TherapeuticsMD, Inc.
Form 8-K
August 03, 2018

**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): July 30, 2018**

**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.)** |

**6800 Broken Sound Parkway NW, Third Floor**

**Boca Raton, FL 33487**

**(Address of Principal Executive Office) (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))
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.**

***License Agreement with the Population Council***

On July 30, 2018, TherapeuticsMD, Inc., a Nevada corporation (the Company ), entered into an exclusive license agreement (the Council License Agreement ) with the Population Council to commercialize in the United States ( U.S. ) the Population Council s investigational segesterone acetate/ethinyl estradiol one-year vaginal system for contraception. The one-year vaginal contraceptive system is in the shape of a ring and combines a novel progestin, segesterone acetate (Nestorone®), with a widely used estrogen (ethinyl estradiol) to prevent ovulation for an entire year (13 cycles).

The new drug application ( NDA ) for the one-year vaginal contraceptive system is currently under review by the U.S. Food and Drug Administration (the FDA ) and has a Prescription Drug User Fee Act ( PDUFA ) target action date for the completion of the FDA s review of the NDA of August 17, 2018.

Under the terms of the Council License Agreement, the Company is required to pay the Population Council milestone payments of $20 million within 30 days following approval by the FDA of the NDA for the one-year vaginal contraceptive system and $20 million within 30 days following the release of the first commercial batch of the one-year vaginal contraceptive system.

However, if a complete response letter or continuance of greater than 90 days is received by the Population Council with respect to the one-year vaginal contraceptive system or the one-year vaginal contraceptive system is approved with additional post-marketing requirements or commitments in excess of $1 million, beyond the post-approval studies that may be required by the FDA noted below, then the Company or the Population Council may terminate the Council License Agreement, provided that the Company cannot agree with the Population Council on a strategy to address such issues. If the one-year vaginal contraceptive system is approved with a shelf life of less than 18 months of stability or is not approved as a new chemical entity that is entitled to five years regulatory exclusivity in the U.S., then the Company may terminate the Council License Agreement.

The Company is required to pay the Population Council milestone payments of $40 million upon cumulative net sales of the one-year vaginal contraceptive system in the U.S. by the Company and its affiliates and permitted sublicensees of $200 million, $400 million and $1 billion.

In addition, the Company is required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of the one-year vaginal contraceptive system in the U.S. by the Company and its affiliates and permitted licensees as follows: (i) if annual net sales are less than or equal to $50 million, a royalty of 5% of net sales; (ii) for annual net sales greater than $50 million and less than or equal to $150 million, a royalty of 10% of such net sales; and (iii) for net sales greater than $150 million, a royalty of 15% of such net sales. The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of the one-year vaginal contraceptive system that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate.

The Population Council has agreed to perform and pay the costs and expenses associated with four post-approval studies that may be required by the FDA for the one-year vaginal contraceptive system. The Company has agreed to perform and pay the costs and expenses associated with a post-approval study that may be required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will be offset against royalties or other payments owed by the Company to the Population Council under the Council License Agreement.

The Company and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Council License Agreement. The Company will be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee.

Unless earlier terminated, the Council License Agreement will remain in effect until the later of the expiration of the last-to-expire of the Population Council s U.S. patents that are licensed to the Company under the Council License Agreement, or the date following such expiration that follows a continuous period of six months during which the Company and its affiliates have not made a commercial sale of the one-year vaginal contraceptive system in the U.S. The Council License Agreement may also be terminated for certain breach and bankruptcy-related events and by the Company on 180 days prior notice to the Population Council.

As part of the Council License Agreement, the Company has the exclusive right to negotiate co-development and U.S. marketing rights for two other investigational vaginal contraceptive systems in development by the Population Council: a three-month contraceptive ring using Nestorone plus bio-identical estradiol, which is currently in phase 2 clinical trials; and a new one-year contraceptive ring using Nestorone plus ethinyl estradiol, which is designed as a life cycle management product for the one-year vaginal contraceptive system that the Company has licensed.

***Amendment to Credit Agreement***

Also on July 30, 2018, the Company entered into Amendment No. 1 (the Amendment ) to that certain Credit and Security Agreement (the Credit Agreement ), by and among the Company, as borrower, the Company s subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time, in order to permit the Company s entry into the Council License Agreement. As part of the Amendment, the Company is required to receive aggregate net cash proceeds of at least $75 million from the issuance of the Company s equity securities within thirty days of entering into the Council License Agreement. Failure to complete this obligation will constitute an automatic event of default under the Credit Agreement.

***Underwriting Agreement***

On August 1, 2018, the Company entered into an underwriting agreement (the Underwriting Agreement ) with Goldman Sachs & Co. LLC, as representative of the underwriters named in Schedule I to the Underwriting Agreement (collectively, the Underwriters ), relating to an underwritten public offering of 12,745,098 shares of the Company s common stock, par value $0.001 per share ( Common Stock ). Pursuant to the Underwriting Agreement, the Company granted to the Underwriters an option, exercisable for a period of 30 days, to purchase up to 1,911,764 additional shares of Common Stock to cover sales by the Underwriters of a number of shares of Common Stock greater than 12,745,098. On August 2, 2018, the Underwriters exercised the foregoing option in full. The net proceeds to the Company from the offering, including the exercise of the option to purchase additional shares, are expected to be approximately $70.0 million, after deducting the underwriting discount and estimated offering expenses payable by the Company. The offering is expected to close on August 6, 2018.

The offering is being made pursuant to the Company s automatically effective shelf registration statement on Form S-3 (Registration No. 333-226452) previously filed with the Securities and Exchange Commission (the Commission ), including the prospectus dated July 31, 2018, as supplemented by a preliminary prospectus supplement filed with the Commission on July 31, 2018 and a final prospectus supplement filed with the Commission on August 2, 2018.

The Underwriting Agreement contains representations, warranties and covenants of the Company that are customary for transactions of this type and customary conditions to closing. Additionally, the Company has agreed to provide the Underwriters with customary indemnification rights under the Underwriting Agreement. The foregoing description of the Underwriting Agreement is qualified in its entirety by reference to the complete text of the Underwriting Agreement, a copy of which is filed as Exhibit 1.1 to this Current Report on Form 8-K and is incorporated herein by reference. A copy of the opinion of Greenberg Traurig, LLP regarding the validity of the shares of Common Stock issued in the offering is filed as Exhibit 5.1 to this Current Report on Form 8-K.

**Item 8.01. Other Events.**

On July 30, 2018, the Company entered into a license and supply agreement (the Knight License Agreement ) with Knight Therapeutics Inc. ( Knight ), pursuant to which the Company granted Knight an exclusive license to commercialize TX-004HR, the Company s FDA-approved product, marketed as Imvexxy (estradiol vaginal inserts) in the U.S., for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause, and TX-001HR, the Company s investigational bio-identical hormone therapy combination of estradiol and progesterone in a single, oral softgel for the treatment of moderate-to-severe vasomotor symptoms due to menopause, in Canada and Israel.

Pursuant to the terms of the Knight License Agreement, Knight will pay the Company a milestone fee upon first regulatory approval in Canada of each of IMVEXXY and TX-001HR, sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY and TX-001HR and royalties based on aggregate annual sales of each of IMVEXXY and TX-001HR in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY and TX-001HR.

The Company may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY and TX-001HR in Canada and Israel within certain specified time periods. The Company also may terminate the Knight License Agreement if Knight challenges the Company s patents. Either party may terminate the Knight License 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.

In connection with the Knight License Agreement, Knight entered into a subscription agreement (the Subscription Agreement ) with the Company pursuant to which Knight agreed to purchase from the Company $20 million of shares of Common Stock concurrently with the closing of the Company s first underwritten public offering of Common Stock to occur within 60 days following the date of the Knight License Agreement with gross proceeds to the Company of not less than $50 million, at a price per share equal to the price per share to the public in such underwritten public offering. In the event that such underwritten public offering does not close, Knight will, in lieu of such $20 million investment, pay the Company a previously negotiated upfront license fee. An uncured breach of the Subscription Agreement by Knight will give the Company the right to terminate the Knight License Agreement.

Knight is effecting its $20 million purchase of Common Stock pursuant to the Company s registered direct offering to Knight under to the Company s effective shelf registration statement on Form S-3 (Registration No. 333-207837) previously filed with the Commission, including the prospectus dated November 17, 2015, as supplemented by a preliminary prospectus supplement filed with the Commission on July 31, 2018 and a final prospectus supplement filed with the Commission on August 2, 2018 (the Registered Direct Offering ). The Registered Direct Offering is expected to close on August 6, 2018. A copy of the opinion of Greenberg Traurig, LLP regarding the validity of the shares of Common Stock issued in the Registered Direct Offering is filed as Exhibit 5.2 to this Current Report on Form 8-K.

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

(d) *Exhibits.*

| **Exhibit** | **Description** |
|---|---|

| Number | |
|---|---|
| 1.1 | Underwriting Agreement, dated August 1, 2018, by and between the Company and Goldman Sachs & Co. LLC, as representative of the several underwriters named therein |
| 5.1 | Opinion of Greenberg Traurig, LLP (re: Commission File No. 333-226452) |
| 5.2 | Opinion of Greenberg Traurig, LLP (re: Commission File No. 333-207837) |
| 23.1 | Consent of Greenberg Traurig, LLP (set forth in Exhibit 5.1) |
| 23.2 | Consent of Greenberg Traurig, LLP (set forth in Exhibit 5.2) |

**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 3, 2018

THERAPEUTICSMD, INC.

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