LaPenta stepped down shrinking the Board from 11 directors to a new total of 9 directors

Therapeutics MD\*