

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): March 26, 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
<b>Common Stock, par value \$0.001 per share</b>	<b>TXMD</b>	<b>The Nasdaq Stock Market LLC</b>

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 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 7.01 Regulation FD Disclosure.**

### *COVID-19 (coronavirus) Business Update*

On March 26, 2020, TherapeuticsMD, Inc., a Nevada corporation (the “Company”), issued a press release providing a business update, including announcing the suspension of the Company’s previously issued 2020 financial guidance due to the unknown impact of COVID-19 (coronavirus) on the Company’s business operations. The Company is unable to predict the impact of the COVID-19 pandemic on its financial results for 2020.

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 information furnished in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

### *Mitchell Krassan 10b5-1 Trading Plan*

On March 23, 2020, Mitchell Krassan, the Chief Strategy & Performance Officer of the Company, terminated his previously announced 10b5-1 trading plan (the “Krassan 10b5-1 Plan”). The Krassan 10b5-1 Plan was originally entered into in December 2019 with respect to an aggregate of 789,658 ten-year options to acquire common stock, \$0.001 per share, of the Company, with exercise prices equal to \$0.19 and \$0.20 per share. The options expire in May 2020 and September 2020. An aggregate of 489,658 options with an exercise price of \$0.20 per share that expire in September 2020 were not sold under the Krassan 10b5-1 Plan.

## **Item 8.01 Other Events.**

### *Risk Factor*

The Company is supplementing the risk factors previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission on February 24, 2020 (the “2019 Form 10-K”), with the following risk factor:

***The Company’s financial condition and results of operations for fiscal year 2020 and beyond may be materially adversely affected by the ongoing COVID-19 (coronavirus) outbreak.***

The outbreak of the novel COVID-19 (coronavirus) has evolved into a global pandemic. COVID-19 has spread to many regions of the world, including the United States and Europe. The full extent to COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

While the Company has developed a comprehensive COVID-19 contingency plan designed to preserve the value of the Company’s investments in its sales and marketing infrastructure, protect the Company’s balance sheet during this period of market disruption and meet the needs of the Company’s patients and prescribers, including cost-containment and spending cuts in the second quarter of 2020 that can be extended through the rest of the year depending on the evolution of COVID-19, the Company has suspended its previously announced 2020 financial guidance due to the unknown impact of COVID-19 on the Company’s business and the rapidly evolving nature of the pandemic. As a result of COVID-19, the Company will, among other things, (i) defer approximately \$10 million in consumer and healthcare practitioner marketing spending for ANNOVERA® and IMVEXXY®, (ii) make cuts of approximately \$20 million in other planned expenses for the year, (iii) negotiate lower fees and/or suspend services from non-critical third party vendors, (iv) implement a hiring freeze, (v) delay or cancel any non-critical information technology projects and (vi) eliminate travel, entertainment, meeting and event expenses.

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Although the Company currently continues to have uninterrupted wholesale and retail distribution of its products and the Company does not anticipate a shortage of its products due to COVID-19 at this time, disruptions may occur for the Company's customers or suppliers that may materially affect the Company's ability to obtain supplies or other components for its products, manufacture additional products or deliver inventory in a timely manner. This would result in lost sales, additional costs, or penalties, or damage to the Company's reputation. In addition, due to closures and restrictions on travel, the Company's sales force is currently functioning largely utilizing digital engagement tools and tactics and virtual detailing, which may be less effective than the Company's ordinary course sales and marketing programs. The Company may also require an increased level of working capital if it experiences extended billing and collection cycles as a result of displaced employees at the Company, payors, revenue cycle management contractors, or otherwise. The Company may also experience other unknown impacts from COVID-19 that cannot be predicted. Accordingly, disruptions to the Company's business as a result of COVID-19 could result in a material adverse effect on the Company's business, results of operations, financial condition and prospects in the near-term and beyond 2020.

#### *Forward-Looking Statements*

This Current Report on Form 8-K may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to the Company'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 the Company's 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 Form 8-K are made as of the date of this Form 8-K, 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 2019 Form 10-K as well as this 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®, 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 U.S. Food and Drug Administration (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.

#### **Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits*

#### **Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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[99.1 Press Release from TherapeuticsMD, Inc., dated March 26, 2020, entitled "TherapeuticsMD Provides COVID-19-Related Business Update".](#)

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.

THERAPEUTICSMD, INC.

Date: March 26, 2020

By: /s/ Daniel A. Cartwright  
Daniel A. Cartwright  
Chief Financial Officer

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**FOR IMMEDIATE RELEASE****TherapeuticsMD Provides COVID-19-Related Business Update**

- Strong preliminary first quarter 2020 total net revenue projected to be more than \$11 million –
- vitaCare Prescription Services model allowing the Company to connect with more than 80% of patients -
- Implementing staged contingency plan that can be adjusted as COVID-19 situation evolves -

**BOCA RATON, Fla.** – March 26, 2020 – TherapeuticsMD, Inc. (NASDAQ: TXMD) (“TherapeuticsMD” or the “Company”), an innovative, leading women’s healthcare company, today provided an update on its operations in response to the continued spread of COVID-19 (coronavirus) pandemic. The Company has developed a comprehensive COVID-19 contingency plan designed to preserve the value of the Company’s investments in its sales and marketing infrastructure, protect the Company’s balance sheet during this period of market disruption, and meet the needs of the Company’s patients and prescribers.

TherapeuticsMD’s COVID-19 contingency plan is designed to be implemented in stages over the second and third quarters of 2020 as the Company continues to evaluate the length of time that COVID-19 may impact its business, allowing the Company to conserve its financial resources during the COVID-19 crisis and re-scale its sales and marketing activity when conditions warrant.

“The health and safety of our employees, patients, prescribers, and community are paramount at this time,” said Robert G. Finizio, Chief Executive Officer of TherapeuticsMD. “We have taken a swift and proactive approach to reduce our near-term cash burn and provide for maximum flexibility to reinstate our launch plans once we have more visibility on the length of the COVID-19 crisis,” said Mr. Finizio. “While we believe we were on track with executing our plan for 2020, including being able to deliver a better-than-planned first quarter, given the uncertainties around COVID-19, we feel it is in the best interests of our Company and our stockholders to temporarily scale down certain aspects of our business to preserve cash during this pandemic. We plan to leverage our best-in-class vitaCare Prescription Services patient model to continue to meet the needs of our patients and prescribers during this difficult time. Our highly-trained sales force remains engaged with prescribers so that we can ramp-up our sales efforts at the appropriate time.”

TherapeuticsMD’s COVID-19 contingency plan focuses on five key areas:

- Containing costs and cutting spending.
- Addressing impacts and trends for the second quarter of 2020.
- Preparing for a potential longer-term impact throughout the year.
- Leveraging vitaCare Prescription Services to continue to meet the needs of our patients and prescribers.
- Ensuring continued availability of our products to patients.

**Cost Containment and Spending Cuts**

TherapeuticsMD is implementing measures to initially cut or defer more than \$30 million in annual spending. This includes the deferral of approximately \$10 million in planned second quarter consumer and healthcare practitioner marketing spend for ANNOVERA® and IMVEXXY® and cuts of approximately \$20 million in other planned expenses for the year.

The Company has the ability to re-accelerate its planned marketing spend for ANNOVERA and IMVEXXY should market conditions improve, or to extend or expand the cost deferrals throughout the year.

The Company’s cost cuts and reductions include permanent cost savings that have been identified by management, as well as the interim cessation of certain spending that may be restarted in future quarters. These cost cuts include:

- Negotiating lower fees or suspending services from third party vendors;
  - Implementing a Company-wide hiring freeze;
  - Delaying or cancelling non-critical IT projects; and
  - Eliminating travel, entertainment, meeting, and event expenses.
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These savings can be extended further throughout the year or expanded depending on the impact of the COVID-19 outbreak.

### **Employees and Sales Force**

At present, the Company's sales force continues to function utilizing digital engagement tools and tactics and virtual detailing to remain engaged with prescribers and distribution channels.

- The Company has enhanced the ability of its sales force to support healthcare providers remotely, including the sales forces' ability to continue to provide healthcare practitioners with access to patient product samples, product marketing information, and information regarding patient affordability programs and support services.
- The Company's sales force is in regular interaction with healthcare providers and also continues product training, including sharing best practices, in advance of the Company's anticipated future sales and marketing ramp.

### **Remote Pharmacy and At-Home Delivery Options**

TherapeuticsMD is prepared to provide continued access to its products for patients.

- The Company's vitaCare Prescription Services patient model assists patients in obtaining easy and convenient access to their prescriptions for products at a retail pharmacy of their choice, including via home delivery retail pharmacy options. The Company anticipates that home delivery pharmacy options will be attractive to patients during the COVID-19 pandemic.
- Through vitaCare, the Company has connected with more than 80% of its patients during the past month. The Company anticipates that vitaCare will support continued patient access to the Company's products during the COVID-19 pandemic and will help sustain the Company's strong refill trends given vitaCare's broad use by the Company's patients.
- The Company has also partnered with independent community pharmacies and multiple third-party online pharmacies (such as PillPack, PillClub, and Simple Health) and telemedicine providers (such as PlushCare) that focus on contraception or menopause to help ensure patients have real-time access to both diagnosis and treatment.

### **Supply of Products**

TherapeuticsMD does not anticipate a shortage of its products due to COVID-19 at this time.

- The company already has sufficient inventory of finished product in its warehouses to meet anticipated demand through at least early third quarter of this year.
- Additionally, the Company currently does not foresee any interruption in its ability to continue to manufacture additional product to be used beyond this period and has sufficient active pharmaceutical ingredients on hand for the continued manufacture of its products.
- At this time, the Company continues to have uninterrupted wholesale and retail distribution of its products and is actively working to ensure that there continues to be an adequate supply of its products at pharmacies for sales to patients.

### **Suspending 2020 Financial Guidance**

Due to the unknown impact of COVID-19 on the Company's business and the rapidly evolving nature of the pandemic, TherapeuticsMD is suspending its full-year 2020 financial guidance that was previously provided in February 2020. The Company's January and February operating results were ahead of the internal forecasts that were included in the Company's full-year guidance. Together with March operating results that will be partially affected by the COVID-19 outbreak in the U.S., the Company projects that preliminary first quarter net revenues will be more than \$11 million. The Company believes that its vitaCare Prescription Services patient model will support continued patient access to the Company's products during the COVID-19 pandemic and will help sustain the Company's strong refill trends across its menopause products.

The foregoing amount is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of March 31, 2020. The review of the Company's consolidated financial statements for the three months ending March 31, 2020 has not commenced and could result in changes to this amounts due to the completion of financial closing procedures, final adjustments and other developments that may arise between now and the time the consolidated financial statements for the three months ended March 31, 2020 are finalized and publicly released. The Company's independent registered public accounting firm, Grant Thornton LLP, has not audited, reviewed, or compiled this estimate.

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## **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](http://www.therapeuticsmd.com) or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

## **Forward-Looking Statements**

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## **Investor Contact**

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