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): December 10, 2021

TherapeuticsMD, Inc.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-00100**	**87-0233535**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 7.01 Regulation FD Disclosure.

On December 10, 2021, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), issued a press release announcing the response from the U.S. Food and Drug Administration (the "FDA") described in Item 8.01 of this Current Report on Form 8-K. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and in Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liabilities under that section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filings.

Item 8.01 Other Events.

On December 10, 2021, the Company announced that the FDA determined that it could not approve revisions to certain manufacturing testing limits for the Company's ANNOVERA® product through the Supplemental New Drug Application ("sNDA") previously submitted by the Company to the FDA. The sNDA requested minor revisions to the *in vitro* release testing specification for ANNOVERA to allow for normal commercial manufacturing variation. In its complete response letter, the FDA provided recommendations and requested additional information that could support approval of revisions to certain manufacturing testing limits. The Company will continue to manufacture and supply ANNOVERA under the existing specification and will work with FDA to address their comments.

Forward Looking Statements

This Current Report on Form 8-K contains 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 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 Current Report on Form 8-K are made as of the date of this Current Report on 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 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 revenue, minimum cash, and other covenants and conditions under its term loan facility; whether the Company will be able to successfully divest, or obtain an investment in, its vitaCare business and how the proceeds that may be generated by any such divestiture or investment will be utilized; the effects of supply chain issues on the supply of the Company's products; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of the Company's current or future approved products or preclude the approval of the Company's future drug candidates; whether the FDA will approve the lower dose of BIJUVA or manufacturing testing limit revisions for ANNOVERA; the Company's ability to protect its intellectual property, including with respect to the Paragraph IV notice letters the company received regarding IMVEXXY and BIJUVA and the corresponding settlement regarding 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 availability of reimbursement from government authorities and health insurance companies for the Company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the impact of leadership transitions; the volatility of the trading price of the Company's common stock and the concentration of power in its stock ownership.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated December 10, 2021.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

SIGNATURES

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

Date: December 10, 2021

THERAPEUTICSMD, INC.

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

U.S. Food and Drug Administration (FDA) Responds to Request from TherapeuticsMD to Revise Certain Manufacturing Testing Limits for ANNOVERA®

- FDA determined that it could not approve proposed revisions to the manufacturing testing limits requested through the Supplemental New Drug Application (sNDA) -
- FDA provided recommendations and requested additional information to address the issues -
- The Company will continue to supply ANNOVERA in compliance with the manufacturing testing limits approved in the original NDA -

BOCA RATON, Fla. – **December 10, 2021** – TherapeuticsMD, Inc. (NASDAQ: TXMD) ("TXMD" or the "Company"), an innovative, leading women's healthcare company, today announced that the FDA determined that it could not approve revisions to certain manufacturing testing limits for ANNOVERA through the sNDA previously submitted by the Company. In its complete response letter, the FDA provided recommendations and requested additional information that could support approval of revisions to certain manufacturing testing limits. The Company will continue to manufacture and supply ANNOVERA under the existing approved specifications.

The sNDA requested minor revisions to the *in vitro* release testing specification for ANNOVERA to allow for normal commercial manufacturing variation. The Company submitted the proposed revisions to the manufacturing testing limits to allow it to efficiently and quickly increase supply to meet anticipated patient demand for ANNOVERA.

"The Company will continue to manufacture and supply ANNOVERA under the existing specification and will work with the FDA to address their comments," said Hugh O'Dowd, President of TherapeuticsMD.

ANNOVERA was approved by the FDA in August 2018 as the only long-lasting, reversible, procedure-free birth control.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is an innovative, leading healthcare company, focused on developing and commercializing novel products exclusively for women. Our products are designed to address the unique changes and challenges women experience through the various stages of their lives with a therapeutic focus in family planning, reproductive health, and menopause management. The company is committed to advancing the health of women and championing awareness of their healthcare issues. To learn more about TherapeuticsMD, please visit therapeuticsmd.com or follow us on Twitter: @TherapeuticsMD and on Facebook: TherapeuticsMD.

Forward-Looking Statements

This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are

outside of the company’s control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company’s filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: the effects of the COVID-19 pandemic; the company’s ability to maintain or increase sales of its products; the company’s ability to develop and commercialize IMVEXXY®, ANNOVERA®, and BIJUVA® and obtain additional financing necessary therefor; whether the company will be able to comply with the revenue, minimum cash, and other covenants and conditions under its term loan facility; whether the company will be able to successfully divest, or obtain an investment in, its vitaCare business and how the proceeds that may be generated by any such divestiture or investment will be utilized; the effects of supply chain issues on the supply of the company’s products; the potential of adverse side effects or other safety risks that could adversely affect the commercialization of the company’s current or future approved products or preclude the approval of the company’s future drug candidates; whether the FDA will approve the lower dose of BIJUVA or manufacturing testing limit revisions for ANNOVERA; the company’s ability to protect its intellectual property, including with respect to the Paragraph IV notice letters the company received regarding IMVEXXY and BIJUVA and the corresponding settlement regarding 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 availability of reimbursement from government authorities and health insurance companies for the company’s products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the impact of leadership transitions; the volatility of the trading price of the company’s common stock and the concentration of power in its stock ownership.

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