**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): May 1, 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 (*see* General Instruction A.2 below):

☐ 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.**

On May 1, 2018, TherapeuticsMD, Inc., a Nevada corporation (the "Company"), entered into a 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 (and together with the Company, the "Borrowers"), MidCap Financial Trust ("MidCap"), as agent ("Agent") and as lender, and the additional lenders party thereto from time to time (together with MidCap as a lender, the "Lenders").

The Credit Agreement provides a secured term loan facility in an aggregate principal amount of up to $200 million (the "Term Loan"). Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches (each, a "Tranche"), with each Tranche to be made available to the Company, at the Company's option, upon the Company's achievement of certain milestones. The first Tranche of $75.0 million (" Tranche 1") may be drawn by the Company on or before July 31, 2018, provided that the Company satisfies certain conditions described in the Credit Agreement, including approval by the U.S. Food and Drug Administration (the "FDA") of the New Drug Application ("NDA") for the Company's TX-004HR drug candidate. The second Tranche of $75.0 million ("Tranche 2") may be drawn by the Company on or before May 31, 2019, provided that the Company satisfies certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for the Company's TX-001HR drug candidate and (iii) the Company has consummated its first commercial sale in the United States of TX-001HR. The third Tranche of $50.0 million ("Tranche 3") may be drawn by the Company on or before December 31, 2019, provided that the Company satisfies certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) the Borrowers have generated at least $75.0 million of consolidated net revenue attributable to commercial sales of TX-001HR and TX-004HR during the twelve-month period ending immediately prior to the funding of Tranche 3.

Amounts borrowed under the Term Loan will bear interest at a rate equal to the sum of (i) one month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum. Interest on amounts borrowed under the Term Loan will be due and payable monthly in arrears. Principal on each Tranche will be payable in 36 equal monthly installments beginning May 1, 2020 until paid in full on May 1, 2023 (the "Maturity Date"), *provided*, *however*, that if the Borrowers generate at least $95.0 million of consolidated net revenue attributable to commercial sales of TX-001HR and TX-004HR by December 31, 2019, the Borrowers may extend the interest-only period by an additional 12 months to May 1, 2021.

The Term Loan may be prepaid, in whole or in part, subject to a prepayment fee on the amount being prepaid (or required to be prepaid, if such amount is greater) of (i) 4.0% for the first year following the Tranche 1 funding date, (ii) 3.0% for the second year following the Tranche 1 funding date and (iii) 2.0% thereafter. Upon repayment of the Term Loan at the Maturity Date or prepayment on any earlier date, the Company will be required to pay a termination payment based on the principal amount paid or prepaid. In connection with the execution of the Credit Agreement, the Company paid Agent, for the benefit of all Lenders, an origination fee equal to 1.00% of the maximum potential amount of the Term Loan. The Borrowers will also pay Agent an annual administration fee based on the amounts borrowed under the Term Loan, in addition to other fees and expenses.

The obligations of the Borrowers under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all existing and after-acquired assets of the Borrowers. The obligations under the Credit Agreement will be guaranteed by each of the Company's future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions).

The Credit Agreement contains customary restrictions and covenants applicable to the Borrowers. Among other requirements, the Borrowers must (i) maintain a minimum cash balance of $50.0 million and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of the Company's products. The Credit Agreement also contains customary covenants that limit, among other things, the ability of the Borrowers to (i) incur indebtedness, (ii) incur liens on their property, (iii) pay dividends or make other distributions, (iv) sell their assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions.

The Credit Agreement contains customary representations and warranties and events of default relating to, among other things, payment defaults, breaches of covenants, the occurrence of any fact, event or circumstance that could reasonably be expected to result in a Material Adverse Effect (as defined in the Credit Agreement), delisting of the Company's common stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments and inaccuracies of representations and warranties. Upon or after an event of default, Agent and the Lenders may declare all or a portion of the Company's obligations under the Credit Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Credit Agreement.

The foregoing summary of the terms of the Credit Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Credit Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

**Item 2.02. Results of Operations and Financial Condition.**

On May 3, 2018, the Company issued a press release announcing its financial results for its first quarter ended March 31, 2018. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) is furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

The Company does not have, and expressly disclaims, any obligation to release publicly any updates or any changes in its expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

**Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.**

The information set forth above under Item 1.01 is hereby incorporated by reference into this Item 2.03.

**Item 7.01. Regulation FD Disclosure.**

On May 3, 2018, the Company issued a press release announcing the Company's financial results for its first quarter ended March 31, 2018 and its entry into the Credit Agreement. The press release is furnished as Exhibit 99.1 hereto. The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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

(d) *Exhibits.*

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release from TherapeuticsMD, Inc., dated May 3, 2018, entitled TherapeuticsMD Announces First Quarter 2018 Financial Results. |

**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: May 3, 2018

THERAPEUTICSMD, INC.

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

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

**TherapeuticsMD Announces First Quarter 2018 Financial Results**

*- $200 Million Non-Dilutive Term Loan Financing Completed to Support Commercialization -*

*- PDUFA target action date of May 29, 2018 for TX-004HR -*

*- PDUFA target action date of October 28, 2018 for TX-001HR -*

**BOCA RATON, Fla. – May 3, 2018** – TherapeuticsMD, Inc. (NASDAQ: TXMD), an innovative women's healthcare company, today announced its financial results for the quarter ended March 31, 2018.

**First Quarter and Recent Developments**

- Entered into a definitive loan agreement with MidCap Financial, managed by Apollo Capital Management, L.P., for $200 million in non-dilutive term loan financing. The term loan will be available to the company in three tranches following specific milestones through December 31, 2019: $75 million will be available upon the approval of TX-004HR, $75 million will be available upon the approval and launch of TX-001HR, and $50 million will be available upon certain sales milestones in calendar year 2019, in each case subject to certain terms and conditions. The term loan will accrue interest at 1-month LIBOR plus 7.75%, subject to a LIBOR floor of 1.50%. Interest on amounts borrowed under the term loan will be payable monthly in arrears; principal on each tranche borrowed under the term loan will be payable in 36 equal monthly installments beginning May 1, 2020, subject to the company's ability to extend the interest-only period by an additional 12 months if the company generates certain revenues with respect to TX-004HR and TX-001HR. The maturity date is May 1, 2023.
- Entered into negotiations with the U.S. Food and Drug Administration (FDA) regarding the proposed label for TX-004HR, the company's investigational applicator-free estradiol vaginal softgel capsule for the treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause, in April 2018. The PDUFA target action date for the completion of the FDA's review of the NDA is May 29, 2018.
- Submitted the NDA for 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, on December 28, 2017. The FDA in its 74-day letter stated that the application was sufficiently complete to permit a substantive review and that, at such time, the FDA had not identified any potential review issues. The PDUFA target action date for the completion of the FDA's review of the NDA is October 28, 2018.
- Net revenue for the company's prescription prenatal vitamin business was approximately $3.8 million for the first quarter of 2018, compared with approximately $4.0 million for the first quarter of 2017.
- Net loss was approximately $24.4 million for the first quarter of 2018, compared with approximately $21.2 million for the first quarter of 2017.
- Ended the quarter with approximately $107.3 million in cash and no debt.
- Grew the company's intellectual property portfolio to a current total of 216 patent filings, including 126 international filings, with one allowed and 19 issued U.S. patents.

"Our company has tremendous opportunity in the coming year," said TherapeuticsMD CEO Robert G. Finizio. "We have the potential for approvals of both of our late-stage product candidates in 2018, representing major inflection points for our company."

**Summary of First Quarter 2018 Financial Results**

Net revenue from the company's prescription prenatal vitamin business was approximately $3.8 million for the first quarter of 2018 compared with net revenue of approximately $4.0 million for the prior year's quarter. These changes were primarily due to a decrease in the average net sales price of the company's products, partially offset by an increase in the number of units sold.

Cost of goods sold was approximately $0.6 million for the first quarter of 2018, compared with approximately $0.7 million for the prior year's quarter.

Total operating expenses for the first quarter of 2018 included research and development (R&D) expenses and sales, general, and administrative expenses (SG&A). R&D expenses for the first quarter of 2018 were approximately $7.0 million compared with approximately $7.7 million for the prior year's quarter. The decrease in R&D was a direct result of the completion of the Replenish Trial for TX-001HR. SG&A expenses for the first quarter of 2018 were approximately $20.8 million compared with approximately $16.8 million for the prior year's quarter, primarily due to higher sales, marketing, and personnel costs to support future commercialization.

Net loss for the first quarter of 2018 was approximately $24.4 million, or $0.11 per basic and diluted share, compared with approximately $21.2 million, or $0.11 per basic and diluted share, for the first quarter of 2017.

At March 31, 2018, cash on hand was approximately $107.3 million, compared with approximately $127.1 million at December 31, 2017.

Additional information regarding the company's loan agreement with MidCap Financial is available in the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission today. Cowen acted as lead arranger and financial advisor to TherapeuticsMD with respect to the MidCap Financial transaction and Oppenheimer & Co. acted as co-financial advisor in the transaction.

**Conference Call Today**

As previously announced, TherapeuticsMD will host a conference call today to discuss these financial results and provide a business update. Details for the call are:

**Date:** Thursday, May 3, 2018
**Time:** 4:30 p.m. EST
**Telephone Access (US):** 866-665-9531
**Telephone Access (International):** 724-987-6977
**Access Code for All Callers:** 9196916

Additionally, a live webcast can be accessed on the company's website, www.therapeuticsmd.com, on the Home Page or under the "Investors & Media" section. A digital recording of the conference call will be available for replay beginning two hours after the call's completion and for at least 30 days with the dial-in 855-859-2056 or international 404-537-3406 and Conference ID: 9196916.

**About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. With its SYMBODA™ technology, TherapeuticsMD is developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. The Company's late stage clinical pipeline includes two product candidates that have completed phase 3 trials and are awaiting approval by the FDA: TX-001HR for treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause and TX-004HR for treatment of moderate-to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause. The Company also manufactures and distributes branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

**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 resolve the deficiencies identified by the FDA in the company's new drug application for its TX-004HR product candidate and the time frame associated with such resolution; whether the FDA will approve the amended NDA for the company's TX-004HR product candidate and whether such approval will occur by the PDUFA target action date; whether the FDA will approve the NDA for the company's TX-001HR product candidate and whether such approval will occur by the PDUFA target action date; the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the company be able to comply with the covenants and conditions under its term loan agreement; the length, cost and uncertain results of the company's clinical trials, including any additional clinical trials that the FDA may require in connection with TX-004HR; the potential of adverse side effects or other safety risks that could preclude the approval of the company's hormone therapy drug candidates; the company's reliance on third parties to conduct its clinical trials, research and development and manufacturing; 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.*

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**Investor Contact**

David DeLucia
Director, Investor Relations
561-961-1900
David.DeLucia@TherapeuticsMD.com

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**

| | March 31, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash | $ 107,349,460 | $ 127,135,628 |
| Accounts receivable, net of allowance for doubtful accounts of $403,535 and $380,580, respectively | 5,096,731 | 4,328,802 |
| Inventory | 1,620,872 | 1,485,358 |
| Other current assets | 5,098,132 | 6,604,284 |
| Total current assets | 119,165,195 | 139,554,072 |
| Fixed assets, net | 425,539 | 437,055 |
| Other Assets: | | |
| Intangible assets, net | 3,220,686 | 3,099,747 |
| Security deposit | 150,522 | 139,036 |
| Total other assets | 3,371,208 | 3,238,783 |
| Total assets | $ 122,961,942 | $ 143,229,910 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | $ 6,283,824 | $ 4,097,600 |
| Other current liabilities | 9,375,818 | 9,223,595 |
| Total current liabilities | 15,659,642 | 13,321,195 |
| Commitments and Contingencies | | |
| Stockholders' Equity: | | |
| Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock - par value $0.001; 350,000,000 shares authorized: 216,584,274 and 216,429,642 issued and outstanding, respectively | 216,584 | 216,430 |
| Additional paid-in capital | 518,146,665 | 516,351,405 |
| Accumulated deficit | (411,060,949) | (386,659,120) |
| Total stockholders' equity | 107,302,300 | 129,908,715 |
| Total liabilities and stockholders' equity | $ 122,961,942 | $ 143,229,910 |

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended | |
|---|---|---|
| | March 31, 2018 | March 31, 2017 |
| Revenues, net | $ 3,773,392 | $ 3,985,464 |
| Cost of goods sold | 633,623 | 659,635 |
| Gross profit | 3,139,769 | 3,325,829 |
| Operating expenses: | | |
| Sales, general, and administrative | 20,757,237 | 16,837,617 |
| Research and development | 7,039,297 | 7,724,840 |
| Depreciation and amortization | 59,621 | 49,699 |
| Total operating expenses | 27,856,155 | 24,612,156 |
| Operating loss | (24,716,386) | (21,286,327) |
| Other income | | |
| Miscellaneous income | 314,557 | 125,968 |
| Accreted interest | — | 3,867 |
| Total other income | 314,557 | 129,835 |
| Loss before income taxes | (24,401,829) | (21,156,492) |
| Provision for income taxes | — | — |
| Net loss | $ (24,401,829) | $ (21,156,492) |
| Loss per share, basic and diluted: | | |
| Net loss per share, basic and diluted | $ (0.11) | $ (0.11) |
| Weighted average number of common shares outstanding, basic and diluted | 216,525,316 | 197,790,040 |

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Unaudited)**

| | Three Months Ended | |
|---|---|---|
| | March 31, 2018 | March 31, 2017 |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Net loss | $ (24,401,829) | $ (21,156,492) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 38,424 | 33,600 |
| Amortization of intangible assets | 21,197 | 16,099 |
| Provision for (recovery of) doubtful accounts | 22,955 | (1,603) |
| Share-based compensation | 1,751,358 | 1,413,195 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (790,885) | 580,943 |
| Inventory | (135,514) | (262,297) |
| Other current assets | 1,506,152 | (253,518) |
| Accounts payable | 2,186,224 | (1,212,236) |
| Other current liabilities | 152,223 | 316,638 |
| Net cash used in operating activities | (19,649,695) | (20,525,671) |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Patent costs | (142,136) | (107,487) |
| Purchase of fixed assets | (26,908) | (27,834) |
| Payment of security deposit | (11,486) | — |
| Net cash used in investing activities | (180,530) | (135,321) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Proceeds from exercise of options | 44,057 | 192,310 |
| Proceeds from exercise of warrants | — | 2,460,000 |
| Net cash provided by financing activities | 44,057 | 2,652,310 |
| Decrease in cash | (19,786,168) | (18,008,682) |
| Cash, beginning of period | 127,135,628 | 131,534,101 |
| Cash, end of period | $ 107,349,460 | $ 113,525,419 |