

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): June 6, 2019

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.)

6800 Broken Sound Parkway NW, Third Floor
Boca Raton, FL 33487

(Address of principal executive offices) (Zip Code)

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

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(s)	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 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 1.01. Entry into a Material Definitive Agreement.

On June 6, 2019, TherapeuticsMD, Inc., a Nevada corporation (the “Company”), entered into a Licensing and Supply Agreement (the “Licensing Agreement”) with Theramex HQ UK Limited, a company formed under the laws of England (“Theramex”), pursuant to which the Company granted Theramex an exclusive, perpetual license to commercialize for human use the Company’s FDA-approved products BIJUVA™ (estradiol and progesterone capsules) and IMVEXXY® (estradiol vaginal inserts) outside of the United States, except for Canada and Israel, for which the Company has licensed BIJUVA™ and IMVEXXY® to Knight Therapeutics (such licensed area to Theramex, the “Territory”).

Pursuant to the terms of the Licensing Agreement, Theramex will pay the Company an upfront fee of EUR 14 million in cash within 60 days of entering into the Licensing Agreement. The Company is also eligible to receive up to an additional EUR 29.5 million in cash milestone payments, comprised of (i) an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for each of BIJUVA™ and IMVEXXY® in certain specified markets and (ii) an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones in the Territory ranging from EUR 25 million to EUR 100 million. The Company is also entitled to receive quarterly royalty payments based on net sales of BIJUVA™ and IMVEXXY® in the Territory.

Theramex will be responsible for all regulatory and commercial activities in the Territory related to BIJUVA™ and IMVEXXY®. Theramex has agreed to submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA™ and IMVEXXY® in certain specified markets within certain specified time periods and the Company may terminate the Licensing Agreement if Theramex does not submit certain of such regulatory applications, submissions and/or registrations. The Company may also terminate the Licensing Agreement if Theramex challenges the Company’s patents. Either party may terminate the Licensing Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters.

Theramex may sublicense its rights to commercialize BIJUVA™ and IMVEXXY® in the Territory, except for certain specified markets.

Pursuant to the terms of the Licensing Agreement, the Company has agreed to supply, or cause to be supplied, BIJUVA™ and IMVEXXY® to Theramex.

The Company and Theramex have agreed to form a joint product committee responsible for advising and overseeing activities under the Licensing Agreement.

The foregoing summary of the terms of the Licensing Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Licensing Agreement, a copy of which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

Item 7.01 Regulation FD Disclosure.

On June 7, 2019, the Company issued a press release announcing that it had entered into the Licensing Agreement. A copy of the press release is attached as Exhibit 99.1 hereto.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Index

Exhibit Number	Description
99.1	Press Release, dated June 7, 2019, issued by TherapeuticsMD, Inc. titled TherapeuticsMD and Theramex Enter into Exclusive License and Supply Agreement to Commercialize BIJUVA™ and IMVEXXY® Outside the United States.

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.

Dated: June 7, 2019

THERAPEUTICSMD, INC.

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



FOR IMMEDIATE RELEASE

TherapeuticsMD and Theramex Enter into Exclusive License and Supply Agreement to Commercialize BIJUVA™ and IMVEXXY® Outside the United States

-Agreement leverages Theramex's extensive women's health capabilities and infrastructure to the benefit of menopausal women outside of U.S.-

-TherapeuticsMD to receive EUR 14 million as an upfront fee and is eligible to receive up to EUR 29.5 million in regulatory and sales milestone payments, as well as a royalty on net sales -

BOCARATON, Fla., June 7, 2019 – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative, leading women's healthcare company, today announced that it has entered into an exclusive license and supply agreement with Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercialize BIJUVA (estradiol and progesterone capsules) and IMVEXXY (estradiol vaginal inserts) outside of the United States. Theramex is a portfolio company of CVC Capital Partners.

Theramex will have exclusive commercialization rights for BIJUVA and IMVEXXY outside the U.S., excluding Canada and Israel, for which TherapeuticsMD has licensed BIJUVA and IMVEXXY to Knight Therapeutics. Theramex will be responsible for conducting all regulatory and commercial activities in connection with BIJUVA and IMVEXXY in the licensed territories.

Under the terms of the license and supply agreement, Theramex will pay TherapeuticsMD EUR 14 million in cash as an upfront fee. TherapeuticsMD is eligible to receive up to an additional EUR 29.5 million in cash milestone payments, comprised of (i) an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for each of BIJUVA and IMVEXXY in certain specified markets and (ii) an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on first attaining certain aggregate annual net sales milestones in the licensed territories ranging from EUR 25 million to EUR 100 million. TherapeuticsMD is also entitled to receive royalty payments on net sales of BIJUVA and IMVEXXY in the licensed territories.

"We are very pleased to announce our partnership with Theramex to bring BIJUVA and IMVEXXY to women outside of the United States," said Robert G. Finizio, CEO of TherapeuticsMD. "We believe this agreement provides our company with important non-dilutive upfront capital to help fund our product launches in the United States as well as an incremental royalty stream to support future growth."

Anish Mehta, CEO of Theramex, said, "This partnership with TherapeuticsMD marks another exciting milestone in the execution of our women's health growth strategy. By leveraging our best in class commercial capabilities and global footprint, we intend to rapidly commercialize these novel and innovative medicines for women around the world."

"BIJUVA and IMVEXXY strengthens Theramex's already exciting range of women's health treatment options for doctors and their patients," said Fred Hassan, Chairman of Theramex.

Additional information concerning the license and supply agreement is contained in the Form 8-K filed by TherapeuticsMD today with U.S. Securities and Exchange Commission.

Copies of the U.S. Full Prescribing Information, including Boxed Warnings, for BIJUVA and IMVEXXY are available at <https://www.bijuva.com/pi.pdf> and www.imvexxy.com/pi.pdf, respectively.

About Theramex

Theramex is a leading, global specialty pharmaceutical company dedicated to women and their health. With a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis, Theramex supports women at every stage of their lives. Theramex's commitment is to understand its patients, serve their needs, and offer healthcare solutions to help improve their lives. Theramex's vision is to be a lifetime partner for women and the healthcare professionals who treat them by providing innovative, effective solutions that care for and support women as they advance through each stage of their lives. To learn more about Theramex, please visit www.theramex.com.

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 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 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; 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; 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 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.

Investor Contact

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