

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): August 4, 2016

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 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))

Item 2.02. Results of Operations and Financial Condition.

On August 4, 2016, TherapeuticsMD, Inc. issued a press release announcing its results of operations for its second fiscal quarter ended June 30, 2016. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 2.02 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 this Current Report shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

We do not have, and expressly disclaim, any obligation to release publicly any updates or any changes in our expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

The text included with this Current Report on Form 8-K is available on our website located at www.therapeuticsmd.com, although we reserve the right to discontinue that availability at any time.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit

Number

99.1

Description

Press Release from TherapeuticsMD, Inc., dated August 4, 2016, entitled “TherapeuticsMD Announces Second Quarter 2016 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: August 4, 2016

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit
Number
99.1

Description

[Press Release from TherapeuticsMD, Inc., dated August 4, 2016, entitled TherapeuticsMD Announces Second Quarter 2016 Financial Results.](#)



FOR IMMEDIATE RELEASE

TherapeuticsMD Announces Second Quarter 2016 Financial Results

- New Drug Application submitted for Yuvvexy™ (TX-004HR) -

- Topline phase 3 data for TX-001HR Replenish Trial on track for fourth quarter of 2016 -

BOCA RATON, Fla. – August 4, 2016 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced its second quarter financial results for the quarter ended June 30, 2016.

Second Quarter and Recent Developments

- Submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration for Yuvvexy, the conditionally approved trade name for TX-004HR, the company’s applicator-free vaginal estradiol softgel drug candidate for the treatment of moderate- to-severe vaginal pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA) due to menopause. The NDA is supported by the complete Yuvvexy clinical program, including positive results of the recently completed phase 3 Rejoice Trial. The submission included all three doses of Yuvvexy (4 mcg, 10 mcg and 25 mcg) that were evaluated in the Rejoice Trial.
- Net revenue from the company’s prescription prenatal vitamin business was approximately \$4.4 million for the second quarter of 2016, compared with approximately \$4.8 million for the second quarter of 2015.
- Net loss was approximately \$21.1 million for the second quarter of 2016, compared with approximately \$27.2 million for the second quarter of 2015.
- Ended the quarter with approximately \$166.5 million in cash and no debt.
- Anticipate topline results in the fourth quarter of 2016 for the ongoing Replenish Trial, a phase 3 clinical trial of the company’s TX-001HR product candidate, which, if approved, would be the first and only FDA-approved bio-identical combination of estradiol and progesterone for the treatment of moderate-to-severe vasomotor symptoms due to menopause. Approximately 1,642 patients have already exited the trial.
- Presented posters on the positive results of the phase 3 Rejoice Trial for Yuvvexy at major medical conferences, including the Endocrine Society annual meeting (ENDO 2016) and the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting.
- Launched innovative new compliance packaging for vitaMedMD’s vitaPearl™ prenatal multivitamin and BocaGreen’s Prena1 Pearl, the brand’s authorized generic.
- Grew the company’s intellectual property portfolio to a current total of 135 patent filings, including 72 international filings, with 17 issued U.S. patents.
- Strengthened relationships with medical, pharmacy, patient and industry organizations worldwide, including ongoing activity with the leadership of the International Association of Compounding Pharmacists.

“The second quarter was transformative for our company, with the submission of our NDA for Yuvvexy as a highly-differentiated potential treatment for moderate to severe dyspareunia, a symptom of VVA, due to menopause,” said TherapeuticsMD CEO Robert G. Finizio. “The Yuvvexy NDA reflects a significant corporate achievement and we are thankful for the contributions of everyone involved. As we prepare for future commercialization of Yuvvexy, if approved, we also look forward to the topline data in the fourth quarter of 2016 from our Replenish Trial for TX-001HR, our second novel hormone therapy program. If approved, we believe TX-001HR would be the first and only FDA-approved bio-identical combination of estradiol and progesterone for treatment of moderate-to-severe vasomotor symptoms due to menopause. We are very pleased with our progress this year.”

Summary of Second Quarter 2016 Financial Results

For the quarter ended June 30, 2016, net revenue from the company's prescription prenatal vitamins was approximately \$4.4 million compared with net revenue of approximately \$4.8 million for the prior year's quarter. The change in net revenue during the quarter was primarily attributable 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 \$1.1 million for the three months ended June 30, 2016, compared with approximately \$1.0 million in the prior year's quarter.

Total operating expenses for the second quarter of 2016 included research and development (R&D) expenses and sales, general and administrative expenses (SG&A). R&D expenses during the second quarter of 2016 were approximately \$13.8 million compared to approximately \$24.2 million during the prior year's quarter, reflecting a significant decline in the company's clinical trial costs, partially offset by an increase in scale-up and manufacturing activities to support future commercialization. SG&A expenses for the second quarter of 2016 were approximately \$10.6 million compared with approximately \$6.9 million for the prior year's quarter, primarily due to the company's investments in human resources and sales and marketing to support future commercialization.

Net loss for the second quarter of 2016 was approximately \$21.1 million, or \$0.11 per basic and diluted share, compared with approximately \$27.2 million, or \$0.16 per basic and diluted share, for the second quarter of 2015.

At June 30, 2016, cash on hand was approximately \$166.5 million, compared with approximately \$64.7 million at December 31, 2015.

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, August 4, 2016 |
| Time: | 4:30 p.m. EDT |
| Telephone Access (US): | 866-665-9531 |
| Telephone Access (International): | 724-987-6977 |
| Access Code for All Callers: | 88600937 |

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: 46530545.

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 clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® brands. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com and www.bocagreenmd.com.

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 its hormone therapy drug candidates and obtain additional financing necessary therefor; whether the FDA will accept and, if accepted, approve the company's new drug application for its TX-004HR product candidate; the length, cost and uncertain results of the company's clinical trials; 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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Contacts

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | June 30, 2016 (Unaudited) | December 31, 2015 |
|---|------------------------------|-------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash | \$ 166,532,446 | \$ 64,706,355 |
| Accounts receivable, net of allowance for doubtful accounts of \$529,298 and \$81,910, respectively | 4,477,308 | 3,049,715 |
| Inventory | 883,656 | 690,153 |
| Other current assets | 2,136,735 | 2,233,897 |
| Total current assets | 174,030,145 | 70,680,120 |
| Fixed assets, net | 444,412 | 198,592 |
| Other Assets: | | |
| Intangible assets, net | 1,983,829 | 1,615,251 |
| Prepaid expense | — | 1,109,883 |
| Security deposit | 129,864 | 125,000 |
| Total other assets | 2,113,693 | 2,850,134 |
| Total assets | \$ 176,588,250 | \$ 73,728,846 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 3,039,388 | \$ 3,126,174 |
| Other current liabilities | 6,299,783 | 7,539,526 |
| Total current liabilities | 9,339,171 | 10,665,700 |
| Total liabilities | 9,339,171 | 10,665,700 |
| 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; 196,492,195 and 177,928,041 issued and outstanding, respectively | 196,492 | 177,928 |
| Additional paid in capital | 428,902,951 | 282,712,078 |
| Accumulated deficit | (261,850,364) | (219,826,860) |
| Total stockholders' equity | 167,249,079 | 63,063,146 |
| Total liabilities and stockholders' equity | \$ 176,588,250 | \$ 73,728,846 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|------------------------|------------------------------|------------------------|
| | 2016 | 2015 | 2016 | 2015 |
| Revenues, net | \$ 4,403,247 | \$ 4,847,934 | \$ 9,333,338 | \$ 9,322,983 |
| Cost of goods sold | 1,130,108 | 1,033,089 | 2,238,551 | 2,076,730 |
| Gross profit | <u>3,273,139</u> | <u>3,814,845</u> | <u>7,094,787</u> | <u>7,246,253</u> |
| Operating expenses: | | | | |
| Sales, general, and administration | 10,619,006 | 6,865,442 | 20,297,558 | 13,029,054 |
| Research and development | 13,841,193 | 24,190,714 | 28,938,210 | 42,367,549 |
| Depreciation and amortization | 24,262 | 14,280 | 43,859 | 27,852 |
| Total operating expense | <u>24,484,461</u> | <u>31,070,436</u> | <u>49,279,627</u> | <u>55,424,455</u> |
| Operating loss | <u>(21,211,322)</u> | <u>(27,255,591)</u> | <u>(42,184,840)</u> | <u>(48,178,202)</u> |
| Other income: | | | | |
| Miscellaneous income | 114,320 | 25,585 | 155,937 | 44,098 |
| Accreted interest | 2,863 | 2,560 | 5,399 | 12,402 |
| Total other income | <u>117,183</u> | <u>28,145</u> | <u>161,336</u> | <u>56,500</u> |
| Loss before taxes | (21,094,139) | (27,227,446) | (42,023,504) | (48,121,702) |
| Provision for income taxes | <u>—</u> | <u>—</u> | <u>—</u> | <u>—</u> |
| Net loss | <u>\$ (21,094,139)</u> | <u>\$ (27,227,446)</u> | <u>\$ (42,023,504)</u> | <u>\$ (48,121,702)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.11)</u> | <u>\$ (0.16)</u> | <u>\$ (0.21)</u> | <u>\$ (0.29)</u> |
| Weighted average number of common shares outstanding | <u>196,325,715</u> | <u>172,782,264</u> | <u>195,613,639</u> | <u>168,734,760</u> |

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

| | Six Months Ended | |
|---|-----------------------|----------------------|
| | June 30, 2016 | June 30, 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | \$ (42,023,504) | \$ (48,121,702) |
| Adjustments to reconcile net loss to net cash flows used in operating activities: | | |
| Depreciation of fixed assets | 19,216 | 14,248 |
| Amortization of intangible assets | 24,643 | 13,604 |
| Provision for doubtful accounts | 447,388 | 30,767 |
| Share-based compensation | 9,200,844 | 2,968,811 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,874,980) | (1,190,068) |
| Inventory | (193,503) | (66,606) |
| Other current assets | 1,001,120 | 383,194 |
| Other assets | — | (12,410) |
| Accounts payable | (86,786) | (508,511) |
| Deferred revenue | — | (522,613) |
| Other current liabilities | (1,239,743) | 2,047,264 |
| Other long-term liabilities | — | 967,286 |
| Net cash used in operating activities | <u>(34,725,305)</u> | <u>(43,996,736)</u> |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Patent costs | (393,221) | (78,792) |
| Purchase of fixed assets | (265,036) | (15,559) |
| Payment of security deposit | (4,864) | — |
| Net cash used in investing activities | <u>(663,121)</u> | <u>(94,351)</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from sale of common stock, net of costs | 134,863,475 | 59,117,827 |
| Proceeds from exercise of warrants | 1,373,000 | 366,000 |
| Proceeds from exercise of options | 978,042 | 491,351 |
| Net cash provided by financing activities | <u>137,214,517</u> | <u>59,975,178</u> |
| Increase in cash | 101,826,091 | 15,884,091 |
| Cash, beginning of period | 64,706,355 | 51,361,607 |
| Cash, end of period | <u>\$ 166,532,446</u> | <u>\$ 67,245,698</u> |