

**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): September 2, 2021**

**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 8.01 Other Events.**

As previously disclosed, in February 2020, TherapeuticsMD, Inc., a Nevada corporation (the “Company”), received a Paragraph IV certification notice letter (the “Notice Letter”) regarding an Abbreviated New Drug Application (“ANDA”) submitted to the U.S. Food and Drug Administration (“FDA”) by Teva Pharmaceuticals USA, Inc. (“Teva”). The ANDA seeks approval from FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of the Company’s IMVEXXY (estradiol vaginal inserts) pharmaceutical product for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy due to menopause. In the Notice Letter, Teva alleged that the Company patents listed in FDA’s Orange Book that claim compositions and methods of IMVEXXY, are invalid, unenforceable, and/or will not be infringed by Teva’s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY patents identified in the Notice Letter expire in 2032 or 2033.

In April 2020, the Company filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva’s ANDA filing with FDA, seeking, among other relief, an order that the effective date of any FDA approval of Teva’s ANDA would be a date no earlier than the expiration of the IMVEXXY patents and equitable relief enjoining Teva from infringing the IMVEXXY patents. Teva filed its answer and counterclaim to the complaint, alleging that the IMVEXXY patents are invalid and not infringed.

In July 2021, following a proposal by Teva, the District Court entered an order temporarily staying all proceedings in the IMVEXXY litigation, which order was filed under seal.

On September 2, 2021, the District Court made available a public version of the order following the parties’ agreement to a consent motion to redact information Teva contended was confidential.

The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place.

The length of the stay of the IMVEXXY litigation is dependent on further action by Teva.

### **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 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 report, 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 effects of the IMVEXXY Paragraph IV litigation.

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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: September 7, 2021

THERAPEUTICSMD, INC.

/s/ James C. D'Arecca

James C. D'Arecca  
Chief Financial Officer