TherapeuticsMD, Inc.
Form 8-K
November 06, 2013

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): November 4, 2013

TherapeuticsMD, Inc.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**000-16731**	**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))

Item 2.02. Results of Operations and Financial Condition.

As described in Item 7.01, we are furnishing this Current Report on Form 8-K in connection with the disclosure of information during a conference call and webcast on November 4, 2013 discussing our third quarter fiscal 2013 financial results. The disclosure provided in Item 7.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 2.02.

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 purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 7.01. Regulation FD Disclosure.

We are furnishing this Current Report on Form 8-K in connection with the disclosure of information during a conference call and webcast on November 4, 2013 discussing our third quarter fiscal 2013 financial results. The transcript of the conference call and webcast is included as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 7.01 and 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. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in the Current Report on Form 8-K that is required to be disclosed solely by Regulation FD.

The text included with this Current Report on Form 8-K and the replay of the conference call and webcast on November 4, 2013 is available on our website located at www.therapeuticsmd.com, although we reserve the right to discontinue that availability at any time.

Certain statements contained in this Current Report on Form 8-K may be deemed to be forward-looking statements under federal securities laws, and we intend that such forward-looking statements be subject to the safe harbor created thereby. Such forward-looking statements include, but are not limited to, statements regarding the impact of the increases in the number of physicians writing prescriptions for our product, the productivity of our sales force, the average net sales price of our product, and the new products introduced in 2012; the impact of development of our new hormone replacement therapy product candidates and the initiation of two clinical trials; the impact of the prenatal business on our revenue, our ability to develop infrastructure that will be crucial to launching our hormone therapy products going forward, our brand recognition, and on our ability to build trust with women; our belief that our representatives are building strong relationships with the OB/GYN community, and that the OB/GYN community will be our key call point for our hormone therapy products; our belief in the merits of our sales and distribution network; the focus of our business; our belief that the hormone therapy is an area that has largely been overlooked for close to a decade; our expectation that the first NDA we file will be for our low-dose oral progesterone candidate; our belief in the benefits and attributes of our proposed hormone therapy products; our goals regarding the clinical development of our proposed hormone therapy products; the designs of clinical trials for our proposed hormone therapy products; our expectation regarding when we will announce data from a phase 3 clinical trial and when we will file an NDA for our low-dose oral progesterone candidate; enrollment in a phase 3 clinical trial for our combination drug product and our goals for enrollment in such trial; our expectation regarding when we will announce data from a phase 3 clinical trial and when we will file an NDA for our combination drug candidate; the size of the vulvar and vaginal atrophy market; our belief that our estradiol VagiCap™ product will give us a competitive edge in the vulvar and vaginal market; our expectation regarding when we will file an IND update and phase 3 clinical trial protocol, initiate the phase 3 clinical trial, and file an NDA for our estradiol VagiCap™ product; our patent strategy and our expectation regarding the timeframe of patent exclusivity; our expectation that we will file a number of additional patent applications in the fourth quarter of 2013 fiscal year; our expectation that our Opera patent will issue this quarter and will expire in 2031; our belief that our strong cash position and combined revenues from our prenatal franchise are sufficient to fund the execution of our key R&D programs; the impact of the addition of Dr. Mirkin to our team; our goal to have all the sites for the phase 3 clinical trial for our combination drug candidate enrolled by December 31, 2013 and to have all the patients in within one year from the start of the phase 3 clinical trial; the attributes, benefits, and impact of the Opera patent; the results of our dialogue with the IP office; our expectation regarding when we will have the results of the PK study for our estradiol VagiCap™ product; our expectation that Senate will bring the compounding legislation to a vote this month and that the compounding legislation will be passed and signed within the next six months; our position on the compounding legislation; our belief that pharmacies will be good customers of our company; our belief that we are on pace to begin the phase 3 clinical trial for our estradiol VagiCap™ product in the second quarter of 2014 fiscal year and that there are no roadblocks; clinical development of a transdermal version of our combination drug product; our plan to proceed only with the clinical and pre-clinical development of the drugs currently in our pipeline; future R&D spend and its relation to how well the trial is going; our plan to develop the bioidentical compounds ourselves before entertaining any partnership offerings at all; and our belief that the growth of the prenatal vitamin business is strong and that the growth is going in the right direction are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. We caution that these statements are qualified by important factors that could cause actual results to differ materially from those reflected by such forward-looking statements. 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 our business and finances in general; and other risks detailed in our filings with the U.S. Securities and Exchange Commission including our annual report on Form 10-K filed on March 12, 2013, reports on Form 10-Q and Form 8-K, and other such filings.

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.

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

(d) *Exhibits.*

Exhibit Number	Description
99.1	Transcript of conference call and webcast conducted on November 4, 2013

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: November 6, 2013 THERAPEUTICSMD, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Transcript of conference call and webcast conducted on November 4, 2013