

TherapeuticsMD, Inc.  
Form 424B5  
March 15, 2013  
Table of Contents

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-186189

**PROSPECTUS SUPPLEMENT**

(To Prospectus dated February 5, 2013)

**29,411,765 Shares**

**TherapeuticsMD, Inc.**

**Common Stock**

We are offering 29,411,765 shares of our common stock. Our common stock is quoted on the OTCQB under the symbol TXMD. On March 14, 2013, the last reported sale price of our common stock on the OTCQB was \$2.30 per share.

**Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page S-6 of this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<b>PER SHARE</b>	<b>TOTAL</b>
Public Offering Price	\$ 1.700	\$ 50,000,001
Underwriting Discounts and Commissions	\$ 0.119	\$ 3,500,000
Proceeds to TherapeuticsMD, before expenses	\$ 1.581	\$ 46,500,001

Delivery of the shares of common stock is expected to be made on or about March 20, 2013. In addition, we have granted the underwriters an option for a period of 30 days to purchase up to an additional 4,411,765 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discount payable by us will be \$4,025,000 and the total proceeds to us, before expenses, will be \$53,475,001.

*Sole Book-Running Manager*

# **Jefferies**

*Co-Manager*

## **Noble Financial Capital Markets**

Prospectus Supplement dated March 14, 2013

**Table of Contents**

**TABLE OF CONTENTS**

<b>PROSPECTUS SUPPLEMENT</b>	<b>PAGE</b>
<u>ABOUT THIS PROSPECTUS SUPPLEMENT</u>	S-ii
<u>CAUTIONARY STATEMENT ABOUT FORWARD LOOKING INFORMATION</u>	S-iii
<u>PROSPECTUS SUPPLEMENT SUMMARY</u>	S-1
<u>RISK FACTORS</u>	S-6
<u>USE OF PROCEEDS</u>	S-27
<u>MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS</u>	S-28
<u>DILUTION</u>	S-29
<u>BUSINESS</u>	S-30
<u>MANAGEMENT</u>	S-50
<u>PRINCIPAL STOCKHOLDERS</u>	S-56
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK</u>	S-59
<u>UNDERWRITING</u>	S-62
<u>NOTICE TO INVESTORS</u>	S-66
<u>LEGAL MATTERS</u>	S-69
<u>EXPERTS</u>	S-69
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	S-69

<b>PROSPECTUS</b>	<b>PAGE</b>
<u>ABOUT THIS PROSPECTUS</u>	ii
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	5
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	6
<u>FORWARD-LOOKING STATEMENTS</u>	7
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	8
<u>PROSPECTUS SUPPLEMENTS</u>	9
<u>RATION OF EARNINGS TO FIXED CHARGES</u>	9
<u>DILUTION</u>	9
<u>USE OF PROCEEDS</u>	10
<u>SECURITIES WE MAY OFFER</u>	10
<u>DESCRIPTION OF COMMON STOCK</u>	11
<u>DESCRIPTION OF PREFERRED STOCK</u>	13
<u>DESCRIPTION OF DEBT SECURITIES</u>	17
<u>DESCRIPTION OF DEPOSITARY SHARES</u>	29
<u>DESCRIPTION OF WARRANTS</u>	32
<u>DESCRIPTION OF PURCHASE CONTRACTS</u>	35
<u>DESCRIPTION OF UNITS</u>	36
<u>CERTAIN PROVISIONS OF NEVADA LAW AND OUR CHARTER AND BYLAWS</u>	38
<u>LEGAL OWNERSHIP OF SECURITIES</u>	41
<u>PLAN OF DISTRIBUTION</u>	45
<u>LEGAL MATTERS</u>	47
<u>EXPERTS</u>	47

We have not, and the underwriters have not, authorized anyone to provide you with different information than that contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectus that we have authorized for use in connection with this offering. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus, or any related free writing prospectus, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus supplement entitled **Incorporation of Certain Information by Reference**.

**Table of Contents**

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the prospectus, we are referring to both parts combined. This prospectus supplement may add, update, or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein.

Unless the context otherwise requires, the terms Therapeutics, TXMD, Company, our company, we, us, or our refer to TherapeuticsMD, a Nevada corporation, and its subsidiaries, VitaMedMD, LLC, a Delaware limited liability company, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation, or BocaGreenMD.

This prospectus supplement and the accompanying prospectus relate to the offering of shares of our common stock. Before buying any shares of our common stock offered hereby, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated herein and therein by reference as described under the headings Where You Can Find More Information and Incorporation of Certain Information by Reference. These documents contain important information that you should consider when making your investment decision. This prospectus supplement contains information about the common stock offered hereby and may add, update, or change information in the accompanying prospectus.

This prospectus supplement and the accompanying prospectus contain summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been or will be filed as exhibits to the registration statement of which this prospectus is a part or as exhibits to documents incorporated by reference herein, and you may obtain copies of those documents as described below under the headings Where You Can Find More Information and Incorporation of Certain Information by Reference.

The industry and market data and other statistical information contained in the documents we incorporate by reference are based on management's own estimates, independent publications, government publications, reports by market research firms or other published independent sources, and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

---

**Table of Contents**

**CAUTIONARY STATEMENT ABOUT FORWARD LOOKING INFORMATION**

This prospectus supplement, including the sections entitled Prospectus Supplement Summary, Risk Factors, and Business, the accompanying prospectus, and the documents incorporated by reference herein and therein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in or incorporated by reference into this prospectus supplement or the accompanying prospectus, including statements regarding our future operating results and financial position, business strategy, and plans and objectives of management for future operations, are forward-looking statements. In many cases, you can identify forward-looking statements by terms such as may, should, expects, plans, anticipates, could, intends, target, projects, believes, estimates, predicts, potential, or continue or the negative of these terms or other similar expressions.

The forward-looking statements contained in or incorporated by reference into this prospectus supplement or the accompanying prospectus reflect our views as of the date of this prospectus supplement about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances that may cause our actual results, performance, or achievements to differ significantly from those expressed or implied in any forward-looking statement. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future events, results, performance, or achievements. A number of important factors could cause actual results to differ materially from those indicated by the forward-looking statements, including, without limitation, those factors described in Risk Factors. Some of the key factors that could cause actual results to differ from our expectations include the following:

- n our operating losses incurred since inception and anticipated for the foreseeable future;
- n our ability to continue as a going concern;
- n our ability to maintain or increase sales of our products;
- n the ability of our products to produce the intended effects;
- n our ability to develop and commercialize our proposed advanced hormone therapies;
- n our estimates regarding our capital requirements and our ability to obtain additional financing;
- n our lack of experience in bringing a drug to regulatory approval;
- n the uncertainty of results from our clinical trials;
- n delays, suspensions, or discontinuation of our clinical trials;
- n our reliance on third parties to conduct our clinical trials and research and development;
- n the effects of laws, regulations, and enforcement;

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- n our dependence on third-party manufacturers;
- n our ability to gain and retain market acceptance for our products;
- n our expectations with respect to the potential commercial value of our proposed products;
- n the competitive nature of the industries in which we conduct our business;
- n the availability of reimbursement from government authorities and health insurance companies for our products;
- n the impact of product liability lawsuits;
- n unfavorable publicity or lack of customer acceptance;
- n our ability to use hazardous or biological materials in compliance with applicable law;
- n our reliance on our executive officers and key personnel;
- n our ability to expand our direct sales force;
- n our dependence on certain customers and distribution channels;
- n our ability to maintain optimal inventory levels;
- n our response to changing consumer preferences and demand;
- n product recalls, withdrawals, or safety alerts;
- n our inability to manage our growth;

S-iii

**Table of Contents**

- n the conduct of our employees;
  
- n our ability to protect our intellectual property and not infringe on the intellectual property of others;
  
- n our ability to use the proceeds from this offering in an effective manner; and
  
- n our ability to establish and maintain proper internal controls and comply with the financial reporting obligations of the SEC and Sarbanes-Oxley.

Readers are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on these forward-looking statements. All of the forward-looking statements we have included in or incorporated by reference into this prospectus supplement or the accompanying prospectus are based on information available to us on the date of the applicable document. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as otherwise required by law. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this prospectus supplement and the accompanying prospectus, together with the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we may authorize for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.



---

**Table of Contents**

**PROSPECTUS SUPPLEMENT SUMMARY**

*The following summary of our business highlights some of the information contained elsewhere in or incorporated by reference into this prospectus supplement or the accompanying prospectus. Because this is only a summary, however, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, which are described under *Incorporation of Certain Information by Reference* in this prospectus supplement and the accompanying prospectus. You should also carefully consider the matters discussed in the section in this prospectus supplement entitled *Risk Factors* and in the accompanying prospectus and in other documents incorporated herein by reference.*

**Our Company**

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, or HT, 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 three proposed products and intend to begin clinical trials for two of those products. We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed products following a successful completion of this offering, and we may file an IND to begin clinical studies of our proposed suppository vulvar and vaginal atrophy estradiol product later in 2013. We intend to leverage and grow our current marketing and sales organization to commercialize these 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, vulvo and vaginal atrophy, and premature ovarian failure. During the 12 months ended June 30, 2012, the total FDA-approved menopause-related progestin market was approximately \$400 million in U.S. sales; the total FDA-approved menopause-related estrogen market was approximately \$2.3 billion in U.S. sales; and the total FDA-approved menopause-related combination progestin/estrogen market was approximately \$600 million in U.S. sales.

The hormone therapy market includes two segments: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. 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. Compounders are currently under a substantial amount of national scrutiny due to recent widely published incidents involving patient death and illness. The FDA also may take action to cause compounders to cease the production of products that would be deemed copies of our FDA-approved products.

---

## **Table of Contents**

As we continue the clinical development of our proposed hormone therapy products, we continue to market and expand our prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal vitamins, vegan docosahexaenoic acid, or DHA, iron supplements, vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD brand name and duplicate formulations of our prescription prenatal vitamins products, also referred to as generic formulations, under our BocaGreenMD Prenal 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 40 full-time professionals that calls on healthcare providers in the obstetrics and gynecologic, or OB/GYN, 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 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:

- n 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;
- n focusing on our development, clinical trials, and commercialization of hormone therapy products designed to (1) alleviate the systems 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;
- n providing an alternative to the non-FDA approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies;
- n 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;
- n pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and our website;
- n expanding our geographic market and sales team to cover the entire country by increasing our current 36 sales territories to 60 sales territories by the end of 2013; and
- n 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 combination drug of progesterone and estradiol, an oral progesterone drug, and a suppository vulvar

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

and vaginal atrophy estradiol drug. Early pharmacokinetic, or PK, studies of our proposed combination

S-2

**Table of Contents**

estradiol and progesterone drug demonstrate 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.

**Recent Developments**

***Fourth Quarter 2012 Results and Cash Position***

During the quarter ended December 31, 2012, we generated revenue of approximately \$1.2 million, bringing our revenue to approximately \$3.8 million for the year ended December 31, 2012. Our cash, cash equivalents, and current marketable securities were approximately \$1.5 million as of December 31, 2012. These financial results should be read in conjunction with our audited consolidated financial statements as of and for the year ended December 31, 2012, as filed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. You should carefully read that document in its entirety, including the audited consolidated financial statements, before making an investment decision.

***Debt Offering***

On January 31, 2013, we issued a Multiple Advance Revolving Credit Note, or the Note, to Plato and Associates, LLC, or Plato. The Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6.0% per annum. Plato may make advances to us from time to time under the Note at our request, which advances will be of a revolving nature. Interest payments will be due and payable on a quarterly basis, commencing on April 10, 2013, and the principal balance outstanding under the Note, together with all accrued interest and other amounts payable under the Note, if any, shall be due and payable on February 24, 2014. As additional consideration for the Note, we issued to Plato a warrant to purchase 1,250,000 shares of our common stock at an exercise price \$3.20 per share. This warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to its January 31, 2019 expiration date.

**Our Offices**

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487. Our telephone number is (561) 961-1911. Our company maintains websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com), and [www.bocagreenmd.com](http://www.bocagreenmd.com). The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

**Table of Contents**

**THE OFFERING**

**Common stock offered by us** 29,411,765 shares

**Common stock to be outstanding immediately after this offering** 129,196,747 shares

**Underwriters option to purchase additional shares** We have granted the underwriters an option to purchase up to 4,411,765 additional shares of our common stock. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.

**Directed share program** The underwriters have reserved for sale to our directors, officers, and employees and to certain persons having business relationships with the Company up to 30,000 of the shares of the common stock offered by this prospectus at the public offering price. We will offer these shares to the extent permitted under applicable regulations in the United States and in various countries. The number of shares available for sale to the general public in this offering will be reduced to the extent these persons purchase reserved shares. Any reserved shares not purchased will be offered by the underwriters to the general public on the same terms as the other shares. See the section entitled "Underwriting - Directed Share Program."

**Use of proceeds** We intend to use the net proceeds from the sale of the shares of common stock under this prospectus supplement for general corporate purposes, including funding our Phase 3 clinical trials for our proposed hormone therapy products, other research and development, repayment of indebtedness, securing manufacturing technology and capacity, and working capital. Please see the section entitled "Use of Proceeds" on page S-27 of this prospectus supplement.

**Risk factors** This investment involves a high degree of risk. See the information contained in or incorporated by reference under "Risk Factors" beginning on page S-6 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.

**Common stock symbol** Our common stock is quoted on the OTCQB under the symbol "TXMD." Pursuant to a Securities Purchase Agreement dated September 26, 2012, we granted certain of our stockholders that purchased an aggregate of 3,953,489 shares of our common stock thereunder, the right, if they elect, to purchase on the same terms as in this offering, a number of shares of common stock that is sufficient to maintain their respective pro rata ownership percentage of our common stock. None of these stockholders exercised their preemptive rights in connection with this offering.

**Table of Contents**

The number of shares of common stock to be outstanding immediately after this offering is based on 99,784,982 shares outstanding on December 31, 2012 and excludes the following as of that date:

- n outstanding options representing the right to purchase a total of 13,733,488 shares of common stock at a weighted average exercise price of \$1.16 per share;
- n outstanding warrants representing the right to purchase a total of 12,193,499 shares of common stock at a weighted-average exercise price of \$1.63 per share; and

- n 19,242,667 shares of common stock reserved for future issuance under our non-qualified stock option plan.

If the underwriters' option to purchase additional shares is exercised in full, we will issue and sell an additional 4,411,765 shares of our common stock and will have 133,608,512 shares outstanding after the offering.

Except as otherwise noted, all information in this prospectus supplement assumes no exercise of the underwriters' option to purchase additional shares.

**Table of Contents**

**RISK FACTORS**

*An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below, together with the other information in this prospectus supplement and the accompanying prospectus and the information contained in our other filings with the SEC, which are incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference herein and therein, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.*

**Risks Related to Our Business**

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

We have incurred recurring net losses, including net losses of \$35.1 million and \$12.9 million for the years ended December 31, 2012 and 2011. As of December 31, 2012, we had an accumulated deficit of approximately \$52.1 million. We have generated limited revenue and have funded our operations to date primarily from private sales of equity and debt securities. We expect to incur substantial additional losses over the next several years as our research, development, and clinical trial activities increase, especially those related to our proposed hormone therapy products. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our proposed hormone therapy products. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

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

As a result of our continued losses, our independent registered public accounting firms have included an explanatory paragraph in their reports on our financial statements for the years ended December 31, 2012 and 2011, expressing substantial doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our independent registered public accounting firms may make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we might obtain.

***We currently derive all of our revenue from sales of our women's health 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.***

We currently derive all of our revenue from sales of women's health products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, natural menopause relief, and scar reduction creams. While sales of our vitamin products grew from 2010 through 2012, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- n the presence of new or existing competing products, including generic copies of our prescription dietary supplement products;
- n any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;
- n changed or increased regulatory restrictions or regulatory actions by the FDA;

---

**Table of Contents**

- n changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal healthcare programs;
- n the impact or efficacy of any price increases we may implement in the future;
- n changes to our label and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- n acceptance of our products as safe and effective by physicians and patients.

If revenue from sales of our existing prescription and over-the-counter dietary supplements and cosmetics does not continue or increase, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects, or we may not be able to commence or continue clinical trials in order to seek approval for and commercialize our proposed hormone therapy products or any other products we may choose to develop in the future.

***If our products do not have the effects intended or cause undesirable side effects, our business may suffer.***

Although many of the ingredients in our current dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. Although we believe all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects would be harmed significantly.

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

Our future success will depend in large part on our ability to successfully develop and commercialize our proposed hormone therapy products designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes, osteoporosis, and vaginal dryness. We have submitted IND applications for our three proposed hormone therapy products, which the FDA has made effective and which permit us to conduct clinical testing on these proposed products. We intend to clinically test two of those proposed products and may submit an IND application for another proposed hormone therapy product later in 2013. However, we may not be able to complete the development of these proposed products, the results of the clinical trials may not be sufficient to support a New Drug Application, or NDA, for any of them, and even if we believe the results of our clinical trials are sufficient to support any NDA that we submit, the FDA may disagree and may not approve our NDA. In addition, even if the FDA approves one or more of our NDAs, it may do so with restrictions on the intended uses that may make commercialization of the product or products financially untenable. The failure to commercialize or obtain necessary approval for any one or more of these products would substantially harm our prospects and our business.

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

We need substantial amounts of cash to complete the clinical development of our proposed hormone therapy products. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We do not currently have any committed external source of funds. We will attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot





---

**Table of Contents**

guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- n significantly delay, scale back, or discontinue our product development and commercialization efforts;
  
- n seek collaborators for our proposed hormone therapy products at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and
  
- n license, potentially on unfavorable terms, our rights to our proposed hormone therapy products that we otherwise would seek to develop or commercialize ourselves.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing discovery, development, and commercialization efforts, and our ability to generate revenue and achieve or sustain profitability will be substantially harmed.

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

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude, after review of our data, that our applications are insufficient to obtain regulatory approval of any of our proposed hormone therapy products. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our proposed hormone therapy products, generating revenue from these proposed products, and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our proposed hormone therapy products, which would materially adversely affect our business and could potentially cause us to cease operations.

***Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Two proposed hormone therapy products are currently in various stages of clinical testing, and we have received a third accepted IND application from the FDA, but have not undertaken clinical trials for any proposed products. We may submit an IND application for a fourth proposed product in 2013. Clinic trials are expensive, can take many years to complete, and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our proposed hormone therapy products fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations, and prospects.

**Table of Contents**

*Delays in clinical trials are common for many reasons, and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.*

We may experience delays in clinical trials for our proposed hormone therapy products. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- n delays in obtaining regulatory approval to commence a trial;
- n imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- n imposition of a clinical hold because of safety or efficacy concerns by the data safety monitoring board, or DSMB, the FDA, an Institutional Review Board, or IRB, or us;
- n delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- n delays in obtaining required institutional review board approval at each site;
- n delays in identifying, recruiting, and training suitable clinical investigators;
- n delays in recruiting suitable patients to participate in a trial;
- n delays in having patients complete participation in a trial or return for post-treatment follow-up;
- n clinical sites dropping out of a trial to the detriment of enrollment;
- n time required to add new sites;
- n delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredient, or API; or
- n delays resulting from negative or equivocal findings of the DSMB for a trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenue.

*We may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of our proposed hormone therapy products.*

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the DSMB or the IRB for a clinical trial. An institutional review board may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from any of these proposed products will be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

## **Table of Contents**

*We rely on third parties to conduct our research and development activities, including our clinical trials, and we may experience delays in obtaining or may be unsuccessful in obtaining regulatory approval for, or in commercializing our proposed hormone therapy products if these third parties do not successfully carry out their contractual duties or meet expected deadlines.*

We do not have the resources to independently conduct research and development activities. Therefore, we have relied, and plan to continue to rely, on various third-party CROs to conduct our research and development activities and to recruit patients and monitor and manage data for our on-going clinical programs for our proposed hormone therapy products, as well as for the execution of our clinical studies. Although we control only certain aspects of our CROs' activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot assure you that the CROs will conduct the research properly or in a timely manner, or that the results will be reproducible. We and our CROs are required to comply with the FDA's Current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid, and the FDA may require us to perform additional clinical trials before approving our proposed products. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, to evaluate the safety and effectiveness compared to placebo of our proposed hormone therapy products to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process.

In addition, we do not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our on-going clinical and pre-clinical programs. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our proposed hormone therapy products that we seek to develop. As a result, our financial results and the commercial prospects for our proposed hormone therapy products that we seek to develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed or ended.

We typically engage one or more CROs on a project-by-project basis for each study or trial. While we have developed and plan to maintain our relationships with CROs that we have previously engaged, we also expect to enter into agreements with other CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to on-going clinical programs and, specifically, the compilation of clinical trial data for submission with an NDA for each of our proposed hormone therapy products. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. Although we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations, or prospects.

---

## **Table of Contents**

***Future legislation, regulations, and policies adopted by the FDA or other regulatory authorities may increase the time and cost required for us to conduct and complete clinical trials for our proposed hormone therapy products.***

The FDA has established regulations, guidelines, and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations, or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing, and completion of the clinical trials for our proposed hormone therapy products.

In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit, or delay regulatory approval of our product candidates, or impose more stringent product labeling and post-marketing testing and other requirements. If we are slow or unable to adapt to such changes, our business, prospects, and ability to achieve or sustain profitability would be adversely affected.

***Even if we obtain regulatory approval for our proposed hormone therapy products, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.***

Even if we obtain regulatory approval for one or more of our proposed hormone therapy products in the United States, the FDA may still impose significant restrictions on a product's indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including Phase 4 clinical trials, or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for our proposed hormone therapy products, if approved, may include restrictions on use or warnings. The Food and Drug Administration Amendments Act of 2007, or FDAAA, gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved Risk Evaluation and Mitigation Strategies, or REMS, programs. If approved, our proposed hormone therapy products will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority under the FDAAA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our proposed hormone therapy products once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of an approved NDA also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's Current Good Manufacturing Practice, or cGMPs, regulations. If we or a regulatory agency discovers previously unknown problems with a product,

**Table of Contents**

such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- n conduct an investigation into our practices and any alleged violation of law;
- n issue warning letters or untitled letters asserting that we are in violation of the law;
- n seek an injunction or impose civil or criminal penalties or monetary fines;
- n suspend or withdraw regulatory approval;
- n require that we suspend or terminate any ongoing clinical trials;
- n refuse to approve pending applications or supplements to applications filed by us;
- n suspend or impose restrictions on operations, including costly new manufacturing requirements;
- n seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- n exclude us from providing our products to those participating in government healthcare programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

The occurrence of any of the foregoing events or penalties may force us to expend significant amounts of time and money and may significantly inhibit our ability to bring to market or continue to market our products and generate revenue. Similar regulations apply in foreign jurisdictions.

***Our dependence upon third parties for the manufacture and supply of our existing women's healthcare products and our proposed hormone therapy products may cause delays in, or prevent us from, successfully developing, commercializing, and marketing our products.***

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture our existing women's healthcare products. For example, we depend on Lang Naturals, Inc., or Lang, to supply approximately 80% of our *vitaMed* products. We also rely on third-party contract manufacturing organizations, or CMOs to supply our proposed hormone therapy products for use in the conduct of our clinical trials. We rely on these third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We do not have long-term contracts for the commercial supply of our products or our proposed hormone therapy products. We intend to pursue long-term manufacturing agreements, but we may not be able to negotiate such agreements on acceptable terms, if at all.

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

In addition, regulatory requirements could pose barriers to the manufacture of our products, including our proposed hormone therapy products. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers must be approved by the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party CMO. All of our existing products are and our proposed hormone therapy products, if approved, will be manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to

S-12



## **Table of Contents**

secure the applicable approval for their manufacturing facilities. If these facilities are not approved for the commercial manufacture of our existing products or our proposed hormone therapy products, we may need to find alternative manufacturing facilities, which would result in disruptions of our sales and significant delays of up to several years in obtaining approval for our proposed hormone therapy products. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMP regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations, and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier of the product for our proposed hormone therapy products experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of the agreement between us, or does not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our proposed hormone therapy products, which could impair our ability to supply our proposed hormone therapy products at the levels required for our clinical trials and commercialization and prevent or delay their successful development and commercialization.

***The commercial success of our existing products and our proposed hormone therapy products that we develop, if approved in the future, will depend upon gaining and retaining significant market acceptance of these products among physicians and payors.***

Physicians may not prescribe our products, including any of our proposed hormone therapy products, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent us from generating revenue or becoming profitable. Market acceptance of our products, including our proposed hormone therapy products by physicians, patients, and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- n the clinical indications for which our proposed hormone therapy products are approved, if at all;
- n acceptance by physicians and payors of each product as safe and effective treatment;
- n the cost of treatment in relation to alternative treatments, including numerous generic drug products;
- n the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- n the availability and efficacy of competitive drugs;
- n the effectiveness of our sales force and marketing efforts;
- n the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- n the availability of adequate reimbursement by third parties, such as insurance companies and other healthcare payors, or by government healthcare programs, including Medicare and Medicaid;
- n limitations or warnings contained in a product's FDA-approved labeling; and

<sup>n</sup> prevalence and severity of adverse side effects.

Even if the medical community accepts that our products are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. We cannot assure you that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our products, including, in particular our proposed hormone therapy products, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

S-13

## **Table of Contents**

***Our products, including our proposed hormone therapy products, if approved, face significant competition from branded and generic products, and our operating results will suffer if we fail to compete effectively.***

Development and awareness of our brand will depend largely upon our success in increasing our customer base. The dietary supplement and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our products, including any proposed hormone therapy products that are approved, face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. Many of these companies have greater financial and other resources, such as larger research and development staffs and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly and may be more effective in selling and marketing their products. They also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we sell or develop obsolete. As a result, our competitors may succeed in commercializing products before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If we are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed. In addition, our efforts to provide an alternative to the non FDA-approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies may not be successful.

***Reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably.***

Market acceptance and sales of our products, including any proposed hormone therapy products, will depend on coverage and reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors generally do not cover over-the-counter products, and coverage for vitamins and dietary supplements varies. We cannot be sure that coverage and reimbursement will be available for our products, including any proposed hormone therapy products, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our existing dietary supplement products or successfully commercialize our proposed hormone therapy products.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others, and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products, including our proposed hormone therapy products, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. The goal of PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. Among other measures, PPACA imposes increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect PPACA will have on federal reimbursement policies in general or on our business specifically, the PPACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

---

**Table of Contents**

The availability of generic products at lower prices than branded products, may also substantially reduce the likelihood of reimbursement for branded products, such as our proposed hormone therapy products, if approved. We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

***Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.***

We face an inherent risk of product liability claims as a result of the marketing of our current products and the clinical testing of our proposed hormone therapy products despite obtaining appropriate informed consents from our clinical trial participants, and we will face an even greater risk if we obtain FDA approval and commercialize our proposed hormone therapy products in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or proposed hormone therapy products, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- n decreased demand for our products or products that we may develop in the future;
- n loss of revenue;
- n injury to our reputation;
- n difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- n initiation of investigations by regulators;
- n costs to defend the related litigation;
- n a diversion of management's time and our resources;
- n substantial monetary awards to trial participants or patients;
- n product recalls or withdrawals;
- n labeling, marketing, or promotional restrictions;
- n exhaustion of any available insurance and our capital resources;

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

n the inability to commercialize our products or proposed hormone therapy products; and

n a decline in our stock price.

Although we maintain general liability insurance of up to \$10 million in the aggregate and clinical trial liability insurance of \$10 million in the aggregate for our proposed hormone therapy products, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects.

***Our business may be affected by unfavorable publicity or lack of consumer acceptance.***

We are highly dependent upon consumer acceptance of the safety and quality of our products, as well as similar products distributed by other companies. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention, and other publicity about product use. A product may be received favorably resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or any of our particular products and may not be consistent with earlier favorable research or publicity. A future research report or

S-15

## **Table of Contents**

publicity that is perceived by our consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates consumption of our product or any other similar product with illness or other adverse effects, or that questions the benefits of our product or a similar product, or that claims that such products do not have the effect intended could have a material adverse effect on our business, reputation, financial condition or results of operations.

*If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.*

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological, and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state, and local laws and regulations in the United States govern the use, manufacture, storage, handling, and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing, and disposing of these materials (all of which only occur at third-party sites operated by our contractors) comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. We also cannot predict the impact on our business of new or amended environmental laws or regulations, or any changes in the way existing and future laws and regulations are interpreted or enforced. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources, and we do not carry liability insurance covering the use of hazardous materials. If we fail to comply with applicable requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs, or capital expenditures for control equipment or operational changes necessary to achieve or maintain compliance. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which adversely affect our business, financial condition, results of operations, and prospects.

*We are subject to extensive and costly government regulation.*

The products we currently market, including the vitamins and cosmetic creams, and the pharmaceutical products we are developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of our proposed hormone therapy products to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations, and prospects.

---

**Table of Contents**

*We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.*

We are subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- n the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- n federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- n federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- n state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations, and financial condition.

PPACA also imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to healthcare providers and ownership of their stock by healthcare providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests that are not reported. Manufacturers will be required to begin data collection on August 1, 2013 and report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

*If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.*

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock options that vest over time. The value to employees of stock options will be significantly affected by movements in our stock price that we

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

S-17



---

**Table of Contents**

Despite our efforts to retain valuable employees, members of our management, scientific, and medical teams may terminate their employment with us on short notice. We do not have employment agreements with a number of our key employees. As a result, most employees are employed on an at-will basis, which means that any of these employees could leave our employment at any time, with or without notice, and may go to work for a competitor. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, and financial condition. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled scientific and medical personnel.

***Any failure to adequately expand a direct sales force will impede our growth.***

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets in which we do business. While there presently exists a high rate of unemployment, if we are unable to hire and develop sufficient numbers of productive sales personnel our business prospects could suffer.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and longer histories than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we offer. If we are unable to continue to attract and retain high-quality personnel, our ability to commercialize drug candidates will be limited.

***Our success is tied to our distribution channels.***

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. However, over 98% of our product shipments since inception were to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. Our business would be harmed if any of these customers refused to distribute our products or refused to purchase our products on commercially favorable terms to us.

***A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our reputation and subject us to financial losses.***

Our ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. In some instances, our products have unique ingredients used under license arrangements. If our manufacturers are unsuccessful in obtaining raw materials, if we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and brands could be harmed, and physicians may be less likely to recommend our products in the future, each of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

***Our success depends on how efficiently we respond to changing consumer preferences and demand.***

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences. We may not be able to respond in a timely or commercially appropriate manner to these changes. Our failure to accurately predict these trends could negatively impact our inventory levels, sales, and consumer opinion of us as a source for the latest product. The success of our new product offerings depends upon a number of factors, including our ability to achieve the following:

- n accurately anticipate customer needs;
  
- n innovate and develop new products;

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- n successfully commercialize new products in a timely manner;
- n competitively price our products in the market;
- n procure and maintain products in sufficient volumes and in a timely manner; and
- n differentiate our product offerings from those of our competitors.

S-18

---

**Table of Contents**

If we do not introduce new products, make enhancements to existing products, or maintain the appropriate inventory levels to meet customers demand in a timely manner, our business, results of operations, and financial condition could be materially and adversely affected.

***We may initiate product recalls or withdrawals, or may be subject to regulatory enforcement actions that could negatively affect our business.***

We may be subject to product recalls, withdrawals, or seizures if any of the products we formulate, manufacture, or sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal, or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and could materially and adversely affect our business, financial condition, and results of operations.

***We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of December 31, 2012, we had 69 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our proposed hormone therapy products, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately, or to disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

---

**Table of Contents****Risks Related to our Intellectual Property**

***Another party could develop hormone therapy products and obtain FDA regulatory exclusivity in the United States before we do, potentially preventing our ability to commercialize our proposed hormone therapy products and other products in development.***

We plan to seek to obtain market exclusivity for our proposed hormone therapy products and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also be seeking marketing exclusivity and may be in various stages of development, including some more advanced than us. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our proposed hormone therapy products, and materially adversely affect our business, financial condition, and results of operations.

***If our efforts to protect the proprietary nature of the intellectual property covering our proposed hormone therapy products and other products are not adequate, we may not be able to compete effectively in our market.***

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent positions as well as our ability to maintain adequate protection of other intellectual property for our proposed hormone therapy products and other products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent positions of pharmaceutical companies are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action, and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the recently adopted America Invents Act of 2011, may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- n the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- n patents issued or licensed to us or our partners may be challenged, discovered to have been issued on the basis of insufficient or incorrect information, or held to be invalid or unenforceable;
- n the scope of any patent protection may be too narrow to exclude other competitors from developing or designing around these patents;
- n we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- n we or our licensors were not the first to file patent applications for these inventions;
- n we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- n future product candidates may not be patentable;
  
- n others will claim rights or ownership with regard to patents and other proprietary rights that we hold or license;

S-20

---

**Table of Contents**

<sup>n</sup> delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our product candidates under patent protection; and

<sup>n</sup> we may fail to timely apply for patents on our technologies or products.

While we apply for patents covering our technologies and products, as we deem appropriate, many pharmaceutical companies and university and research institutions already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our proposed hormone therapy products. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the U.S. Patent and Trademark Office, or USPTO, or applicable foreign patent regulatory authorities to determine our rights in the invention, which may be time-consuming and expensive. Moreover, issued patents may be challenged during post-grant proceedings brought by a third party or the USPTO, or in foreign countries, or in the courts. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our proposed hormone therapy products or future product candidates, if approved, may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to our patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as at risk launches to challenge our patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

***If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. We are aware of numerous third-party U.S. and non-U.S. issued patents and pending applications that exist in the areas of hormone therapy, including compounds, formulations, treatment methods, and synthetic processes that may be applied towards the synthesis of hormones. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance, if at all. As such, there may be other third-party patents and pending applications of which we are currently unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or product candidates. Therefore, we cannot ever know with certainty the nature or existence of every third-party patent filing. We cannot provide assurances that we or our partners will be free to manufacture or market our product candidates as planned, or that we or our licensors and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of any of our product candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

---

## **Table of Contents**

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry generally. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations, and prospects, including the following:

- n infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management's attention from our business;
- n substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;
- n a court prohibiting us from selling or licensing our technologies or future products unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;
- n if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; and
- n redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes, or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our product candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

***We may be required to file lawsuits or take other actions to protect or enforce our patents or the patents of our licensors, which could be expensive and time consuming.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions, or other interim proceedings or developments to be negative, the price of our common stock could be adversely affected. The occurrence of any of the above could adversely affect our business, financial condition, results of operations, and prospects.





---

## **Table of Contents**

*If we are unable to protect the confidentiality of certain information, the value of our products and technology could be materially adversely affected.*

We also rely on trade secrets, know-how, and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers, and collaborators. We cannot, however, ensure that these protective arrangements will be honored by third parties, and we may not have adequate remedies if these arrangements are breached. In addition, enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, or technological advancements is expensive, time-consuming, and uncertain. Non-U.S. courts are sometimes less willing than U.S. courts to protect this information. Moreover, our trade secrets, know-how, and technological advancements may otherwise become known or be independently developed by competitors in a manner providing us with no practical recourse against the competing parties. If any such events were to occur, they could adversely affect our business, financial condition, results of operations, and prospects.

*We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.*

As is common in the pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations, and prospects.

### **Risks Related to this Offering and Ownership of Our Common Stock**

*The market price of our common stock may be highly volatile, and you could lose all or part of your investment.*

The trading price of our common stock is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include the following:

- n any delay in commencement of our Phase 3 clinical trials for our proposed hormone therapy products;
- n adverse results or delays in clinical trials;
- n any delay in filing our NDAs for our proposed hormone therapy products and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a refusal to file letter or a request for additional information;
- n changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- n unanticipated serious safety concerns related to the use of our proposed hormone therapy products;
- n a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- n the inability to obtain adequate clinical supply for our proposed hormone therapy products or the inability to do so at acceptable prices;

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- n adverse regulatory decisions;
  
- n the introduction of new products or technologies offered by us or our competitors;
  
- n the effectiveness of our or our potential strategic partners' commercialization efforts;
  
- n developments concerning our sources of manufacturing supply and any commercialization strategic partners;
  
- n the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
  
- n disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
  
- n the inability to effectively manage our growth;
  
- n actual or anticipated variations in quarterly operating results;
  
- n the failure to meet or exceed the estimates and projections of the investment community;

S-23

**Table of Contents**

- n the overall performance of the U.S. equity markets and general political and economic conditions;
- n announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- n additions or departures of key scientific or management personnel;
- n adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- n sales of our common stock by our stockholders in the future;
- n significant lawsuits, including patent or stockholder litigation;
- n changes in the market valuations of similar companies;
- n the trading volume of our common stock;
- n increases in our common stock available for sale upon expiration of lock-up agreements;
- n effects of natural or man-made catastrophic events or other business interruptions; and
- n other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the OTCQB Bulletin Board and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

At February 28, 2013, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 78% of our common stock on an as-if converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management was required to deliver a report that assesses the effectiveness of our internal control over financial reporting for the year ended December 31, 2012. Our independent registered public accounting firm also was required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ended December 31, 2012.

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

There can be no assurance that we will not identify one or more additional material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act in future periods. The presence of additional material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results. If we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish

S-24

---

## **Table of Contents**

research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the value of their stock.

***Some provisions of our charter documents and Nevada law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our articles of incorporation and bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if an acquisition would benefit our stockholders, and could also make it more difficult to remove our current management. These provisions in our articles of incorporation and bylaws include the following:

- n authorizing the issuance of blank check preferred stock that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;
- n prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- n advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

In addition, we are subject to Nevada's Combination with Interested Stockholders statute (Nevada Revised Statute Sections 78.411-78.444) which prohibits an interested stockholder from entering into a combination with the corporation, unless certain conditions are met. An interested stockholder is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10% or more of the corporation's capital stock entitled to vote.

***You will experience immediate and substantial dilution in the book value per share of the common stock you purchase.***

The public offering price of our common stock being offered is substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate substantial dilution of \$1.37 in net tangible book value per share from the price you paid. For a further description of the dilution that you will experience immediately after this offering, see the section titled Dilution.

***We have broad discretion to determine how to use the proceeds raised in this offering, and we may not use the proceeds effectively.***

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways with which you may not agree or that do not yield a favorable return. We intend to use the net proceeds from the sale of the shares of common stock under this prospectus supplement for general corporate purposes, including funding our Phase 3 clinical trials for our proposed hormone therapy products, other research and development, repayment of indebtedness, securing manufacturing technology and capacity, and working capital. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products, and technologies, although we have no current plans, commitments or agreements with respect to any such acquisitions or investments, and we have not allocated the net proceeds from this offering for any specific purposes. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.



**Table of Contents**

*We are not currently listed on a national securities exchange, and there can be no assurance we will ever be listed.*

Currently, our common stock is quoted on the OTCQB marketplace under the symbol TXMD. We have applied for our common stock to be listed on the NYSE MKT, but we do not currently meet all of the requirements for listing on the NYSE MKT. We do not know when, if ever, our common stock will be listed on the NYSE MKT or another national securities exchange. In addition, if we become eligible, we cannot be certain that the NYSE MKT or any other exchange will approve our stock for listing. In order to be eligible for listing, we must meet the initial listing criteria for NYSE MKT or another national exchange, including a minimum per share price.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds from the sale of shares of common stock that we are offering will be approximately \$45.6 million, or approximately \$52.6 million if the underwriters exercise in full their option to purchase additional shares, based on the public offering price of \$1.70 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for general corporate purposes, including funding our Phase 3 clinical trials for our proposed hormone therapy products, other research and development, securing manufacturing technology and capacity, and working capital. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products, and technologies. Although we have no specific agreements, commitments or understandings with respect to any acquisition, we evaluate acquisition opportunities and engage in related discussions with other companies from time to time.

We also intend to use the net proceeds from this offering to repay secured promissory notes issued on June 19, 2012 to Steven Johnson and Plato & Associates, LLC in the principal amounts of \$2,347,128 and \$2,344,719, respectively, with accrued interest at February 28, 2013 of \$97,836 and \$97,736, respectively. These notes bear interest at 6.0% and mature on February 24, 2014. We used the proceeds of these notes to fund our research and development and working capital.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds from this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in, and costs of, our Phase 3 clinical trials for our proposed hormone therapy products, the timing of our revenue, and the amount of cash used by our operations. Accordingly, we will retain broad discretion over the use of such proceeds.

Pending use of the proceeds as described above or otherwise, we intend to invest the net proceeds in short-term interest-bearing, investment-grade securities.



**Table of Contents****MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS**

Our common stock is quoted on the OTCQB under the symbol TXMD. The following table sets forth for the periods indicated the high and low bid prices of our common stock on the OTCQB. The below quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. Prices listed are historic prices that have been adjusted to reflect the 1:100 reverse split that was effective on October 3, 2011.

	<b>HIGH</b>	<b>LOW</b>
<b>2013</b>		
First Quarter (through March 14, 2013)	\$ 3.70	\$ 2.30
<b>2012</b>		
Fourth Quarter	\$ 3.50	\$ 1.25
Third Quarter	\$ 3.60	\$ 2.61
Second Quarter	\$ 2.84	\$ 2.06
First Quarter	\$ 2.50	\$ 1.43
<b>2011</b>		
Fourth Quarter	\$ 1.70	\$ 0.51
Third Quarter	\$ 4.00	\$ 1.00
Second Quarter	\$ 7.00	\$ 1.00
First Quarter	\$ 10.00	\$ 2.00

**Transfer Agent**

Computershare Trust Co., Inc. is the transfer agent and registrar for our common stock.

**Holders**

On December 31, 2012, we had 346 holders of record of our common stock.

**Dividend Policy**

Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations, and capital requirements as well as other factors deemed relevant by our Board of Directors.

**Table of Contents****DILUTION**

Our net tangible book value as of December 31, 2012 was approximately \$(3.1) million, or \$(0.03) per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of December 31, 2012. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 29,411,765 shares of our common stock in this offering at the public offering price of \$1.70 per share and after deducting the underwriting discounts and commissions and estimated offering expenses we must pay, our as adjusted net tangible book value as of December 31, 2012 would have been approximately \$42.5 million, or \$0.33 per share. This represents an immediate increase in net tangible book value of \$0.36 per share to existing stockholders and immediate dilution in net tangible book value of \$1.37 per share to new investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

Public offering price per share		\$ 1.70
Net tangible book value per share as of December 31, 2012	\$ (0.03)	
Increase per share attributable to new investors	\$ 0.36	
As adjusted net tangible book value per share after this offering		\$ 0.33
Dilution per share to new investors in this offering		\$ 1.37

If the underwriters exercise in full their option to purchase 4,411,765 additional shares of common stock at the public offering price of \$1.70 per share, the as adjusted net tangible book value after this offering would be \$0.37 per share, representing an increase in net tangible book value of \$0.40 per share to existing stockholders and immediate dilution in net tangible book value of \$1.33 per share to new investors purchasing our common stock in this offering.

The above discussion and table are based on 99,784,982 shares outstanding on December 31, 2012 and exclude the following as of that date:

- n outstanding options representing the right to purchase a total of 13,733,488 shares of common stock at a weighted average exercise price of \$1.16 per share;
- n outstanding warrants representing the right to purchase a total of 12,193,499 shares of common stock at a weighted-average exercise price of \$1.63 per share; and
- n 19,242,667 shares of common stock reserved for future issuance under our non-qualified stock option plan.

To the extent that outstanding options or warrants are exercised or we issue shares of stock under our stock incentive plans, investors purchasing our common stock in this offering will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution

to our stockholders.

S-29

---

**Table of Contents**

**BUSINESS**

**Introduction**

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, or HT, 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 three proposed products and intend to begin clinical trials for two of those products. We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed products following a successful completion of this offering, and we may file an IND to begin clinical studies of our proposed suppository vulvar and vaginal atrophy estradiol product later in 2013. We intend to leverage and grow our current marketing and sales organization to commercialize these 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, vulvo and vaginal atrophy, and premature ovarian failure. During the 12 months ended June 30, 2012, the total FDA-approved menopause-related progestin market was approximately \$400 million in U.S. sales; the total FDA-approved menopause-related estrogen market was approximately \$2.3 billion in U.S. sales; and the total FDA-approved menopause-related combination progestin/estrogen market was approximately \$600 million in U.S. sales.

The hormone therapy market includes two segments: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. 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. Compounders are currently under a substantial amount of national scrutiny due to recent widely published incidents involving patient death and illness. The FDA also may take action to cause compounders to cease the production of products that would be deemed copies of our FDA-approved products.

As we continue the clinical development of our proposed hormone therapy products, we continue to market and expand our prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal vitamins, vegan docosahexaenoic acid, or DHA, iron supplements, vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD brand name and duplicate formulations of our prescription prenatal vitamins products, also referred to as generic formulations, under our BocaGreenMD 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 40 full-time professionals that calls on healthcare providers in the OB/GYN 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

## **Table of Contents**

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.

## **Industry and Market**

### ***Healthcare and Pharmaceutical Market***

According to statistics compiled by Kaiser Family Foundation, a non-profit foundation focusing on the major healthcare issues facing the United States, healthcare expenditures were approximately \$2.6 trillion in 2010 based on U.S. Census Bureau information, representing 17.9% of our nation's gross domestic product, or GDP, up from 7.2% of GDP in 1970 and 12.5% of GDP in 1990. In 2010, healthcare spending in the United States averaged \$8,402 per person.

Pharmaceuticals are a major driver of U.S. healthcare costs. In a report issued by Centers for Medicare & Medicaid Services, the total national spending on prescription drugs, both private and public, from retail outlets exceeded \$259 billion in 2010, or approximately 10% of all national healthcare spending. Total national spending on prescription drugs, both private and public, from retail outlets increased on average by about 10% a year from 1998 through 2009 faster than the average 6.7% a year increase in total U.S. health expenditures for the same period. The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products.

### ***Women's Healthcare Market***

The U.S. Census Bureau estimates that there were approximately 157 million women and 152 million men living in the United States in 2010. Women are major consumers of healthcare services, negotiating not only their own healthcare but often managing care for their family members as well. Their reproductive health needs and greater healthcare spending and longer life spans as compared with men make women's relationships with the healthcare system complex.

### ***Hormone Therapy Market***

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. It is defined as the final menstrual period and is confirmed when a woman has not had her period for 12 consecutive months. Hormone therapy is the only government-approved treatment in the United States and Canada for relief of menopausal symptoms. These symptoms are caused by the reduced levels of circulating estrogen as the ovarian production shuts down. The symptoms include hot flashes, night sweats, sleep disturbances, and vaginal dryness. According to Source Healthcare Analytics, for the 12 months ended June 30, 2012, prescriptions for hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis generated total sales of over \$3.2 billion on over 37.5 million prescriptions. Oral hormone therapy accounted for \$1.6 billion on 24.5 million prescriptions over the same time period.

Prescriptions for menopausal hormone therapy in the United States dropped significantly following the Women's Health Initiative, or WHI, study in 2002 that found that subjects using estrogen plus synthetic progestin had, among other things, a greater incidence of coronary heart disease, breast cancer, stroke, and pulmonary embolism.

A number of additional studies regarding the benefits and risks of hormone therapy have been conducted over the last decade since the WHI results were first published. In general, recommendations for hormone therapy use are to be judged on an individual basis, and the FDA recommends that women with moderate to severe menopausal symptoms who want to try menopausal hormone therapy for relief use it for the shortest time needed and at the lowest effective dose.

There were approximately 41.7 million women in the United States between the ages of 45 and 64 in 2010, projected to increase slightly (2.8%) to 42.9 million in 2015 and to approximately 44.3 million in 2040, according to the 2010 National Census population figures. These women are the target market for hormone therapy to treat menopausal related symptoms.

---

**Table of Contents*****Hormone Therapy Products***

Estrogen (with or without a progestin) is the most effective treatment for menopause-related vasomotor symptoms according to the North American Menopause Society, or NAMS. Sales of total oral and transdermal hormone therapy products were approximately \$2.3 billion for the 12 months ended June 2012. That was up approximately 4.7% over the same time period from the prior year according to Source Healthcare Analytics. The three primary hormone therapy products are estrogen, progestin, and combination of estrogen and progestin and are produced in a variety of forms, including oral tablets or capsules, skin patches, gels, emulsion, or vaginal suppositories and creams.

***Estrogen-Only Therapies***

Estrogen therapies are used for vasomotor symptoms (hot flashes and night sweats) of menopause that are a direct result of the decline in estrogen levels associated with ovarian shutdown at menopause. Estrogen therapy has been used to manage these symptoms for more than 50 years. Estrogen is a generic term for any substance, natural or synthetic, that exerts biological effects characteristic of estrogenic hormones, such as estradiol. Based upon the age demographic for all women receiving prescriptions for estrogen therapy and the average age range during which women experience vasomotor symptoms, we believe that estrogen is primarily used for the treatment of vasomotor symptoms, but also prescribed for the prevention of osteoporosis.

Estrogen-only therapy, or ET, is used mainly in women who have had a hysterectomy and are undergoing a surgical menopause, as those women do not require a progestin to protect the uterine endometrium from proliferation. Approximately 600,000 women undergo a hysterectomy each year in the United States according to the U.S. Centers for Disease Control and Prevention. Sales of oral ET were approximately \$864.1 million for a 12-month total at June 2012, according to Source Healthcare Analytics.

ET is also used for vulvar and vaginal atrophy, which has a variety of indications, including vaginal dryness, pain, bleeding, urinary symptoms, incontinence, painful intercourse, and other symptoms. Sales of ET for vulvar and vaginal atrophy were approximately \$823.2 million for a 12-month total at June 2012, according to Source Healthcare Analytics.

Estrogen therapy is approved for the prevention of osteoporosis. Multiple studies conducted on various estrogen compositions, including studies published in the Journal of the American Medical Association in 2002, Osteoporosis International in 2000, The Lancet in 2002, Maturitas in 2008, and Climacteric in 2005, demonstrated efficacy based on increases in bone mineral density. Epidemiological and some fracture prevention studies, such as the study published in the New England Journal of Medicine in 1980, also have demonstrated a decrease in bone fractures as a result of estrogen therapy.

***Progestin-Only Therapies***

Progestins include the naturally occurring hormone progesterone and a number of synthetic progestin compounds that have progestational activity. These agents are used for a variety of indications and conditions, but most often, progestins are used either alone or in combination with an estrogen for hormonal contraception and to prevent endometrial hyperplasia from unopposed estrogen in hormone therapy. They are also used alone or in combination with estrogens for postmenopausal women to treat vasomotor symptoms associated with menopause. Progestins alone are also used to treat women with secondary amenorrhea in order to create withdrawal bleeding in these women who have not had regular menses. Progestins are also used to treat dysfunctional uterine bleeding and endometriosis. Progesterone has also been used to prevent threatened or recurrent pregnancy loss and for the prevention of preterm birth. Progestins have also been used in fertility treatments. Progestins have also been used as a palliative measure for metastatic endometrial carcinoma and in the treatment of renal and breast carcinoma.

***Estrogen/Progestin Combination Products***

Progestins are used in combination with estrogen in women with uteruses to avoid an increase in the incidence of endometrial hyperplasia. This is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that, after one year, the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. In accordance with FDA recommendations, doctors typically recommend that a menopausal or postmenopausal woman who has a uterus take estrogen plus a progestin, either as

---

## **Table of Contents**

a combination drug or as two separate drugs. Source Healthcare Analytics estimates that sales of estrogen/progestin combinations were approximately \$519.1 million in the United States for the 12 months ended June 2012, up approximately 3.2% over the same time period a year prior. The segment is still dominated by products in the Premarin® family that constituted approximately 56% of that market segment.

### *Limitations of Existing Estrogen/Progestin Therapies*

The most commonly prescribed progestin is a synthetic progestin (medroxyprogesterone acetate) which can cause some women to experience painful vaginal bleeding, breast tenderness, and bloating and may reduce cardio-protective benefits potentially associated with estrogen therapy by limiting the estrogen's ability to raise high-density lipoprotein, or HDL, cholesterol and lower low-density lipoprotein, or LDL, cholesterol.

A widely prescribed naturally occurring progesterone is known as Prometrium® (progesterone USP), sold by AbbVie Inc., a spinoff business of Abbott Laboratories. Natural progesterone is used in combination with estrogen for hormone therapy; however, we believe there are currently no FDA-approved hormone therapy combination products with natural progesterone.

### *Prenatal Vitamin Market*

According to the American Pregnancy Association, approximately six million women become pregnant each year resulting in approximately four million births. Of these women, over 75% receive prenatal care during the first trimester, and most doctors encourage taking a prenatal vitamin as the recommended standard of care. Prenatal vitamins are dietary supplements intended to be taken before and during pregnancy and during postnatal lactation that provide nutrients recognized by the various health organizations as helpful for a healthy pregnancy outcome.

There are hundreds of prenatal vitamins available, with both prescription and OTC (non-prescription) choices. According to Source Healthcare Analytics, there were 9.2 million prescriptions for prenatal vitamins sold for a total of approximately \$340 million for the 12 months ended July 2012, with sales between branded and generic products split nearly evenly. According to the 2012 Gallup Target Market Report on Prenatal Vitamins, supplement use has been fairly constant overall between 2008 and 2011. However, shifts have occurred in terms of types used, with the trend toward OTC prenatal vitamins and away from prescription prenatal vitamins. During this same period, the use of OTC products surpassed the use of prescription products, largely driven by increased use among women currently pregnant.

### **Our Business Model**

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women, including products specifically for pregnancy, childbirth, nursing, pre-menopause, and menopause. We intend to use our current prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal vitamins, vegan DHA, iron supplements, vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams, as the foundation of our business platform. If approved and commercialized, our proposed hormone therapy drugs will allow us to enter the \$3.3 billion hormone therapy market segment, based on 2012 total sales of the hormone therapy market according to Source Healthcare Analytics.

Our current product line is marketed and sold by a direct national sales force that calls on healthcare providers in the OB/GYN market space, as well as through our website to consumers who have been referred to our website by physicians. We market our prescription prenatal vitamins, over-the-counter dietary supplements, and other products under our vitaMedMD® brand name and duplicate formulations of our prescription prenatal vitamin products, also referred to as generic formulations, under our BocaGreenMD Prenal brand name. We believe that our vitaMedMD® brand name has become a recognized name for high quality women's healthcare, while our BocaGreenMD products will provide physicians, women, and payors with a lower cost alternative for prenatal supplements. We intend to leverage our existing relationships and distribution system to introduce our proposed hormone therapy products, if approved, which will enable us to provide a comprehensive line of women's healthcare products all under one brand.

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 40 full-time professionals that calls on healthcare providers in the OB/GYN market space as well as through our website

**Table of Contents**

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.

As healthcare becomes increasingly consumer driven, patients are seeking more information, control, and convenience, which places additional time and financial pressures on physicians, and as a result, physicians are looking for improved ways to provide better service to their patients. A recent study by IMS Health Incorporated concludes that physicians desire fewer but more encompassing relationships with companies that can provide more valuable information, deliver more relevant services, and better respond to specific needs of their practice and patients. Our goal is to meet this challenge by focusing on the opportunities in women's health, specifically the OB/GYN market, to provide a better customer experience for physician, payor, and patient through the following means:

- n We believe we will offer physicians a comprehensive product line of women's healthcare products, including our proposed hormone therapy products, if approved.
- n Our proposed hormone therapy products are designed to use the lowest effective dose for the shortest duration.
- n We believe the attributes of our dietary supplements will result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality products incorporating patented ingredients, such as Quatrefolic®, chelated iron and life's DHA. All of our prenatal vitamins are gluten, sugar, and lactose free.
- n We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.
- n We believe healthcare providers are able to offer alternatives to patients that meet the patient's individual nutritional and financial requirements and help patients realize cost savings over competing products.
- n Healthcare provider practices that choose to dispense our OTC products directly to their patients through their offices could earn revenue from the sale of the products.
- n Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

**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:

*Exclusive Focus on Women's Health Issues.* We plan to focus 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.

*Focus on Hormone Therapy Products.* We plan to focus on the 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



## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

flashes, osteoporosis, and vaginal dryness, and (2) provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products.

*Penetrate Bioidentical Market with FDA-approved Products.* As we are not aware of any current FDA-approved bioidentical hormone therapy products, we believe that our proposed hormone therapy products for estradiol and progesterone, if approved by the FDA, will provide a safer and more effective alternative to non-FDA approved compounded bioidentical hormone therapy products, at a lower price to patients due to insurance coverage.

S-34

**Table of Contents**

*Marketing Emphasis.* We plan to maintain an 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.

*Multiple Distribution Channels.* We are pursuing multiple distribution channels, including physicians and pharmacies through our sales force and our website.

*Geographical Expansion.* We plan to expand our geographic market and sales team to cover the entire country by increasing our current 36 sales territories to 60 sales territories by the end of 2013.

*Introducing New Products.* We plan to introduce 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 the development of our proposed hormone therapy products consisting of a (1) bioidentical oral combination of progesterone and estradiol product, (2) an oral progesterone product, and (3) a suppository vulvar and vaginal atrophy estradiol product. Early pharmacokinetic, or PK, studies of our proposed combination estradiol and progesterone drug demonstrate 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).

**Our Products**

We offer a wide range of products targeted for women’s health specifically associated with pregnancy, child birth, nursing, post-child birth, and menopause, including prescription and over-the-counter prenatal vitamins, vegan DHA, iron supplements, vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD brand name and duplicate formulations of our prescription prenatal vitamin products, referred to as generic formulations, under our BocaGreenMD Prenal name.

In March 2012, we launched our first prescription-only prenatal vitamin, vitaMedMD Plus Rx, with subsequent launches of our second prescription-only prenatal vitamin, vitaMedMD One Rx, in April 2012 and our third prescription-only prenatal vitamin, vitaMedMD RediChew Rx in May 2012. In the fourth quarter 2012, our BocaGreenMD brand was launched and our first products include three prescription products Prenal Plus, Prenal , and Prenal Chew, which are duplicate, or generic formulations of our vitaMedMD-branded prescription prenatals. Our product line is detailed below.

***vitaMedMD Plus (Prenatal Women’s Multivitamin + DHA)***

*vitaMedMD Plus Prenatal* is a once-daily, two pill combo pack that contains a complete multivitamin with 16 essential vitamins and minerals and 300 mg of life’s DHA (a trademarked product of Martek Bioscience Corporation), and is Vegan and Kosher certified. Based on recent medical and scientific research, we have optimized many of the nutrients found in *vitaMedMD Plus*. All minerals, including iron, zinc, and copper, are chelated to improve absorption. The 300 mg of plant-based DHA (most comes from fish-based sources) is a critically important component to many pregnant women and healthcare providers due to concerns over contamination and the associated burp-backs and taste of fish-based DHA.

***vitaMedMD One Prenatal Multivitamin***

*vitaMedMD One* is a single-dose daily multivitamin that provides 14 vitamins and minerals and 200 mg of vegetarian, plant-based life’s DHA , which is 100% fish-free with no ocean-borne contaminants, such as mercury or polychlorinated biphenyls, or PCBs. Each convenient, easy-to-swallow softgel also features 975 mcg of folic acid.

***vitaMedMD Plus Rx Prenatal Multivitamin***

*vitaMedMD Plus Rx* is a once-daily, two pill combo prescription-only product containing one prenatal vitamin tablet with Quatrefol<sup>®</sup>, the fourth generation folate, and one plant-based life’s DHA 300 mg capsule. Quatrefol<sup>®</sup> is a registered trademark of Gnosis S.P.A. All minerals, including iron, zinc, and copper, are chelated to improve absorption.

***vitaMedMD One Rx Prenatal Multivitamin***

*vitaMedMD One Rx* is a prescription-only product with a single-dose daily multivitamin that provides 14 vitamins and minerals, Quatrefol<sup>®</sup>, and 200 mg of vegetarian, plant-based life’s DHA .



**Table of Contents**

***vitaMedMD RediChew Rx Prenatal Multivitamin***

*vitaMedMD RediChew Rx* is a prescription-only easy-to-chew, small vanilla-flavored chewable tablet containing Quatrefolic, vitamin D3 to promote healthy birth weight, vitamin B2 to support bone, muscle, and nerve development, and vitamin B6 and vitamin B12 to help relieve nausea and morning sickness. We believe *vitaMedMD RediChew Rx* is an excellent option for women who have difficulty swallowing tablets or softgels, or are experiencing nausea and morning sickness.

***vitaMedMD Iron 21/7***

*vitaMedMD Iron 21/7* is an iron replacement supplement with a 3-weeks-on/1-week-off dosing schedule intended to maximize absorption and enhance tolerability. It is formulated with 150 mg of chelated iron to help improve tolerability and limit typical side effects associated with iron replacements. Each easy-to-swallow single tablet serving also includes 800 mcg of folic acid, plus vitamins C and B12, and succinic acid to aid in absorption.

***vitaMedMD Menopause Relief with Lifenol® Plus Bone Support***

*vitaMedMD Menopause Relief with Lifenol® Plus Bone Support* offers a natural treatment for hot flashes, night sweats, and mood disturbances. Each single tablet dosage delivers 120 mg of Lifenol®, a well-studied female hops extract recognized for its potency and support in alleviating hot flashes, plus plant phytoestrogens. It also includes calcium and vitamin D3 for added bone support.

***vitaMedMD Vitamin D3 50,000 IU and Vitamin D3 2,000 IU***

*vitaMedMD Vitamin D3 50,000 IU and Vitamin D3 2,000 IU* are dietary supplements provided in a small easy-to-swallow gel capsule that help replenish and maintain beneficial levels of vitamin D in the body. Sustaining adequate levels of vitamin D in the body is essential to bone health, enhancing the absorption of calcium and phosphorus. Vitamin D3, also known as cholecalciferol, is considered the most preferred form of vitamin D as it is the most active form of the nutrient. We believe *vitaMedMD Vitamin D3 50,000 IU and Vitamin D3 2,000 IU* are ideal for pregnant, breastfeeding, and menopausal women to sustain adequate levels of vitamin D.

***vitaMedMD Stretch Mark Body Cream***

*vitaMedMD Stretch Mark Body Cream* contains naturally derived ingredients, including peptides, shea butter, sweet almond oil, and fruit extracts. This combination of ingredients hydrates, soothes, and pampers skin to make it softer, smoother, and younger-looking. It helps reduce the appearance of stretch marks, scars, and other skin irregularities by hydrating and replenishing the skin's moisture, diminishing the look of fine lines and wrinkles, and encouraging the fading of age spots and sun spots. *vitaMedMD Stretch Mark Body Cream* is hypoallergenic, paraben-free, and non-comedogenic.

***vitaMedMD Scar Reduction Body Cream***

*vitaMedMD Scar Reduction Body Cream* is rich in vitamins and naturally derived extracts. It helps to minimize the size and appearance of old and new scars, reduce scar tissue, diminish the appearance of fine line and wrinkles, and encourage the fading of age spots. It is paraben-free, non-comedogenic, and hypoallergenic.

***BocaGreenMD Prenal Plus***

*BocaGreenMD Prenal Plus* is a prescription-only, comprehensive single-dose dietary supplement containing one prenatal tablet with 16 vitamins and minerals, plus one softgel with 300 mg of plant-based life's DHA.

***BocaGreenMD Prenal***

*BocaGreenMD Prenal* is a prescription-only, convenient single-dose softgel with 14 vitamins, minerals and 200 mg of plant-based life's DHA.

***BocaGreenMD Prenal Chew***

*BocaGreenMD Prenal Chew* is a prescription-only, single daily easy-to-chew, vanilla-flavored, chewable tablet well-suited for women planning a pregnancy and those with difficulty swallowing tablets or capsules, or when nausea or morning sickness make taking tablets or capsules

difficult.

All *BocaGreenMD* Prenal multivitamins contain a combination of folic acid and Quatrefolic® and are available by prescription only.

S-36

## Table of Contents

### **Our Proposed Hormone Therapy Products**

The FDA has permitted us to begin clinical testing of three of our proposed hormone therapy products. We also may seek FDA acceptance to conduct a clinical trial for the fourth drug candidate later in 2013. Our goal is to improve bioavailability of our progesterone when used alone or in combination with estrogen over currently marketed and FDA-approved options. Early PK studies of our proposed combination estradiol and progesterone drug demonstrate that it 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 0.8000 to 1.2500). We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed drugs following the successful completion of this offering, and may file an IND to begin clinical studies of our proposed suppository vulvar and vaginal atrophy estradiol product later in 2013. Progestins and estrogens are well-understood by both the FDA and healthcare providers. Although regulatory testing results cannot be guaranteed, we are optimistic that the clinical trials for our proposed hormone products will achieve our goals. Our proposed hormone therapy products are detailed below. We are currently planning to focus our efforts on relief of vasomotor symptoms associated with menopause, but will also be considering the treatment and prevention of osteoporosis and other conditions of hypoestrogenism.

#### ***Therapeutics TX 12-001HR***

*Therapeutics TX 12-001HR* is a drug candidate consisting of a combination of estradiol and progesterone. We are developing the product 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. We are planning to conduct the necessary safety study to show protection against endometrial hyperplasia over a 12-month duration, at the lowest effective combination dosage. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be packaged as both a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily), as well as a sequentially-combined regimen (where the estrogens are taken daily and the progesterone is taken in combination for two weeks of every month). 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 *Therapeutics TX 12-001HR* to be approximately \$20 to \$25 million.

We conducted a PK study of *Therapeutics TX 12-001HR* to demonstrate that the proposed product is bioequivalent to the reference listed drug based on the criterion that the 95% confidence interval on the test-to-reference ratio is contained entirely within the interval 80% to 125%. The study compared our combined capsule *TX 12-001HR* of 2 mg estradiol and 200 mg of progesterone to 2 mg of Estrace® and 200 mg of Prometrium®.

The study compared the mean plasma concentrations for free estradiol between *TX 12-001HR* and Estrace® in 62 female test subjects. When the results of a single dose-fed study were compared over 48 hours by the test drug versus reference drug, the ratio was 0.93 with the standard deviation within the subject being 0.409 for an upper 95% confidence bound of -0.089. The maximum plasma concentration levels of free estradiol showed drug versus reference drug ratio was 0.88 with the standard deviation within the subject being 0.344 for an upper 95% confidence bound of -0.040 over 48 hours.

The study also compared the mean plasma concentrations for progesterone between *TX 12-001HR* and Prometrium® in 62 female test subjects. When the results were compared over 48 hours of the test drug versus reference drug, the ratio was 1.05 with the standard deviation within the subject being 0.956 for an upper 95% confidence bound of 0.542. The maximum plasma concentration levels of progesterone showed drug versus reference drug ratio as 1.16 with the standard deviation within the subject being 1.179 for an upper 95% confidence bound of -0.785 over 48 hours.

We believe these data are sufficient to demonstrate the bioequivalence of *TX 12-001HR* to Estrace® and Prometrium® based on the criteria for demonstrating bioequivalence established in connection with the study.

#### ***Therapeutics TX 12-002HR***

*Therapeutics TX 12-002HR* is a progesterone drug candidate under development for treatment of secondary amenorrhea. It 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 but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for *Therapeutics TX 12-002HR* to be approximately \$5 to \$8 million.



## **Table of Contents**

### ***Therapeutics TX 12-003HR***

*Therapeutics TX 12-003HR* is an estradiol drug candidate under development for postmenopausal women for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness for women with or without a uterus. It would be an estradiol product, chemically bio-identical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this product candidate.

### ***Other Programs***

We are also evaluating various other indications for our hormone technology, including oral contraception and treatment of preterm birth, vulvo and vaginal atrophy, and premature ovarian failure. *Therapeutics TX 12-004HR* is a proposed suppository vulvar and vaginal atrophy estradiol product for post-menopausal women with vaginal linings that do not receive enough estrogen. *Therapeutics TX 12-004HR* is currently in pre-clinical development, and we believe it will be a more effective product than traditional treatments for vulvar and vaginal atrophy due, in part, to its lower dosage requirements and ease of application. We may file an IND to begin clinical studies of *Therapeutics TX 12-004HR* later in 2013.

### **Sales and Marketing**

Although our direct national sales force is similar to that of a traditional pharmaceutical company in that sales representatives call on OB/GYN practices to provide education and sampling, we believe our sales representatives are more customer centric in their sales approach by offering physicians more than just differences in our products from the competition; they are also able to offer an array of partnering opportunities to promote efficiency and cost savings.

Our national rollout strategy has been to focus first on the largest metropolitan areas in the United States. In order to accelerate the sales ramp in a new territory, we employ a national sales/large practice sales effort to identify key practices in new or expanding markets. Concurrent with our provider sales effort, we work with commercial insurance payors for partnerships in which the payor can support the prescribing and/or recommendation of our products for the benefit of patient, physician and payor with an end result of providing better outcomes for all three constituents.

At the forefront of our sales approach is the philosophy that the physician should recommend or prescribe products based only on what is best for the patient. In general, a better outcome is achieved by providing patients with the best products and care at the best value. We believe having an assortment of high-quality product options that can be recommended or prescribed by both the physician and payor is the foundation of providing valuable options to the patient.

We believe our sales force has developed strong relationships and partnerships in the OB/GYN market segment to sell our current products. We have also established relationships with some of the largest OB/GYN practices their respective markets. By delivering additional products through the same sales channel, we believe we can leverage our already deployed assets to increase our sales and achieve profitability.

### ***Online Commerce***

A vast majority of our over-the-counter product sales are completed online. The Internet has continued to increase its influence over communication, content, and commerce. We believe several factors will contribute to this increase, including convenience, expanded range of available products and services, improved security and electronic payment technology, increased access to broadband Internet connections and widespread consumer confidence and acceptance of the Internet as a means of commerce.

### ***Retail Commerce***

The vast majority of our prescription product sales are completed through the traditional pharmacy distribution network. Although online and mail order pharmacy commerce continue to grow, the majority of products are still purchased directly by the consumer locally at traditional stores. As this segment of our business expands, we will continue to employ strategies that help us reduce inefficiencies in this channel and develop relationships that allow our products to be differentiated from the competition.



## **Table of Contents**

### **Seasonality**

The specialty pharmaceutical industry is not subject to seasonal sales fluctuation.

### **Products in Development**

Our branded prescription products were introduced in the first and second quarters of 2012, and we recently introduced our first prescription generic product line. Our market objective is to develop an entire suite of products that are condition-specific and geared to the women's health sector. Our focus is to introduce products in which we use proprietary or patented molecules or ingredients that will differentiate our products from the competition. We currently have numerous products in development, including our proposed hormone therapy products as described above.

### **Raw Materials for Our Products**

We acquire all raw materials and ingredients for our proprietary products from a group of third-party suppliers specializing in raw material manufacturing, processing, and specialty distribution. Our primary manufacturer maintains multiple supply and purchasing relationships throughout the raw materials marketplace to provide an uninterrupted supply of product to meet our manufacturing requirements.

### **Availability of and Dependence Upon Suppliers**

We currently obtain approximately 80% of our *vitaMed* products from Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars, and functional foods in the dietary supplement category; therefore, we are dependent on Lang for the manufacture of most of our products. We believe the terms of our agreements with Lang are competitive with other suppliers and manufacturers. Although we anticipate continuing our relationship with Lang, we believe that we could obtain similar terms with other suppliers to provide the same services. We have experienced no difficulties in obtaining the products we need in the amounts we require and do not anticipate those issues in the future.

### **Manufacturing of Our Products**

Our vitamin products are manufactured in accordance with FDA's cGMPs for dietary supplements. In addition, we employ an outside third party to enforce rigorous quality audits.

All of our manufacturing is performed by third-party manufacturers. In addition to manufacturing substantially all of our products, Lang also provides a variety of additional services to us, including development processes, prototype development, raw materials sourcing, regulatory review, and packaging production. At present, we believe our relationship with Lang is excellent, and we intend to continue to use Lang as our third-party manufacturer for most of our products. In the event our relationship with Lang terminates for any reason, there are a number of other manufacturers available to us; accordingly, we do not believe that such termination would have a material adverse effect on our business.

We use third-party manufacturers to source key raw materials and manufacture and package our products. The FDA must approve the manufacturing facility for compliance with the FDA's drug cGMP regulations before an NDA for a new drug is approved. Accordingly, we intend to engage only those third-party contract manufacturers that have consistently shown the ability to satisfy these requirements for our proposed hormone therapy products.

### **Quality Control for Our Products**

A quality assurance team establishes process controls and documents and tests every stage of the manufacturing process to ensure we meet product specifications and that our finished dietary supplements contain the correct ingredients, purity, strength, and composition in compliance with FDA regulations. We test incoming raw materials and finished goods to ensure they meet or exceed FDA and U.S. Pharmacopeia standards, including quantitative and qualitative assay and microbial and heavy metal contamination.

Our manufacturers' quality and production standards are designed to meet or exceed current FDA regulations. To ensure the highest quality, our manufacturing operations are audited by AIB International, Inc., or AIB, among



## **Table of Contents**

others, for independent cGMP certification. AIB is an independent, not-for-profit organization that offers programs and services to augment and support the work of regulatory officials around the country, including standards development, product testing and certification, and onsite audits and inspections. The manufacturing facilities we primarily use are also ISO 9001 certified, which is a family of standards related to quality management systems and are designed to help organizations ensure they meet the needs of customers.

### **Distribution of our Products**

We use a variety of distribution channels dependent upon product type. We sell our prescription dietary supplement products to patients through their pharmacies. Since the launch of our prescription products, in addition to third-party logistics providers, we use some of the same national and regional distributors as other pharmaceutical companies, including Cardinal, McKesson, AmerisourceBergen, H.D. Smith and Smith Drug. Wholesaler product inventory is monitored daily and sales out is monitored weekly. National and regional retail chain pharmacies are also an area of focus to make sure our products are purchased and dispensed properly. We sell our OTC products directly to consumers via our website and phone sales and the products are shipped directly from us to the consumer's home. In a few instances, we sell OTC product to physicians, who then sell the products directly to their patients.

### **Customer Service**

Our goal is 100% customer satisfaction by consistently delivering superior customer experiences before, during, and after the sale. To achieve this goal, we maintain a fully staffed customer care center that uses current customer relationship management software to respond to healthcare providers, pharmacies, and consumers and accept orders for non-prescription products via incoming and outgoing telephone calls, e-mails, and live-chat. We believe our customer service initiatives allow us to establish and maintain long-term customer relationships and facilitate repeat visits and purchases. We also facilitate repeat customer orders through our auto-ship feature.

Our representatives receive regular training so that they can effectively and efficiently field questions from current and prospective customers and are also trained not to answer questions that should be directed to a customer's physician. Having a quality customer care center allows our representatives to provide an array of valuable data in the areas of sales, market research, quality assurance, lead generation, and customer retention.

### **Our Return Policy**

Our prescription products are sold through third-party logistics providers, major distributors, and pharmacies, all of whom may return product within six months prior to or after the expiration date of the product. Once customers buy a product from the pharmacy, the product may not be returned. Non-prescription customers may return or exchange our products for any reason by returning the product within 30 days of receipt. We will refund the entire purchase price, less shipping. The customer is responsible for the cost of returning the products to us, except in cases where the product is being returned because of a defect or an error made in our order fulfillment. If the purchased product exceeded a 30-day supply, the unused product must be returned to receive the full refund. All unopened OTC products may be exchanged for different products; the customer will be responsible for the difference in price if the replacement product is more expensive or we will refund the difference if the replacement product is less expensive.

### **Our Quality Guarantee**

We proudly stand behind the quality of our products. We believe our guarantee makes it easy, convenient, and safe for customers to purchase our products. Under our quality guarantee, we:

- n ensure the potency and quality of our vitamin products;
- n help healthcare providers and payors by delivering information on patient compliance and satisfaction;
- n provide a 30-day money back guarantee for all of our OTC products; and

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

<sup>n</sup> ensure a safe, secure online shopping experience through our encrypted website.  
We value frequent communication with and feedback from our customers in order to continue to improve our offerings and services.

S-40

## **Table of Contents**

### **Intellectual Property**

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing the proprietary rights of others. Our intellectual property portfolio is one of the means by which we attempt to protect our competitive position. We rely primarily on a combination of know-how, trade secrets, patents, trademarks, and contractual restrictions to protect our products and to maintain our competitive position. We are diligently seeking ways to protect our intellectual property through various legal mechanisms in relevant jurisdictions.

We have filed several provisional patent applications with the USPTO with respect to our proposed hormone therapy products. We intend to file additional patent applications when appropriate; however, we may not file any such applications or, if filed, the patents may not be issued. We hold multiple U.S. trademark registrations and have numerous pending trademark applications. Issuance of a federally registered trademark creates a rebuttable presumption of ownership of the mark; however, it is subject to challenge by others claiming first use in the mark in some or all of the areas in which it is used. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We believe our patents and trademarks are valuable and provide us certain benefits in marketing our products. We intend to actively protect our patents, trademarks, trade secrets, and other intellectual property.

We intend to aggressively prosecute, enforce, and defend our patents, trademarks, and proprietary technology. The loss, by expiration or otherwise, of any one patent may have a material effect on our business. Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that the patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing on validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

OPERA is our patent-pending information technology platform used in our business. We believe the deployment of OPERA and the further development and deployment of related technology creates a sustainable competitive advantage in clinical development and product improvement. We are currently developing additional intellectual property in the area of new product technologies and formulations.

As we continue to develop proprietary intellectual property, we will expand our protection by applying for patents on future technologies, including developing mobile applications to more effectively communicate with patients. As we examine our current product offerings and new product pipeline, we are in the process of modifying and developing new formulations that will enable us to gain patent protection for these products.

Generally, our nutritional product formulations are proprietary in that in designing them, we attempt to blend an optimal combination of nutrients that appear to have beneficial impact based upon scientific literature and input from physicians; however, we are generally prohibited from making disease treatment and prevention claims in the promotion of our products that use these formulations.

While we seek broad coverage under our patent applications, there is always a risk that an alteration to the process may provide sufficient basis for a competitor to avoid infringement claims. In addition, patents expire and we cannot provide any assurance that any patents will be issued from our pending application or that any potentially issued patents will adequately protect our intellectual property.

### **Government Regulation**

In the United States, the FDA regulates pharmaceuticals, dietary supplements, and cosmetics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. These products are also subject to other federal, state, and local statutes and regulations, including federal and state consumer protection laws, laws protecting the privacy of health-related information, and laws prohibiting unfair and deceptive acts and trade practices.

---

## **Table of Contents**

### **Pharmaceutical Regulation**

The process required by the FDA before a new drug product may be marketed in the United States generally involves the following:

- n completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- n submission to the FDA of an IND, which FDA must allow to become effective before human clinical trials may begin and must be updated annually;
- n performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication; and
- n submission to the FDA of an NDA after completion of all pivotal clinical trials.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. We currently have effective INDs for three of our four proposed hormone therapy products, *TX 12-001HR*, *TX 12-002HR*, and *TX 12-003HR*, although we have no current plans to conduct clinical trials for *TX 12-003HR*.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials are usually conducted in three phases. Phase 1 clinical trials are normally conducted in small groups of healthy volunteers to assess safety and find the potential dosing range. After a safe dose has been established, the drug is administered to small populations of sick patients (Phase 2) to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group reviews unblinded data from clinical trials and provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things.

Once the NDA submission has been accepted for filing, the FDA's goal is to review applications within 10 months of filing. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product will be formulated and its API will be produced, it may issue an approval letter or, instead, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific

S-42

**Table of Contents**

indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Our HT products may compete with unapproved HT products supplied by compounding pharmacies. Pharmacy compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. The medications created by the compounding pharmacy are technically new drugs subject to the new drug approval requirements of the FDCA. However, FDA's 2002 Compliance Policy Guide 460.200 states that FDA will exercise enforcement discretion to exclude compounded drugs from the new drug approval requirements except where compounding pharmacies act more akin to traditional drug manufacturers. FDA does not exercise the same authority to regulate compounding pharmacies as pharmaceutical manufacturers. For example, compounding pharmacies are not required to report adverse events associated with compounded drugs, while commercial drug manufacturers are subject to stringent regulatory reporting requirements.

***505(b)(2) Applications***

We intend to submit NDAs for our proposed hormone therapy products, assuming that the clinical data justify submission, under section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change



**Table of Contents**

from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. In regards to *TX 12-001HR*, we will be required to conduct Phase 3 studies for vasomotor symptoms versus placebo and an endometrial protection study.

Phase 3 clinical trials for secondary amenorrhea versus placebo will be required for *TX 12-002HR*. *TX 12-003HR* would be required to undergo Phase 3 studies of vasomotor symptoms compared to placebo, though we currently do not have plans to continue development of this proposed product.

As part of our submission, we intend to certify that all of the patents for approved products referenced in the NDA for each of the proposed hormone therapy products as listed in the FDA's Orange Book have expired and that we will not be compelled to certify that any patent is invalid, unenforceable or will not be infringed by the new product. If, in fact, this assessment is incorrect, it can have a serious and significant adverse effect on our ability to obtain FDA approval or market our new product. If we are compelled to certify that a patent is invalid, unenforceable or not infringed, then the holder of that patent can initiate a patent infringement suit against us and the FDA is precluded from approving our product for 30 months or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier.

***Marketing Exclusivity***

A 505(b)(2) NDA applicant may be eligible for its own regulatory exclusivity period, such as three-year exclusivity. The first approved 505(b)(2) NDA applicant for a particular condition of approval, or change to a marketed product, such as a new extended release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from making effective any other application for the same condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has run. Additional exclusivities may also apply.

Additionally, the 505(b)(2) NDA applicant may have relevant patents in the Orange Book, and if it does, it can initiate patent infringement litigation against those applicants that challenge such patents, which could result in a 30-month stay delaying those applicants.

***Dietary Supplement and Cosmetic Regulation***

Our currently marketed products are regulated as dietary supplements and cosmetics. The processing, formulation, safety, manufacturing, packaging, labeling, advertising and distribution of these products are subject to regulation by one or more federal agencies, including the FDA and the Federal Trade Commission, or the FTC, and by various agencies of the states and localities in which our products are sold.

The Dietary Supplement Health and Education Act of 1994, or DSHEA, amended the FDCA to establish a new framework governing the composition, safety, labeling, manufacturing and marketing of dietary supplements. Generally, under the FDCA, dietary ingredients that were marketed in the United States prior to October 15, 1994 may be used in dietary supplements without notifying the FDA. New dietary ingredients (*i.e.*, dietary ingredients that were not marketed in the United States before October 15, 1994) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been present in the food supply as an article used for food without being chemically altered. A new dietary ingredient notification must provide the FDA evidence of a history of use or other evidence of safety establishing that use of the dietary ingredient will reasonably be expected to be safe. A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing of the new dietary ingredient. The FDA may determine that a new dietary ingredient notification does not provide an adequate basis to conclude that a dietary ingredient is reasonably expected to be safe. Such a determination could prevent the marketing of such dietary ingredient. The FDA recently issued draft guidance governing the notification of new dietary ingredients. FDA guidance is not mandatory and companies are free to use an alternative approach if the approach satisfies the requirements of applicable laws and regulations. However, FDA guidance is a strong indication of the FDA's current thinking on the topic discussed in the guidance, including its position on enforcement. The draft guidance on new dietary ingredients is expected to be significantly revised when published in final form. Moreover, Congress can amend the dietary supplement provisions of the FDCA to impose additional restrictions on labeling and marketing of dietary supplements. Such action would have material adverse impact on our business and growth prospects.

---

## **Table of Contents**

The FDA or other agencies could take actions against products or product ingredients that in its determination present an unreasonable health risk to consumers that would make it illegal for us to sell such products. In addition, the FDA could issue consumer warnings with respect to the products or ingredients in such products. Such actions or warnings could be based on information received through FDCA-mandated reporting of serious adverse events. The FDCA requires that reports of serious adverse events be submitted to the FDA, and based in part on such reports, the FDA has issued public warnings to consumers to stop using certain third party dietary supplement products.

The FDCA permits statements of nutritional support to be included in labeling for dietary supplements without premarket approval. Such statements must be submitted to the FDA within 30 days of marketing. Such statements may describe how a particular dietary ingredient affects the structure, function or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect body structure, function or well-being, but may not expressly or implicitly represent that a dietary supplement will diagnose, cure, mitigate, treat or prevent a disease. A company that uses a statement of nutritional support in labeling must possess scientific evidence substantiating that the statement is truthful and not misleading. If the FDA determines that a particular statement of nutritional support is an unacceptable drug claim, conventional food claim or an unauthorized version of a health claim, or, if the FDA determines that a particular claim is not adequately supported by existing scientific data or is false or misleading, we would be prevented from using the claim.

In addition, DSHEA provides that so-called third-party literature, such as a reprint of a peer-reviewed scientific publication linking a particular dietary ingredient with health benefits, may be used in connection with the sale of a dietary supplement to consumers without the literature being subject to regulation as labeling. The literature: (1) must not be false or misleading; (2) may not promote a particular manufacturer or brand dietary supplement; (3) must present a balanced view of the available scientific information on the subject matter; (4) if displayed in establishment, must be physically separate from the dietary supplements; and (5) should not have appended to it any information by sticker or another method. If the literature fails to satisfy each of these requirements, we may be prevented from disseminating such literature with our products, and any dissemination could subject our product to regulatory action as an illegal drug.

In June 2007, pursuant to the authority granted by the FDCA as amended by DSHEA, the FDA published detailed cGMP regulations that govern the manufacturing, packaging, labeling and holding operations of dietary supplement manufacturers. The cGMP regulations, among other things, impose significant recordkeeping requirements on manufacturers. The cGMP requirements are in effect for all manufacturers, and the FDA is conducting inspections of dietary supplement manufacturers pursuant to these requirements. There remains considerable uncertainty with respect to the FDA's interpretation of the regulations and their actual implementation in manufacturing facilities. In addition, the FDA's interpretation of the regulations will likely change over time as the agency becomes more familiar with the industry and the regulations. The failure of a manufacturing facility to comply with the cGMP regulations renders products manufactured in such facility adulterated, and subjects such products and the manufacturer to a variety of potential FDA enforcement actions. In addition, under the Food Safety Modernization Act, or FSMA, which was enacted on January 2, 2011, the manufacturing of dietary ingredients contained in dietary supplements will be subject to similar or even more burdensome manufacturing requirements, which will likely increase the costs of dietary ingredients and will subject suppliers of such ingredients to more rigorous inspections and enforcement. The FSMA will also require importers of food, including dietary supplements and dietary ingredients, to conduct verification activities to ensure that the food they might import meets applicable domestic requirements.

The FDA has broad authority to enforce the provisions of federal law applicable to dietary supplements, including powers to issue public Warning Letters or Untitled Letters to a company, publicize information about illegal products, detain products intended for import, require the reporting of serious adverse events, request a recall of illegal or unsafe products from the market, and request that the Department of Justice initiate a seizure action, an injunction action or a criminal prosecution in the U.S. courts. The FSMA expands the reach and regulatory powers of the FDA with respect to the production and importation of food, including dietary supplements. The expanded reach and regulatory powers include the FDA's ability to order mandatory recalls, administratively detain domestic products, require certification of compliance with domestic requirements for imported foods associated with safety issues and administratively revoke manufacturing facility registrations, effectively enjoining manufacturing of dietary ingredients and dietary supplements without judicial process. The regulation of dietary supplements may increase or become more restrictive in the future.

---

## **Table of Contents**

Our cosmetic products, such as our topical creams, are also subject to regulation by the FDA. Such products and their ingredients do not require premarket approval prior to sale, but are subject to specific labeling regulations. While the FDA has not promulgated specific cGMPs for the manufacture of cosmetics, the FDA has provided guidelines for cosmetic manufacturers to follow to ensure that their products are neither misbranded or adulterated.

The FTC exercises jurisdiction over the advertising of dietary supplements and cosmetics. In recent years, the FTC has instituted numerous enforcement actions against companies for failure to have adequate substantiation for claims made in advertising or for the use of false or misleading advertising claims.

In recent years, the FTC has instituted numerous enforcement actions against dietary supplement companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions have often resulted in consent decrees and the payment of civil penalties and/or restitution by the companies involved. The FTC also regulates other aspects of consumer purchases, including promotional offers of savings compared policies, telemarketing, continuity plans, and free offers.

We are also subject to regulation under various state, local, and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements and drugs. For example, Proposition 65 in the state of California is a list of substances deemed to pose a risk of carcinogenicity or birth defects at or above certain levels. If any such ingredient exceeds the permissible levels in a dietary supplement, cosmetic, or drug, the product may be lawfully sold in California only if accompanied by a prominent warning label alerting consumers that the product contains an ingredient linked to cancer or birth defect risk. Private attorney general actions as well as California attorney general actions may be brought against non-compliant parties and can result in substantial costs and fines.

### *Other U.S. Healthcare Laws and Compliance Requirements*

We are also subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

- n The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- n The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.
- n The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.
- n Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.
- n The federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

S-46

## **Table of Contents**

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Although we believe that our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from third party payor programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians, providers, or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded healthcare programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, or by other federal, state, local, or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, such as DSHEA, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals, or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have a material adverse effect on our business.

The growth and demand for eCommerce could result in more stringent consumer protection laws that impose additional compliance burdens on online retailers. These consumer protection laws could result in substantial compliance costs and could interfere with the conduct of our business.

There is currently great uncertainty in many states whether or how existing laws governing issues such as property ownership, sales and other taxes, and libel and personal privacy apply to the Internet and commercial online retailers. These issues may take years to resolve. For example, tax authorities in a number of states, as well as a Congressional advisory commission, are currently reviewing the appropriate tax treatment of companies engaged in online commerce and new state tax regulations may subject us to additional state sales and income taxes. New legislation or regulation, the application of laws and regulations from jurisdictions whose laws do not currently apply to our business, or a change in application of existing laws and regulations to the Internet and commercial online services could result in significant additional taxes on our business. These taxes could have an adverse effect on our results of operations.

## **Legal Proceedings**

We are party to various legal actions arising in the ordinary course of business, including actions related to our intellectual property. While it is not feasible to determine the actual outcome of these actions at this time, we do not currently believe that these matters, including those described below, will have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

### ***Aceto Corporation***

On November 13, 2012, Aceto Corporation filed a lawsuit against TherapeuticsMD and BocaGreen in the United States District Court for the Southern District of Florida. The lawsuit alleges, among other things, that we are improperly obtaining and using the Quatrefolic product and related trademarks that we have acquired from Pernix Therapeutics, LLC, a subsidiary of Pernix Therapeutics Holdings, Inc., or Pernix. Cooper C. Collins, a member of our Board of Directors, is the President, Chief Executive Officer, and a director of Pernix. The lawsuit seeks to enjoin us from using the Quatrefolic product and trademarks, in addition to unspecified actual and punitive damages. We filed

---

## **Table of Contents**

a motion to dismiss on January 2, 2013. Based on our initial assessment of currently available information, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

### ***Avion Pharmaceuticals, LLC***

On November 30, 2012, Avion Pharmaceuticals, LLC, or Avion, filed a lawsuit against TherapeuticsMD and BocaGreen in the United States District Court for the Northern District of Georgia. The lawsuit alleges, among other things, unfair competition and trademark infringement against Avion's Prenate trademarks based on the use of BocaGreen's Prenal branded products which were launched in November 2012. The lawsuit seeks to enjoin BocaGreen from using the Prenal name, in addition to unspecified actual and punitive damages. We filed an answer and counterclaim on January 17, 2013, as amended on February 27, 2013. Based on our initial assessment of currently available information, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

### **Our Offices**

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487. Our telephone number is (561) 961-1911. We maintain websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com), and [www.bocagreenmd.com](http://www.bocagreenmd.com).

### **Properties**

On July 9, 2009, we entered into a 45-month lease for approximately 7,130 square feet of office space for our principal executive offices. Over the term of this lease, we will pay an average monthly cost of \$9,352, which includes base rent, common area fees, taxes, and insurance. Terms of this lease provide for an extension for an additional two-year period. The primary functions performed at our corporate headquarters are accounting, marketing, human resources, product development oversight, product sales, and fulfillment. We believe that the leased premises are suitable and adequate to meet our current needs.

### **Employees**

As of December 31, 2012, we had 69 full-time employees, four of whom are executive officers. Additionally, from time to time, we hire temporary contract employees. None of our employees are covered by a collective bargaining agreement, and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike, or dispute. We consider our relationship with our employees to be good.

### **Our History**

We were incorporated in Utah in 1907 under the name Croff Mining Company and subsequently changed our name to Croff Oil Company in 1952 and to Croff Enterprises, Inc. in 1996. Prior to 2008, Croff's operations consisted entirely of oil and natural gas leases. Due to a spin-off of its operations in December 2007, Croff had no business operations or revenue source and had reduced its operations to a minimal level although it continued to file reports required under the Securities Exchange Act of 1934. As a result of the spin-off, Croff was a shell company under the rules of the SEC. In July 2009, Croff (i) closed a transaction to acquire America's Minority Health Network, Inc. as a wholly owned subsidiary, (ii) ceased being a shell company, and (iii) experienced a change in control in which the former stockholders of America's Minority Health Network, Inc. acquired control of our company. On September 14, 2009, we changed our name to AMHN, Inc. On June 11, 2010, we closed a transaction to acquire Spectrum Health Network, Inc. as a wholly owned subsidiary. On July 20, 2010, we filed Articles of Conversion and Articles of Incorporation to redomicile in the state of Nevada. On July 31, 2010, we transferred the assets of America's Minority Health Network, Inc. to a secured noteholder in exchange for the satisfaction of certain associated debt. On February 15, 2011, we transferred the assets of Spectrum Health Network, Inc. to a secured noteholder in exchange for the satisfaction of associated debt and in exchange for a licensing agreement under which we subsequently sold subscription services and advertising on the Spectrum Health Network for commissions.

**Table of Contents**

On August 3, 2011 (with an effective date of August 29, 2011), in anticipation of closing a merger with VitaMed, we filed Amended and Restated Articles of Incorporation to change our name to TherapeuticsMD, Inc. and to increase the shares of common stock authorized for issuance to 250,000,000. On October 3, 2011, we completed a 1:100 reverse split of our common stock, and on October 4, 2011, we closed the merger with VitaMed pursuant to which all outstanding membership units of VitaMed were exchanged for shares of our common stock. In addition, all outstanding VitaMed options and warrants were exchanged and converted into options and warrants for the purchase of our common stock. All of these units, options, and warrants were exchanged on a pro-rata basis for shares or a right to acquire shares of common stock at a ratio of 1.227425 to 1. Pursuant to this conversion ratio, we subsequently (i) issued 58,407,331 shares of our common stock in exchange for the units, (ii) reserved for issuance an aggregate of 10,119,796 shares issuable upon the exercise of our options, and (iii) reserved for issuance an aggregate of 1,472,916 shares issuable upon the exercise of our warrants. As of December 31, 2011, we determined that VitaMed would become the sole focus of our company and services previously performed relative to the aforementioned licensing agreement were discontinued.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The table below lists all current executive officers and directors of our company. All executive officers serve at the discretion of the Board of Directors. The term of office of each of our directors continues until our next annual meeting of stockholders or until his or her successor is duly elected and qualified.

NAME	AGE	POSITION
Robert G. Finizio	42	Chief Executive Officer, Director
John C.K. Milligan IV	50	President, Secretary, Director
Daniel A. Cartwright	55	Chief Financial Officer, Vice President of Finance, Treasurer
Mitchell L. Krassan	47	Executive Vice President, Chief Strategy Officer
Brian Bernick, M.D.	44	Chief Medical Officer, Director
Tommy G. Thompson	71	Chairman
Samuel A. Greco	61	Director
Cooper C. Collins	33	Director
Robert V. LaPenta, Jr.	44	Director
Nicholas Segal	30	Director

*Robert G. Finizio* has served as Chief Executive Officer and a director of our company since October 2011. As co-founder of our VitaMed subsidiary, Mr. Finizio served as its Chief Executive Officer and a director from April 2008 to October 2011. Mr. Finizio has 16 years of successful early stage company development experience in the healthcare industry. Mr. Finizio co-founded and served from August 2001 to February 2008 as President of Care Fusion, LLC and then as Chief Executive Officer of CareFusion, Inc., which was acquired by Cardinal Health, Inc. Mr. Finizio's early business experience was with Omnicell, Inc. (formerly known as Omnicell Technologies, Inc.) and Endoscopy Specialists, Inc. in the healthcare IT and surgical space, respectively. We believe Mr. Finizio's intimate knowledge and experience with all aspects of the business, operations, opportunities, and challenges of our company and experience with early stage company development in the healthcare industry provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. Finizio earned a B.A. from the University of Miami.

*John C.K. Milligan, IV* has served as President, Secretary, and a director of our company since October 2011. From December 2008 to October 2011, Mr. Milligan served as President and Director of VitaMed. Prior to VitaMed, Mr. Milligan co-founded CareFusion, LLC, serving as President and General Manager from August 2001 to February 2008, and then as President and Chief Operating Officer of CareFusion, Inc. From 1997 to 2001, Mr. Milligan was Vice President, Sales and Operations for Omnicell, Inc., a provider of pharmaceutical supply chain management systems and services. Prior to Omnicell, Mr. Milligan also held executive management positions at Serving Software Inc. and HBO & Co., both subsequently acquired by McKesson Corporation. We believe Mr. Milligan's significant experience in creating, developing and guiding growth-oriented healthcare companies and knowledge of our business provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. Milligan is a graduate of the U.S. Naval Academy.

*Daniel A. Cartwright* has served as Chief Financial Officer, Vice President of Finance, and Treasurer of our company since October 2011. From July 2011 to October 2011, Mr. Cartwright served as Chief Financial Officer of VitaMed. From May 1996 to July 2011, Mr. Cartwright served as Chief Financial Officer and Executive Vice President of Circle F Ventures, LLC, an Arizona venture capital firm that made investments in more than 50 companies. During the same period, Mr. Cartwright served as Chief Financial Officer and Treasurer of Fleming Securities, formerly a registered broker dealer involved with raising capital for public and private companies. From 1993 to 1996, Mr. Cartwright served as Chief Financial Officer of American Wireless Systems, Inc., a provider of entertainment video services. Mr. Cartwright currently serves as a member of the board of directors of Primetrica, Inc., a private information research company for the telecommunications industry, and formerly



## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

served on the board of directors of Antenna Technologies Company, Inc. and WEB Corp. Mr. Cartwright earned his B.S. in Accounting from Arizona State University.

S-50

**Table of Contents**

*Mitchell L. Krassan* has served as Executive Vice President and Chief Strategy Officer of our company since October 2011. From April 2010 to October 2011, Mr. Krassan served as Chief Strategy and Performance Officer of VitaMed. Mr. Krassan has been a partner with EquiMark Limited, a private investment partnership, since October 1997. From November 1994 to July 1997, Mr. Krassan served as Chief Financial Officer and Chief Operating Officer of The Reich Group/Telespectrum Worldwide, a fully integrated direct marketing firm that provided clients expertise in market research and analysis, strategic planning, marketing, creative, and production services, telemarketing and database development. The Reich Group became a leading company in a roll-up and \$180 million initial public offering of Telespectrum Worldwide. Mr. Krassan earned a B.S. in Accounting from University of Maryland, received his certification as a CPA in the state of Maryland, and earned his M.B.A. in Management from New York University.

*Dr. Brian Bernick* has served as a director of our company since October 2011. Dr. Bernick also has served as the Chief Medical Officer of our company since February 2012. As co-founder of VitaMed, Dr. Bernick served on VitaMed's board of directors from its inception. Dr. Bernick is a practicing and board certified obstetrician/gynecologist with 20 years of clinical medical experience. Dr. Bernick is the past Chairman of the Department of Obstetrics and Gynecology at Boca Raton Regional Hospital and has served as a member of its Medical Executive Board. He has served on the board of directors of the Palm Beach Medical Society and VitalMD Group Holding, LLC, the largest physician-owned and managed group of obstetricians/gynecologists in Florida covering more than 250 physicians/practices. Dr. Bernick is the recipient of several national and regional awards including the American Medical Association Foundation's Leadership Award and was recognized by both Super Doctors and National Consumers Survey for being in the top 5% of doctors. Dr. Bernick is an Associate Professor of Medicine at Florida Atlantic University and provides medical education in conjunction with Emory University and Florida Atlantic University School of Nursing and Medicine. We believe Dr. Bernick's experience in the OB/GYN field gives him an understanding of sales channels and the needs and requirements of our customers and provides the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Dr. Bernick earned a B.A. in economics from Northwestern University and a doctorate in medicine from the University of Chicago Medical School. He completed his residency at the University of Pennsylvania.

*Tommy G. Thompson* has served as the Chairman of the Board of Directors of our company since May 2012. As the former Secretary of the U.S. Department of Health & Human Services, or HHS, from February 2001 to January 2005, Secretary Thompson served as the nation's leading advocate for the health and welfare of all Americans. Secretary Thompson is the former Independent Chairman of the Deloitte Center for Health Solutions and is a former partner of the international law firm of Akin Gump Strauss Hauer & Feld LLP, or Akin Gump. At the Deloitte Center for Health Solutions and at Akin Gump, Secretary Thompson built on his efforts at HHS to work toward developing solutions to the healthcare challenges facing American families, businesses, communities, states, and the nation as a whole. As the Governor of Wisconsin from January 1987 to February 2001, Secretary Thompson was perhaps best known for his efforts to revitalize the Wisconsin economy, for his national leadership on welfare reform, and for his work toward expanding healthcare access across all segments of society. Secretary Thompson also serves as Chairman of CareView Communications, Inc. [OTCQB: CRVW], and serves as a member of the board of directors for the following public companies: C. R. Bard, Inc. [NYSE: BCR], Centene Corporation [NYSE: CNC], United Therapeutics Corporation [NASDAQ: UTHR], and Cytori Therapeutics, Inc. [NASDAQ: CYTX]. Secretary Thompson also served as a member of the boards of directors of PURE Bioscience, Inc. [NASDAQ: PURE] from February 2006 to August 2009, SpectraScience, Inc. [OTCBB: SCIE] from September 2007 to December 2009, AGA Medical Holdings, Inc. [NASDAQ: ASAM] from August 2005 to November 2010, and CNS Response, Inc. [OTCBB: CNSO.OB] from September 2009 to March 2010. We believe Secretary Thompson's experience in public service, particularly his services and knowledge related to the healthcare industry as a whole, makes him well suited to be a director of our company. He received both his B.S. and his J.D. from the University of Wisconsin-Madison.

*Samuel A. Greco* has served as a director of our company since February 2012. Mr. Greco has served as Chief Executive Officer of CareView Communications, Inc. since September 2007 and as a director of CareView since February 2009 [OTCQB: CRVW]. CareView is an information technology provider to the healthcare industry. Mr. Greco has spent over 30 years in hospital administration, beginning at an independent city hospital and progressing to Senior Vice President of Financial Operations at Columbia/HCA Healthcare Corporation, the industry's largest operator of healthcare facilities. Over the past 10 years, Mr. Greco has provided consulting services to hospital management companies. He was instrumental in the development of the CareView System. We believe Mr. Greco's experience in the healthcare industry and knowledge of supply chain strategies, vendor partnering, and

**Table of Contents**

logistics management provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. Greco earned his B.A. in Accounting from Bryant College and is a frequent speaker at various healthcare symposiums.

*Cooper C. Collins* has served as a director of our company since February 2012. Mr. Collins has served as the President, Chief Executive Officer, and a director of Pernix Therapeutics Holdings, Inc. [NASDAQ: PTX] since the close of the merger between Pernix and Golf Trust of America, Inc. in March 2010. Mr. Collins joined Pernix in 2002. Pernix is a specialty pharmaceutical company focused on the sales, marketing, and development of branded and generic pharmaceutical products primarily for the pediatric market. He was appointed a director of Pernix in January 2007, Pernix's President in December 2007, and Pernix's Chief Executive Officer in June 2008. From December 2005 to December 2007, Mr. Collins served as Vice President of Business and Product Development of Pernix and as Pernix's Territory Manager from December 2003 to December 2005. Mr. Collins was employed for three years by the National Football League franchise, The New Orleans Saints, in its media relations department. We believe Mr. Collins's specialty pharmaceutical company knowledge and executive experience provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. While on a football scholarship, Mr. Collins received a B.A. from Nicholls State University, where he later received an M.B.A.

*Robert V. LaPenta, Jr.* has served as a director of our company since February 2012. Since August 2011, Mr. LaPenta has served as a Partner of Aston Capital, a private equity investment firm with a current focus on investments in the aerospace, defense, and intelligence markets. Prior to Aston Capital, Mr. LaPenta served as Vice President of Mergers and Acquisitions and Corporate Strategy for L-1 Identity Solutions, Inc., or L-1, provider of technology, products, systems and solutions, and services that protect and secure personal identities and assets. From April 2007 through July 2011, Mr. LaPenta assisted L-1 senior management in identifying acquisition candidates and investments while assisting in due diligence, structuring, valuation, execution, and related financing. Prior to L-1, Mr. LaPenta spent 13 years as an institutional equity trader focused on healthcare sector trading for both customer and proprietary accounts. From February 2003 to March 2007, Mr. LaPenta served as Managing Director, Co-Head of Equity Trading at Banc of America Securities LLC where he managed capital commitment, proprietary trading, and risk management within cash trading. Prior to Banc of America Securities, he served as Director or Vice President of Equity Trading with Credit Suisse First Boston, PaineWebber, Inc., and Salomon Smith Barney, Inc. Previously, as a Senior Associate at Coopers & Lybrand LLP, Mr. LaPenta assisted with auditing, consulting, due diligence, and SEC reporting. Mr. LaPenta is Co-Investment Manager of a \$250 million family/friends/partners asset portfolio consisting of individual equities, fixed income, equity options, hedge fund strategies, private equity, and alternative investments. He is an active participant and fund raiser for New York City's W. 63rd Street YMCA, Turn the Corner Foundation, and numerous other charities. Mr. LaPenta has recently been added to the board of directors of Revolution Lighting Technologies, Inc. [NASDAQ: RVLTL], a public company engaged in the design, manufacture, marketing and installation of LED lighting systems. We believe Mr. LaPenta's diverse investing background, capital markets knowledge, and his relationships within the financial community provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. LaPenta graduated in 1991 from Boston College with a B.A. in Accounting and Finance and is a registered CPA (inactive) in the State of New York.

*Nicholas Segal* has served as a director of our company since February 2012. Since June 2007, Mr. Segal has served as a director of Seavest Capital Partners, a private investment company that invests in early and growth-stage companies, primarily in the education, healthcare, consumer technology, and media sectors. Representing investments of Seavest, Mr. Segal previously served on the board of directors of VitaMed prior to its acquisition by our company. Mr. Segal serves on the board of directors of AutoSquad Corporation, a private company specializing in online tire sales and installation directly to the consumer. He also serves as a member of the board of directors of Tout Industries, Inc., a private company with a new social media platform, and Autonet Mobile, a private company specializing in the first Internet-based service platform for the automotive transportation market. Mr. Segal founded and currently serves as Chief Executive Officer of Polar Generation, LLC, an early-stage consumer products company. Prior to joining Seavest, Mr. Segal served as a senior analyst in the Finance and Business Development group at ESPN from September 2004 to April 2007. We believe Mr. Segal's broad base of knowledge in technologies and products directed to the consumer market provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. He graduated with a B.A. from Duke University in 2004.

---

**Table of Contents**

***Non-Executive Officers***

*Julia Amadio* has served as Chief Product Officer of our company since January 2012. Ms. Amadio has a 25-year background in general management and leading pharmaceutical marketing and product development organizations. From June 2011 to January 2012, Ms. Amadio was President of JMA Consulting, LLC, a consulting company that she formed in 2008. From June 2009 to May 2011, she served as Global Vice President of Marketing for MeadWestvaco's Healthcare Division. Previously, Ms. Amadio was President of a start-up Patients & Consumers Pharma, in 2007. She was Vice President of Marketing & Marketing Services with Daiichi Pharmaceutical Co., Ltd. from 2004 to 2006, Vice President of Aventis Pharmaceutical Inc. from 1997 to 2004, Senior Director, New Products Women's Health at Wyeth from 1991 to 1997, and started her career at Johnson & Johnson's McNeil Pharmaceutical. Ms. Amadio is an active member and leader in the Healthcare Businesswomen's Association. She was an adjunct lecturer at St. Joseph's University in the pharmaceutical M.B.A. program and authored a chapter on Marketing, Market Research and Insights in the book *Pharmaceutical Development for Woman* (Wiley & Sons). Ms. Amadio earned a B.S. in Accounting from St. Joseph's University and an M.B.A. from Drexel University.

*Jason Spitz* has served as Vice President Marketing of our company since December 2011. Mr. Spitz has a 24-year career in marketing, advertising, and general management experience in pharmaceutical and biopharmaceutical markets. From June 2008 to December 2010, Mr. Spitz served as Managing Director, Oncology & Hematology at Beacon Healthcare Communications, a company specializing in pharmaceutical and healthcare advertising. From September 2004 to June 2008, he served as General Manager, Canada and Commercial Strategy and Development at MGI Pharma, Inc. (later acquired by Eisai Co., Ltd.), a company specializing in oncology and cancer supportive care products. From February 2004 to September 2004, he served as Vice President of Marketing and Sales at Aesgen, Inc., a company specializing in cancer products and drug delivery systems, which was acquired by MGI Pharma. Mr. Spitz began his career at Schering-Plough Corporation as a sales representative, rising within the organization over 15 years to lead a global pharmaceutical franchise. Mr. Spitz earned his B.B.A. in Marketing from The University of Texas at Austin and his M.B.A. in Pharmaceutical Studies from Fairleigh Dickinson University.

*Christian Bloomgren* has served as Vice President Sales of our company since June 2011. Mr. Bloomgren has 14 years of leadership experience in the pharmaceutical, biotechnology, and diagnostic industry. From 2005 to 2011, Mr. Bloomgren served as Region Manager at ViaCell, Inc., a biotechnology company dedicated to enabling the widespread application of human cells as medicine, later acquired by PerkinElmer, Inc. From 2000 to 2002, Mr. Bloomgren served as a specialty Account Manager at Eli Lilly and Company and from 2002 to 2005 as District Manager at KV Pharmaceutical. Mr. Bloomgren served as an officer in the U.S. Air Force and holds a B.S. degree from California State University and an M.S. degree from Troy State University.

There are no arrangements or understandings between our officers and directors and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there are no arrangements, plans, or understandings as to whether non-management stockholders will exercise their voting rights to continue to elect the current Board of Directors. There are also no arrangements, agreements, or understandings to our knowledge between non-management stockholders that may directly or indirectly participate in or influence the management of our affairs.

**Identification of Certain Significant Employees**

We consider the following non-executive officers to be significant employees: Julia Amadio (Chief Product Officer), Dr. Brian Bernick (Chief Medical Officer), Jason Spitz (Vice President Marketing) and Christian Bloomgren (Vice President Sales). An overview of their business experience is included above.

**Family Relationships**

There are no family relationships between any of our officers or directors.

**Other Directorships**

Other than as indicated above, none of our directors hold or have been nominated to hold a directorship in any company with a class of securities registered pursuant to Section 12 of the Exchange Act, or subject to the requirements of Section 15(d) of the Securities Act or any company registered as an investment company under the Investment Company Act of 1940.

## **Table of Contents**

### **Committees of the Board**

Our Board of Directors has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The members of each of the committees are independent directors within the meaning of the applicable requirements.

#### ***Audit Committee***

The purpose of the Audit Committee is to oversee the financial and reporting processes of our company and the audits of the financial statements of our company and to provide assistance to our Board of Directors with respect to its oversight of the integrity of the financial statements of our company, our company's compliance with legal and regulatory matters, the independent registered public accountant's qualifications and independence, and the performance of our company's independent registered public accountant. The primary responsibilities of the Audit Committee are set forth in its charter and include various matters with respect to the oversight of our company's accounting and financial reporting process and audits of the financial statements of our company on behalf of our Board of Directors. The Audit Committee also selects the independent registered public accountant to conduct the annual audit of the financial statements of our company; reviews the proposed scope of such audit; reviews accounting and financial controls of our company with the independent registered public accountant and our financial accounting staff.

The members of the Audit Committee are Robert V. LaPenta, Jr., Samuel A. Greco, and Nicholas Segal. Mr. LaPenta, Jr. serves as Chair and audit committee financial expert.

#### ***Compensation Committee***

The purpose of the Compensation Committee includes determining, or recommending to our Board of Directors for determination, the compensation of the Chief Executive Officer and other executive officers of our company and discharging the responsibilities of our Board of Directors relating to compensation programs of our company.

The members of the Compensation Committee are Cooper C. Collins and Nicholas Segal. Mr. Collins serves as Chair.

#### ***Nominating and Corporate Governance Committee***

The purpose of the Nominating and Corporate Governance Committee includes the selection or recommendation to our Board of Directors of nominees to stand for election as directors at each election of directors, the oversight of the selection and composition of committees of our Board of Directors, the oversight of the evaluations of our Board of Directors and management, the development and recommendation to our Board of Directors of a set of corporate governance principles applicable to our company, and review of possible conflicts of interest between us and our directors, officers, and their affiliates.

The members of the Nominating and Corporate Governance Committee are Tommy G. Thompson and Robert LaPenta, Jr. Mr. Thompson serves as Chair.

### **Board Policies**

#### ***Code of Conduct and Ethics***

Our Board of Directors has adopted a Code of Conduct and Ethics applicable to all of our directors and executive officers. This code is intended to focus the members of the Board of Directors and each executive officer on areas of ethical risk, provide guidance to directors and executive officers to help them recognize and deal with ethical issues, provide mechanisms to report unethical conduct, and help foster a culture of honesty and accountability. All members of the Board of Directors and all executive officers are required to sign this code on an annual basis.

#### ***Code of Ethics for the CEO and Senior Financial Officers***

Our Board of Directors has adopted a Code of Ethics for the CEO and Senior Financial Officers. This code governs the professional and ethical conduct of our financial executives, and directs that they (i) provide disclosure in the periodic reports that is complete, fair, accurate, timely, and understandable; (ii) promptly inform the Audit Committee of any significant deficiencies in internal controls or fraud by management or other employees who play a significant role in our financial reporting, disclosures, or internal controls; (iii) promptly inform the Audit Committee of any violations of the Code of Conduct and Ethics or Code of Ethics for the CEO and Senior Financial Officers, as well as any conflicts of

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

interest involving management or other employees who play a significant role in our financial reporting, disclosures, or internal controls; and (iv) promptly inform the Audit Committee of any material violations of the laws, rules, or regulations applicable to us and operation of our business, by us or any of our agents.

S-54

**Table of Contents**

**Director Independence**

Five members of our Board of Directors qualify as independent directors under applicable requirements; namely, Tommy G. Thompson, Samuel A. Greco, Cooper C. Collins, Robert V. LaPenta, Jr., and Nicholas Segal.

**Compensation Committee Interlocks and Insider Participation**

Upon its formation on February 29, 2012, our Compensation Committee initially consisted of three members of our Board of Directors, namely, Cooper C. Collins (Chair), Robert G. Finizio, and Nicholas Segal. Of those members, only Mr. Finizio was an officer and employee of our company. On February 11, 2013, Mr. Finizio stepped down from the Compensation Committee, and subsequently, the Compensation Committee has been comprised of independent directors. No current member of our Compensation Committee serves as a member of a board of directors or compensation committee of any entity that has one or more executive officers serving as members of our Board of Directors or Compensation Committee.

S-55

**Table of Contents****PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding the beneficial ownership of our common stock as of February 28, 2013 by the following:

n each of our directors and executive officers;

n all of our directors and executive officers as a group; and

n each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she, or it possesses sole or shared voting or investment power of that security, including options and warrants that are currently exercisable or exercisable within 60 days of February 28, 2013. Shares issuable pursuant to stock options, warrants, and convertible securities are deemed outstanding for computing the percentage of the person holding such options, warrants, or convertible securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o TherapeuticsMD, Inc., 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487.

NAME OF BENEFICIAL OWNER	SHARES BENEFICIALLY OWNED PRIOR TO THIS OFFERING		SHARES BENEFICIALLY OWNED UPON COMPLETION OF THIS OFFERING	
	NUMBER	PERCENT <sup>(1)</sup>	NUMBER	PERCENT <sup>(2)</sup>
<b>Executive Officers and Directors:</b>				
Robert G. Finizio, Chief Executive Officer and director <sup>(3)</sup>	24,163,496	23.74%	24,163,496	18.42%
John C.K. Milligan, IV, President, Secretary, and director <sup>(4)</sup>	9,035,645	8.82%	9,035,645	6.85%
Daniel A. Cartwright, Chief Financial Officer, Vice President, Finance, and Treasurer <sup>(5)</sup>	320,448	*	320,448	*
Mitchell L. Krassan, Executive Vice President and Chief Strategy Officer <sup>(6)</sup>	779,413	*	779,413	*
Brian Bernick, M.D., Chief Medical Officer and director <sup>(7)</sup>	10,854,049	10.69%	10,854,049	8.29%
Tommy G. Thompson, Chairman of the Board <sup>(8)</sup>	675,000	*	705,000	*
Samuel A. Greco, director <sup>(9)</sup>	450,000	*	450,000	*
Cooper C. Collins, director <sup>(10)</sup>	2,706,579	2.71%	2,706,579	2.09%
Robert V. LaPenta, Jr., director <sup>(11)</sup>	80,000	*	80,000	*
Nicholas Segal, director <sup>(12)</sup>	3,998,719	4.00%	3,998,719	3.09%
All executive officers and directors as a group (10 persons) <sup>(13)</sup>	53,063,349	46.89%	53,093,349	37.24%
<b>5% Stockholders:</b>				
Robert J. Smith <sup>(14)</sup>	9,663,257	9.43%	9,663,257	7.33%
Steven G. Johnson <sup>(15)</sup>	9,453,149	9.22%	9,453,149	7.17%
FMR LLC <sup>(16)</sup>	9,128,507	9.15%	9,128,507 <sup>(18)</sup>	7.07%
Wellington Management Company, LLP <sup>(17)</sup>	7,386,893	7.40%	7,386,893 <sup>(18)</sup>	5.72%



## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

\* Represents less than 1% of the outstanding shares of our common stock.

(1) Applicable percentage of ownership is based on 99,784,982 shares of common stock outstanding as of February 28, 2013, as adjusted for each stockholder.

S-56

**Table of Contents**

- (2) Applicable percentage of ownership is based on 129,196,747 shares of common stock outstanding upon the completion of this offering, as adjusted for each stockholder.
- (3) This amount includes (i) 22,161,586 shares directly owned by Mr. Finizio, (ii) 1,822,910 shares due to Mr. Finizio upon exercise of vested shares under options and (iii) 179,000 shares due to Mr. Finizio upon exercise of vested shares under a warrant. The percentage beneficially owned by Mr. Finizio is based on 101,786,892 and 131,198,657 shares which would be outstanding if all of Mr. Finizio's vested shares under the options and warrant were exercised prior to and upon completion of this offering, respectively.
- (4) This amount includes (i) 6,368,018 shares directly owned by Mr. Milligan, (ii) 2,427,255 shares due to Mr. Milligan upon exercise of vested shares under options, and (iii) 240,372 shares due to Mr. Milligan upon exercise of vested shares under warrants. The percentage beneficially owned by Mr. Milligan is based on 102,452,609 and 131,864,374 shares which would be outstanding if all of Mr. Milligan's vested shares under the options and warrants were exercised prior to and upon completion of this offering, respectively.
- (5) This amount includes (i) 75,000 shares due to Mr. Cartwright upon exercise of vested shares under options, and (ii) 245,448 shares due to Mr. Cartwright upon exercise of vested shares under a warrant. The percentage beneficially owned by Mr. Cartwright is based on 100,105,430 and 129,517,195 shares which would be outstanding if all of Mr. Cartwright's vested shares under the options and warrant were exercised prior to and upon completion of this offering, respectively.
- (6) This amount includes 779,413 shares due to Mr. Krassan upon exercise of vested shares under options. The percentage of class for Mr. Krassan is based on 100,564,395 and 129,976,160 shares which would be outstanding if all of Mr. Krassan's vested shares under the options were exercised prior to and upon completion of this offering, respectively.
- (7) This amount includes (i) 9,119,767 shares beneficially owned by BF Investment Enterprises, Ltd., or BF Investment, a company controlled by Dr. Bernick, (ii) 1,672,910 shares due to BF Investment upon exercise of vested shares under options and (iii) 61,372 shares due to BF Investment upon exercise of vested shares under a warrant. The percentage beneficially owned by Dr. Bernick is based on 101,519,264 and 130,931,029 shares which would be outstanding if all of BF Investment's vested shares under the options and warrant were exercised prior to and upon completion of this offering, respectively.
- (8) This amount includes (i) 600,000 shares directly owned by Thompson Family Investments, LLC, an entity solely owned by Thompson Family Holdings, LLC, an entity solely owned by Mr. Thompson, and (ii) 75,000 shares due to Mr. Thompson upon exercise of vested shares under options. The percentage beneficially owned by Mr. Thompson is based on 99,859,982 and 129,301,747 shares which would be outstanding if all of Mr. Thompson's vested shares under the options were exercised prior to and upon completion of this offering, respectively. Mr. Thompson purchased 30,000 shares in this offering pursuant to our directed share program.
- (9) This amount includes (i) 400,000 shares directly owned by Mr. Greco which shares are currently pledged as security for a promissory note and (ii) 50,000 shares due to Mr. Greco upon exercise of vested shares under options. The percentage beneficially owned by Mr. Greco is based on 99,834,982 and 129,246,747 shares which would be outstanding if all of Mr. Greco's vested shares under the options were exercised prior to and upon completion of this offering, respectively.
- (10) This amount includes (i) 2,631,579 shares beneficially owned by Pernix Therapeutics Holdings, Inc., of which Mr. Collins is CEO, director and largest shareholder, all of which have been pledged as collateral to secure a loan. Mr. Collins exercises voting control in part with the remaining directors of Pernix and disclaims beneficial ownership of the shares and (ii) 75,000 shares due to Mr. Collins upon exercise of vested shares under options. The percentage beneficially owned by Mr. Collins is based on 99,859,982 and 129,271,747 shares which would be outstanding if all of Mr. Collins' vested shares under the options were exercised prior to and upon completion of this offering, respectively.
- (11) This amount includes (i) 5,000 shares directly owned by Mr. LaPenta and (ii) 75,000 shares due to Mr. LaPenta upon exercise of vested shares under options. The percentage beneficially owned by Mr. LaPenta is based on 99,859,982 and 129,271,747 shares which would be outstanding if all of Mr. LaPenta's vested shares under the options were exercised prior to and upon completion of this offering, respectively.
- (12) This amount includes (i) 245,485 shares directly owned by Mr. Segal, and (ii) 142,057 shares due to Mr. Segal upon exercise of vested shares under an option. Mr. Segal owns 11.5812% of Fourth Generation Equity Partners, or Fourth Generation, which (i) owns 3,549,805 shares and (ii) has the right to acquire 61,372 shares upon exercise of vested shares under a warrant. Mr. Segal claims ownership equal to 411,110 shares and 7,107 vested shares under the Fourth Generation warrant. Mr. Segal disclaims beneficial ownership to the remaining shares and remaining vested shares under the warrant owned by Fourth Generation. The percentage beneficially owned by Mr. Segal is based on 99,988,411 and 129,400,176 shares which would be outstanding if all of Mr. Segal's and Fourth Generation's vested shares under options were exercised prior to and upon completion of this offering, respectively.
- (13) This amount includes all shares directly and indirectly owned by all officers and directors and all shares to be issued directly and indirectly upon exercise of vested shares under options and warrants held by our officers and directors. The percentage beneficially owned by all officers and directors is based on 107,767,091 and 137,178,856 shares which would be outstanding if all of the officers' and directors' vested shares under options and warrants were exercised prior to and upon completion of this offering, respectively.
- (14) The information is as reported on Schedule 13D as filed February 4, 2013. This amount includes (i) 5,531,029 shares beneficially owned through Plato and Associates, LLC, or Plato, an entity solely owned by Robert J. Smith, (ii) 1,432,228 shares beneficially owned through Energy Capital, LLC, an entity solely owned by Mr. Smith, and (iii) 2,700,000 shares due to Plato upon the exercise of vested warrants. The percentage beneficially owned by Plato is based on 102,484,982 and 131,896,747 shares which would be outstanding if all of Mr. Smith's shares under the vested warrants were exercised prior to and upon completion of this offering, respectively. Mr. Smith exercises voting and dispositive power over all such shares. Mr. Smith's address is 13650 Fiddlesticks Boulevard, #202-324, Ft. Myers, Florida 33912.
- (15) The information is as reported on Schedule 13D as filed February 4, 2013. This amount includes (i) 6,753,149 shares beneficially owned through SJ Capital, LLC, an entity solely owned by Steven G. Johnson, and (ii) 2,700,000 shares due to Mr. Johnson upon the exercise of vested warrants. The percentage beneficially owned by Mr. Johnson is based on 102,484,982 and 131,896,747 shares

**Table of Contents**

which would be outstanding if all of Mr. Johnson's shares under the vested warrants were exercised prior to and upon completion of this offering, respectively. Mr. Johnson exercises voting and dispositive power over all such shares. Mr. Johnson's address is 804 Tree Haven Court, Highland Village, Texas 75077.

- (16) The information is as reported on Schedule 13G as filed February 14, 2013. Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC and a registered investment adviser, is the beneficial owner of all such shares as a result of its acting as investment adviser to various investment companies, or the Fidelity Funds. The ownership of one such Fidelity Fund, Puritan Fund, amounted to 7,722,000 shares or 7.739% of the common stock outstanding. Edward C. Johnson III and FMR LLC, through its control of Fidelity Management & Research Company, each has sole power to dispose of the 9,128,507 shares owned by the Fidelity Funds. Neither FMR LLC nor Edward C. Johnson III, as Chairman of FMR LLC, has sole power to vote or direct the voting of the shares owned directly by the Fidelity Funds, which power resides with the Fidelity Funds' board of trustees. The address of FMR LLC and Puritan Fund is 82 Devonshire Street, Boston, Massachusetts 02109.
- (17) The information is as reported on Amendment No. 1 to Schedule 13G as filed February 14, 2013. The shares are beneficially owned by Wellington Management Company, LLP, in its capacity as investment adviser, for its clients. Those clients have the right to receive, or the power to direct the receipt of, dividends from, or the proceeds from the sale of such shares. No such client is known to have such right or power with respect to more than five percent. Wellington Management Company, LLP has shared voting power over 5,897,322 shares and sole dispositive power over all such shares. Wellington Management Company, LLP's address is 280 Congress Street, Boston, MA 02210.
- (18) This amount does not include shares purchased in this offering by entities affiliated with this stockholder.

Under Rule 144 promulgated under the Securities Act, our officers, directors and beneficial stockholders may sell up to one percent (1%) of the total outstanding shares (or an amount of shares equal to the average weekly reported volume of trading during the four calendar weeks preceding the sale) every three months provided that (i) current public information is available about our company, (ii) the shares have been fully paid for at least one year, (iii) the shares are sold in a broker's transaction or through a market-maker, and (iv) the seller files a Form 144 with the SEC.

**Table of Contents**

**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS**

**FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a discussion of material U.S. federal income tax considerations to non-U.S. holders with respect to their ownership and disposition of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is neither a U.S. person nor a partnership for U.S. federal income tax purposes. A U.S. person is any of the following:

- n an individual who is a citizen or resident of the United States;
- n a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- n an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- n a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code)), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a United States person.

This discussion is based on current provisions of the Internal Revenue Code, U.S. Treasury Regulations promulgated under the Internal Revenue Code, judicial opinions, published positions of the Internal Revenue Service, or IRS, and all other applicable authorities, all of which are subject to change, possibly with retroactive effect, or to differing interpretations. No ruling has been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a contrary position or that any such contrary position would not be sustained by a court. This discussion assumes that the non-U.S. holder will hold our common stock as a capital asset (generally property held for investment).

This discussion does not address all aspects of U.S. federal income taxation or any aspects of alternative minimum, estate, state, local, or non-U.S. taxation. It also does not consider any specific facts or circumstances that may apply to particular non-U.S. holders that may be subject to special treatment under the U.S. federal income tax laws, including, but not limited to:

- n insurance companies;
- n tax-exempt organizations;
- n financial institutions;
- n regulated investment companies;
- n tax-qualified retirement plans;
- n brokers or dealers in securities;

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

- n investors that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- n S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- n controlled foreign corporations;
- n passive foreign investment companies; and
- n U.S. expatriates.

If a partnership or any other entity or arrangement taxed as a partnership for U.S. federal income tax purposes is a beneficial owner of our common stock, the treatment of an equity owner in the partnership will generally depend upon the status of the equity owner of such partnership and the activities of the partnership. Accordingly, partnerships (and entities and arrangements taxed as partnerships) that hold our common stock and owners in such partnerships (or other entities or arrangements taxed as partnerships) are urged to consult their tax advisors regarding the specific U.S. federal income tax consequences to them of acquiring, owning or disposing of our common stock.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR**

**Table of Contents****U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF SHARES OF OUR COMMON STOCK, AS WELL AS THE U.S. FEDERAL, STATE, LOCAL AND NON-U.S. INCOME AND OTHER TAX CONSIDERATIONS OF ACQUIRING, OWNING AND DISPOSING OF SHARES OF COMMON STOCK.****Dividends**

Historically, we have not paid dividends on our common stock, and we do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital and will first reduce the recipient's adjusted tax basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under the heading **Gain on Sale or Other Disposition of Common Stock**.

Dividends paid to a non-U.S. holder will be subject to U.S. federal withholding tax at a rate equal to 30% of the gross amount of the dividend, or a lower rate prescribed by an applicable income tax treaty, unless the dividends are effectively connected with a trade or business carried on by the non-U.S. holder within the United States (and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment maintained by the non-U.S. holder). Under applicable Treasury Regulations, a non-U.S. holder will be required to satisfy certain certification requirements, generally on IRS Form W-8BEN (or applicable successor form), directly or through an intermediary, in order to claim a reduced rate of withholding under an applicable income tax treaty. If tax is withheld in an amount in excess of the amount prescribed by an applicable income tax treaty, a refund of the excess amount may be obtained by the non-U.S. holder by timely filing an appropriate claim for refund with the IRS.

Dividends that are effectively connected with such a U.S. trade or business (and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment maintained by the recipient) will not be subject to U.S. withholding tax if the non-U.S. holder files the required forms, generally an IRS Form W-8ECI (or applicable successor form), with the payor of the dividend, but instead will be subject to U.S. federal income tax on a net income basis in the same manner as if the non-U.S. holder were a resident of the United States. A foreign corporation that receives dividends constituting effectively connected income may, under certain circumstances, be subject to an additional branch profits tax at a rate of 30%, or a lower rate prescribed by an applicable income tax treaty, with respect to such effectively connected income.

**Gain on Sale or Other Disposition of Common Stock**

A non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of the non-U.S. holder's shares of common stock unless:

- n the gain is effectively connected with a trade or business carried on by the non-U.S. holder within the United States (and, if required by an applicable tax treaty, is attributable to a U.S. permanent establishment or a fixed base maintained by the non-U.S. holder), in which case the non-U.S. holder generally will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates and, if the non-U.S. holder is a corporation, the branch profits tax may apply, at a 30% rate or such lower rate as may be specified by an applicable income tax treaty;
- n the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of disposition (and is not otherwise treated as a U.S. resident alien for U.S. federal income tax purposes) and certain other conditions are met, in which case the non-U.S. holder will be required to pay a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such non-U.S. holder's country of residence) on the net gain derived from the disposition, which tax may be offset by U.S. source capital losses, if any, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- n our common stock constitutes a U.S. real property interest by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock.



---

## **Table of Contents**

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the non-U.S. holder actually or constructively held more than five percent of our common stock at any time during the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock.

### **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock, the name and address of the recipient and the amount, if any, of tax withheld. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected dividends or withholding was reduced by an applicable income tax treaty. Under tax treaties or other agreements, the IRS may make its reports available to tax authorities in the country in which the non-U.S. holder resides or is established.

Dividend payments made to a non-U.S. holder that is not an exempt recipient generally will be subject to backup withholding at the then applicable rate (currently 28%) unless the non-U.S. holder certifies as to its foreign status, which certification may be made by providing the Company with an IRS Form W-8BEN or IRS Form W-8ECI, as applicable, and certain other requirements are met. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that the holder is a U.S. person that is not an exempt recipient.

Information reporting and backup withholding may apply to the proceeds of a sale of our common stock within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale of our common stock outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Rather, the amount of tax withheld is applied to the U.S. federal income tax liability of persons subject to backup withholding. If backup withholding results in an overpayment of U.S. federal income taxes, a refund may be obtained, provided the required documents are timely filed with the IRS.

### **Legislation Relating to Foreign Accounts**

The Internal Revenue Code generally will impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined for this purpose) unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). The legislation also will generally impose a U.S. federal withholding tax of 30% on dividends to, and the gross proceeds of a disposition of our common stock by a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides certain information regarding direct and indirect U.S. owners of the entity. Under certain transition rules, any obligation under this legislation to withhold with respect to dividends on our common stock will not begin until January 1, 2014 and with respect to gross proceeds of a sale or other disposition of our common stock will not begin until January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.



**Table of Contents****UNDERWRITING**

Subject to the terms and conditions set forth in the underwriting agreement dated March 14, 2013 among us and Jefferies LLC, as representative of the underwriters named below and the sole book-running manager of this offering, we have agreed to sell to the underwriters, and each of the underwriters have agreed, severally and not jointly, to purchase from us, the number of shares of common stock shown opposite its name below:

<b>Underwriters</b>	<b>NUMBER OF SHARES</b>
Jefferies LLC	23,529,412
Noble Financial Capital Markets	5,882,353
<b>Total</b>	<b>29,411,765</b>

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares if any of them are purchased, except as described below under "Option to Purchase Additional Shares." If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you will receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Commission and Expenses**

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$0.0714 per share of common stock. The underwriters will not allow, nor will dealers reallow, a discount from the concession to brokers and dealers. After the offering, the public offering price and concession to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus supplement.

**Table of Contents**

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	\$1.700	\$1.700	\$50,000,001	\$57,500,001
Underwriting discounts and commissions paid by us	\$0.119	\$0.119	\$3,500,000	\$4,025,000
Proceeds to us, before expenses	\$1.581	\$1.581	\$46,500,001	\$53,475,001

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$900,000.

**Listing**

Our common stock is stock is quoted on the OTCQB under the symbol TXMD.

**Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of 4,411,765 shares from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus supplement.

**No Sales of Similar Securities**

We, our officers, directors and certain holders of our outstanding capital shares and other securities have agreed, subject to specified exceptions, not to, among other things, directly or indirectly:

- n sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open put equivalent position within the meaning of Rule 16a-1(h) under the Exchange Act, or

- ⁿ otherwise dispose of any common shares, options or warrants to acquire common shares, or securities exchangeable or exercisable for or convertible into common shares currently or hereafter owned either of record or beneficially, or
  
- ⁿ publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of Jefferies LLC.

This restriction terminates after the close of trading of the common shares on and including the 90th day after the date of this prospectus supplement. However, subject to certain exceptions, in the event that either:

- ⁿ during the last 17 days of the 90-day restricted period, we issue an earnings release, disclose material news or a material event relating to us occurs, or
  
- ⁿ prior to the expiration of the 90-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day restricted period,

S-63

## **Table of Contents**

then in either case the expiration of the 90-day restricted period will be extended until the expiration of the 18-day period beginning on the date of the issuance of an earnings release, disclosure of material news or the occurrence of the material event, as applicable, unless Jefferies LLC waives, in writing, such an extension.

The representatives may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares not otherwise permitted by the lock-up agreements prior to the expiration of the lock-up period.

## **Stabilization**

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either covered short sales or naked short sales.

Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

Naked short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

## **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any

## **Table of Contents**

other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### **Directed Share Program**

At our request, the underwriters have reserved for sale, at the public offering price, up to 30,000 shares of common stock offered by this prospectus for sale to our directors, officers, and employees and persons having business relationships with the Company. Reserved shares purchased by certain of our directors, officers and employees and persons having business relationships with the Company will be subject to the lock-up provisions described above. The number of shares of our common stock available for sale to the general public will be reduced to the extent these persons purchase such reserved shares. Any reserved shares of our common stock that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act in connection with sales of the directed shares.

### **Other Activities and Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

---

**Table of Contents**

**NOTICE TO INVESTORS**

**Australia**

This prospectus supplement and the accompanying prospectus are not disclosure documents for the purposes of Australia's Corporations Act 2001 (Cth) of Australia (the Corporations Act) have not been lodged with the Australian Securities & Investments Commission and are only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

A. You confirm and warrant that you are either:

- n a sophisticated investor under section 708(8)(a) or (b) of the Corporations Act;
- n a sophisticated investor under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- n professional investor within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

B. You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

**European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date), no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- n to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- n to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- n in any other circumstances falling within Article 3(2) of the Prospectus Directive;

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

S-66

---

## **Table of Contents**

### **Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus supplement and the accompanying prospectus have not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

### **Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (the FIEL ) and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

### **Singapore**

This prospectus supplement and the accompanying prospectus have not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA ), (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- n a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- n a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- n to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and





## **Table of Contents**

units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;

n where no consideration is given for the transfer; or

n where the transfer is by operation of law.

### **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ( SIX ) or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ( CISA ). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

### **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order ) and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a relevant person ).

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Greenberg Traurig, LLP, Phoenix, Arizona. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP, San Diego, California.

**EXPERTS**

The consolidated financial statements of TherapeuticsMD, Inc. as of December 31, 2012 and 2011 appearing in TherapeuticsMD, Inc.'s Annual Report (Form 10-K) for the fiscal year ended December 31, 2012 incorporated into this prospectus supplement and the accompanying prospectus by reference have been audited by Rosenberg Rich Baker Berman & Company, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. The consolidated financial statements of TherapeuticsMD, Inc. as of December 31, 2010 appearing in TherapeuticsMD, Inc.'s Annual Report (Form 10-K) for the fiscal year ended December 31, 2011 incorporated into the accompanying prospectus by reference have been audited by Parks & Company, LLC, independent registered accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firms as experts in accounting and auditing.

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information that we incorporate by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and accompany prospectus automatically updates and supersedes previously filed information as applicable.

We incorporate by reference into this prospectus supplement and the accompanying prospectus the following documents file by us with the SEC, other than any portion of any such documents that are not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules:

- n Annual Report on Form 10-K for the fiscal year ended December 31, 2012.
  
- n Current Report on Form 8-K filed with the SEC on January 25, 2013.
  
- n Current Report on Form 8-K filed with the SEC on February 6, 2013.

We also incorporate by reference into this prospectus supplement and the accompanying prospectus all documents (other than any portions of any such documents that are not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules) filed by us under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of the initial registration statement and before effectiveness of this registration statement, and after the date of this prospectus supplement.

**Table of Contents**

You may request a copy of these filings at no cost, by writing or telephoning us as follows:

**TherapeuticsMD, Inc.**

**Attention: Corporate Secretary**

**951 Broken Sound Parkway NW, Suite 320**

**Boca Raton, Florida 33487**

**(561) 961-1911**

Any statement contained in a document that is incorporated by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus supplement and the accompanying prospectus, or in any other document that is subsequently filed with the SEC and incorporated by reference (including, without limitation, our Annual Report on Form 10-K for the fiscal year ended December 31, 2012), modifies, or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus supplement or the accompanying prospectus, except as so modified or superseded. Since information that we later file with the SEC will update and supersede previously incorporated information, you should look at all of the SEC filings that we incorporate by reference (including, without limitation, our Annual Report on Form 10-K for the fiscal year ended December 31, 2012) to determine if any of the statements in this prospectus supplement or the accompanying prospectus or in any documents previously incorporated by reference have been modified or superseded.

S-70

**Table of Contents**

**PROSPECTUS**

**\$125,000,000**

**Common Stock**

**Preferred Stock**

**Debt Securities**

**Depositary Shares**

**Warrants**

**Purchase Contracts**

**Units**

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of \$125,000,000.

This prospectus provides you with a general description of the securities we may offer and sell. We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities and their compensation will be described in the applicable prospectus supplement.

Our common stock is listed on the OTCQB under the symbol TXMD. The last reported sale price of our common stock on January 24, 2013 was \$3.27 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on the OTCQB or any securities market or other exchange of the securities covered by the applicable prospectus supplement.

This prospectus may not be used to consummate a sale of our securities unless accompanied by the applicable prospectus supplement.

**You should consider the risks that we have described in this prospectus and in the accompanying prospectus supplement before you invest. See Risk Factors beginning on page 5.**

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

**The date of this prospectus is February 5, 2013**

**Table of Contents**

**TABLE OF CONTENTS**

<u>ABOUT THIS PROSPECTUS</u>	ii
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	5
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	6
<u>FORWARD-LOOKING STATEMENTS</u>	7
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	8
<u>PROSPECTUS SUPPLEMENTS</u>	9
<u>RATIO OF EARNINGS TO FIXED CHARGES</u>	9
<u>DILUTION</u>	9
<u>USE OF PROCEEDS</u>	10
<u>SECURITIES WE MAY OFFER</u>	10
<u>DESCRIPTION OF COMMON STOCK</u>	11
<u>DESCRIPTION OF PREFERRED STOCK</u>	13
<u>DESCRIPTION OF DEBT SECURITIES</u>	17
<u>DESCRIPTION OF DEPOSITARY SHARES</u>	29
<u>DESCRIPTION OF WARRANTS</u>	32
<u>DESCRIPTION OF PURCHASE CONTRACTS</u>	35
<u>DESCRIPTION OF UNITS</u>	36
<u>CERTAIN PROVISIONS OF NEVADA LAW AND OUR CHARTER AND BYLAWS</u>	38
<u>LEGAL OWNERSHIP OF SECURITIES</u>	41
<u>PLAN OF DISTRIBUTION</u>	45
<u>LEGAL MATTERS</u>	47
<u>EXPERTS</u>	47

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings, up to a total dollar amount of \$125,000,000. This prospectus provides you with general information regarding the securities we may offer. We will provide a prospectus supplement that contains specific information about any offering by us.

The prospectus supplement also may add, update, or change information contained in the prospectus. You should read both this prospectus and the prospectus supplement related to any offering as well as additional information described under the heading **Where You Can Find More Information**.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or any accompanying prospectus supplement or any free writing prospectus. We are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus and in any accompanying prospectus supplement is accurate only as of the date of their covers, regardless of the time of delivery of this prospectus or any prospectus supplement or of any sale of our securities. Our business, financial condition, results of operations, and prospects may have changed since those dates. You should rely only on the information contained or incorporated by reference in this prospectus or any accompanying prospectus supplement. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus or any prospectus supplement—the statement in the document having the later date modifies or supersedes the earlier statement.

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**.



---

**Table of Contents**

**PROSPECTUS SUMMARY**

*The following summary does not contain all of the information that may be important to purchasers of our securities. Prospective purchasers of securities should carefully review the detailed information and financial statements, including the notes thereto, appearing elsewhere in or incorporated by reference into this prospectus.*

**Our Company**

We are a specialty pharmaceutical company focused on creating safe and effective branded prescription, generic prescription, and over-the-counter (non-prescription) products targeted exclusively for women. We are focused on the clinical trials for and commercialization of three advanced hormone therapy 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. These proposed hormone therapy products, which contain estrogen and progestin alone or in combination, are being tested to provide equivalent efficacy at lower doses, enabling an enhanced side effect profile compared with competing products. These proposed hormone therapy products have received Investigational New Drug application, or IND, acceptance by the U.S. Food and Drug Administration, or FDA. We plan to begin phase 3 clinical trials of these proposed products in 2013. We intend to leverage and grow our current marketing and sales organization to commercialize these 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, preterm birth, vulvo and vaginal atrophy, and premature ovarian failure. The oral progestin market was approximately \$400 million in 2011 U.S. sales; the estrogen market was approximately \$800 million in 2011 U.S. sales; and the combination Progestin/Estrogen market was \$600 million in 2011 U.S. sales.

As we continue the clinical development of our proposed hormone therapy products, we continue to market and expand our branded prescription, generic prescription, and over-the-counter product lines consisting of prenatal vitamins, over-the-counter prenatal vitamins, vegan docosahexaenoic acid, or DHA, iron supplements, Vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD name and our generic prescription prenatal vitamins products under our BocaGreenMD Prenal name. All of our prenatal vitamins are gluten, sugar, and lactose free. We believe our product attributes result in greater patient 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 products through a direct national sales force of approximately 40 full-time professionals that calls on healthcare providers in the obstetrics and gynecologic, or OB/GYN, market space as well as through our website to consumers. We strive to demonstrate to physicians that recommending our products enable them to realize office efficiencies and patient and payor cost savings over competitive products, strategies, and distribution models. In addition, our products offer healthcare providers an alternative to patients to meet their individual nutritional and financial requirements related to co-pay and cost of care considerations. We also believe that our combination of branded, generic, and over-the-counter lines allows physicians, women, and payors cost-effective alternatives for top quality care. We supply our prescription products to consumers through retail pharmacies. We supply our over-the-counter products either directly to consumers via the Internet and phone sales followed by home shipment as well as through physicians who then sell them to their patients. Our fully staffed customer care center uses current customer relationship management technologies 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 through our auto-ship feature.

## **Table of Contents**

### **Our 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 three hormone therapy products designed to alleviate the symptoms of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products;

maintaining a marketing emphasis on large group OB/GYN practices that provide opportunities to large patient bases and that are receptive to the data and savings we provide that facilitate them in negotiating contracts with insurance companies;

pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and the Internet;

expanding our geographic market and sales team to cover the entire country by increasing our current 36 sales territories to 60 sales territories by the end of 2013; and

introducing new products to build upon the introduction of our first three prescription 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 proposed hormone therapy products consisting of a bioidentical oral combination of progesterone and estradiol product, an oral progesterone product, and a suppository vulvar and vaginal atrophy estradiol product. Early pharmacokinetic, or PK, studies on our HT products indicate achievement of 80-125% comparability of the reference listed drugs approved by the FDA for the combined progestin and estrogen product.

### **Our Offices**

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487. Our telephone number is (561) 961-1911. The Company maintains websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com), and [bocagreenmd.com](http://bocagreenmd.com). The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

### **The Securities That May Be Offered**

We may offer up to \$125,000,000 of common stock, preferred stock, debt securities, depositary shares, warrants, purchase contracts, and units in one or more offerings and in any combination. In this prospectus, we refer to the common stock, preferred stock, debt securities, depositary shares, warrants, purchase contracts, and units collectively as securities. This prospectus provides you with a general description of the securities we may offer. A prospectus supplement, which we will provide each time we offer securities, will describe the specific amounts, prices, and terms of the securities we offer. We will also include in the prospectus supplement information, when applicable, about material U.S. federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed. This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.



## **Table of Contents**

### *Common Stock*

We may offer shares of our common stock, par value \$0.001 per share, either alone or underlying other registered securities convertible or exercisable into our common stock. All outstanding shares of our common stock are of the same class and have equal rights and attributes. The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders of our company. Our common stock does not have cumulative voting rights. Holders of our common stock are entitled to share equally in dividends, if any, as may be declared from time to time by our board of directors. In the event of liquidation, dissolution or winding up of our company, subject to the preferential liquidation rights of any series of preferred stock that we may from time to time designate, the holders of our common stock are entitled to share ratably in all of our assets remaining after payment of all liabilities and preferential liquidation rights. Holders of our common stock have no conversion, exchange, sinking fund, redemption or appraisal rights (other than such as may be determined by our board of directors in its sole discretion) and, except pursuant to contractual arrangements, have no preemptive rights to subscribe for any of our securities.

### *Preferred Stock*

Under the terms of our amended and restated articles of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Each series of preferred stock will be more fully described in the particular prospectus supplement that will accompany this prospectus, including redemption provisions, rights in the event of our liquidation, dissolution or winding up, voting rights and rights to convert into common stock.

### *Debt Securities*

We may offer secured or unsecured obligations in the form of one or more series of senior or subordinated debt. The senior debt securities and the subordinated debt securities are together referred to in this prospectus as the debt securities. The subordinated debt securities generally will be entitled to payment only after payment of our senior debt. Senior debt generally includes all debt for money borrowed by us, except debt that is stated in the instrument governing the terms of that debt to not be senior to, or to have the same rank in right of payment as, or to be expressly junior to, the subordinated debt securities. We may issue debt securities that are convertible into shares of our common stock. If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

The senior and subordinated debt securities will be issued under an indenture between us and a trustee. We have summarized the general features of the debt securities to be governed by the indenture. The indenture has been filed as an exhibit to the registration statement of which this prospectus forms a part. We encourage you to read the indenture. Instructions on how you can get copies of this document are provided in the section entitled *Where You Can Find More Information* on page 4 of the prospectus.

### *Depositary Shares*

We may issue receipts for depositary shares representing fractional shares of preferred stock. The shares of any series of preferred stock underlying any depositary shares that we may sell under this prospectus will be deposited under a deposit agreement between us and a depositary selected by us. The fractional share of the applicable series of preferred stock represented by each depositary share will be set forth in the applicable prospectus supplement that will accompany this prospectus.

**Table of Contents**

*Warrants*

We may issue warrants for the purchase of common stock, preferred stock, or debt securities. We may issue warrants independently or together with other securities.

*Purchase Contracts*

We may issue purchase contracts, including purchase contracts issued as part of a unit with one or more other securities, for the purchase or sale of our common stock or preferred stock. The price per share of common stock or preferred stock, as applicable, may be fixed at the time the purchase contracts are issued or may be determined by reference to a specific formula contained in the purchase contracts. We may issue purchase contracts in such amounts and in as many distinct series as we wish.

*Units*

We may issue units comprised of one or more of the other classes of securities issued by us as described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit.

**Table of Contents**

**RISK FACTORS**

Investing in our securities involves a high degree of risk. Please see the risk factors described under the caption "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 on file with the SEC, each subsequently filed Quarterly Report on Form 10-Q, and our Current Report on Form 8-K dated January 25, 2013, each of which are incorporated by reference in this prospectus and in any accompanying prospectus supplement. Before making an investment decision, you should carefully consider these risks as well as information we include or incorporate by reference in this prospectus and in any accompanying prospectus supplement. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly, and current reports; proxy statements; and other information with the SEC under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Through our website at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), you may access, free of charge, our filings, as soon as reasonably practical after we electronically file them with or furnish them to the SEC. Other information contained in our website is not incorporated by reference in, and should not be considered a part of, this prospectus or any accompanying prospectus supplement. You also may read and copy any document we file with the SEC at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings are also available to the public from the SEC's website at [www.sec.gov](http://www.sec.gov).

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC to register the securities offered hereby under the Securities Act of 1933, as amended, or the Securities Act. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC's Internet website.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus and each prospectus supplement includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this prospectus or any prospectus supplement regarding our strategy, prospects, plans, objectives, future operations, future revenue and earnings, projected margins and expenses, technological innovations, future products or product development, product development strategies, potential acquisitions or strategic alliances, the success of particular product or marketing programs, the amount of revenue generated as a result of sales to significant customers, financial position, and liquidity and anticipated cash needs and availability are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would, and similar expressions are intended to identify forward-looking statements.

Actual results or events could differ materially from the forward-looking statements we make. Among the factors that could cause actual results to differ materially are the factors discussed under Risk Factors in our Form 10-K for the fiscal year ended December 31, 2011 and our Form 8-K dated January 25, 2013. We also will include or incorporate by reference in each prospectus supplement important factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Should one or more known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated, projected, or implied by these forward-looking statements. You should consider these factors and the other cautionary statements made in this prospectus, any prospectus supplement, or the documents we incorporate by reference in this prospectus as being applicable to all related forward-looking statements wherever they appear in this prospectus, any prospectus supplement or the documents incorporated by reference. While we may elect to update forward-looking statements wherever they appear in this prospectus, any prospectus supplement, or the documents incorporated by reference, we do not assume, and specifically disclaim, any obligation to do so, whether as a result of new information, future events, or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.



**Table of Contents**

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information that we incorporate by reference is considered to be part of this prospectus. Information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information as applicable.

We incorporate by reference into this prospectus the following documents file by us with the SEC, other than any portion of any such documents that are not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules:

Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.

Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

Current Report on Form 8-K filed with the SEC on January 25, 2012.

Current Report on Form 8-K/A filed with the SEC on February 2, 2012.

Current Report on Form 8-K/A filed with the SEC on February 3, 2012.

Current Report on Form 8-K filed with the SEC on February 24, 2012.

Current Report on Form 8-K filed with the SEC on March 2, 2012.

Current Report on Form 8-K filed with the SEC on May 17, 2012.

Current Report on Form 8-K filed with the SEC on June 21, 2012.

Current Report on Form 8-K filed with the SEC on October 2, 2012.

Current Report on Form 8-K filed with the SEC on January 25, 2013.

We also incorporate by reference into this prospectus all documents (other than any portions of any such documents that are not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules) filed by us under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of the initial registration statement and before effectiveness of this registration statement, and after the date of

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

this prospectus.

You may request a copy of these filings at no cost, by writing or telephoning us as follows:

TherapeuticsMD, Inc.

Attention: Corporate Secretary

951 Broken Sound Parkway NW, Suite 320

Boca Raton, Florida 33487

(561) 961-1911

Any statement contained in a document that is incorporated by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus or any accompanying prospectus supplement, or in any other document that is subsequently filed with the SEC and incorporated by reference, modifies, or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus or any accompanying prospectus supplement, except as so modified or superseded. Since information that we later file with the SEC will update and supersede previously incorporated information, you should look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or any accompanying prospectus supplement or in any documents previously incorporated by reference have been modified or superseded.

**Table of Contents**

**PROSPECTUS SUPPLEMENTS**

This prospectus provides you with a general description of the proposed offering of our securities. Each time that we sell securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may add to, update, or change information contained in this prospectus and should be read as superseding this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading **Where You Can Find More Information**.

The prospectus supplement will describe the terms of any offering of securities, including the offering price to the public in that offering, the purchase price and net proceeds of that offering, and the other specific terms related to that offering of securities.

**RATIO OF EARNINGS TO FIXED CHARGES**

Our ratio of earnings to fixed charges for each of the five most recently completed fiscal years and any required interim periods will each be specified in a prospectus supplement or in a document that we file with the SEC and incorporate by reference pertaining to the issuance, if any, by us of debt securities in the future.

**DILUTION**

We will set forth in a prospectus supplement the following information regarding any material dilution of the equity interests of investors purchasing securities in an offering under this prospectus:

the net tangible book value per share of our equity securities before and after the offering;

the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and

the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.

**Table of Contents**

**USE OF PROCEEDS**

Except as may be otherwise set forth in any prospectus supplement accompanying this prospectus, we will use the net proceeds we receive from sales of securities offered hereby for general corporate purposes, which may include the repayment of indebtedness outstanding from time to time and for working capital, capital expenditures, acquisitions, and repurchases of our common stock or other securities. Pending these uses, the net proceeds may also be temporarily invested in cash equivalents or short-term securities. When specific securities are offered, the prospectus supplement relating thereto will set forth our intended use of the net proceeds that we receive from the sale of such securities.

**SECURITIES WE MAY OFFER**

The following is a general description of the terms and provisions of the securities we may offer and sell by this prospectus. These summaries are not meant to be complete. This prospectus and the applicable prospectus supplement will contain the material terms and provisions of the various types of securities that we may offer. Any prospectus supplement may also add, update, or change information contained in this prospectus, including the material terms and provisions of the securities as described in this prospectus. We will also include in the prospectus supplement information, when applicable, about material U.S. federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

In this prospectus, we refer to the common stock (including the associated rights), preferred stock, debt securities, depositary shares, warrants, purchase contracts, and units collectively as securities. The total dollar amount of all securities that we may issue under this prospectus will not exceed \$125,000,000.

If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

**Table of Contents**

**DESCRIPTION OF COMMON STOCK**

This section describes the general terms of our common stock. A prospectus supplement may provide information that is different from this prospectus. If the information in the prospectus supplement with respect to our common stock being offered differs from this prospectus, you should rely on the information in the prospectus supplement. A copy of our amended and restated articles of incorporation has been incorporated by reference from our filings with the SEC as an exhibit to the registration statement of which this prospectus forms a part. Our common stock and the rights of the holders of our common stock are subject to the applicable provisions of the Nevada Private Corporation Code, which we refer to as Nevada law, our amended and restated articles of incorporation, our bylaws, the rights of the holders of our preferred stock, if any, as well as some of the terms of our outstanding indebtedness.

As of December 31, 2012 under our amended and restated articles of incorporation, we had the authority to issue 250,000,000 shares of common stock, par value \$0.001 per share, of which 99,784,982 shares of our common stock were outstanding as of that date.

The following description of our common stock, and any description of our common stock in a prospectus supplement may not be complete and is subject to, and qualified in its entirety by reference to, Nevada law and the actual terms and provisions contained in our amended and restated articles of incorporation and our bylaws, each as amended from time to time.

**Voting Rights**

Each outstanding share of our common stock is entitled to one vote per share of record on all matters submitted to a vote of stockholders and to vote together as a single class for the election of directors and in respect of other corporate matters. At a meeting of stockholders at which a quorum is present, for all matters other than the election of directors, a majority of the votes cast decides all questions, unless the matter is one upon which a different vote is required by express provision of law or our of amended and restated articles incorporation or our bylaws. Directors will be elected by a plurality of the votes of the shares present at a meeting. Holders of shares of common stock do not have cumulative voting rights with respect to the election of directors or any other matter.

**Dividends**

Holders of our common stock are entitled to receive dividends or other distributions when, as, and if declared by our board of directors. The right of our board of directors to declare dividends, however, is subject to any rights of the holders of other classes of our capital stock, any indebtedness outstanding from time to time, and the availability of sufficient funds under Nevada law to pay dividends.

**Preemptive Rights**

The holders of our common stock generally do not have preemptive rights to purchase or subscribe for any of our capital stock or other securities. However, pursuant to a Securities Purchase Agreement dated September 26, 2012, we granted certain of our stockholders that purchased an aggregate of 3,953,489 shares of our common stock under such agreement the right to purchase securities that enable them to maintain their respective pro rata ownership percentages of our common stock if we undertake a public or private offering for a 36-month period from the October 2, 2012 closing date of that transaction.

**Redemption**

The shares of our common stock are not subject to redemption by operation of a sinking fund or otherwise.

## **Table of Contents**

### **Liquidation Rights**

In the event of any liquidation, dissolution, or winding up of our company, subject to the rights, if any, of the holders of other classes of our capital stock, the holders of shares of our common stock are entitled to receive any of our assets available for distribution to our stockholders ratably in proportion to the number of shares held by them.

### **Options and Other Stock-Based Rights**

From time to time, we have issued and expect to continue to issue options and other stock-based rights to various lenders, investors, consultants, employees, officers, and directors of our company. As of December 31, 2012, we had outstanding (i) stock options to purchase 13,733,488 shares of our common stock, of which 8,370,408 shares of common stock were issuable upon exercise of vested stock options as of that date, and (ii) warrants for the purchase of 11,784,408 shares of our common stock.

### **Listing**

Our common stock is listed on the OTCQB under the symbol TXMD.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Co., Inc., 350 Indiana Street, Suite 800, Golden, Colorado 80401.

**Table of Contents**

**DESCRIPTION OF PREFERRED STOCK**

This section describes the general terms of our preferred stock to which any prospectus supplement may relate. A prospectus supplement will describe the terms relating to any preferred stock to be offered by us in greater detail and may provide information that is different from terms described in this prospectus. If the information in the prospectus supplement with respect to the particular preferred stock being offered differs from this prospectus, you should rely on the information in the prospectus supplement. A copy of our amended and restated articles of incorporation has been incorporated by reference from our filings with the SEC as an exhibit to the registration statement of which this prospectus forms a part. A certificate of designation or amendment to the amended and restated articles of incorporation will specify the terms of the preferred stock being offered, and will be filed or incorporated by reference as an exhibit to the registration statement before the preferred stock is issued. The following description of our preferred stock, and any description of the preferred stock in a prospectus supplement may not be complete and is subject to, and qualified in its entirety by reference to, Nevada law and the actual terms and provisions contained in our amended and restated articles of incorporation and bylaws, each as amended from time to time.

As of December 31, 2012 under our amended and restated articles of incorporation, we had the authority to issue 10,000,000 shares of preferred stock, par value \$0.001 per share, which are issuable in series on terms to be determined by our board of directors. Accordingly, our board of directors is authorized, without action by the stockholders, to issue preferred stock from time to time with such dividend, liquidation, conversion, voting, and other rights and restrictions as it may determine. All shares of any one series of our preferred stock will be identical, except that shares of any one series issued at different times may differ as to the dates from which dividends may be cumulative. All series will rank equally and will provide for other terms as described in the applicable prospectus supplement. As of December 31, 2012, there were no outstanding shares of our preferred stock.

**Terms of Preferred Stock**

Unless provided in a prospectus supplement, the shares of our preferred stock to be issued will have no preemptive rights. Any prospectus supplement offering our preferred stock will furnish the following information with respect to the preferred stock offered by that prospectus supplement:

the title and stated value of the preferred stock;

the number of shares of preferred stock to be issued and the offering price of the preferred stock;

any dividend rights;

any dividend rates, periods, or payment dates, or methods of calculation of dividends applicable to the preferred stock;

the date from which distributions on the preferred stock will accumulate, if applicable;

the terms and conditions, if applicable, upon which the preferred stock will be convertible into our common stock, including the conversion price (or manner of calculation thereof);

any right to convert the preferred stock into a different type of security;

any voting rights attributable to the preferred stock;

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

any rights and preferences upon our liquidation, dissolution, or winding up of our affairs;

any terms of redemption;

the procedures for any auction and remarketing, if any, for the preferred stock;

the provisions for a sinking fund, if any, for the preferred stock;

any listing of the preferred stock on any securities exchange;



## **Table of Contents**

a discussion of federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to distribution rights (including whether any liquidation preference as to the preferred stock will be treated as a liability for purposes of determining the availability of assets for distributions to holders of stock ranking junior to the shares of preferred stock as to distribution rights);

any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the series of preferred stock being offered as to distribution rights and rights upon the liquidation, dissolution, or winding up of our affairs; and

any other specific terms, preferences, rights, limitations, or restrictions of the preferred stock.

## **Rank**

Unless otherwise indicated in the applicable prospectus supplement, shares of our preferred stock will rank, with respect to payment of distributions and rights upon our liquidation, dissolution, or winding up, and allocation of our earnings and losses as follows:

senior to all classes or series of our common stock and to all of our equity securities ranking junior to the preferred stock;

on a parity with all equity securities issued by us, the terms of which specifically provide that these equity securities rank on a parity with the preferred stock; and

junior to all equity securities issued by us, the terms of which specifically provide that these equity securities rank senior to the preferred stock.

## **Distributions**

Subject to any preferential rights of any outstanding stock or series of stock, our preferred stockholders are entitled to receive distributions when, as, and if declared by our board of directors, out of legally available funds, and to share pro rata based on the number of preferred shares, common stock, and other parity equity securities outstanding. The rates and dates of payment of dividends will be set forth in the prospectus supplement relating to the applicable series of preferred stock. Dividends will be payable to holders of record of preferred stock as they appear on our books or, if applicable, the records of the depository referred to below on the record dates fixed by our board of directors. Dividends on a series of preferred stock may be cumulative or noncumulative.

We may not declare, pay, or set apart for payment dividends on the preferred stock unless full dividends on other series of preferred stock that rank on an equal or senior basis have been paid or sufficient funds have been set apart for payment for:

all prior dividend periods of other series of preferred stock that pay dividends on a cumulative basis; or

the immediately preceding dividend period of other series of preferred stock that pay dividends on a noncumulative basis.

Partial dividends declared on shares of preferred stock and each other series of preferred stock ranking on an equal basis as to dividends will be declared pro rata. A pro rata declaration means that the ratio of dividends declared per share to accrued dividends per share will be the same for each series of preferred stock. Similarly, we may not declare, pay, or set apart for payment non-stock dividends or make other payments on the common stock or any other of our stock ranking junior to the preferred stock until full dividends on the preferred stock have been paid or set apart for payment for

all prior dividend periods if the preferred stock pays dividends on a cumulative basis; or

the immediately preceding dividend period if the preferred stock pays dividends on a noncumulative basis.

## **Table of Contents**

### **Voting Rights**

Unless otherwise indicated in the applicable prospectus supplement, holders of our preferred stock will not have any voting rights.

### **Liquidation Preference**

Upon the voluntary or involuntary liquidation, dissolution, or winding up of our affairs, then, before any distribution or payment will be made to the holders of any common stock or any other class or series of stock ranking junior to the preferred stock in our distribution of assets upon any liquidation, dissolution, or winding up, the holders of each series of our preferred stock will be entitled to receive, after payment or provision for payment of our debts and other liabilities, out of our assets legally available for distribution to stockholders, liquidating distributions in the amount of the liquidation preference per share (set forth in the applicable prospectus supplement), plus an amount, if applicable, equal to all distributions accrued and unpaid thereon (which will not include any accumulation in respect of unpaid distributions for prior distribution periods if the preferred stock does not have a cumulative distribution). Unless otherwise specified in the applicable prospectus supplement, after payment of the full amount of the liquidating distributions to which they are entitled, the holders of preferred stock will have no right or claim to any of our remaining assets. In the event that, upon our voluntary or involuntary liquidation, dissolution, or winding up, the legally available assets are insufficient to pay the amount of the liquidating distributions on all of our outstanding preferred stock and the corresponding amounts payable on all of our other classes or series of equity securities ranking on a parity with the preferred stock in the distribution of assets upon liquidation, dissolution, or winding up, then the holders of our preferred stock and all other such classes or series of equity securities will share ratably in the distribution of assets in proportion to the full liquidating distributions to which they would otherwise be respectively entitled.

If the liquidating distributions are made in full to all holders of preferred stock, our remaining assets will be distributed among the holders of any other classes or series of equity securities ranking junior to the preferred stock upon our liquidation, dissolution, or winding up, according to their respective rights and preferences and in each case according to their respective number of shares of stock.

### **Conversion Rights**

The terms and conditions, if any, upon which shares of any series of preferred stock are convertible into other securities will be set forth in the applicable prospectus supplement. These terms will include the amount and type of security into which the shares of preferred stock are convertible, the conversion price (or manner of calculation thereof), the conversion period, provisions as to whether conversion will be at the option of the holders of the preferred stock or us, the events requiring an adjustment of the conversion price, and provisions affecting conversion in the event of the redemption of that preferred stock.

### **Redemption**

If so provided in the applicable prospectus supplement, our preferred stock will be subject to mandatory redemption or redemption at our option, in whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such prospectus supplement. Unless we default in the payment of the redemption price, dividends will cease to accrue after the redemption date on shares of preferred stock called for redemption and all rights of holders of such shares will terminate, except for the right to receive the redemption price. No series of preferred stock will receive the benefit of a sinking fund except as set forth in the applicable prospectus supplement.

### **Registrar and Transfer Agent**

The registrar and transfer agent for our preferred stock will be set forth in the applicable prospectus supplement.

**Table of Contents**

If our board of directors decides to issue any preferred stock, it may discourage or make more difficult a merger, tender offer, business combination or proxy contest, assumption of control by a holder of a large block of our securities, or the removal of incumbent management, even if these events were favorable to the interests of stockholders. Our board of directors, without stockholder approval, may issue preferred stock with voting and conversion rights and dividend and liquidation preferences that may adversely affect the holders of our other equity or debt securities.

---

**Table of Contents**

**DESCRIPTION OF DEBT SECURITIES**

This prospectus describes certain general terms and provisions of the debt securities we may offer under this prospectus and one or more prospectus supplements. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a prospectus supplement. The following description of debt securities will apply to the debt securities offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of debt securities may specify different or additional terms.

We may issue senior, senior subordinated, or subordinated, debt securities. Senior securities will be direct obligations of ours and will rank equally and ratably in right of payment with other indebtedness of ours that is not subordinated. Senior subordinated securities will be subordinated in right of payment to the prior payment in full of senior indebtedness, as defined in the applicable prospectus supplement, and may rank equally and ratably with any other senior subordinated indebtedness. Subordinated securities will be subordinated in right of payment to senior subordinated securities.

We need not issue all debt securities of one series at the same time. Unless we provide otherwise, we may reopen a series, without the consent of the holders of such series, for issuances of additional securities of that series.

We will issue the senior debt securities and senior subordinated debt securities under a senior indenture, which we will enter into with a trustee to be named in the senior indenture, and we will issue the subordinated debt securities under a subordinated indenture, which we will enter into with a trustee to be named in the subordinated indenture. We use the term indenture or indentures to refer to both the senior indenture and the subordinated indenture. Each indenture will be subject to and governed by the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act, and we may supplement the indenture from time to time. Any trustee under any indenture may resign or be removed with respect to one or more series of debt securities, and we may appoint a successor trustee to act with respect to that series. We have filed a form of indenture as an exhibit to this registration statement, of which this prospectus forms a part. The terms of the senior indenture and subordinated indenture will be substantially similar, except that the subordinated indenture will include provisions pertaining to the subordination of the subordinated debt securities and senior subordinated debt securities to the senior debt securities and any other of our senior securities. The following statements relating to the debt securities and the indenture are summaries only, are subject to change, and are qualified in their entirety to the detailed provisions of the indenture, any supplemental indenture, and the discussion contained in any prospectus supplements.

**General**

The debt securities will be our direct obligations. We may issue debt securities from time to time and in one or more series as our board of directors may establish by resolution or as we may establish in one or more supplemental indentures. The particular terms of each series of debt securities will be described in a prospectus supplement relating to the series. We may issue debt securities with terms different from those of debt securities that we previously issued.

We may issue debt securities from time to time and in one or more series with the same or various maturities, at par, at a premium, or at a discount. We will set forth in a prospectus supplement, relating to any series of debt securities being offered, the initial offering price, and the following terms of the debt securities:

the title of the debt securities;

the series designation and whether they are senior securities, senior subordinated securities, or subordinated securities;

the aggregate principal amount of the debt securities and any limit on the aggregate amount of the series of debt securities;

**Table of Contents**

the price or prices (expressed as a percentage of the aggregate principal amount) at which we will issue the debt securities and, if other than the principal amount of the debt securities, the portion of the principal amount of the debt securities payable upon the maturity of the debt securities;

the date or dates on which we will pay the principal on the debt securities;

the rate or rates (which may be fixed or variable) per annum or the method used to determine the rate or rates (including any commodity, commodity index, stock exchange index, or financial index) at which the debt securities will bear interest, the date or dates from which interest will accrue, the date or dates on which interest will commence and be payable, and any regular record date for the interest payable on any interest payment date;

the place where principal, interest, and any additional amounts will be payable and where the debt securities can be surrendered for transfer, exchange, or conversion;

the terms, if any, by which holders of the debt securities may convert or exchange the debt securities for our common stock, preferred stock, or any other security or property;

if convertible, the initial conversion price, the conversion period, and any other terms governing such conversion;

any subordination provisions or limitations relating to the debt securities;

any sinking fund requirements;

any obligation we have to redeem or purchase the debt securities pursuant to any sinking fund or analogous provisions or at the option of a holder of debt securities;

the dates on which and the price or prices at which we will repurchase the debt securities at the option of the holders of debt securities and other detailed terms and provisions of these repurchase obligations;

the denominations in which the debt securities will be issued, if other than denominations of \$1,000 and any integral multiple thereof;

the portion of principal amount of the debt securities payable upon declaration of acceleration of the maturity date, if other than the principal amount;

whether we will issue the debt securities in certificated or book-entry form;

whether the debt securities will be in registered or bearer form and, if in registered form, the denominations if other than in even multiples of \$1,000 and, if in bearer form, the denominations and terms and conditions relating thereto;

the currency of denomination of the debt securities;

the designation of the currency, currencies, or currency units in which payment of principal of, premium, and interest on the debt securities will be made;

if payments of principal of, and interest and any additional amounts on the debt securities will be made in one or more currencies or currency units other than that or those in which the debt securities are denominated, the manner in which the exchange rate with respect to these payments will be determined;

the manner in which the amounts of payment of principal of, and interest and any additional amounts on the debt securities will be determined, if these amounts may be determined by reference to an index based on a currency or currencies other than that in which the debt securities are denominated or designated to be payable or by reference to a commodity, commodity index, stock exchange index, or financial index;

any applicability of the defeasance provisions described in this prospectus or any prospectus supplement;

**Table of Contents**

whether and under what circumstances, if any, we will pay additional amounts on any debt securities in respect of any tax, assessment, or governmental charge and, if so, whether we will have the option to redeem the debt securities instead of making this payment;

any addition to or change in the events of default described in this prospectus or in the indenture with respect to the debt securities and any change in the acceleration provisions described in this prospectus or in the indenture with respect to the debt securities;

any addition to or change in the covenants described in this prospectus or in the indenture with respect to the debt securities;

if the debt securities are to be issued upon the exercise of debt warrants, the time, manner, and place for them to be authenticated and delivered;

any securities exchange on which we will list the debt securities;

any restrictions on transfer, sale, or other assignment;

any provisions relating to any security provided for the debt securities;

any provisions relating to any guarantee of the debt securities;

any other terms of the debt securities, which may modify or delete any provision of the indenture as it applies to that series; and

any depositaries, interest rate calculation agents, exchange rate calculation agents, or other agents with respect to the debt securities. We may issue debt securities that are exchangeable for or convertible into shares of our common stock or other securities or property. The terms, if any, on which the debt securities may be exchanged for or converted into shares of our common stock or other securities or property will be set forth in the applicable prospectus supplement. Such terms may include provisions for conversion, either mandatory, at the option of the holder or at our option, in which case the number of shares of common stock or other securities or property to be received by the holders of debt securities would be calculated as of a time and in the manner stated in the prospectus supplement.

We may issue debt securities at less than the principal amount payable upon maturity. We refer to these securities as original issue discount securities. If material or applicable, we will describe in the applicable prospectus supplement special U.S. federal income tax, accounting, and other considerations applicable to original issue discount securities.

If we denominate the purchase price of any of the debt securities in a foreign currency or currencies or a foreign currency unit or units, or if the principal of and interest and any additional amounts on any series of debt securities is payable in a foreign currency or currencies or a foreign currency unit or units, we will provide you with information on the restrictions, elections, general tax considerations, specific terms, and other information with respect to that issue of debt securities and such foreign currency or currencies or foreign currency unit or units in the applicable prospectus supplement.

Except as may be set forth in any prospectus supplement relating to the debt securities, an indenture will not contain any other provisions that would limit our ability to incur indebtedness or that would afford holders of the debt securities protection in the event of a highly leveraged or similar transaction involving us or in the event of a change in control. You should review carefully the applicable prospectus supplement for information with respect to events of default and any covenants applicable to the debt securities being offered.

**Payments and Paying Agents**



## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

## **Table of Contents**

We will pay principal of, and interest and any additional amounts on, the debt securities of a particular series at the office of the paying agents designated by us, except that, unless we otherwise indicate in the applicable prospectus supplement, we may make interest payments by check, which we will mail to the holder, or by wire transfer to certain holders. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series.

### **Form, Transfer, and Exchange**

Each debt security will be represented by either one or more global securities registered in the name of The Depository Trust Company, as depository, or a nominee of the depository (as a book-entry debt security), or a certificate issued in definitive registered form (as a certificated debt security), as described in the applicable prospectus supplement. Except as described under Global Debt Securities and Book-Entry System below, book-entry debt securities will not be issuable in certificated form.

#### *Certificated Debt Securities*

You may transfer or exchange certificated debt securities at the trustee's office or paying agencies in accordance with the terms of the indenture. No service charge will be made for any transfer or exchange of certificated debt securities, but we may require payment of a sum sufficient to cover any tax or other governmental charge payable in connection with a transfer or exchange.

You may transfer certificated debt securities and the right to receive the principal of, and interest and any additional amounts on, certificated debt securities only by surrendering the old certificate representing those certificated debt securities and either we or the trustee will reissue the old certificate to the new holder, or we or the trustee will issue a new certificate to the new holder.

#### *Global Debt Securities and Book-Entry System*

Each global debt security representing book-entry debt securities will be deposited with, or on behalf of, the depository, and registered in the name of the depository or a nominee of the depository. Ownership of beneficial interests in book-entry debt securities will be limited to persons that have accounts with the depository for the related global debt security, whom we refer to as participants, or persons that may hold interests through participants.

Except as described in this prospectus or any applicable prospectus supplement, beneficial owners of book-entry debt securities will not be entitled to have securities registered in their names, will not receive or be entitled to receive physical delivery of a certificate in definitive form representing securities, and will not be considered the owners or holders of those securities under the indenture. Accordingly, to exercise any rights of a holder under the indenture, each person beneficially owning book-entry debt securities must rely on the procedures of the depository for the related global debt security and, if that person is not a participant, on the procedures of the participant through which that person owns its interest.

We understand, however, that under existing industry practice, the depository will authorize the persons on whose behalf it holds a global debt security to exercise certain rights of holders of debt securities, and the indenture provides that we, the trustee, and our respective agents will treat as the holder of a debt security the persons specified in a written statement of the depository with respect to that global debt security for purposes of obtaining any consents or directions required to be given by holders of the debt securities pursuant to the indenture.

We will make payments of principal of, and interest and any additional amounts on, book-entry debt securities to the depository or its nominee, as the case may be, as the registered holder of the related global debt

## **Table of Contents**

security. We, the trustee, and any other agent of ours or agent of the trustee will not have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests in a global debt security or for maintaining, supervising, or reviewing any records relating to such beneficial ownership interests.

Any certificated debt securities issued in exchange for a global debt security will be registered in such name or names as the depositary shall instruct the trustee. We expect that such instructions will be based upon directions received by the depositary from participants with respect to ownership of book-entry debt securities relating to such global debt security.

For additional discussion of book entry and certificated securities, see the section entitled "Legal Ownership of Securities" included in this prospectus. We have obtained the foregoing information in this section and the "Legal Ownership of Securities" section concerning the depositary and the depositary's book-entry system from sources we believe to be reliable. We take no responsibility for the depositary's performance of its obligations under the rules and regulations governing its operations.

### **No Protection in the Event of a Change in Control**

Unless we provide otherwise in the applicable prospectus supplement, the debt securities will not contain any provisions that may afford holders of the debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction (whether or not such transaction results in a change in control).

### **Covenants**

Unless we provide otherwise in the applicable prospectus supplement, the debt securities will not contain any restrictive covenants, including covenants restricting us or any of our subsidiaries from incurring, issuing, assuming, or guaranteeing any indebtedness secured by a lien on any of our or our subsidiaries' property or capital stock or restricting us or any of our subsidiaries from entering into any sale and leaseback transactions.

### **Merger, Consolidation, and Sale of Assets**

Unless we provide otherwise in the applicable prospectus supplement, we may not merge with or into or consolidate with, or convey, transfer, or lease all or substantially all of our properties and assets to, any person (a "successor person"), and we may not permit any person to merge into, or convey, transfer, or lease its properties and assets substantially as an entirety to us, unless the following applies:

either (a) the company is the surviving entity or (b) the successor person is a corporation, partnership, trust, or other entity organized and validly existing under the laws of any U.S. domestic jurisdiction and expressly assumes our obligations on the debt securities and under the indenture;

immediately after giving effect to the transaction, no event of default, and no event that, after notice or lapse of time, or both, would become an event of default, will have occurred and be continuing under the indenture; and

certain other conditions that may be set forth in the applicable prospectus supplement are met.

This covenant would not apply to any recapitalization transaction, a change in control of us, or a transaction in which we incur a large amount of additional debt unless the transactions or change in control included a merger, consolidation, or transfer or lease of substantially all of our assets. Except as may be described in the applicable prospectus supplement, there are no covenants or other provisions in the indenture providing for a put right or increased interest or that would otherwise afford holders of debt securities additional protection in the event of a recapitalization transaction, a change in control of us, or a transaction in which we incur a large amount of additional debt.

---

**Table of Contents**

**Events of Default Under the Indenture**

Unless we provide otherwise in the applicable prospectus supplement, an event of default will mean, with respect to any series of debt securities, any of the following:

default in the payment of any interest upon any debt security of that series when it becomes due and payable and continuance of that default for a period of 30 days (unless the entire amount of such payment is deposited by us with the trustee or with a paying agent before the expiration of the 30-day period);

default in the payment of principal of, and any other amounts due on, any debt security of that series when due and payable either at maturity, redemption, or otherwise;

default in the deposit of any sinking fund payment, when and as due in respect of any debt security of that series;

default in the performance or breach of any other covenant or warranty by us in the indenture (other than a covenant or warranty that has been included in the indenture solely for the benefit of a series of debt securities other than that series) or in the debt security, which default continues uncured for a period of 60 days after we receive written notice from the trustee or we and the trustee receive written notice from the holders of not less than a majority in principal amount of the outstanding debt securities of that series as provided in the indenture;

we, pursuant to or within the meaning of any applicable bankruptcy law, commence a voluntary case, consent to the entry of an order for relief against us in an involuntary case, consent to the appointment of a custodian for all or substantially all of our property, make a general assignment for the benefit of our creditors, or admit in writing our inability generally to pay our debts as they become due; or, similarly, a court enters an order or decree under any applicable bankruptcy law that provides for relief against us in an involuntary case, appoints a custodian for all or substantially all of our properties, or orders our liquidation (and the order remains in effect for 60 days); and

any other event of default provided with respect to debt securities of that series that is included in any supplemental indenture or is described in the applicable prospectus supplement accompanying this prospectus.

No event of default with respect to a particular series of debt securities (except as to certain events of bankruptcy, insolvency, or reorganization) necessarily will constitute an event of default with respect to any other series of debt securities. An event of default may also be an event of default under our bank credit agreements or other debt securities in existence from time to time and under certain guaranties by us of any subsidiary indebtedness. In addition, certain events of default or an acceleration under the indenture may also be an event of default under some of our other indebtedness outstanding from time to time.

Unless we provide otherwise in the applicable prospectus supplement, if an event of default with respect to debt securities of any series at the time outstanding occurs and is continuing (other than certain events of our bankruptcy, insolvency, or reorganization), then the trustee or the holders of not less than a majority in principal amount of the outstanding debt securities of that series may, by written notice to us (and to the trustee if given by the holders), declare to be due and payable immediately the principal (or, if the debt securities of that series are discount securities, that portion of the principal amount as may be specified in the terms of that series) of and accrued and unpaid interest, if any, of all debt securities of that series. In the case of an event of default resulting from certain events of bankruptcy, insolvency, or reorganization, the principal (or such specified amount) of and accrued and unpaid interest, if any, of all outstanding debt securities will become and be immediately due and payable without any declaration or other act by the trustee or any holder of outstanding debt securities.

At any time after an acceleration with respect to debt securities of a series has been made, but before a judgment or decree for payment of the money due has been obtained by the trustee, the holders of not less than a majority in principal amount of the outstanding debt securities of that series may cancel the acceleration and



## **Table of Contents**

annul its consequences if the rescission would not conflict with any judgment or decree and if all existing events of default with respect to that series have been cured or waived except nonpayment of principal (or such lesser amount) or interest that has become due solely because of the acceleration.

The indenture also provides that the holders of not less than a majority in principal amount of the outstanding debt securities of any series may waive any past default with respect to that series and its consequences, except a default involving the following:

our failure to pay the principal of, and interest and any additional amounts on, any debt security; or

a covenant or provision contained in the indenture that cannot be modified or amended without the consent of the holders of each outstanding debt security affected by the default.

The trustee is generally required to give notice to the holders of debt securities of each affected series within 90 days of a default actually known to a responsible officer of the trustee unless the default has been cured or waived. The indenture provides that the trustee may withhold notice to the holders of debt securities of any series of any default or event of default (except in payment on any debt securities of that series) with respect to debt securities of that series if it in good faith determines that withholding notice is in the interest of the holders of those debt securities.

Unless we provide otherwise in the applicable prospectus supplement, the indenture will provide that the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request or discretion of any holder of any such outstanding debt securities unless the trustee receives indemnity satisfactory to it against any loss, liability, or expense. Subject to certain rights of the trustee, the holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method, and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee with respect to the debt securities of that series. The trustee may, however, refuse to follow any discretion that conflicts with the indenture or any law or which may be unduly prejudicial to the holders of the debt securities of the applicable series not joining in the discretion.

Unless we provide otherwise in the applicable prospectus supplement, no holder of any debt security of any series will have any right to institute any proceeding, judicial or otherwise, with respect to the indenture or for the appointment of a receiver or trustee, or for any remedy under the indenture, unless:

that holder has previously given to the trustee written notice of a continuing event of default with respect to debt securities of that series; and

the holders of at least 25% in principal amount of the outstanding debt securities of that series have made written request, and offered reasonable indemnity, to the trustee to institute such proceeding as trustee, and the trustee will not have received from the holders of a majority in principal amount of the outstanding debt securities of that series a direction inconsistent with that request and has failed to institute the proceeding within 60 days.

Notwithstanding the foregoing, except as provided in the subordination provisions, if any, the holder of any debt security will have an absolute and unconditional right to receive payment of the principal of, and any interest or additional amounts on, that debt security on or after the due dates expressed in that debt security and to institute suit for the enforcement of payment.

The indenture requires us, within 120 days after the end of our fiscal year, to furnish to the trustee a certificate as to compliance with the indenture, or, in the event of noncompliance, specify the noncompliance and the nature and status of the noncompliance.

## **Modification of Indenture and Waiver**

Except as specified below, modifications and amendments to the indenture require the approval of not less than a majority in principal amount of our outstanding debt securities.



**Table of Contents**

*Changes Requiring the Unanimous Approval*

We and the trustee may not make any modification or amendment to the indenture without the consent of the holder of each affected debt security then outstanding if that amendment will have any of the following results:

reduce the rate of or extend the time for payment of interest, including default interest, on any debt security;

reduce the principal of or any additional amounts on or change the fixed maturity of any debt security or reduce the amount of, or postpone the date fixed for, the payment of any sinking fund or analogous obligation with respect to any series of debt securities;

reduce the principal amount of discount securities payable upon acceleration of maturity;

waive a default in the payment of the principal, interest, or any additional amounts on any debt security, except a rescission of acceleration of the debt securities of any series by the holders of at least a majority in aggregate principal amount of the then outstanding debt securities of that series and a waiver of the payment default that resulted from that acceleration;

make the principal of, or interest or any additional amounts on, any debt security payable in currency other than that stated in the debt security;

change the place of payment on a debt security;

change the currency or currencies of payment of the principal of, and any premium, make-whole payment, interest, or additional amounts on, any debt security;

impair the right to initiate suit for the enforcement of any payment on or with respect to any debt security;

reduce the percentage of holders of debt securities whose consent is needed to modify or amend an indenture, to waive compliance with certain provisions of an indenture, or to waive certain defaults;

reduce the percentage of the holders of outstanding debt securities of any series necessary to modify or amend the indenture, to waive compliance with provisions of the indenture or defaults and their consequences under the indenture, or to reduce the quorum or voting requirements contained in the indenture;

make any change that adversely affects the right to convert or exchange any debt security other than as permitted by the indenture or decrease the conversion or exchange rate or increase the conversion or exchange price of any such debt security;

waive a redemption payment with respect to any debt security; or



## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

make any change to certain provisions of the indenture relating to, among other things, the right of holders of debt securities to receive payment of the principal of, and interest and any additional amount on, those debt securities, the right of holders to institute suit for the enforcement of any payment or the right of holders to waive past defaults.

### *Changes Not Requiring Approval of Debt Holders*

We and the trustee may modify or amend an indenture, without the consent of any holder of debt securities, for any of the following purposes:

to evidence the succession of another person to us as obligor under the indenture;

to add to our existing covenants additional covenants for the benefit of the holders of all or any series of debt securities, or to surrender any right or power conferred upon us in the indenture;

to add events of default for the benefit of the holders of all or any series of debt securities;

## **Table of Contents**

to add or change any provisions of the indenture to facilitate the issuance of, or to liberalize the terms of, debt securities in bearer form, or to permit or facilitate the issuance of debt securities in uncertificated form, provided that this action will not adversely affect the interests of the holders of the debt securities of any series in any material respect;

to add, change, or eliminate any provisions of the indenture, provided that any addition, change, or elimination (a) shall neither (i) apply to any debt security of any series created prior to the execution of such supplemental indenture and entitled to the benefit of such provision nor (ii) modify the rights of the holder of any debt security with respect to such provision, or (b) shall become effective only when there are no outstanding debt securities;

to establish additional series of debt securities;

to secure previously unsecured debt securities;

to establish the form or terms of debt securities of any series, including the provisions and procedures, if applicable, for the conversion or exchange of the debt securities into our common stock, preferred stock, or other securities or property;

to evidence and provide for the acceptance or appointment of a successor trustee or facilitate the administration of the trusts under the indenture by more than one trustee;

to make any provision with respect to the conversion or exchange of rights of holders pursuant to the requirements of the indenture;

to cure any ambiguity, defect, or inconsistency in the indenture, provided that the action does not adversely affect the interests of holders of debt securities of any series issued under the indenture;

to close the indenture with respect to the authentication and delivery of additional series of debt securities or to qualify, or maintain qualification of, the indenture under the Trust Indenture Act; or

to supplement any of the provisions of the indenture to the extent necessary to permit or facilitate defeasance and discharge of any series of debt securities, provided that the action shall not adversely affect the interests of the holders of the debt securities of any series in any material respect.

A vote by holders of debt securities will not be required for clarifications and certain other changes that would not adversely affect holders of the debt securities.

## **Defeasance of Debt Securities and Certain Covenants in Certain Circumstances**

### *Legal Defeasance*

Unless the terms of the applicable series of debt securities provide otherwise, we may be discharged from any and all obligations in respect of the debt securities of any series (except for certain obligations to register the transfer or exchange of debt securities of the series; to replace stolen, lost, or mutilated debt securities of the series; and to maintain paying agencies and certain provisions relating to the treatment of funds held by paying agents). We will be so discharged upon the deposit with the trustee, in trust, of money and/or U.S. government obligations or, in the case of debt securities denominated in a single currency other than U.S. dollars, foreign government obligations (as described at the end of this section), that, through the payment of interest and principal in accordance with their terms, will provide money in an amount sufficient to pay and discharge each installment of principal, interest, and any additional amounts on and any mandatory sinking fund payments in respect of the debt securities of that series on the stated maturity of such payments in accordance with the terms of the indenture and those debt securities.

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

This discharge may occur only if, among other things, we have delivered to the trustee an officers certificate and an opinion of counsel stating that we have received from, or there has been published by, the U.S. Internal Revenue Service a ruling or, since the date of execution of the indenture, there has been a change in the applicable U.S. federal income tax law, in either case to the effect that holders of the debt securities of such

---

**Table of Contents**

series will not recognize income, gain, or loss for U.S. federal income tax purposes as a result of the deposit, defeasance, and discharge and will be subject to U.S. federal income tax on the same amount and in the same manner and at the same times as would have been the case if the deposit, defeasance, and discharge had not occurred.

*Defeasance of Certain Covenants*

Unless the terms of the applicable series of debt securities provide otherwise, upon compliance with certain conditions, we may omit to comply with the restrictive covenants contained in the indenture, as well as any additional covenants contained in the applicable prospectus supplement.

The conditions include, among others, the following:

depositing with the trustee money and/or U.S. government obligations or, in the case of debt securities denominated in a single currency other than U.S. dollars, foreign government obligations, that, through the payment of interest and principal in accordance with their terms, will provide money in an amount sufficient, in the opinion of a nationally recognized firm of independent public accountants, to pay principal, interest, and any additional amounts on and any mandatory sinking fund payments in respect of the debt securities of that series on the stated maturity of those payments in accordance with the terms of the indenture and those debt securities; and

delivering to the trustee an opinion of counsel to the effect that the holders of the debt securities of that series will not recognize income, gain, or loss for U.S. federal income tax purposes as a result of the deposit and related covenant defeasance and will be subject to U.S. federal income tax in the same amount and in the same manner and at the same times as would have been the case if the deposit and related covenant defeasance had not occurred.

*Covenant Defeasance and Events of Default*

If we exercise our option, as described above, not to comply with certain covenants of the indenture with respect to any series of debt securities, and the debt securities of that series are declared due and payable because of the occurrence of any event of default, the amount of money and/or U.S. government obligations or foreign government obligations on deposit with the trustee will be sufficient to pay amounts due on the debt securities of that series at the time of their stated maturity but may not be sufficient to pay amounts due on the debt securities of that series at the time of the acceleration resulting from the event of default. However, we will remain liable for those payments.

Foreign government obligations means, with respect to debt securities of any series that are denominated in a currency other than United States dollars:

direct obligations of the government that issued or caused to be issued such currency for the payment of which obligations its full faith and credit is pledged, which are not callable or redeemable at the option of the issuer thereof; or

obligations of a person controlled or supervised by or acting as an agency or instrumentality of that government, the timely payment of which is unconditionally guaranteed as a full faith and credit obligation by that government, which are not callable or redeemable at the option of the issuer thereof.

**Guarantees**

Our payment obligations under any series of debt securities may be guaranteed by us or one or more of our subsidiaries. The terms of any such guarantee will be set forth in the applicable prospectus supplement.

## **Table of Contents**

### **Subordination**

We will set forth in the applicable prospectus supplement the terms and conditions, if any, upon which any series of senior subordinated securities or subordinated securities is subordinated to debt securities of another series or to other indebtedness of ours. The terms will include a description of the following:

the indebtedness ranking senior to the debt securities being offered;

any restrictions on payments to the holders of the debt securities being offered while a default with respect to the senior indebtedness is continuing;

any restrictions on payments to the holders of the debt securities being offered following an event of default; and

provisions requiring holders of the debt securities being offered to remit some payments to holders of senior indebtedness.

### **Conversion and Exchange Rights**

The terms on which debt securities of any series may be convertible into or exchangeable for our common stock, preferred stock, or other securities or property of our company will be described in the applicable prospectus supplement. These terms will include the following:

the conversion or exchange price, or the manner of calculating the price;

the exchange or conversion period;

whether the conversion or exchange is mandatory, or voluntary at the option of the holder, or at our option;

any restrictions on conversion or exchange in the event of redemption of the debt securities and any restrictions on conversion or exchange; and

the means of calculating the number of shares of our common stock, preferred stock, or other securities or property of our company to be received by the holders of debt securities.

The conversion or exchange price of any debt securities of any series that are convertible into our common stock or preferred stock may be adjusted for any stock dividends, stock splits, reclassification, combinations, or similar transactions, as set forth in the applicable prospectus supplement.

### **Redemption of Debt Securities**

The debt securities may be subject to optional or mandatory redemption on terms and conditions described in the applicable prospectus supplement. Subject to such terms, we may opt at any time to redeem the debt securities in whole or in part.

If less than all the debt securities of any series are to be redeemed or purchased in an offer to purchase at any time, the trustee will select the debt securities of that series to be redeemed or purchased as follows: (1) if the securities of such series are listed on any national securities exchange, in compliance with the requirements of the principal national securities exchange on which the debt securities of that series are listed, or, (2) if

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

the debt securities of that series are not listed on a national securities exchange, on a pro rata basis, by lot, or by such other method as the trustee deems fair and appropriate.

Except as otherwise provided as to any particular series of debt securities, at least 30 days but not more than 60 days before a redemption date, we or the trustee will mail a notice of redemption to each holder whose debt securities are to be redeemed. From and after notice has been given as provided in the applicable indenture, if funds for the redemption of any debt securities called for redemption shall have been made available on the

**Table of Contents**

redemption date, the debt securities will cease to bear interest on the date fixed for the redemption specified in the notice, and the only right of the holders of the debt securities will be to receive payment of the redemption price.

**Governing Law**

The indentures and the debt securities will be governed by and construed in accordance with the laws of the state of New York, except to the extent that the Trust Indenture Act is applicable.

## **Table of Contents**

### **DESCRIPTION OF DEPOSITARY SHARES**

We may issue receipts for depositary shares representing fractional shares of preferred stock. The fractional share of the applicable series of preferred stock represented by each depositary share will be set forth in the applicable prospectus supplement.

The shares of any series of preferred stock underlying any depositary shares that we may sell under this prospectus will be deposited under a deposit agreement between us and a depositary selected by us. Subject to the terms of the deposit agreement, each holder of a depositary share will be entitled, in proportion to the applicable fraction of a share of the preferred stock underlying the depositary share, to all of the rights, preferences, and privileges, and will be subject to the qualifications and restrictions, of the preferred stock underlying that depositary share.

The depositary shares will be evidenced by depositary receipts issued under the deposit agreement. Depositary receipts will be distributed to the holders of the depositary shares that are sold in the applicable offering. We will incorporate by reference into the registration statement of which this prospectus forms a part the form of any deposit agreement, including a form of depositary receipt, that describes the terms of any depositary shares we are offering before the issuance of the related depositary shares. The following summaries of material provisions of the deposit agreement, the depositary shares and the depositary receipts are subject to, and qualified in their entirety by reference to, all of the provisions of the deposit agreement applicable to a particular offering of depositary shares. We urge you to read the prospectus supplements relating to any depositary shares that are sold under this prospectus, as well as the complete deposit agreement and depositary receipt.

#### **Form**

Pending the preparation of definitive depositary receipts, the depositary may, upon our written order, issue temporary depositary receipts substantially identical to the definitive depositary receipts but not in definitive form. These temporary depositary receipts will entitle their holders to all of the rights of definitive depositary receipts. Temporary depositary receipts will then be exchangeable for definitive depositary receipts at our expense.

#### **Dividends and Other Distributions**

The depositary will distribute all cash dividends or other cash distributions received with respect to the underlying preferred stock to the record holders of depositary shares in proportion to the number of depositary shares owned by those holders.

If there is a distribution other than in cash, the depositary will distribute property received by it to the record holders of depositary shares in proportion to the number of depositary shares owned by those holders, unless the depositary determines that it is not feasible to do so. If this occurs, the depositary may, with our approval, sell the property and distribute the net proceeds from the sale to those holders in proportion to the number of depositary shares owned by them.

The amount distributed to holders of depositary shares will be reduced by any amounts required to be withheld by us or the preferred stock depositary on account of taxes or other governmental charges.

#### **Liquidation Preference**

If a series of preferred stock underlying the depositary shares has a liquidation preference, in the event of our voluntary or involuntary liquidation, dissolution, or winding up, holders of depositary shares will be entitled to receive the fraction of the liquidation preference accorded each share of the applicable series of preferred stock, as set forth in the applicable prospectus supplement.



## **Table of Contents**

### **Withdrawal of Underlying Preferred Stock**

Except as otherwise provided in a prospectus supplement, holders may surrender depositary receipts at the principal office of the depositary and, upon payment of any unpaid amount due to the depositary, be entitled to receive the number of whole shares of underlying preferred stock and all money and other property represented by the related depositary shares. We will not issue any partial shares of preferred stock. If the holder delivers depositary receipts evidencing a number of depositary shares that represent more than a whole number of shares of preferred stock, the depositary will issue a new depositary receipt evidencing the excess number of depositary shares to the holder.

### **Redemption of Depositary Shares**

If the preferred stock underlying any depositary shares we may sell under this prospectus is subject to redemption, the depositary shares will be redeemed from the proceeds received by the depositary resulting from any such redemption, in whole or in part, of that underlying preferred stock. The redemption price per depositary share will be equal to the applicable fraction of the redemption price per share payable with respect to the underlying preferred stock. Whenever we redeem shares of underlying preferred stock that are held by the depositary, the depositary will redeem, as of the same redemption date, the number of depositary shares representing the shares of underlying preferred stock so redeemed. If fewer than all of the depositary shares are to be redeemed, the depositary shares to be redeemed will be selected by lot or proportionately, as may be determined by the depositary.

After the date fixed for redemption, the depositary shares called for redemption will no longer be deemed to be outstanding, and all rights of the holders of the depositary shares will cease, except the right to receive the monies payable and any other property to which the holders were entitled upon the redemption upon surrender to the preferred stock depositary of the depositary receipts evidencing the depositary shares. Any funds deposited by us with the preferred stock depositary for any depositary shares that the holders fail to redeem will be returned to us after a period of two years from the date the funds are deposited.

### **Voting**

Upon receipt of notice of any meeting at which holders of the preferred stock underlying any depositary shares that we may sell under this prospectus are entitled to vote, the depositary will mail the information contained in the notice to the record holders of the depositary shares. Each record holder of the depositary shares on the record date, which will be the same date as the record date for the underlying preferred stock, will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the amount of the underlying preferred stock represented by the holder's depositary shares. The depositary will then try, as far as practicable, to vote the number of shares of preferred stock underlying those depositary shares in accordance with those instructions, and we will agree to take all reasonable actions which may be deemed necessary by the depositary to enable the depositary to do so. The depositary will not vote the underlying preferred stock to the extent it does not receive specific instructions with respect to the depositary shares representing such preferred stock.

### **Conversion of Preferred Stock**

If the prospectus supplement relating to any depositary shares that we may sell under this prospectus states that the underlying preferred stock is convertible into our common stock or other securities, the following will apply. The depositary shares, as such, will not be convertible into any of our securities. Rather, any holder of the depositary shares may surrender the related depositary receipts to the depositary with written instructions that direct us to cause conversion of the preferred stock represented by the depositary shares into or for whole shares of our common stock or other securities, as applicable. Upon receipt of those instructions and any amounts payable by the holder in connection with the conversion, we will cause the conversion using the same procedures as those provided for conversion of the underlying preferred stock. If only some of a holder's depositary shares are converted, a new depositary receipt or receipts will be issued to the holder for any depositary shares not converted.

## **Table of Contents**

### **Amendment and Termination of the Deposit Agreement**

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may at any time be amended by agreement between us and the depositary. However, any amendment which materially and adversely alters the rights of the holders of depositary shares will not be effective until 90 days after notice of that amendment has been given to the holders. Each holder of depositary shares at the time any amendment becomes effective shall be deemed to consent and agree to that amendment and to be bound by the deposit agreement as so amended. The deposit agreement may be terminated by us or by the depositary only if all outstanding depositary shares have been redeemed or converted into any other securities into which the underlying preferred stock is convertible or there has been a final distribution, including to holders of depositary receipts, of the underlying preferred stock in connection with our liquidation, dissolution, or winding up.

### **Charges of Depositary**

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangement. We will also pay charges of the depositary in connection with the initial deposit of the preferred stock, the initial issuance of the depositary shares, any redemption of the preferred stock, and all withdrawals of preferred stock by owners of depositary shares. Holders of depositary receipts will pay transfer, income, and other taxes and governmental charges and other specified charges as provided in the deposit arrangement for their accounts. If these charges have not been paid, the depositary may refuse to transfer depositary shares, withhold dividends and distributions, and sell the depositary shares evidenced by the depositary receipt.

### **Limitation on Liability**

Neither we nor the depositary will be liable if either of us is prevented or delayed by law or any circumstance beyond our control in performing our respective obligations under the deposit agreement. Our obligations and those of the depositary will be limited to performance of our respective duties under the deposit agreement without, in our case, negligence or bad faith or, in the case of the depositary, negligence or willful misconduct. We and the depositary may rely upon advice of counsel or accountants, or upon information provided by persons presenting the underlying preferred stock for deposit, holders of depositary receipts, or other persons believed by us in good faith to be competent and on documents believed to be genuine.

### **Corporate Trust Office of Preferred Stock Depositary**

The preferred stock depositary's corporate trust office will be set forth in the applicable prospectus supplement relating to a series of depositary shares. The preferred stock depositary will act as transfer agent and registrar for depositary receipts, and, if shares of a series of preferred stock are redeemable, the preferred stock depositary will act as redemption agent for the corresponding depositary receipts.

### **Resignation and Removal of Depositary**

The depositary may resign at any time by delivering notice to us of its election to resign. We may remove the depositary at any time. Any resignation or removal will take effect upon the appointment of a successor depositary and its acceptance of the appointment. The successor depositary must be appointed within 60 days after delivery of the notice of resignation or removal and must be a bank or trust company having its principal office in the United States and having a combined capital and surplus of at least \$50,000,000.

### **Reports to Holders**

We will deliver all required reports and communications to holders of the preferred stock to the preferred stock depositary, and it will forward those reports and communications to the holders of depositary shares. Upon request, the preferred stock depositary will provide for inspection to the holders of depositary shares the transfer books of the depositary and the list of holders of receipts; provided that any requesting holder certifies to the preferred stock depositary that such inspection is for a proper purpose reasonably related to such person's interest as an owner of depositary shares evidenced by the receipts.

**Table of Contents**

**DESCRIPTION OF WARRANTS**

**General**

We may issue warrants to purchase common stock (which we refer to as common stock warrants), preferred stock (which we refer to as preferred stock warrants), debt securities (which we refer to as debt security warrants), or depositary shares (which we refer to as depositary share warrants). Any of these warrants may be issued independently or together with any other securities offered by this prospectus and may be attached to or separate from those securities.

While the terms we have summarized below will generally apply to any future warrants we may offer under this prospectus, we will describe the particular terms of any warrants that we may offer in more detail in the applicable prospectus supplement. The terms of any warrants we offer under a prospectus supplement may differ from the terms we describe below.

We may issue the warrants under a warrant agreement, which we will enter into with a warrant agent to be selected by us. Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

We will incorporate by reference into the registration statement of which this prospectus forms a part the form of warrant agreement, including a form of warrant certificate, that describes the terms of the series of warrants we are offering before the issuance of the related series of warrants. The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement applicable to a particular series of warrants. We urge you to read the applicable prospectus supplements related to the warrants that we sell under this prospectus, as well as the complete warrant agreements that contain the terms of the warrants.

We will set forth in the applicable prospectus supplement the terms of the warrants in respect of which this prospectus is being delivered, including, when applicable, the following:

the title of the warrants;

the aggregate number of the warrants;

the price or prices at which the warrants will be issued;

the designation, number, and terms of the securities purchasable upon exercise of the warrants;

the designation and terms of the other securities, if any, with which the warrants are issued and the number of warrants issued with each such security;

the date, if any, on and after which the warrants and the related underlying securities will be separately transferable;

the price at which each underlying security purchasable upon exercise of the warrants may be purchased;

Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

the date on which the right to exercise the warrants will commence and the date on which such right will expire;

the minimum amount of the warrants that may be exercised at any one time;

any information with respect to book-entry procedures;

## **Table of Contents**

the effect of any merger, consolidation, sale, or other disposition of our business on the warrant agreement and the warrants;

any other terms of the warrants, including terms, procedures, and limitations relating to the transferability, exchange, and exercise of such warrants;

the terms of any rights to redeem or call, or accelerate the expiration of, the warrants;

the date on which the right to exercise the warrants begins and the date on which that right expires;

the U.S. federal income tax consequences of holding or exercising the warrants; and

any other specific terms, preferences, rights, or limitations of, or restrictions on, the warrants.

Unless specified in an applicable prospectus supplement, common stock warrants, preferred stock warrants, debt security warrants, or depositary shares warrants will be in registered form only.

A holder of warrant certificates may exchange them for new certificates of different denominations, present them for registration of transfer, and exercise them at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement. Until any common stock warrants, preferred stock warrants, debt security warrants, or depositary shares warrants are exercised, holders of the warrants will not have any rights of holders of the underlying common stock, preferred stock, debt securities, or depositary shares, including any rights to receive dividends or to exercise any voting rights, except to the extent set forth under the heading "Warrant Adjustments" below.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase for cash shares of common stock, preferred stock, debt securities, or depositary shares at the applicable exercise price set forth in, or determined as described in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised by delivering to the corporation trust office of the warrant agent or any other officer indicated in the applicable prospectus supplement (a) the warrant certificate properly completed and duly executed and (b) payment of the amount due upon exercise. As soon as practicable following exercise, we will forward the shares of common stock, preferred stock, debt securities, or depositary shares. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or a part of the exercise price for the warrants.

### **Amendments and Supplements to the Warrant Agreements**

We may amend or supplement a warrant agreement without the consent of the holders of the applicable warrants to cure ambiguities in the warrant agreement, to cure or correct a defective provision in the warrant agreement, or to provide for other matters under the warrant agreement that we and the warrant agent deem necessary or desirable, so long as, in each case, such amendments or supplements do not materially and adversely affect the interests of the holders of the warrants.

### **Warrant Adjustments**

Unless the applicable prospectus supplement states otherwise, the exercise price of, and the number of securities covered by, a common stock warrant, preferred stock warrant, debt security warrant, or depositary



**Table of Contents**

share warrant will be adjusted proportionately if we subdivide or combine our common stock, preferred stock, or depositary shares, as applicable. In addition, unless the prospectus supplement states otherwise, if we, without payment:

issue capital stock or other securities convertible into or exchangeable for common stock or preferred stock, or any rights to subscribe for, purchase, or otherwise acquire any of the foregoing, as a dividend or distribution to holders of our common stock or preferred stock;

pay any cash to holders of our common stock or preferred stock other than a cash dividend paid out of our current or retained earnings or other than in accordance with the terms of the preferred stock;

issue any evidence of our indebtedness or rights to subscribe for or purchase our indebtedness to holders of our common stock or preferred stock; or

issue common stock or preferred stock or additional stock or other securities or property to holders of our common stock or preferred stock by way of spinoff, split-up, reclassification, combination of shares, or similar corporate rearrangement, then the holders of common stock warrants, preferred stock warrants, debt security warrants, and depositary share warrants, as applicable, will be entitled to receive upon exercise of the warrants, in addition to the securities otherwise receivable upon exercise of the warrants and without paying any additional consideration, the amount of stock and other securities and property such holders would have been entitled to receive had they held the common stock, preferred stock, debt securities, or depositary shares, as applicable, issuable under the warrants on the dates on which holders of those securities received or became entitled to receive such additional stock and other securities and property.

Except as stated above, the exercise price and number of securities covered by a common stock warrant, preferred stock warrant, debt security warrant, and depositary share warrant, and the amounts of other securities or property to be received, if any, upon exercise of those warrants, will not be adjusted or provided for if we issue those securities or any securities convertible into or exchangeable for those securities, or securities carrying the right to purchase those securities or securities convertible into or exchangeable for those securities.

Holders of common stock warrants, preferred stock warrants, debt security warrants, and depositary share warrants may have additional rights under the following circumstances:

certain reclassifications, capital reorganizations, or changes of the common stock, preferred stock, or depositary shares, as applicable;

certain share exchanges, mergers, or similar transactions involving us and which result in changes of the common stock, preferred stock, or depositary shares, as applicable; or

certain sales or dispositions to another entity of all or substantially all of our property and assets.

If one of the above transactions occurs and holders of our common stock, preferred stock, debt securities, or depositary shares are entitled to receive stock, securities, or other property with respect to or in exchange for their securities, the holders of the common stock warrants, preferred stock warrants, debt security warrants, and depositary share warrants then outstanding, as applicable, will be entitled to receive upon exercise of their warrants the kind and amount of shares of stock and other securities or property that they would have received upon the applicable transaction if they had exercised their warrants immediately before the transaction.

---

**Table of Contents**

**DESCRIPTION OF PURCHASE CONTRACTS**

We may issue purchase contracts, including contracts obligating holders to purchase from us, and for us to sell to holders, a specific or varying number of debt securities, shares of common stock or preferred stock, depositary shares, warrants, or any combination of the above, at a future date or dates. Alternatively, the purchase contracts may obligate us to purchase from holders, and obligate holders to sell to us, a specific or varying number of debt securities, shares of common stock or preferred stock, depositary shares, warrants, or any combination of the above. The price of the securities subject to the purchase contracts may be fixed at the time the purchase contracts are issued or may be determined by reference to a specific formula described in the purchase contracts. We may issue purchase contracts separately or as a part of units each consisting of a purchase contract and one or more of the other securities described in this prospectus or securities of third parties, including U.S. Treasury securities, securing the holder's obligations under the purchase contract. If we issue a purchase contract as part of a unit, the applicable prospectus supplement will state whether the purchase contract will be separable from the other securities in the unit before the purchase contract settlement date. The purchase contracts may require us to make periodic payments to holders or vice versa and the payments may be unsecured or pre-funded on some basis. The purchase contracts may require holders to secure the holder's obligations in a manner specified in the applicable prospectus supplement, and in certain circumstances, we may deliver newly issued prepaid purchase contracts, often known as prepaid securities, upon release to a holder of any collateral securing such holder's obligations under the original purchase contract.

The applicable prospectus supplement will describe the terms of any purchase contracts in respect of which this prospectus is being delivered, including, to the extent applicable, the following:

whether the purchase contracts obligate the holder or us to purchase or sell, or both purchase and sell, the securities subject to purchase under the purchase contract, and the nature and amount of each of those securities, or the method of determining those amounts;

whether the purchase contracts are to be prepaid or not;

whether the purchase contracts will be issued as part of a unit and, if so, the other securities comprising the unit;

whether the purchase contracts are to be settled by delivery, or by reference or linkage to the value, performance, or level of the securities subject to purchase under the purchase contract;

any acceleration, cancellation, termination, or other provisions relating to the settlement of the purchase contracts; and

whether the purchase contracts will be issued in fully registered or global form.

Material U.S. federal income tax consideration applicable to the purchase contracts and the purchase units will also be discussed in the applicable prospectus supplement.



## **Table of Contents**

### **DESCRIPTION OF UNITS**

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. Units may be offered independently or together with common stock, preferred stock, debt securities, depositary shares, and warrants offered by any prospectus supplement, and may be attached to or separate from those securities. While the terms we have summarized below will generally apply to any future units that we may offer under this prospectus, we will describe the particular terms of any series of units that we may offer in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

We will incorporate by reference into the registration statement of which this prospectus forms a part the form of unit agreement, including a form of unit certificate, if any, that describes the terms of the series of units we are offering before the issuance of the related series of units. The following summaries of material provisions of the units and the unit agreements are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the units that we sell under this prospectus, as well as the complete unit agreements that contain the terms of the units.

#### **General**

We may issue units consisting of common stock, preferred stock, debt securities, depositary shares, and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time, or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including the following:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions of the governing unit agreement that differ from those described below; and

any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities comprising the units. The provisions described in this section, as well as those described under Description of Common Stock, Description of Preferred Stock, Description of Debt Securities, Description of Depositary Shares, and Description of Warrants, will apply to each unit and to any common stock, preferred stock, debt security, depositary share, or warrant included in each unit, respectively.

#### **Issuance in Series**

We may issue units in such amounts and in such numerous distinct series as we determine.

#### **Enforceability of Rights by Holders of Units**

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit, without the consent of the related unit agent or the holder of any other unit, may enforce by appropriate legal action its rights as holder under any security included in the unit.

**Table of Contents**

**Title**

We, the unit agent, and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purposes and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary.

**Table of Contents**

**CERTAIN PROVISIONS OF NEVADA LAW AND  
OUR CHARTER AND BYLAWS**

The following paragraphs summarize certain provisions of the Nevada law and our amended and restated articles of incorporation and bylaws. The summary does not purport to be complete and is subject to and qualified in its entirety by reference to Nevada law and to our amended and restated articles of incorporation and bylaws, copies of which are on file with the SEC as exhibits to reports previously filed by us. See [Where You Can Find More Information](#).

**General**

Certain provisions of our amended and restated articles of incorporation and bylaws and Nevada law could make our acquisition by a third party, a change in our incumbent management, or a similar change in control more difficult, including:

an acquisition of us by means of a tender or exchange offer;

an acquisition of us by means of a proxy contest or otherwise; or

the removal of a majority or all of our incumbent officers and directors.

These provisions, which are summarized below, are likely to discourage certain types of coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that these provisions help to protect our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, and that this benefit outweighs the potential disadvantages of discouraging such a proposal because our ability to negotiate with the proponent could result in an improvement of the terms of the proposal. The existence of these provisions which are described below could limit the price that investors might otherwise pay in the future for our securities.

**Articles of Incorporation and Bylaws**

*Authorized But Unissued Capital Stock.* We have shares of common stock and preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of any securities exchange on which our stock may be listed. We may utilize these additional shares for a variety of corporate purposes, including for future public offerings to raise additional capital or facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a controlling interest in our company by means of a merger, tender offer, proxy contest, or otherwise. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

*Blank Check Preferred Stock.* Our board of directors, without stockholder approval, has the authority under our amended and restated articles of incorporation to issue preferred stock with rights superior to the rights of the holders of common stock. As a result, preferred stock could be issued quickly and easily, could impair the rights of holders of common stock, and could be issued with terms calculated to delay or prevent a change in control or make removal of management more difficult.

*Election of Directors.* Our bylaws provide that a majority of directors then in office may fill any vacancy occurring on our board of directors, even though less than a quorum may then be in office. These provisions may discourage a third party from voting to remove incumbent directors and simultaneously gaining control of our board of directors by filling the vacancies created by that removal with its own nominees.

---

## **Table of Contents**

*Removal of Directors.* Except in certain cases for directors elected by the holders of any series of preferred stock, a director may be removed from office only with cause and only by the affirmative vote of two-thirds or more of the combined voting power of the then issued and outstanding shares of our capital stock entitled to vote in the election of directors, voting together as a single class.

*Stockholder Meetings.* Our bylaws provide that stockholders may not call a special meeting of stockholders. Rather, only our board of directors or such person or persons authorized by our board of directors will be able to call special meetings of stockholders. This provision may discourage another person or entity from making a tender offer, even if it acquired a majority of our outstanding voting stock, because the person or entity could only take action at a duly called stockholders meeting.

### **Anti-takeover Effects of Nevada Law**

#### *Business Combinations with Interested Stockholders*

The business combination with interested stockholders provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statutes, or NRS, generally prohibit a Nevada corporation with at least 200 stockholders of record from engaging in various combination transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by our board of directors prior to the date the interested stockholder obtained such status or the combination is approved by our board of directors and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless:

the combination was approved by our board of directors prior to the person becoming an interested stockholder or the transaction by which the person first became an interested stockholder was approved by our board of directors before the person became an interested stockholder or the combination is later approved by a majority of the voting power held by disinterested stockholders, or

if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.

A combination is generally defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an interested stockholder having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, (c) 10% or more of the earning power or net income of the corporation, and (d) certain other transactions with an interested stockholder or an affiliate or associate of an interested stockholder.

In general, an interested stockholder is a person who, together with affiliates and associates, owns (or within two years, did own) 10% or more of a corporation's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire our company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

#### *Control Share Acquisitions*

The control share provisions of Sections 78.378 to 78.3793, inclusive, of the NRS apply to issuing corporations that are Nevada corporations with at least 200 stockholders of record, including at least 100 stockholders of record who are Nevada residents, and that conduct business directly or indirectly in Nevada.

## **Table of Contents**

The control share statute prohibits an acquirer, under certain circumstances, from voting its shares of a target corporation's stock after crossing certain ownership threshold percentages, unless the acquirer obtains approval of the target corporation's disinterested stockholders. The statute specifies three thresholds: one-fifth or more but less than one-third, one-third but less than a majority, and a majority or more, of the outstanding voting power. Generally, once an acquirer crosses one of the above thresholds, those shares in an offer or acquisition and acquired within 90 days thereof become control shares and such control shares are deprived of the right to vote until disinterested stockholders restore the right. These provisions also provide that if control shares are accorded full voting rights and the acquiring person has acquired a majority or more of all voting power, all other stockholders who do not vote in favor of authorizing voting rights to the control shares are entitled to demand payment for the fair value of their shares in accordance with statutory procedures established for dissenters' rights.

A corporation may elect to not be governed by, or opt out of, the control share provisions by making an election in its articles of incorporation or bylaws, provided that the opt-out election must be in place on the 10th day following the date an acquiring person has acquired a controlling interest, that is, crossing any of the three thresholds described above. We have not opted out of the control share statutes, and will be subject to these statutes if we are an issuing corporation as defined in such statutes.

The effect of the Nevada control share statutes is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of our company.

### **Limitations of Liability and Indemnification of Officers and Directors**

Our articles of incorporation and bylaws limit the liability of directors to the fullest extent permitted by Nevada law. In addition, our amended and restated certificate of incorporation and bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by law.

### **Indemnification for Securities Act Liabilities**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, officers, or controlling persons pursuant to the provisions described in the preceding paragraph, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## **Table of Contents**

### **LEGAL OWNERSHIP OF SECURITIES**

We can issue securities in registered form or in the form of one or more global securities. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depository or warrant agent maintain for this purpose as the holders of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as indirect holders of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

See also the section entitled Description of Debt Securities Form, Transfer, and Exchange above for additional discussion of book entry and certificated form of ownership as such forms of ownership impact the rights and obligations of purchasers of debt securities to be issued under this prospectus.

#### **Book-Entry Holders**

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers. Upon the issuance of a global security, the depository will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal amounts of the book-entry securities represented by the global security beneficially owned by such participants. The accounts to be credited will be designated by any dealers, underwriters, or agents participating in the distribution of the book-entry securities. Ownership of book-entry securities will be shown on, and the transfer of the ownership interests will be effected only through, records maintained by the depository for the related global security (with respect to interests of participants) and on the records of participants (with respect to interests of persons holding through participants). The laws of some states may require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may impair the ability to own, transfer, or pledge beneficial interests in book-entry securities.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depository or its participants. Consequently, for securities issued in global form, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker, or other financial institution that participates in the depository's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

#### **Street Name Holders**

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in street name. Securities held by an investor in street name would be registered in the name of a bank, broker, or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he, she, or it maintains at that institution.

For securities held in street name, we will recognize only the intermediary banks, brokers, and other financial institutions in whose names the securities are registered as the holders of those securities, and we will

## **Table of Contents**

make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

### **Legal Holders**

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name, or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depository participants or customers or by law, to pass it along to the indirect holders but does not do so. Whether and how the holders contact the indirect holders is up to the holders.

### **Special Considerations For Indirect Holders**

If you hold securities through a bank, broker, or other financial institution, either in book-entry form or in street name, you should check with your own institution to determine the following:

how it handles securities payments and notices;

whether it imposes fees or charges;

how it would handle a request for the holders' consent, if ever required;

whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;

how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

### **Global Securities**

A global security is a security that represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms. Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee, or a successor depository, unless special termination situations arise. We describe those situations below under "Special Situations When a Global Security Will Be Terminated." As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank, or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect

holder of a beneficial interest in the global security.



## **Table of Contents**

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

We may at any time and in our sole discretion determine not to have any of the book-entry securities of any series represented by one or more global securities and, in that event, we will issue certificated securities in exchange for the global securities of that series.

### **Special Considerations For Global Securities**

The rights of an indirect holder relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

an investor cannot cause the securities to be registered in his, her, or its name, and cannot obtain non-global certificates for his, her, or its interest in the securities, except in the special situations we describe below;

an investor will be an indirect holder and must look to his, her, or its own bank or broker for payments on the securities and protection of his, her, or its legal rights relating to the securities, as we describe above;

an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;

an investor may not be able to pledge his, her, or its interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges, and other matters relating to an investor's interest in a global security;

we and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security, nor do we or any applicable trustee supervise the depositary in any way;

the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and

financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices, and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

### **Special Situations When a Global Security Will Be Terminated**

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

**Table of Contents**

Unless we provide otherwise in the applicable prospectus supplement, the global security will terminate when the following special situations occur:

if the depositary notifies us that it is unwilling, unable, or no longer qualified under the Exchange Act to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

if we notify any applicable trustee that we wish to terminate that global security; or

if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived. The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular types and series of securities covered by the applicable prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

**Table of Contents**

**PLAN OF DISTRIBUTION**

We may sell the securities described in this prospectus from time to time in one or more of the following ways:

to or through underwriters or dealers,

directly to one or more purchasers,

through agents, or

through a combination of any of those methods of sale.

The prospectus supplement with respect to the offered securities will describe the terms of the offering, including the following:

the name or names of any underwriters or agents,

any public offering price,

the proceeds from such sale,

any underwriting discounts or agency fees and other items constituting underwriters' or agents' compensation,

any over-allotment options under which underwriters may purchase additional securities from us,

any discounts or concessions allowed or reallocated or paid to dealers, and

any securities exchanges on which the securities may be listed.

We may distribute the securities from time to time in one or more of the following ways:

at a fixed public offering price or prices, which may be changed,

at prices relating to prevailing market prices at the time of sale,

at varying prices determined at the time of sale, or

## Edgar Filing: TherapeuticsMD, Inc. - Form 424B5

at negotiated prices.

Unless otherwise indicated in the applicable prospectus supplement, if we use underwriters for a sale of securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities in one or more transactions, including negotiated transactions, at a fixed public offering price, or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. Unless otherwise indicated in a prospectus supplement, the underwriters will be obligated to purchase all the securities of the series offered if they purchase any of the securities of that series. We may change from time to time any initial public offering price and any discounts or concessions the underwriters allow or reallow or pay to dealers. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement naming the underwriter the nature of any such relationship. We may designate agents who agree to use their reasonable efforts to solicit purchases for the period of their appointment or to sell securities on a continuing basis. We may also sell securities directly to one or more purchasers without using underwriters or agents.

Underwriters, dealers, or agents may receive compensation in the form of discounts, concessions, or commissions from us or from purchasers of the securities as their agents in connection with the sale of the securities. These underwriters, dealers, or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions, or profits on resale received by underwriters, dealers, or agents may be treated as underwriting discounts and commissions. Each prospectus supplement will identify any underwriter, dealer, or agent and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

## **Table of Contents**

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is listed on the OTCQB. We may elect to apply for listing of our common stock on another securities exchange or to list any other class or series of securities on any exchange, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

In connection with any offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, and penalty bids in accordance with Regulation M under the Exchange Act.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Over-allotment involves sales by the underwriters of shares of our common stock in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of our common stock over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares of our common stock involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares of our common stock in the open market.

Syndicate covering transactions involve purchases of our common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares of our common stock available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option so that if there is a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares of our common stock in the open market after the pricing of any offering that could adversely affect investors who purchase in that offering.

Penalty bids permit the representatives of the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, over-allotments, syndicate covering transactions, and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the OTCQB or otherwise and, if commenced, may be discontinued at any time.

Underwriters, dealers, and agents may be entitled under agreements entered into with us to indemnification against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments they may be required to make in respect of these liabilities thereof. Underwriters, dealers, and agents and their affiliates may be customers of, may engage in transactions with, or perform services for us in the ordinary course of business for which they receive compensation.

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities offered hereby will be passed upon by Greenberg Traurig, LLP, Phoenix, Arizona.

**EXPERTS**

The consolidated financial statements of TherapeuticsMD, Inc. as of December 31, 2011 appearing in TherapeuticsMD, Inc.'s Annual Report (Form 10-K) for the fiscal year ended December 31, 2011 have been audited by Rosenberg Rich Baker Berman & Company, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. The consolidated financial statements of TherapeuticsMD, Inc. as of December 31, 2010 appearing in TherapeuticsMD, Inc.'s Annual Report (Form 10-K) for the fiscal year ended December 31, 2010 have been audited by Parks & Company, LLC, independent registered accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firms as experts in accounting and auditing.

Table of Contents

**29,411,765 Shares**

**TherapeuticsMD, Inc.**

**Common Stock**

**PROSPECTUS SUPPLEMENT**

*Sole Book-Running Manager*

**Jefferies**

*Co-Manager*

**Noble Financial Capital Markets**

March 14, 2013