

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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): August 6, 2020

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

001-00100

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

951 Yamato Road, Suite 220
Boca Raton, FL 33431

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	TXMD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230-405) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 6, 2020, TherapeuticsMD, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 August 6, 2020, the Company issued a press release announcing the Company's financial results for its second quarter ended June 30, 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release from TherapeuticsMD, Inc., dated August 6, 2020, entitled "TherapeuticsMD Announces Second Quarter 2020 Financial Results."
99.2	TherapeuticsMD, Inc. Presentation dated August 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: August 6, 2020

THERAPEUTICSMD, INC.

By: /s/ James C. D'Arecca

Name: James C. D'Arecca

Title: Chief Financial Officer



FOR IMMEDIATE RELEASE

TherapeuticsMD[®] Announces Second Quarter 2020 Financial Results

- 2Q20 total net product revenue of \$10.7 million resilient despite COVID-19 pandemic -
- ANNOVERA[®] prescriptions increased approximately 100% for the eight weeks ended July 24, 2020 over the previous eight week period-
- IMVEXXY[®] new prescriptions increased 33% for the eight weeks ended July 24, 2020 over the previous eight week period-
- Consumer campaign for ANNOVERA achieved over 3 million unique views in first 30 days -
 - Initial consumer marketing campaign for IMVEXXY to be launched in August -
- Amended Sixth Street Partners revenue covenants to reflect impact of COVID-19 pandemic -
 - Conference call scheduled for 8:30 a.m. ET today -

BOCA RATON, Fla. – August 6, 2020 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women’s healthcare company, today reported financial results for the second quarter ended June 30, 2020.

“Our organization made significant progress in the second quarter while navigating the COVID-19 pandemic and its impact on our business,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. “We delivered a strong quarter of operational execution during very unique circumstances, quickly reducing our operating expenses, reorienting our sales force, and addressing our credit facility future minimum net revenue covenants. These strategic and operational changes and our reshaped Board of Directors and management team are focused on driving revenue and achieving our goal of reaching EBITDA break even in 2021, which we believe will result in long-term shareholder value.”

Recent Updates

- Prescription volume for ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) for the eight weeks ended July 24, 2020 increased approximately 100% over the previous eight weeks (the time period most heavily impacted by COVID-19). ANNOVERA current prescription trend exceeds the product’s pre-COVID-19 launch trajectory.
- The Company initiated the direct-to-consumer marketing campaign for ANNOVERA on July 1, 2020. Digital metrics show that the “Unapologetically ANNOVERA” campaign has quickly gained visibility resulting in over 100 million impressions and 3 million unique views since launch.
- The Company is working with the Department of Defense, public health organizations, and telehealth platforms to expand access to women and contribute to the Company’s growth in the second half of the year.
- As of July 1, 2020, ANNOVERA achieved 79% commercial coverage and 46% Medicaid coverage. The vast majority of patients are covered without a copay.
- IMVEXXY (estradiol vaginal inserts) new prescriptions for the eight weeks ended July 24, 2020 increased 33% over the previous eight weeks ended May 29, 2020 (the time period most heavily impacted by COVID-19). IMVEXXY continues to experience strong refill rates. These trends should positively impact total prescriptions going forward.
- The Company plans to launch the consumer marketing campaign for IMVEXXY during August 2020.
- IMVEXXY’s commercial market access is 72% unrestricted commercial coverage, including all of the top ten commercial payors of VVA products. The Company added Wellcare as a Medicare Part D payor.
- As of July 1, 2020, BIJUVA[®] (estradiol and progesterone) capsules commercial market access increased to 73% unrestricted commercial coverage with nine of the top ten commercial payors.

Sixth Street Update

- The Company worked with Sixth Street Partners (“Sixth Street”) to adjust the total minimum net revenue covenant in its financing agreement to reflect the impact of COVID-19. The covenants begin with the results for the fourth quarter of 2020.



- The total minimum net revenue requirement for ANNOVERA, IMVEXXY, and BIJUVA was adjusted to \$20 million for the fourth quarter of 2020. In 2021, the minimum net revenue covenant will be \$25 million, \$37.5 million, \$47.5 million, and \$57.5 million for the first, second, third, and fourth quarters, respectively. Given the Company's current rate of growth, the Company believes it is well positioned to meet or exceed these minimum covenants.
- The Company and Sixth Street are not moving forward with the undrawn \$50 million tranche under the financing agreement, which was designed to be drawn following the successful full commercial launch of ANNOVERA in the second quarter, due to the pause in the launch timing caused by the COVID-19 pandemic. There continues to be an active dialogue with Sixth Street regarding potential additional financing.

Second Quarter Highlights

- Net product revenue for the second quarter of 2020 was \$10.7 million.
- The COVID-19 pandemic had a significant impact on the Company's product revenue early in the second quarter of 2020. The Company's products returned to growth mid to late quarter. Notwithstanding COVID-19, the Company expects continued growth in the second half of 2020.
- In the second quarter 2020, ANNOVERA net revenue was \$1.8 million. Approximately 2,400 ANNOVERA prescriptions were dispensed. Net revenue per unit, calculated from sales to wholesalers and pharmacies, was \$1,332.
- In the second quarter 2020, IMVEXXY net revenue was \$5.1 million. Approximately 118,000 IMVEXXY prescriptions were dispensed. Net revenue per unit was \$41. Strong IMVEXXY refill rates continued with patients adhering to therapy.
- In the second quarter 2020, BIJUVA net revenue was \$1.4 million. Approximately 27,600 BIJUVA prescriptions were dispensed. Net revenue per unit was \$45 for the second quarter of 2020.

Net Product Revenue

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Three Months Ended March 31, 2020
ANNOVERA	\$ 1,835,460	\$ —	\$ 2,272,761
IMVEXXY	5,085,190	3,121,711	6,392,601
BIJUVA	1,352,001	134,282	1,111,604
Prenatal vitamins	2,428,382	2,822,872	2,473,691
Net revenue	<u>\$ 10,701,033</u>	<u>\$ 6,078,865</u>	<u>\$ 12,250,657</u>

Net product revenue for the second quarter of 2020 was affected by the COVID-19 pandemic across all of our products.

Cost of Goods Sold/Gross Margin

Cost of goods sold increased \$1.7 million for the second quarter of 2020 compared to the first quarter of 2020, as the result of a non-cash write-off of \$1.9 million primarily related to BIJUVA inventory obsolescence, partially offset by the impact of an overall decline in unit sales. The charge is the result of the Company's reprioritization of selling resources to ANNOVERA and IMVEXXY along with the impact of the COVID-19 pandemic on sales forecasts of BIJUVA for future quarters. This charge caused gross margin percentage to decline from 78% for the quarter ended March 31, 2020 to 59% for the quarter ended June 30, 2020.

Expense, EPS and Related Information

Total operating expenses decreased by \$9.2 million to \$51.3 million for the second quarter of 2020 as compared to \$60.5 million for the first quarter of 2020. The decrease in operating expenses was primarily a result of the Company's cost containment and spend-rebalancing efforts to reduce overall spend in the remaining quarters of the 2020 fiscal year. For the remainder of 2020, spend will focus on delivering the necessary resources to support the launch of ANNOVERA, continued ramp-up of IMVEXXY, and ongoing brand management of BIJUVA. The second quarter of 2020 was impacted by \$3.9 million in charges related to product samples expense as a result of the Company's decision to reduce sampling of BIJUVA.

Net loss for the quarter ended June 30, 2020 decreased to \$52.0 million, or \$0.19 per basic and diluted share, compared with \$56.8 million, or \$0.21 per basic and diluted share, for the quarter ended March 31, 2020. Net loss per share for the second quarter of 2020 was impacted by inventory and sample expense charges related primarily to BIJUVA of \$0.02 per basic and diluted share.

Balance Sheet

As of June 30, 2020, the Company's cash on hand totaled \$113.8 million, compared with \$170.1 million on March 31, 2020. The decline in cash was due primarily to the net loss for the quarter ended June 30, 2020, less certain non-cash items, as well as the timing of advertising, marketing, and social media campaigns for ANNOVERA that were incurred at the end of the quarter ended March 31, 2020 and funded early in the quarter ended June 30, 2020. Total outstanding debt, net of issuance costs, was \$243.8 million as of June 30, 2020, compared to \$243.4 million as of March 31, 2020. The change is due to the amortization of debt discount of \$400,000.

Sixth Street Additional Information

- In connection with the adjustment to the Sixth Street total minimum net revenue covenant and in lieu of a cash amendment fee, the Company issued to the Sixth Street lenders warrants to purchase an aggregate of approximately 4.75 million shares of the Company's common stock with an exercise price of \$1.58 per share and a ten year term. The warrants are unregistered, do not have registration rights, and do not have anti-dilution protection, other than for customary stock splits and similar transactions.
- The total minimum net revenue requirement for ANNOVERA, IMVEXXY, and BIJUVA in 2022 will be \$65 million, \$75 million, \$85 million, and \$95 million for the first, second, third, and fourth quarters, respectively, and will remain at \$95 million for subsequent quarters.

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, August 6, 2020
Time:	8:30 a.m. ET
Telephone Access (US):	866-665-9531
Telephone Access (International):	724-987-6977
Access Code for All Callers:	2963048

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: 2963048.

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

About TherapeuticsMD

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 www.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; 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 copies of the company's historical press releases and financial tables can be viewed and downloaded at its website: www.therapeuticsmd.com/pressreleases.aspx.

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Investor Contact

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Vice President, Investor Relations
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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash	\$ 113,839,234	\$ 160,829,713
Accounts receivable, net of allowance for doubtful accounts of \$722,240 and \$904,040, respectively	18,290,784	24,395,958
Inventory, net	10,172,312	11,860,716
Other current assets	6,641,587	11,329,793
Total current assets	148,943,917	208,416,180
Fixed assets, net	2,145,926	2,507,775
Other Assets:		
License rights, net	37,721,695	39,221,308
Intangible assets, net	5,942,873	5,258,211
Right of use assets	10,337,577	10,109,154
Other assets	446,925	473,009
Total other assets	54,449,070	55,061,682
Total assets	\$ 205,538,913	\$ 265,985,637
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	\$ 17,270,319	\$ 19,181,212
Other current liabilities	29,213,411	33,823,613
Total current liabilities	46,483,730	53,004,825
Long-Term Liabilities:		
Long-term debt	243,801,705	194,634,643
Operating lease liability	9,307,361	9,145,049
Other long-term liabilities	35,000	—
Total long-term liabilities	253,144,066	203,779,692
Total liabilities	299,627,796	256,784,517
Commitments 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; 600,000,000 and 350,000,000 shares authorized; 272,294,380 and 271,177,076 issued and outstanding, respectively	272,294	271,177
Additional paid-in capital	709,885,568	704,351,222
Accumulated deficit	(804,246,745)	(695,421,279)
Total stockholders' (deficit) equity	(94,088,883)	9,201,120
Total liabilities and stockholders' equity	\$ 205,538,913	\$ 265,985,637

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

	Three Months Ended June 30,		Three Months Ended March 31,		Six Months Ended June 30,	
	2020	2019	2020	2019	2020	2019
Product revenue, net	\$ 10,701,033	\$ 6,078,865	\$ 12,250,657	\$ 12,250,657	\$ 22,951,690	\$ 10,025,516
Cost of goods sold	4,400,485	1,248,860	2,715,051	2,715,051	7,115,536	2,011,687
Gross profit	6,300,548	4,830,005	9,535,606	9,535,606	15,836,154	8,013,829
Operating expenses:						
Sales, general, and administrative	48,340,628	41,387,451	56,927,021	56,927,021	105,267,649	76,251,533
Research and development	2,742,032	4,964,368	3,268,829	3,268,829	6,010,861	11,282,250
Depreciation and amortization	256,557	115,059	261,994	261,994	518,551	221,997
Total operating expenses	51,339,217	46,466,878	60,457,844	60,457,844	111,797,061	87,755,780
Operating loss	(45,038,669)	(41,636,873)	(50,922,238)	(50,922,238)	(95,960,907)	(79,741,951)
Other (expense) income						
Loss on extinguishment of debt	—	(10,057,632)	—	—	—	(10,057,632)
Miscellaneous income	88,858	486,597	335,482	335,482	424,340	1,175,318
Interest expense	(7,026,853)	(4,028,609)	(6,262,046)	(6,262,046)	(13,288,899)	(6,118,627)
Total other expense	(6,937,995)	(13,599,644)	(5,926,564)	(5,926,564)	(12,864,559)	(15,000,941)
Loss before income taxes	(51,976,664)	(55,236,517)	(56,848,802)	(56,848,802)	(108,825,466)	(94,742,892)
Provision for income taxes	—	—	—	—	—	—
Net loss	\$ (51,976,664)	\$ (55,236,517)	\$ (56,848,802)	\$ (56,848,802)	\$ (108,825,466)	\$ (94,742,892)
Loss per share, basic and diluted:						
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.23)	\$ (0.21)	\$ (0.21)	\$ (0.40)	\$ (0.39)
Weighted average number of common shares outstanding, basic and diluted	271,876,238	241,221,840	271,459,522	271,459,522	271,667,879	241,114,532

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

	Six Months Ended	
	June 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (108,825,466)	\$ (94,742,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	387,649	133,049
Amortization of intangible assets	130,902	88,948
Write off of patent and trademark costs	—	78,864
Operating lease impairment	81,309	—
Non-cash operating lease expense	689,089	443,734
(Recovery of) provision for doubtful accounts	(181,800)	167,500
Inventory obsolescence reserve	5,965,139	—
Loss on extinguishment of debt	—	10,057,632
Share-based compensation	5,369,279	5,224,212
Amortization of deferred financing fees	692,442	316,880
Amortization of license fee	1,499,613	—
Changes in operating assets and liabilities:		
Accounts receivable	6,286,974	(7,486,691)
Inventory	(4,276,735)	(4,226,770)
Other current assets	4,412,827	1,710,697
Accounts payable	(1,910,893)	(3,244,603)
Accrued expenses and other current liabilities	(5,420,628)	2,801,717
Net cash used in operating activities	<u>(95,100,299)</u>	<u>(88,677,723)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs	(815,564)	(763,247)
Purchase of fixed assets	(25,800)	(1,092,504)
Security deposit	35,000	(20,420)
Net cash used in investing activities	<u>(806,364)</u>	<u>(1,876,171)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options and warrants	166,184	100,107
Repayment of the Credit Agreement	—	(81,660,719)
Proceeds from the Financing Agreement	50,000,000	200,000,000
Payment of deferred financing fees	(1,250,000)	(6,652,270)
Net cash provided by financing activities	<u>48,916,184</u>	<u>111,787,118</u>
Increase (decrease) in cash	(46,990,479)	21,233,224
Cash, beginning of period	160,829,713	161,613,077
Cash, end of period	<u>\$ 113,839,234</u>	<u>\$ 182,846,301</u>
Supplemental disclosure of cash flow information		
Interest paid	<u>\$ 12,032,014</u>	<u>\$ 6,989,570</u>



2Q 2020 Earnings

August 6, 2020

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 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®, 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; 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. This non-promotional presentation is intended for investor audiences only.



Strategic Overview

Strategic Overview

- 2Q20 total net revenue was resilient despite COVID-19
- Set Sixth Street revenue covenants to reflect the impact of COVID-19
- Executed a strategic and multifaceted plan to adapt to the new reality of a global pandemic and drive long-term shareholder value
 - Swift action to right-size our company, reduction of total operating expenses expected to trend to ~\$40M by 4Q20
 - Remain laser focused on reaching goal of EBITDA breakeven on a quarterly basis in 2021
 - Pivoted sales force to operate in a "hybrid" model and support healthcare providers virtually
 - Launched into new channels of distribution including telehealth, public health and Department of Defense to accelerate growth
 - Reshaped Board of Directors and Management Team
- Despite COVID-19, the Company returned product portfolio to growth which is expected to continue throughout 2020



Sixth Street Update

Sixth Street Loan Update

- Revised total minimum net revenue covenants for ANNOVERA, IMVEXXY and BIJUVA

4Q 2020	1Q 2021	2Q 2021	3Q 2021	4Q 2021
\$20M	\$25M	\$37.5M	\$47.5M	\$57.5M

- While not formal guidance, covenants are based on the Company's post-COVID-19 revised forecast
- The Company and Sixth Street are not moving forward with the undrawn \$50 million tranche under the financing agreement, which was designed to be drawn following the successful full commercial launch of ANNOVERA in the second quarter, due to the pause in the launch timing caused by the COVID-19 pandemic
- There continues to be an active dialogue with Sixth Street regarding potential additional financing



Financial Update

Quarterly Net Revenue Trends

- 2Q20 total net revenue of \$10.7M
- Early in the quarter, due to COVID-19 there was a reduction in patient visits to healthcare providers that negatively impacted volumes
- Later in the quarter, we saw patient demand for ANNOVERA outpace wholesaler orders resulting in a drawdown of inventory in the channel
- More recently, we are pleased to see early momentum building through commercial execution of our plans and expect this to continue throughout the rest of 2020

2Q20 Key Metrics



Net Revenue	~\$1.8M	~\$5.1M	~\$1.4M
Average Net Revenue / Unit:	~\$1,332 ¹	~\$41 ²	~\$45 ²
Overall adjudication rate:	~99%	~44%	~56%

¹ Average net revenue per unit calculated based on units sold to wholesalers and pharmacies divided into net revenue for the quarter.
² Average net revenue per unit calculated based on units sold to wholesalers and pharmacies divided into net revenue for the quarter.
 This reflects a change in methodology from previous "calculated net revenue per unit" which used units sold to patients in the quarter.

Financial Results: Comparison 2Q 2020 to 1Q 2020

Comparison of Key Financial Statement Items

	2Q 2020	1Q 2020	
Balance Sheet			
Cash	\$113,839,234	\$170,097,813	<ul style="list-style-type: none"> De-emphasis of BIJUVA triggered write-offs <ul style="list-style-type: none"> \$1.9M impact on cost of sales negatively impacted gross margin \$3.9M one-time charge for write-off of BIJUVA samples
Working Capital	\$102,460,187	\$150,349,000	
Long-term Debt	\$243,801,705	\$243,428,671	
Income Statement			
Product Revenue, Net	\$10,701,033	\$12,250,657	<ul style="list-style-type: none"> Excluding the one-time charge of \$3.9M for BIJUVA write-off of samples, total cash related operating expenses were \$47.4M
Gross Profit	\$6,300,548	\$9,535,606	
% of Gross Margin	59%	78%	<ul style="list-style-type: none"> Expect total operating expenses to trend down to ~\$40M in 4Q20¹ Net cash used in operating activities was impacted by ~\$11M in accrued expenses incurred in the 1Q20 for the launch of ANNOVERA which were paid in the 2Q20
Total Operating Expenses	\$51,339,217	\$60,457,844	
Net Loss	(\$51,976,644)	(\$56,848,802)	
Statement of Cash Flow			
Net Cash Used In Operating Activities	(\$55,990,299)	(\$39,110,980)	

¹Excluding non-cash items; depending on performance additional investment in SG&A to further drive growth and enhance employee retention may be made.



Commercial Updates

2Q20 and Recent Payor Progress

	Coverage May 2020	Coverage July 2020
ANNOVERA		
Commercial	64% UR, 76%	66% UR, 79%*
Medicaid	45%	46%
Department of Defense	On Formulary	On Formulary
IMVEXXY		
Commercial	72%	72%
Part D	27%	37% [^]
BIJUVA		
Commercial	54%	73%

- **ANNOVERA commercial access is 79%* and the vast majority paying \$0 copay**
- **Fee for Service Medicaid unrestricted in 37 states plus D.C.**
- **Added Wellcare as a Part D payor for IMVEXXY**
- **Added CVS and Anthem as commercial payors for BIJUVA; secured 9 of the top 10 commercial payors**

Source: *MMIT as of July 1st, 2020. *95% unrestricted, 79% covered with prior authorization (PA) / step edit.
[^]Includes lives with PA to indication only. UR=unrestricted.

2Q20 Key Performance Metrics: IMVEXXY



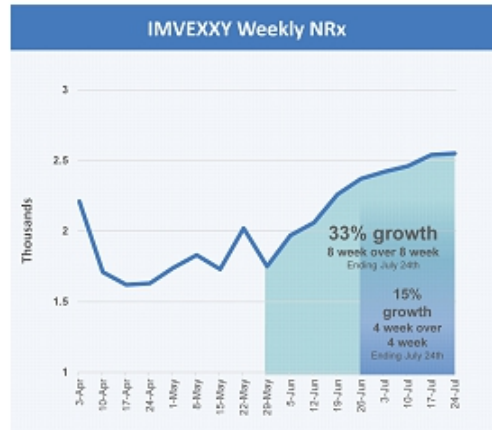
	IMVEXXY 2Q 2020
TRx to patients	~118,000
# Prescribers w/ TRx	~12,000
Overall adjudication rate	~44%

- Focus on fills allows for continued revenue growth
 - Average of 5 fills per patient since launch
- Since 4Q19 the VVA class, on a quarterly basis, declined 15%, largely due to COVID-19
- IMVEXXY modest market share growth vs 4th quarter of 2019
- IMVEXXY New RX increased 33% for 8 weeks ended 7/24/20 over previous 8 weeks setting us up for TRX growth in future months

Data Source: Prescription data per Symphony Health PHAST Data through 7/24/2019

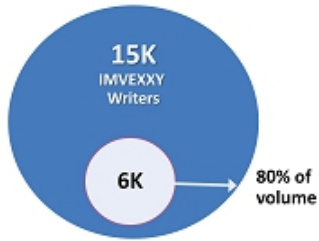
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IMVEXXY Field Force Support Along with DTC Promotion Are Key to Accelerate Growth in the Second Half of 2020

Deepen Prescribing with Core Targets¹



HCP Engagement

- 30% salesforce weighting
- Focus on Efficacy Message in combination with Patient Convenience/Satisfaction Attributes
- Media: Expanded multichannel marketing including custom KOL video programs

Expansion of Direct to Consumer Communications



- New consumer campaign (August)
- Expansion of mediums to display, patient testimonials, videos, social
- Adherence and affordability messaging and programs

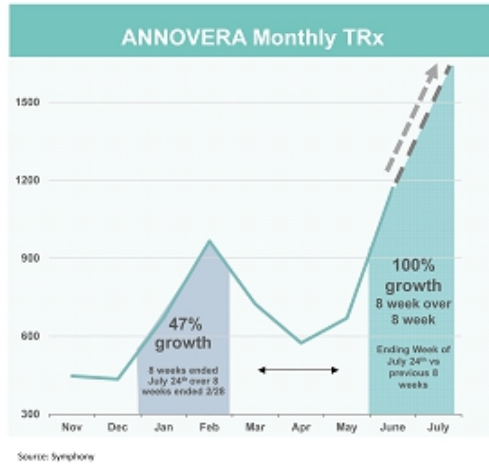
¹Data Source: Prescriber data per IQVIA/TXMD Copay card data

2Q20 Key Performance Metrics: ANNOVERA



	2Q 2020
TRx to patients	~2,400
# Prescribers w/ TRx	~1,100
Adjudication rate	~99%

- Vast majority of patients paying \$0 copay
- Contraception is the largest women's health category valued at \$5B from 18M women



Data Source: Prescription data per Symphony Health PHAST Data through 7/24/2019

ANNOVERA Acceleration throughout Q2 from Fast Adaptation in a Virtual World

Adapted to a Hybrid Selling Model

- ✓ 43% of calls in June were live vs. 11% in May
- ✓ 95% of Sales Representatives were making live calls in June

Expanded Virtual Offerings for Healthcare Providers

- ✓ 250+ HCPs attended virtual speaker programs in Q2



Expanded Opportunities within Telehealth

- ✓ Total of 5 active online platforms



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ANNOVERA – Positive Market Reception



WHO ARE OUR PRESCRIBERS

- NuvaRing writers
- Low IUD writers



WHO ARE OUR CONSUMERS

- Average Age of 31
- Likely switching from current birth control



WHAT ARE THE INSIGHTS

- Option for providers who do not do IUD procedures
- Procedure-free option that fits lifestyle of women moving away from current birth-control

Expectations for a Successful Brand

Contraception Market Size	Time to Achieve 4-5% Market Share	ANNOVERA Revenue at Different Shares
<p> \$5 billion market size</p> <hr/> <p> 28 million new prescriptions annually</p> <hr/> <p> 18 million women</p>	<p><i>Lo Loestrin Fe</i> <small>levonorgestrel and ethinyl estradiol tablets, ethinyl estradiol tablets and loestrin hormone tablets 1 mg/0.02 mg per day</small></p> <p>Lo-Loestrin - ~4 years</p> <hr/> <p><i>NUVARING</i> <small>(etonogestrel/ethinyl estradiol vaginal ring) 0.01 mg/0.02 mg per day</small></p> <p>NuvaRing - ~5 years</p>	<p>1%: 180K Rx, ~\$360M</p> <hr/> <p>2%: 360K Rx, ~\$720M</p> <hr/> <p>3%: 540K Rx, ~\$1.1B</p> <hr/> <p>4%: 720K Rx, ~\$1.4B</p> <hr/> <p>5%: 900K Rx, ~\$1.8B</p>

Data Source: Symphony Health PRACT Data
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ANNOVERA Consumer Campaign Launched on July 1st



TherapeuticsMD[®]

UNAPOLOGETICALLY, ANNOVERA



The Idea

There's a cultural stigma around birth control and women's reproductive health that keeps us from being direct and clear about it all. ANNOVERA wants to finally have an open and honest conversation.



The Focus

Candid conversation



The Line

Unapologetically ANNOVERA



The Voice

Alternative, Straightforward

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ANNOVERA Consumer Campaign Gaining Traction and Visibility within First Month



July/August: Women's Health (15M impressions): "Total Control: Contraceptive Innovations Are Inching Closer Than Ever to Perfection When It Comes to Comfort, Convenience, and Consistent Success. Come Along. Let's Find Your Best New Option"

- 100M impressions and 3.1M YouTube views of the campaign video in less than a month
- 293K visitors to website
- Pick up across media showing culture relevance of product and campaign
- USA Today circulation of 58M
- Women's Health circulation of 15M



UNAPOLOGETICALLY, ANNOVERA



Coronavirus baby boom may actually be a 'baby bust' as experts see spike in birth control orders

Adriana Rodriguez USA TODAY
 Published 1:20pm ET on 8/20/20 | Updated 4:02pm ET on 8/20/20

6700: USA Today (58M+ impressions): Coronavirus baby boom may actually be a "baby bust" as experts see spike in birth control orders

At the start of the COVID-19 pandemic, there were predictions of a baby boom post-pandemic. The article states that a Guttmacher survey of more than 2,000 women ages 18-49 from April 30 to May 6 found that more than 40% of them changed their plans about when to have children or how many children to have due to the pandemic. The article also cited Dr. Minkin, who advised that more people are considering ANNOVERA as an option for birth control during this time, because it is long-acting, reusable and reversible.

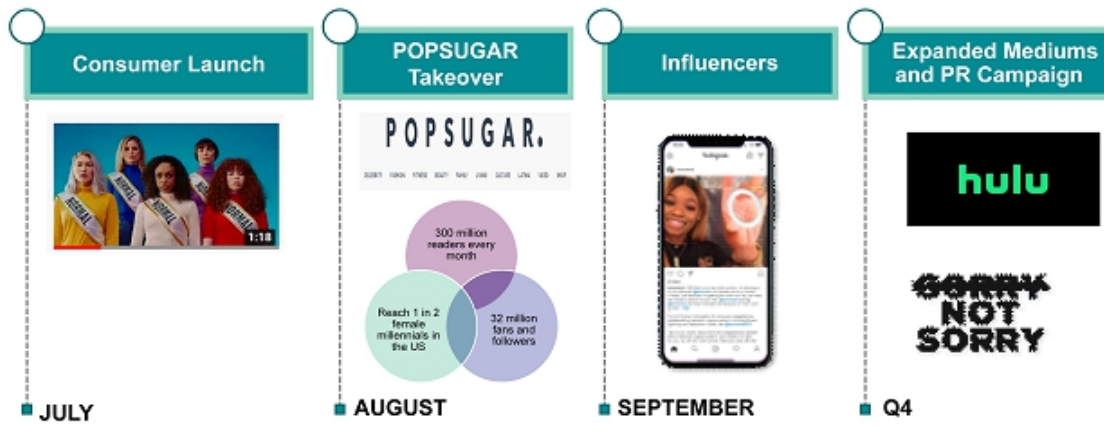
*Data 7/1-7/25 per Google Analytics

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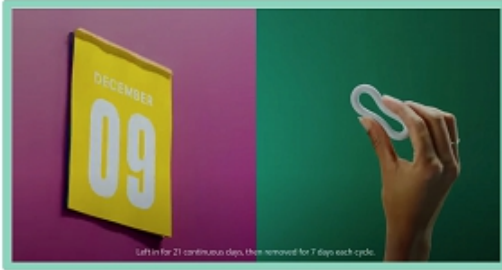
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20

Investment in ANNOVERA Consumer Marketing Remainder of Year



Growth Catalyst: High Future Refill Rate



Phase 3 acceptability study (n=1036 women)**

- After 1 year of use:
 - 85% of the women indicated that they would consider using ANNOVERA if it were free
 - 75% of the women indicated that they would consider using ANNOVERA, even if they had to pay for it
- Vast majority of patients have a \$0 copay

**Questionnaires were administered and completed at cycle 3 by 1036 of the 1135 subjects enrolled in the Phase 3 trial (91%) and 811 subjects at cycle 13.

Mer Katz et al. *Contraception*. 2014;90(5):514-521.

Growth Catalysts by Channel

	 Commercial	 Public Health	 Military	 Online/TeleHealth
% OF MARKET¹	76%	15%	Less than 5%	Emerging and growing channel
RESOURCE	Sales Force	Afaxys: #1 provider of contraception in Medicaid channel	WSI: specialized DoD prescription sales force	5 online platforms
STAGE	<ul style="list-style-type: none"> Launched to core 20K providers with salesforce Marketing focused on white space expansion 	<ul style="list-style-type: none"> Title X (Planned Parenthood) available to order or send script to pharmacy Universities 	<ul style="list-style-type: none"> Rollout was delayed due to COVID-19 Achieved local formulary at 14 of 92 bases 13 bases have ordered 	<ul style="list-style-type: none"> All online platforms now live Expect accelerated growth in 3Q20 and 4Q20

¹Data Source: Symphony Health PHAST Data and Government Reporting for Medicaid and Tricare
TherapeuticsMD

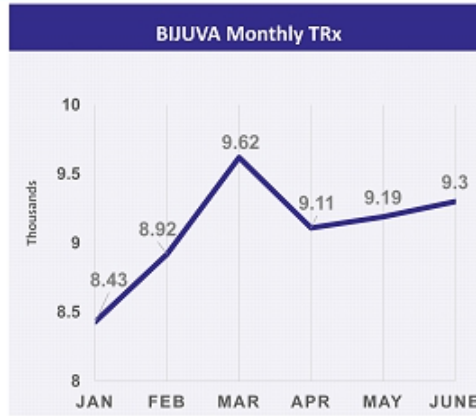
2Q20 Key Performance Metrics: BIJUVA

	2Q 2020
TRx to patients	~27,600
# Prescribers w/ TRx	~4,200
Overall adjudication rate	~56%



Maintain Brand Loyalists

- Targeted approach with team also supporting Bio-Ignite



Source: Symphony

Data Source: Prescription data per Symphony Health PHAST Data through 7/24/2019

Regulation of the Compounding Industry



National Academies of Science, Engineering and Medicine (NASEM)

- Report commissioned by FDA and published on July 1, 2020 looking at bio-identical compounding industry
- NASEM recommendations for stronger regulation and discipline around promotion and dispensing of compounded bio-identical hormones
- NASEM recommendations have been both praised and rebutted by various stakeholders

NASEM Report and Recommendations:

<https://www.nap.edu/resource/25791/cBHT%20Consensus%20Study%20Report%20Highlights.pdf>
<https://www.nap.edu/resource/25791/cBHT%20Recommendations%20Insert.pdf>

Link to compounding industry response:

<https://anh-usa.org/fda-bioidenticals-are-public-health-concern-ban-likely/>

Key Takeaways

- 2Q20 total net revenue was resilient despite COVID-19
- Set Sixth Street revenue covenants to reflect the impact of COVID-19
- Executed a strategic and multifaceted plan to adapt to the new reality of a global pandemic and drive long-term shareholder value
 - Swift action to right-size our company, reduction of total operating expenses expected to trend to ~\$40M by 4Q20
 - Remain laser focused on reaching goal of EBITDA breakeven on a quarterly basis in 2021
 - Pivoted sales force to operate in a "hybrid" model and support healthcare providers virtually
 - Launched into new channels of distribution including telehealth, public health and Department of Defense to accelerate growth
 - Reshaped Board of Directors and Management Team
- Despite COVID-19, the Company returned product portfolio to growth which is expected to continue throughout 2020

Q&A





Appendix

The Commercial Plan supports the Portfolio

- ANNOVERA is our lead product
- IMVEXXY is positioned as a second detail
- BIJUVA focus on maintaining the brand to leverage the opportunity at the right time

Product Focus:

- 1  Annovera
bupropion hydrochloride
extended-release tablets
NADA 141-103-01 (10mg)
- 2  Imvexxy
bupropion hydrochloride
extended-release tablets
NADA 141-103-02 (10mg)

120-130 Sales Reps
Afaxys (Public Health)
and WSI (VA/Military)



Consumer Marketing Plans Across
ANNOVERA and IMVEXXY

Distribution Channels

<u>VA/Military</u>	<u>Retail</u>	<u>Online Platforms</u>
		NURX.
<u>Public Health</u>	National and Regional retail chains	
Medicaid		PILL CLUB
		
		

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