TherapeuticsMD, Inc.
Form 424B3
November 04, 2013

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-185156

PROSPECTUS

3,953,489 Shares

Common Stock

This prospectus relates to the resale of up to 3,953,489 shares of common stock, or the Shares, of TherapeuticsMD, Inc. The Shares will be offered for resale by certain stockholders of Therapeutics listed in this prospectus, or the Selling Stockholders.

The Shares to which this prospectus relates may be sold from time to time by and for the accounts of the Selling Stockholders named in this prospectus or in supplements to this prospectus. The Selling Stockholders may sell all or a portion of these Shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices.

The Shares covered by this prospectus were issued on October 2, 2012 in a private placement, or the October Private Placement, pursuant to a Securities Purchase Agreement, or the Purchase Agreement, dated September 26, 2012, between us and certain investors. As part of the Purchase Agreement, we agreed to file a registration statement, which was filed November 27, 2012. For a more detailed description of the issuance of the Shares pursuant to the Purchase Agreement, see “Summary of the Underlying Transactions” on page 28.

The Selling Stockholders who may sell or otherwise dispose of the Shares are initial investors (or the permitted transferees of such investors) in the October Private Placement described above. The Selling Stockholders may offer the Shares from time to time directly or through underwriters, broker-dealers or agents and in one or more public or private transactions and at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at various prices determined at the time of sale or otherwise at negotiated prices. If the Shares are sold through underwriters, broker-dealers, or agents, the Selling Stockholders (or the purchasers of the Shares as negotiated with the Selling Stockholders) will be responsible for underwriting discounts or commissions or agent commissions, if any. The registration of the Shares does not necessarily mean that any of the Shares will be sold by the Selling Stockholders. The timing and amount of any sale is within the respective Selling Stockholders’ sole discretion, subject to certain restrictions. See “Plan of Distribution” beginning on page 92 of this prospectus.

We will not receive any of the proceeds from the sale of the Shares offered by the Selling Stockholders. We received aggregate net proceeds of $7,896,000 from the initial sale of the Shares to the Selling Stockholders in the October Private Placement on October 2, 2012.

Our common stock is listed on the NYSE MKT under the symbol “TXMD.” On October 8, 2013, the reported closing price of our common stock on the NYSE MKT was $3.74 per share.

See “Risk Factors” beginning on page 6 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus dated October 15, 2013.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, or the SEC or the Commission, utilizing a shelf registration process. Under this shelf registration process, the Selling Stockholders may, from time to time, offer and sell shares of our common stock pursuant to this prospectus. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus supplement before making a decision whether to invest in the common stock.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus and any applicable prospectus supplement or amendment. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in our common stock. You should read this entire prospectus carefully, including "Risk Factors" and our financial statements and related notes. Unless the context otherwise requires, the terms "Therapeutics," "TXMD," "Company," "we," "us," or "our" refer to TherapeuticsMD, Inc., a Nevada corporation, and its subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation, or BocaGreen.

The Company

Our Business

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately $10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in vulvar and vaginal atrophy, or VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be

approximately $25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately $650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately $490 million (as converted from the Euro at an exchange rate of €1.0=US$1.2875) in international sales.

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-002HR to be approximately $6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately $340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately $780 million (as converted from the Euro at an exchange rate of €1.0=US$1.2875) in international sales.

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately $16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately $1 billion in U.S. sales.

We intend to leverage and grow our current marketing and sales organization to commercialize our proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved menopause-related estrogen market was approximately $2.5 billion in U.S. sales.

The hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. We believe the FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies are approximately $1.5 billion per year. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA approved compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

As we continue the clinical development of our proposed hormone therapy products, we continue to market our prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal vitamins, iron supplements, vitamin D supplements, natural menopause relief products, and cosmetic stretch mark creams under our VitaMed brand name and duplicate formulations of our prescription prenatal vitamins products, also referred to as “generic” formulations, under our BocaGreenMD brand name. All of our prenatal vitamins are gluten-, sugar-, and lactose-free. We believe our product attributes result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality and patented ingredients.

Our sales model focuses on the “4Ps”: patient, provider, pharmacist, and payor. We market and sell our current dietary supplement and cosmetic products primarily through a direct national sales force of approximately 30 full-time professionals that calls on healthcare providers in the obstetrics and gynecologic market space as well as through our website directly to consumers. In addition, our products allow healthcare providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded, generic, and over-the-counter lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription dietary supplement products to consumers through retail pharmacies. We market our over-the-counter products either directly to consumers via our website and phone sales followed by home shipment or through physicians who then re-sell them to their patients. Our fully staffed customer care center uses current customer relationship management software to respond to healthcare providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders for our non-prescription products through our website’s auto-ship feature.

Our common stock began trading on the NYSE MKT on April 23, 2013 under the symbol “TXMD” and was previously listed on the OTCQB. We maintain the following websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com and www.bocagreenmd.com.

Our Growth Strategy

Our goal is to become the women's healthcare company recommended by healthcare providers to all patients by becoming the new standard in women's health with a complete line of products all under one quality brand. Key elements of our strategy to achieve this goal are as follows:

- focusing exclusively on women's health issues to enable us to build long-term relationships with women as they move through their life cycles of birth control, pregnancy, child birth, and pre- and post- menopause;

- focusing on our development, clinical trials, and commercialization of hormone therapy products designed to (1) alleviate the symptoms of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and (2) provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products;

- providing an alternative to the non-FDA approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies;

- maintaining a marketing emphasis on large group OB/GYN practices that provide opportunities to reach large patient bases and that are receptive to the data and savings we provide;

- pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and our website;

- expanding our geographic market and sales team to cover the entire country by increasing our current inside sales force; and

- introducing new products to build upon the introduction of our first three prescription prenatal vitamin products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012, as well as our hormone therapy products consisting of a bioidentical oral and topical combination drug of estradiol and progesterone, an oral progesterone drug, and a suppository vulvar and vaginal atrophy estradiol drug. Early pharmacokinetic, or PK, studies of our proposed combination estradiol and progesterone drug demonstrated that the product is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250.

Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

Our independent registered public accounting firm, in its audit reports related to our financial statements for the two years ended December 31, 2012 and 2011, expressed substantial doubt about our ability to continue as a going concern.

We currently derive all of our revenue from sales of our women's healthcare products and our failure to maintain or increase sales of these products would have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

If our products do not have the healthful effects intended, our business may suffer.

Our future success will depend in large part on our ability to commercialize our three proposed hormone replacement products for women designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes, osteoporosis, and vaginal dryness.

We have no experience as a company in bringing a drug to regulatory approval.

We may not be able to complete the development and commercialization of our proposed hormone replacement products if we fail to obtain additional financing.

The Offering

Common stock offered by the Selling Stockholders	3,953,489 shares
Common stock outstanding	144,962,706 shares. This number does not include 14,655,793 shares of common stock reserved for issuance upon exercise of stock options, 14,293,499 shares of common stock reserved for issuance upon exercise of warrants, and 18,258,990 shares of common stock reserved for future issuance under our non-qualified stock option plans.
Use of proceeds	We will not receive any of the proceeds from the sale of Shares to be offered by the Selling Stockholders.
NYSE MKT Symbol	TXMD

Recent Developments

On September 25, 2013, we entered into an underwriting agreement, or the Stifel Underwriting Agreement, with Stifel, Nicolaus and Company, Incorporated, as representative of the underwriters named therein, or the September Underwriters, relating to the issuance and sale of 13,750,000 shares of our common stock. The price to the public in this offering was $2.40 per share and the September Underwriters agreed to purchase the shares from us pursuant to the Stifel Underwriting Agreement at a price of $2.232 per share. The net proceeds to us from this offering was approximately $30.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering was made pursuant to the registration statement on Form S-3 filed with the Commission on January 25, 2013, and deemed effective by the SEC on February 5, 2013, including prospectus supplements filed thereunder.

Our Offices

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. The Company maintains websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and bocagreenmd.com. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus, nor is such content incorporated herein by reference.

Summary Consolidated Financial and Other Data

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statements of operations for the years ended December 31, 2011 and 2012, and the consolidated balance sheet data as of December 31, 2011 and 2012, are derived from our audited consolidated financial statements included in this prospectus. The consolidated statement of operations for the six months ended June 30, 2012 and 2013 and the balance sheet data as of June 30, 2013 are derived from our unaudited consolidated financial statements included in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements.

	Fiscal Year Ended December 31,		Six Months Ended June 30,	
	2011	2012	2012	2013
	(in thousands, except share data)			
Consolidated Statements of Operations Data:				
Revenue, net	$ 2,088	$ 3,818	$ 1,540	$ 3,618
Cost of goods sold	947	1,348	708	844
Gross profit	1,141	2,470	832	2,774
Operating expense:				
Sales, general, and administration	6,406	14,070	6,401	10,003
Research and development	107	4,492	1,245	3,312
Depreciation and amortization	55	56	29	19
Total operating expense	6,568	18,618	7,675	13,334
Operating loss	(5,427)	(16,148)	(6,843)	(10,560)
Other income (expense)				
Loss on extinguishment of debt	(7,390)	(10,308)	(10,308)	—
Beneficial conversion feature	—	(6,717)	(6,717)	—
Amortization of debt discount	(29)	(1,604)	—	—
Financing costs	—	—		