

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 5, 2014

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other

Jurisdiction of Incorporation)

000-16731

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW, 3rd 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.

We are furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of the textual information from a press release issued on May 5, 2014. 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	Description
99.1	Press Release from TherapeuticsMD, Inc., dated May 5, 2014, entitled “TherapeuticsMD Reports First Quarter 2014 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 5, 2014

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright

Name: Daniel A. Cartwright

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	Press Release from TherapeuticsMD, Inc., dated May 5, 2014, entitled "TherapeuticsMD Reports First Quarter 2014 Results".



FOR IMMEDIATE RELEASE

THERAPEUTICSMMD REPORTS FIRST QUARTER 2014 RESULTS

Management to Host Conference Call at 4:30 EDT Today

Boca Raton, FL, May 5, 2014 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women’s health care company, (“TherapeuticsMD,” the “Company,” “we,” or “our”) today announced results for the quarter ended March 31, 2014.

First Quarter 2014 Highlights:

- Net revenue increased to \$2.8 million compared with \$1.5 million for the quarter ended March 31, 2013;
- Net loss was \$9.2 million compared with a net loss of \$6.4 million for the quarter ended March 31, 2013;
- Launched Prena1 Pearl™, the sole generic equivalent formulation of vitaPearl, the smallest complete prescription prenatal multivitamin and the first to contain FOLMAX™, FePlus™, and pur-DHA™;
- Reported positive results of toxicity study of TX-004HR, its estradiol VagiCap drug candidate, for treatment of vulvar vaginal atrophy (VVA), that demonstrated it was “non-irritant” following a 28-day repeated application;
- Filed four additional patent applications, bringing total applications filed and issued to 33; and
- Ended the quarter with \$45.4 million in cash and cash equivalents, and no debt.

Robert G. Finizio, Co-Founder and Chief Executive Officer, stated, “This has been a busy and exciting quarter for us, highlighted by advancements in clinical trials for our principal hormone therapy drug candidates. Our two largest commercial opportunities are our investigational combination estradiol and progesterone (E+P) therapy for treatment of vasomotor symptoms in menopausal women, and estradiol VagiCap for VVA. We remain on track to complete enrollment this fall in the E+P phase 3 trial, where enrollment is strong and patient retention is positive. Pending a successful trial, the U.S. Food and Drug Administration’s (FDA) approval of our E+P drug candidate, we will be well positioned as a first-mover in this multi-billion dollar market to introduce and capitalize on what could be the first safe and effective bioidentical combination hormone therapy product for menopausal women.”

“We are equally excited about the opportunity in VVA. This market more than doubled over the last five years to \$1.1 billion in 2013 without any generic options. Our phase 3 VVA clinical trial is designed to assess the ability of our estradiol VagiCap, which leverages our solubilized lipid-based technology to achieve new, lower effective doses that could potentially reduce or eliminate systemic exposure to estradiol. Our goal is to bring to market an innovative VVA drug candidate with a focus on a positive qualitative user experience for menopausal women, while achieving an improved therapeutic profile.” continued Mr. Finizio.

“Our progesterone-only drug candidate for the treatment of secondary amenorrhea is currently undergoing a phase 3 clinical trial, called the SPRY trial. This clinical trial has faced recruiting challenges. To remedy these challenges, we are meeting with the FDA in early June 2014 to discuss potential changes to our inclusion and exclusion criteria.”

“In summary, an increasingly receptive regulatory environment, our promising product pipeline and strong cash position all are contributing to a positive outlook for the Company and we look forward to our ongoing progress in the important field of women’s health care,” Mr. Finizio concluded.

First Quarter Results

Net revenue for the first quarter of 2014 totaled \$2.8 million compared with net revenue of \$1.5 million for the prior year quarter. The increase of approximately \$1.3 million, or 84%, was directly attributable to an increase in the number of physicians writing prescriptions for our prenatal products, the increased productivity of our sales force, and an increase in the average net sales price of our product. Cost of goods sold increased by \$450,000, or 118%, for the three months ended March 31, 2014 compared with the prior year quarter.

Research and development expenses increased to \$5.9 million for the first quarter of 2014 compared with \$1.6 million for the first quarter of 2013 because of the development of our hormone therapy drug candidates and related clinical trials.

Sales, general, and administrative expenses increased to \$5.0 million for the first quarter of 2014 compared with \$4.5 million for the first quarter of 2013. As a result, our operating loss was \$9.0 million for the first quarter of 2014 compared with \$4.9 million for the first quarter of 2013.

Other non-operating expenses decreased by approximately \$1.2 million for the first quarter of 2014 compared with the comparable quarter in 2013. This decrease was primarily a result of a decrease in interest expense.

As a result, net loss for the first quarter of 2014 was \$9.2 million, or \$0.06 per basic and diluted share, compared with a net loss of \$6.4 million, or \$0.06 per basic and diluted share, for the first quarter of 2013.

Conference Call

As previously announced, today Robert G. Finizio, Co-Founder and Chief Executive Officer, and Dan Cartwright, Chief Financial Officer, will host a conference call, which may include forward-looking statements, to review the financial results as follows:

Date	Monday, May 5, 2014
Time	4:30pm EDT
Telephone access: U.S. and Canada	800-753-0594
Telephone access: International	212-231-2911
Access code for all callers	21714227
Live audio webcast	www.therapeuticsmd.com See <i>Events and Presentations</i> under the <i>Investors</i> tab

An audio replay will be available on-demand shortly after the completion of the call until May 26, 2014 at 11:59 p.m. EDT at www.therapeuticsmd.com and by dialing 800-633-8284 in the U.S. and Canada, or 402-977-9140 for international callers. The access code for all callers is 21714227.

About Hormone Therapy

Hormone therapy (HT) is the administration of hormones to supplement a lack of naturally occurring hormones. HT options include natural, bioidentical, and non-bioidentical (conjugated) hormones. HT is projected to be the largest growth segment in the overall women's health market. The potential market for pharmacy-compounded, bioidentical HT products is estimated to be approximately \$1.5 billion per year.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is a women's health care company focused on developing and commercializing products targeted exclusively for women. We manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under our vitaMedMD® and BocaGreenMD® brands. We are currently developing advanced hormone therapy pharmaceutical drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies. We are also evaluating various other potential indications for our hormone therapy technology, including oral contraception, preterm birth, vulvar and vaginal atrophy, and premature ovarian failure. More information is available at the following websites: www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com.

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Except for the historical information contained herein, the matters set forth in this press release, including statements relating to future events or performance, including statements regarding the results of TX-004HR clinical trial; the Company's performance; the progress of the Company's principal hormone therapy drug candidates; the Company's belief that its combination 17β-estradiol and progesterone (E+P) and estradiol VagiCap are the Company's two largest commercial opportunities; the progress of enrollment in the Company's E+P Phase 3 trial; the Company's belief that it will be well positioned as a first-mover in the [\$1.5 billion] market to introduce and capitalize on what could be the first safe and effective bioidentical combination hormone therapy drug product for menopausal women; the Company's assessment of its opportunity in the VVA market and the increase in the size of the VVA market; the design of the Company's Phase 3 VVA clinical trial; the attributes and potential benefits of VagiCap; the Company's goal of bringing to market an innovative VVA drug candidate with a focus on a positive qualitative user experience for menopausal women, while achieving an improved therapeutic profile; the status of enrollment in the Company's progesterone-only clinical trial and the challenges facing this clinical trial; the results of the meeting with the FDA and any subsequent changes to the inclusion and exclusion criteria in the SPRY Trial; the Company's belief that an increasingly receptive regulatory environment, its promising pipeline and strong cash position are contributing to a positive outlook for the Company; the impact of the number of physicians writing prescriptions for the Company's prenatal products, the increased productivity of the Company's sales force, an increase in the average net sales price of the Company's products; projected growth and the size of the potential market for pharmacy-compounded, bioidentical HT products; and the Company's current product pipeline and hormone technology that the Company is evaluating are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including but not limited to: timely and successful completion of clinical studies and the results thereof; challenges and costs inherent in product marketing; the risks and uncertainties associated with economic and market conditions; risks and uncertainties associated with the Company's business and finances in general; and other risks detailed in the Company's filings with the U.S. Securities and Exchange Commission including its annual report on Form 10-K filed on March 5, 2014, reports on Form 10-Q and Form 8-K, and other such filings. These forward-looking statements are based on current information that may change. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

(financial statements follow)

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEET

	March 31, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current Assets:		
Cash	\$ 45,404,402	\$ 54,191,260
Accounts receivable, net of allowance for doubtful accounts of \$32,601 and \$26,555, respectively	2,339,455	1,690,753
Inventory	920,685	1,043,618
Other current assets	2,303,522	2,477,715
Total current assets	50,968,064	59,403,346
Fixed assets, net	77,888	61,318
Other Assets:		
Prepaid expense	1,630,960	1,750,455
Intangible assets	756,926	665,588
Security deposit	135,686	135,686
Total other assets	2,523,572	2,551,729
Total assets	\$ 53,569,524	\$ 62,016,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,068,730	\$ 2,114,217
Deferred revenue	1,478,309	1,602,580
Other current liabilities	2,271,973	3,601,189
Total current liabilities	6,819,012	7,317,986
Total liabilities	6,819,012	7,317,986
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; 250,000,000 shares authorized; 145,067,060 and 144,976,757 issued and outstanding, respectively	145,067	144,977
Additional paid in capital	136,321,189	135,086,056
Accumulated deficit	(89,715,744)	(80,532,626)
Total stockholders' equity	46,750,512	54,698,407
Total liabilities and stockholders' equity	\$ 53,569,524	\$ 62,016,393

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

	Three Months Ended	
	March 31, 2014	March 31, 2013
Revenues, net	\$ 2,830,533	\$ 1,537,195
Cost of goods sold	<u>830,707</u>	<u>380,346</u>
Gross profit	<u>1,999,826</u>	<u>1,156,849</u>
Operating expenses:		
Sales, general, and administrative	5,029,497	4,526,582
Research and development	5,908,078	1,565,201
Depreciation and amortization	13,068	7,957
Total operating expense	<u>10,950,643</u>	<u>6,099,740</u>
Operating loss	<u>(8,950,817)</u>	<u>(4,942,891)</u>
Other income and (expense)		
Miscellaneous income	18,572	—
Interest income	9,154	—
Financing costs	(260,027)	(263,987)
Interest expense	—	(1,165,831)
Loan guaranty costs	—	(2,944)
Total other income (expense)	<u>(232,301)</u>	<u>(1,432,762)</u>
Loss before taxes	(9,183,118)	(6,375,653)
Provision for income taxes	<u>—</u>	<u>—</u>
Net loss	<u>\$ (9,183,118)</u>	<u>\$ (6,375,653)</u>
Net loss per share, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.06)</u>
Weighted average number of common shares outstanding	<u>145,019,561</u>	<u>103,052,956</u>

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

	Three Months Ended	
	March 31, 2014	March 31, 2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (9,183,118)	\$ (6,375,653)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation	7,122	4,703
Amortization of intangible assets	5,946	3,254
Provision for doubtful accounts	6,046	21,795
Amortization of debt discount	—	1,102,680
Stock based compensation	1,009,526	542,377
Amortization of deferred financing costs	260,027	263,987
Stock based expense for services	314,291	178,959
Loan guaranty costs	—	2,944
Changes in operating assets and liabilities:		
Accounts receivable	(654,748)	(17,978)
Inventory	122,933	277,340
Other current assets	(85,834)	(731)
Other assets	(9,154)	—
Accounts payable	954,513	199,445
Deferred revenue	(124,271)	(2,379)
Accrued expenses and other current liabilities	(1,329,216)	290,575
Net cash flows used in operating activities	<u>(8,705,937)</u>	<u>(3,508,682)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent costs, net of abandoned costs	(97,284)	(80,949)
Purchase of property and equipment	(23,692)	(22,905)
Net cash flows used in investing activities	<u>(120,976)</u>	<u>(103,854)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options	40,055	—
Proceeds from sale of common stock, net of costs	—	45,430,472
Proceeds from revolving credit note	—	400,000
Proceeds from notes and loans payable	—	100,000
Repayment of revolving credit note	—	(400,000)
Repayment of notes payable	—	(4,691,847)
Net cash flows provided by financing activities	<u>40,055</u>	<u>40,838,625</u>
(Decrease) increase in cash	(8,786,858)	37,226,089
Cash, beginning of period	54,191,260	1,553,474
Cash, end of period	<u>\$ 45,404,402</u>	<u>\$ 38,779,563</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	<u>\$ —</u>	<u>\$ 191,258</u>
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:		
Warrants issued for financing	<u>\$ —</u>	<u>\$ 1,711,956</u>