TherapeuticsMD, Inc.
Form 424B7
March 21, 2014
Table of Contents

Filed Pursuant to Rule 424(b)(7)
Registration No. 333-193558

PROSPECTUS SUPPLEMENT

(To Prospectus dated February 3, 2014)

9,000,000 Shares

TherapeuticsMD, Inc.

Common Stock

The selling stockholders named in this prospectus supplement under the caption Selling Stockholders are offering 9,000,000 shares of our common stock in this offering. The selling stockholders will pay all underwriting discounts and selling commissions applicable to the sale of the shares pursuant to this offering. We will not receive any of the proceeds from sales of any of the shares subject to this offering.

Our common stock is listed on the NYSE MKT under the symbol TXMD. On March 20, 2014, the last reported sale price of our common stock on the NYSE MKT was $7.26 per share.

Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page S-5 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.

	PER SHARE	TOTAL
Public Offering Price	$ 7.10	$ 63,900,000.00
Underwriting Discounts and Commissions	$ 0.402925	$ 3,626,325.00
Proceeds to the selling stockholders, before expenses	$ 6.697075	$ 60,273,675.00

Delivery of the shares of common stock is expected to be made on or about March 26, 2014. Certain of the selling stockholders have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,350,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discount payable by the selling stockholders will be $4,170,273.75 and the total proceeds to the selling stockholders, before expenses, will be $69,314,726.25.

Joint Book-Running Managers

Jefferies **Stifel**

Co-Managers

Cowen and Company **Mizuho Securities**

Prospectus Supplement dated March 20, 2014

Table of Contents

TABLE OF CONTENTS

	Page
Prospectus Supplement	
About this Prospectus Supplement	S-ii
Special Note About Forward-Looking Information	S-iii
Prospectus Supplement Summary	S-1
Risk Factors	S-5
Use of Proceeds	S-27
Market Price of our Common Stock and Related Stockholder Matters	S-27
Selling Stockholders	S-28
Material U.S. Federal Income Tax Considerations for Non-U.S. Holders of Common Stock	S-31
Underwriting	S-35
Legal Matters	S-42
Experts	S-42
Incorporation of Certain Documents by Reference	S-42
Prospectus	
Prospectus Summary	1
Risk Factors	3
Special Note Regarding Forward-Looking Statements	3
Use of Proceeds	4
Selling Stockholders	5
Plan of Distribution	5
Legal Matters	7
Experts	7
Incorporation of Certain Information by Reference	8
Where You Can Find More Information	9

Table of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

Unless the context otherwise requires, all references in this prospectus supplement to TherapeuticsMD, TXMD, Company, our 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 BocaGreenMD.

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 the SEC, using a shelf registration process. Under this shelf registration process, the selling stockholders named in this prospectus supplement under the caption Selling Stockholders are offering to sell shares of our common stock using this prospectus supplement and the accompanying prospectus. Both this prospectus supplement and the accompanying prospectus include important information about us, our securities being offered and other information you should know before investing. This prospectus supplement also adds, updates, and changes information contained in the accompanying prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as additional information described in the section entitled Incorporation of Certain Documents by Reference in this prospectus supplement before investing in our securities.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement, the accompanying prospectus, and any free writing prospectus authorized by us. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document filed prior to the date of this prospectus supplement and incorporated by reference, the information in this prospectus supplement will control. We have not, the selling stockholders have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, the selling stockholders 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. The information in this prospectus supplement and the accompanying prospectus is accurate only as of the date it is presented. Our business, financial condition, results of operations and prospects may have changed since these dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference into 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.

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.

vitaMedMD®, TherapeuticsMD®, and BocaGreenMD® are registered trademarks of our company. This prospectus supplement also contains trademarks and trade names of other companies.

Table of Contents

SPECIAL NOTE ABOUT FORWARD LOOKING INFORMATION

This prospectus supplement, including the sections entitled Prospectus Supplement Summary and Risk Factors, the accompanying prospectus, and the documents incorporated by reference herein and therein (including the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013) 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, contemplates, believes, estimates, predicts, potential, or 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 in this prospectus supplement and in the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013. Some of the key factors that could cause actual results to differ from our expectations include the following:

- our operating losses incurred since inception and anticipated for the foreseeable future;
- our ability to maintain or increase sales of our products;
- the ability of our products to produce the intended effects;
- our ability to develop and commercialize our hormone therapy drug candidates;
- our ability to obtain additional financing necessary to complete the development and commercialization of our hormone therapy drug candidates;
- our lack of experience in bringing a drug to regulatory approval;
- the length, cost, and uncertain results of our clinical trials;

delays, suspensions, or discontinuation of our clinical trials;

the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates;

our reliance on third-parties to conduct our clinical trials and research and development;

the effects of laws, regulations, and enforcement;

our dependence on third-party manufacturers;

our ability to gain and retain market acceptance for our hormone therapy drug candidates;

the competitive nature of the industries in which we conduct our business;

the availability of reimbursement from government authorities and health insurance companies for our products;

the impact of product liability lawsuits;

Table of Contents

the influence of extensive and costly government regulation;

the effect of governmental regulations on our business;

the validity of the trading price of our common stock; and

the concentration of power in our stock power in our stock ownership.

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 Documents by Reference in this prospectus supplement and under Incorporation of Certain Information by Reference in 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, in our Annual Report on Form 10-K for the year ended December 31, 2013 and in other documents incorporated herein by reference.

Our Company

We are a women s health care product company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials are 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 hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins and cosmetics.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our hormone therapy drug candidates: TX 12-001HR, our oral combination of progesterone and estradiol; TX 12-002HR, our oral progesterone alone; TX 12-003HR, our oral estradiol alone; and TX 12-004HR, our vaginal suppository estradiol alone.

Hormone Therapy Market

The menopause hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. On November 27, 2013, the Drug Quality and Security Act became law and the FDA was given additional oversight over compounding pharmacies. We believe FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals, when produced and sold by compounding pharmacies, are not easily measured or monitored. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies approximate $1.5 billion per year and the FDA-approved market approximates $625 million per year. Our phase 3 trials are intended to establish an indication of the safety and efficacy of our bioidentical drug candidates at specific dosage levels. We intend our hormone therapy drug candidates, if approved, to provide hormone therapies with well characterized safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bioidentical market. This aim is based on our belief that our drug candidates will offer advantages in terms of demonstrated safety and efficacy consistency in the hormone dose, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains than custom order or formulation by individual compounders.

Table of Contents

Pipeline of our Hormone Therapy Drug Candidates

TX 12-001HR

TX 12-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman s body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone (biologically identical or bioidentical to the estradiol and progesterone produced by the ovaries), would be approved for use in a single combined product. According to Source Healthcare Analytics, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately $625 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-002HR

TX 12-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea 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 will be similarly effective to traditional treatments, but may be effective at lower dosages. According to Source Healthcare Analytics, the total FDA-approved market for oral progestin was approximately $364 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-003HR

TX 12-003HR is a natural estradiol formulation. This hormone therapy drug candidate would be chemically identical to the hormones that naturally occur in a woman s body. We currently do not have plans to further develop this hormone therapy drug candidate. According to Source Healthcare Analytics, the total FDA-approved market for oral estradiol was approximately $130 million in U.S. sales for the 12 months ended December 31, 2013.

TX-12-004HR

TX 12-004HR is a vaginal suppository estradiol drug candidate for the treatment of vulvar and vaginal atrophy, or VVA, in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. According to Source Healthcare Analytics, the total FDA-approved market for VVA treatment was approximately $1 billion in U.S. sales for the 12 months ended December 31, 2013.

Preclinical Development

Based upon leveraging our hormone platform technology, we have seven preclinical projects that include development of our proposed combination estradiol and progesterone and progesterone-alone products in a topical cream and transdermal patch form. We plan to advance these projects into the next stages of development as financial and personnel resources become available. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to South Healthcare Analytics, the total FDA-approved menopause-related market for estrogen alone and in combination was

approximately $3.3 billion in U.S. sales for the 12 months ended December 31, 2013.

Current Products

As we continue the clinical development of our hormone therapy drug candidates, we continue to market our prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal

Table of Contents

vitamins, iron supplements, vitamin D supplements, natural menopause relief products, and cosmetic stretch mark creams under our vitaMedMD® brand name and duplicate formulations of our prescription prenatal vitamin products, also referred to as generic formulations, under our BocaGreenMD® Prena1 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 Growth Strategy

Our goal is to become the women s health care company recommended by health care 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 systems of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and (2) demonstrate equivalent clinical efficacy 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 combination products, we believe that our hormone therapy drug candidate for combined 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.

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 in the next 18 months.

Introducing New Products. We plan to introduce a new prescription prenatal vitamin product under our branded vitaMedMD name and our generic Prena1 name in the first quarter of 2014, as well as the development of our hormone therapy drug candidates 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 combination estradiol and progesterone drug candidate 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 Offices

We are a Nevada corporation. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmd.com*, *www.vitamedmdrx.com*, and *www.bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus supplement.

Table of Contents

The Offering

Common stock offered by the selling stockholders	9,000,000 shares
Common stock outstanding before and after this offering	145,067,060 shares
Underwriters option to purchase additional shares	Certain of the selling stockholders have granted the underwriters an option to purchase up to an additional 1,350,000 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.
Use of proceeds	We will not receive any of the proceeds from this offering.
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-5 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.
Common stock symbol	Our common stock is listed on the NYSE MKT under the symbol TXMD.
Lock-Up agreements	The selling stockholders have agreed with the underwriters that, without the prior written consent of Jefferies LLC, subject to certain exceptions, neither we nor the selling stockholders will, for a period of 90 days, following the date of this prospectus supplement, offer or contract to sell any of our common stock.

The number of shares of common stock outstanding before and after this offering is based on 144,976,757 shares outstanding on December 31, 2013 and excludes the following as of that date:

- outstanding options representing the right to purchase a total of 15,632,742 shares of common stock at a weighted average exercise price of $1.44 per share;
- outstanding restricted stock units representing the right to acquire a total of 50,000 shares of common stock;

outstanding warrants representing the right to purchase a total of 14,293,499 shares of common stock at a weighted-average exercise price of $1.79 per share; and

17,267,990 shares of common stock reserved for future issuance under our non-qualified stock option plans. 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 and the risks described under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013, 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, 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 $28 million, $35 million, and $13 million for the years ended December 31, 2013, 2012, and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of approximately $81 million. We have generated limited revenue and have funded our operations to date primarily from public and private sales of equity and private sales of 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 hormone therapy drug candidates. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our hormone therapy drug candidates. 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.

We currently derive all of our revenue from sales of our women s health care 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 care 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 2013, 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:

- the presence of new or existing competing products, including generic copies of our prescription dietary supplement products;

- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;

changed or increased regulatory restrictions or regulatory actions by the FDA;

changes in health care laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal health care programs;

the impact or efficacy of any price increases we may implement in the future;

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

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 to seek approval for and commercialize our hormone therapy drug candidates 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 hormone therapy drug candidates 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 hormone therapy drug candidates 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 four hormone therapy drug candidates, which the FDA has made effective and which permit us to conduct clinical testing on these proposed products. We intend to clinically test three of those drug candidates. However, we may not be able to complete the development of these drug candidates, the results of the clinical trials may not be sufficient to support 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 hormone therapy drug candidates if we fail to obtain additional financing.

We need substantial amounts of cash to complete the clinical development of our hormone therapy drug candidates. 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 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:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;

Table of Contents

seek collaborators for our hormone therapy drug candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and

license, potentially on unfavorable terms, our rights to our hormone therapy drug candidates 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 hormone therapy drug candidates. 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 hormone therapy drug candidates, 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 hormone therapy drug candidates, 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.

Three hormone therapy drug candidates are currently in various stages of clinical testing. We have recently begun phase 3 clinical trial of our estradiol and progesterone combination and our progesterone alone drug candidates. 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 hormone therapy drug candidates 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 hormone therapy drug candidates. 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:

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

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 hormone therapy drug candidates 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 hormone therapy drug candidates, 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 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 hormone therapy drug candidates 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 hormone therapy drug candidates that we seek to develop. As a result, our financial results and the commercial prospects for our hormone therapy drug candidates 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 hormone therapy drug candidates. 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 hormone therapy drug candidates.

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 hormone therapy drug candidates.

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 drug 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 hormone therapy drug candidates, 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 hormone therapy drug candidates 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 hormone therapy drug candidates, 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 hormone therapy drug candidates 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 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 hormone therapy drug candidates 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

Table of Contents

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 cGMPs regulations. If we or a regulatory agency discovers previously unknown problems with a product, 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 Healthcare 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:

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or

exclude us from providing our products to those participating in government health care 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 health care products and our hormone therapy drug candidates 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 health care products. For example, we depend on Lang to supply approximately 98% of our vitaMedMD products. We also rely on third-party contract manufacturing organizations, or CMOs to supply our hormone therapy drug candidates 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 hormone therapy drug candidates. We intend to pursue long-term manufacturing agreements, but we may not be able to negotiate such agreements on acceptable terms, if at all.

In addition, regulatory requirements could pose barriers to the manufacture of our products, including our hormone therapy drug candidates. 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 hormone therapy drug candidates, 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 secure the applicable approval for their manufacturing facilities. If these facilities are not approved for the commercial manufacture of our existing products or our hormone therapy drug candidates, 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 hormone therapy drug candidates. 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 hormone therapy drug candidates 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 hormone therapy drug candidates, which could impair our ability to supply our hormone therapy drug candidates 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 hormone therapy drug candidates 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 hormone therapy drug candidates, 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 hormone therapy drug candidates, by physicians, patients, and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our hormone therapy drug candidates are approved, if at all;

acceptance by physicians and payors of each product as safe and effective treatment;

the cost of treatment in relation to alternative treatments, including numerous generic drug products;

the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;

the availability and efficacy of competitive drugs;

Table of Contents

the effectiveness of our sales force and marketing efforts;

the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;

the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;

limitations or warnings contained in a product s FDA-approved labeling; and

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 hormone therapy drug candidates, 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.

Our products, including our hormone therapy drug candidates 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 hormone therapy drug candidates 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.

Coverage and 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 hormone therapy drug candidates, will depend on coverage and reimbursement policies and may be affected by health care 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 hormone therapy drug candidates, 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 hormone therapy drug candidates.

Table of Contents

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care 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 hormone therapy drug candidates, 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 Reconciliation Act, or collectively, PPACA, became law in the United States. The goal of PPACA is to reduce the cost of health care and substantially change the way health care 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.

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 hormone therapy drug candidates, if approved. We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed health care, 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 hormone therapy drug candidates 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 hormone therapy drug candidates 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

Table of Contents

to limit commercialization of our existing products or hormone therapy drug candidates, 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:

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

Table of Contents

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 hormone therapy drug candidates to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations, and prospects.

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 health care 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:

the federal health care 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 health care programs such as the Medicare and Medicaid programs;

Table of Contents

- 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 health care programs that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care 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 health care providers and ownership of their stock by health care 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 were required to begin data collection on August 1, 2013 and will be required to 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 health care 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. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Federal or state regulatory authorities may challenge our current or future activities under these laws. 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-based compensation that vests over time. The value to employees of stock-based compensation will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our

efforts to retain valuable employees, members of our management, scientific, and

Table of Contents

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:

accurately anticipate customer needs;

innovate and develop new products;

Table of Contents

successfully commercialize new products in a timely manner;

competitively price our products in the market;

procure and maintain products in sufficient volumes and in a timely manner; and

differentiate our product offerings from those of our competitors.

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, 2013, 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 drug 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 hormone therapy drug candidates, 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 health care 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 health care 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

Table of Contents

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.

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 hormone therapy drug candidates and other products in development.

We plan to seek to obtain market exclusivity for our hormone therapy drug candidates 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 hormone therapy drug candidates, 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 hormone therapy drug candidates 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 hormone therapy drug candidates 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 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:

the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;

patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable;

Table of Contents

the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;

we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;

we or our licensors were not the first inventors to file patent applications for these technologies in the United States or were not the first to file patent applications directed to these technologies abroad;

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;

future drug candidates may not be patentable;

others will claim rights or ownership with regard to patents and other proprietary rights that we hold or license;

delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; and

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 third parties may 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 hormone therapy drug candidates. 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 USPTO or foreign patent regulatory authorities to determine our rights in the technologies, which may be time-consuming and expensive. Moreover, issued patents may be challenged during in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we, 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 hormone therapy drug candidates 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 relevant 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 drug 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

Table of Contents

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. 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 drug 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 drug 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 drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug 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.

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:

- 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;

- 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;

- 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;

- 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; or

- 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 drug 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 drug 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 in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. 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.

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.

Table of Contents

Risks Related to 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 on NYSE MKT 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:

- any delay in commencement of our phase 3 clinical trials for our hormone therapy drug candidates;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our hormone therapy drug candidates 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;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our hormone therapy drug candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate clinical supply for our hormone therapy drug candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;

the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;

disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

the inability to effectively manage our growth;

actual or anticipated variations in quarterly operating results;

the failure to meet or exceed the estimates and projections of the investment community;

the overall performance of the U.S. equity markets and general political and economic conditions;

announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;

additions or departures of key scientific or management personnel;

adverse market reaction to any indebtedness we may incur or securities we may issue in the future;

sales of our common stock by us or our stockholders in the future;

significant lawsuits, including patent or stockholder litigation;

changes in the market valuations of similar companies;

the trading volume of our common stock;

Table of Contents

increases in our common stock available for sale upon expiration of lock-up agreements;

effects of natural or man-made catastrophic events or other business interruptions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general 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 December 31, 2013, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 77% of our common stock on an as 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 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 is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain 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 for future periods as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore 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. 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.

Table of Contents

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:

- 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;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- 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 a company, 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 may experience future dilution as a result of future equity offerings and other issuances of our common stock or other securities. In addition, this offering and future equity offerings and other issuances of our common stock or other securities may adversely affect our common stock price.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering.

As of December 31, 2013, there were outstanding options representing the right to purchase a total of 15,632,742 shares of common stock, outstanding restricted stock units representing the right to acquire a total of 50,000 shares of common stock, outstanding warrants representing the right to purchase a total of 14,293,499 shares of common stock, and 17,267,990 shares of common stock reserved for future issuance under our non-qualified stock option plans. You will incur dilution upon exercise of any outstanding stock options or warrants, upon vesting of any outstanding restricted stock units or upon the issuance of shares of common stock under our stock incentive programs.

In addition, the sale of shares in this offering and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

Table of Contents

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholders pursuant to this offering. All proceeds from this offering will be solely for the account of the selling stockholders.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information on Common Stock

Since April 23, 2013, our common stock has been listed on the NYSE MKT under the symbol TXMD. Prior to that time, our common stock was quoted on the OTCQB. The following table sets forth for the periods indicated the high and low bid or sales prices of our common stock on the OTCQB and the NYSE MKT, as applicable. The below quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. Prices listed in 2011 are historic prices that have been adjusted to reflect the 1:100 reverse split that was effective on October 3, 2011.

	High	Low
2014		
First Quarter (through March 20, 2014)	$ 9.01	$ 4.86
2013		
Fourth Quarter	$ 5.50	$ 2.86
Third Quarter	$ 3.18	$ 2.03
Second Quarter	$ 3.23	$ 1.73
First Quarter	$ 3.70	$ 1.65
2012		
Fourth Quarter	$ 3.50	$ 1.25
Third Quarter	$ 3.60	$ 2.61
Second Quarter	$ 2.84	$ 2.06
First Quarter	$ 2.50	$ 1.43
2011		
Fourth Quarter	$ 1.70	$ 0.51
Third Quarter	$ 4.00	$ 1.00
Second Quarter	$ 7.00	$ 1.00
First Quarter	$ 10.00	$ 2.00

On March 20, 2014, the closing sale price of our common stock was $7.26 per share. On March 20, 2014, there were approximately 330 holders of record of our common stock.

Dividends

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

SELLING STOCKHOLDERS

We have registered 12,000,000 shares of our common stock for sale by holders of our common stock. The following table sets forth:

- The number and percent of shares of our common stock that the selling stockholders beneficially owned prior to the offering of the shares under this prospectus supplement;
- The number of shares of our common stock that may be offered hereby; and
- The number and percent of shares of our common stock to be beneficially owned by the selling stockholders after the offering of the shares.

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 March 21, 2014. Our calculation of the percentage of beneficial ownership is based on 145,067,060 shares of our common stock outstanding as of March 17, 2014. 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.

	Shares Beneficially Owned Prior to the Offering		Shares Offered	Shares Beneficially Owned after the Offering	
Name of Selling Stockholder	**Number**	**Percent**	**for Sale [1]**	**Number**	**Percent**
Robert Finizio[2]	24,313,496	16.5%	982,053	23,331,443	15.8%
John C.K. Milligan Revocable Trust U/A 08/10/2009, as amended 11/22/2011[3]	8,952,311	6.0%	353,412	8,598,899	5.8%
BF Investment Enterprises, Ltd.[4]	9,241,549	6.3%	421,268	8,820,281	6.0%
Nicholas Segal[5]	1,002,317	*	30,000	972,317	*
Gregory Segal[6]	507,496	*	20,000	487,496	*
Fourth Generation Private Equity Partners[7]	4,186,601	2.9%	1,600,000	2,586,601	1.8%
Patricia Lieberman[8]	1,087,859	*	400,000	687,859	*
Reich Family L.P.[9]	1,741,948	1.2%	500,000	1,241,948	*
Gregory G. Mario	609,163	*	189,163	420,000	*
Mario Family Partners LP[10]	1,207,127	*	407,127	800,000	*
DJA Spring Investments L.L.C.[11]	583,412	*	400,000	183,412	*
SGH Holdings, LLC[12]	417,104	*	200,000	217,104	*
Anthony Aquino	293,894	*	250,000	43,894	*
Bradley Douglas	266,715	*	241,715	25,000	*

Seth Becker	69,348	*	44,348	25,000	*
Steven S. Williamson[13]	194,342	*	102,285	92,057	*
Joel Christopher Work	53,344	*	33,344	20,000	*
Mitchell R. Work[14]	102,441	*	40,000	62,441	*
Daniel Kandler	2,941,945	2.0%	1,441,945	1,500,000	1.0%
Donald J. Duberstein	583,432	*	150,000	433,432	*
James Nuckols	193,340	*	193,340		*
Gerald B. Cramer Revocable Trust[15]	3,245,350	2.2%	1,000,000	2,245,350	1.5%

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

Table of Contents

(1) The table does not give effect to the sale of additional shares if the underwriters exercise their option to purchase 1,350,000 additional shares from certain of the selling stockholders. If such option is exercised in full, the following stockholders will sell up to the following number of additional shares:

Robert Finizio	754,680
John C.K. Milligan Revocable Trust U/A 08/10/2009, as amended 11/22/2011.	271,588
BF Investment Enterprises, Ltd.	323,732

(2) Includes (i) 2,122,910 shares issuable upon the exercise of vested stock options, and (ii) 179,000 shares issuable upon the exercise of a vested warrant. Mr. Finizio has served as our Chief Executive Officer and director since October 2011.

(3) Represents (i) 4,245,599 shares held by John C.K. Milligan Revocable Trust U/A 08/10/2009, as amended 11/22/2011, or the Trust, (ii) 1,472,419 shares held by Goldman Sachs & Co f/b/o John Milligan IRA, (iii) 250,000 shares held directly by John Milligan, (iv) 2,743,921 shares issuable to Mr. Milligan upon the exercise of vested stock options, and (v) 240,372 shares issuable to Mr. Milligan upon the exercise of vested warrants. John C.K. Milligan IV serves as the trustee and is the beneficiary of the Trust. Mr. Milligan has served as our President, Secretary, and director since October 2011.

(4) Represents (i) 7,157,267 shares held by BF Investment Enterprises, Ltd., or BF Investment, (ii) 297,000 shares held by Brian Bernick and Beth Familant, as tenants by the entirety, (iii) 3,000 shares held by BF Management, LLC, a general partner of BF Investment, (iv) 1,722,910 shares issuable to BF Investment upon the exercise of vested stock options, and (v) 61,372 shares issuable to BF Investment upon the exercise of vested warrants. Brian Bernick, M.D. serves as the Manager of BF Management, LLC. Dr. Bernick, together with his wife as tenants by the entirety, hold (x) a 75% membership interest in BF Management, LLC, and (y) a 74% limited partner interest in BF Investment. Dr. Bernick and his wife, individually, hold an aggregate of 1% limited partner interest in BF Investment. Dr. Bernick exercises sole voting and dispositive power over the shares held by BF Investment. Accordingly, Dr. Bernick may be deemed to beneficially own the shares owned by BF Investment. Dr. Bernick disclaims beneficial ownership of any such shares in which he does not have a pecuniary interest. Dr. Bernick has served as our Chief Medical Officer from 2012 to 2013, Chief Clinical Officer since November 2013, and our director since October 2011.

(5) Represents (i) 245,485 shares held directly by Nick Segal, (ii) 192,057 shares issuable to Nick Segal upon the exercise of vested stock options, (iii) Nick Segal s aggregate direct and indirect pro rata portion (146,560 shares) of the shares held by Seavest Capital Ventures, LLC, or Seavest, (iv) Nick Segal s pro rata portion (411,107 shares) of the shares held by Fourth Generation Private Equity Partners, or Fourth Generation and (v) Nick Segal s pro rata portion (7,108 shares) of the shares issuable to Fourth Generation upon the exercise of a vested warrants. Nick Segal (x) directly holds an 11.5811% interest in Fourth Generation, (y) directly holds a 4.995% interest in Seavest, and (z) indirectly holds a 4.165% interest, through his ownership interest in Fourth Generation, in Seavest. Nick Segal does not have voting or dispositive power over the shares held by Fourth Generation and Seavest. Richard Segal, in his official capacity, exercises sole voting and dispositive power over the shares held by Fourth Generation. Seavest Inc., as the manager of Seavest, exercises sole voting and dispositive control over the shares held by Seavest. Seavest Inc. is governed by a board of directors, with Richard Segal and Douglas Ray constituting all of the members of the board of directors.

(6) Represents (i) 122,743 shares held directly by Greg Segal, (ii) Greg Segal s pro rata portion (326,231 shares) of the shares held by Fourth Generation, (iii) Greg Segal s indirect pro rata portion (52,882 shares) of the shares held by Seavest, and (iv) Greg Segal s pro rata portion (5,640 shares) of the shares issuable to Fourth Generation upon the exercise of a vested warrant. Greg Segal (x) directly holds a 9.190% interest in Fourth Generation, and

(y) indirectly holds a 3.3051% interest in Seavest. Greg Segal does not have voting or dispositive power over the shares held by Fourth Generation and Seavest. Richard Segal, in his official capacity, exercises sole voting and dispositive power over the shares held by Fourth Generation. Seavest Inc., as the manager of Seavest, exercises sole voting and dispositive control over the shares held by

Table of Contents

Seavest. Seavest Inc. is governed by a board of directors, with Richard Segal and Douglas Ray constituting all of the members of the board of directors.

(7) Represents (i) 3,549,805 shares held directly by Fourth Generation, (ii) 61,372 shares issuable upon the exercise of a vested warrant, and (iii) Fourth Generation s pro rata portion (575,424 shares) of the shares held by Seavest. Fourth Generation holds a 35.964% interest in Seavest. Richard Segal, in his official capacity, exercises sole voting and dispositive power over all such shares.

(8) Represents (i) 800,147 shares held directly by Ms. Lieberman, and (ii) Ms. Lieberman s pro rata portion (287,712 shares) of the shares held by Seavest. Patricia Lieberman directly holds a 17.982% interest in Seavest. Ms. Lieberman does not have voting or dispositive power over the shares held by Seavest. Richard Segal, in his official capacity, exercises sole voting and dispositive power over the shares held by Seavest.

(9) Includes 265,943 shares issuable upon the exercise of a vested warrant. Mitchell Krassan and E. Gerald Riesenbach, in their official capacities with respect to Reich Family L.P., share voting and investment control over the shares held by Reich Family L.P., or Reich LP. Accordingly, Messrs. Krassan and Riesenbach may be deemed to beneficially own the shares owned by Reich LP. Messrs. Krassan and Riesenbach disclaim beneficial ownership of any such shares in which they do not have a pecuniary interest. Mr. Krassan has served as our Executive Vice President and Chief Strategy Officer since October 2011.

(10) Christopher B. Mario exercise sole voting and dispositive power over the shares held by Mario Family Partners L.P., or MFP. Christopher B. Mario is the limited partner of MFP and is the Manager of Melmotte LLC, a general partner of MFP.

(11) Adam Spring is the Manager of DJA Spring Investments L.L.C., or DJA, and exercises sole voting and dispositive power over the shares held by DJA.

(12) Includes 147,291 shares issuable upon the exercise of vested stock options. Navneet Gosal is the sole member of SGH Holdings, LLC, or SGH, and exercises sole voting and dispositive power over the shares held by SGH.

(13) Includes 92,057 shares issuable upon the exercise of vested stock options.

(14) Includes 49,097 shares issuable upon the exercise of vested stock options.

(15) Represents (i) 2,745,350 shares held by Gerald B. Cramer Revocable Trust, or the Cramer Trust, and (ii) 500,000 shares held by Gerald and Daphna Cramer Family FDN. Gerald B. Cramer is the trustee and beneficiary of the Cramer Trust and exercises sole voting and dispositive power over the shares held by the Cramer Trust.

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 purchased by the investor 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:

- an individual who is a citizen or resident of the United States;
- 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;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- 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 the 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:

- insurance companies;
- tax-exempt organizations;
- financial institutions;

regulated investment companies;

tax-qualified retirement plans;

brokers or dealers in securities;

investors that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;

S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;

controlled foreign corporations;

passive foreign investment companies; and

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.

Table of Contents

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 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:

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;

Table of Contents

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

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.

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

Table of Contents

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 July 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 20, 2014 among us, the selling stockholders, and Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, as representatives of the underwriters named below and the joint book-running managers of this offering, the selling stockholders have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from the selling stockholders, the number of shares of common stock shown opposite its name below:

Underwriter	Number of Shares of Common Stock
Jefferies LLC	3,191,630
Stifel, Nicolaus & Company, Incorporated	3,191,630
Cowen and Company, LLC	1,744,493
Mizuho Securities USA Inc.	872,247
Total	9,000,000

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 and the selling stockholders 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 the selling stockholders 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 $0.241755 per share of common stock. After the offering, the public offering price and concession and reallowance 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 the selling stockholders are to pay the underwriters and the proceeds, before expenses, to the selling stockholders 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	$ 7.10	$ 7.10	$ 63,900,000.00	$ 73,485,000.00
Underwriting discounts and commissions paid by the selling stockholders	$ 0.402925	$ 0.402925	$ 3,626,325.00	$ 4,170,273.75
Proceeds to the selling stockholders, before expenses	$ 6.697075	$ 6.697075	$ 60,273,675.00	$ 69,314,726.25

We estimate expenses payable by the selling stockholders in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $165,000.

Option to Purchase Additional Shares

Certain of the selling stockholders 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 1,350,000 shares from them 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.

Listing

Our common stock is stock is listed on the NYSE MKT under the symbol TXMD.

No Sales of Similar Securities

We, our officers and directors and the selling stockholders have agreed, subject to specified exceptions, not to, among other things, directly or indirectly:

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-l(h) under the Exchange Act, or

otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or

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:

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

Table of Contents

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,

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.

Jefferies LLC may in its 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, the selling stockholders nor any of the underwriters make 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.

Table of Contents

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 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.

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.

Disclaimers About Non-U.S. Jurisdictions

Australia

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

a) You confirm and warrant that you are either:

a sophisticated investor under section 708(8)(a) or (b) of the Corporations Act;

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

a professional investor within the meaning of section 708(11)(a) or (b) of the Corporations Act.

Table of Contents

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 supplement 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 supplement 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) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) 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 underwriter for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any shares of our common stock 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 any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, 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.

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 has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus supplement may not be issued, circulated or distributed in Hong Kong, and the

Table of Contents

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 supplement 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), or 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 has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus supplement 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, or 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:

a) 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

b) 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 such securities under Section 275 of the SFA except:

i) 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 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;

ii) where no consideration is given for the transfer; or

iii) 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, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus supplement has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art.

Table of Contents

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 supplement 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 supplement 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 supplement will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or 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

The underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us and the selling stockholders 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, 2013, 2012, and 2011 appearing in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 incorporated into this prospectus supplement and the accompanying prospectus by reference, and the effectiveness of our internal control over financial reporting as of December 31, 2013, 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. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS 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 the accompanying 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 filed 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, 2013.
- Definitive Proxy Statement on Schedule 14A, as filed with the SEC on July 12, 2013.
- The description of our common stock included under the heading Description of Common Stock in the prospectus forming a part of the Registration Statement on Form S-3 (File No. 333-186189), as filed with the SEC on January 25, 2013, including exhibits, which description has been incorporated by reference in Item 1 of the Registrant s Form 8-A (File No. 001-00100), as filed with the SEC on April 22, 2013, including any amendment or report filed with the SEC for the purpose of updating such description.

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.

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

TherapeuticsMD, Inc.

Attention: Corporate Secretary

6800 Broken Sound Parkway NW, Third Floor

Boca Raton, Florida 33487

(561) 961-1900

Table of Contents

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, 2013), 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, 2013) 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.

Table of Contents

PROSPECTUS

12,000,000 Shares

Common Stock

The selling stockholders may offer and sell, from time to time, in one or more offerings, up to 12,000,000 shares of our common stock, par value $0.001 per share. These securities may be sold at fixed prices, prevailing market prices at the times of sale, prices related to the prevailing market prices, varying prices determined at the times of sale, or negotiated prices. The securities offered by this prospectus and any prospectus supplement may be offered by the selling stockholders to or through underwriters, dealers, or other agents, directly to investors, or through any other manner permitted by law, on a continued or delayed basis. See Plan of Distribution beginning on page 5 of this prospectus. The plan of distribution for any particular offering of these securities may also be described in any applicable prospectus supplement.

We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of the securities sold by the selling stockholders. The registration of the securities covered by this prospectus does not necessarily mean that any of these securities will be offered or sold by the selling stockholders. The timing and amount of any sale is within the respective selling stockholders sole discretion, subject to certain restrictions. To the extent that any selling stockholder resells any securities, the selling stockholder may be required to provide you with this prospectus and a prospectus supplement identifying and containing specific information about the selling stockholder and the terms of the securities being offered.

Our common stock is listed on the NYSE MKT under the symbol TXMD. On January 23, 2014, the closing price of our common stock as quoted on the NYSE MKT was $5.89 per share.

See Risk Factors in the section entitled Risk Factors on page 3 of this prospectus and risk factors in any applicable prospectus supplements for a discussion of certain risk factors that should be considered by prospective purchasers of the securities offered under this prospectus.

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 3, 2014

Table of Contents

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
RISK FACTORS	3
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	3
USE OF PROCEEDS	4
SELLING STOCKHOLDERS	5
PLAN OF DISTRIBUTION	5
LEGAL MATTERS	7
EXPERTS	7
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	8
WHERE YOU CAN FIND MORE INFORMATION	9

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf registration process, the selling stockholders may, from time to time, offer and sell the securities offered under this prospectus, as described herein, in one or more offerings. Each time the selling stockholders sell securities, we will provide a prospectus supplement that contains specific information about any offering by the selling stockholders, including the names of any selling stockholders. **This prospectus may not be used to offer or sell securities unless it is accompanied by a prospectus supplement.**

To the extent we file any prospectus supplements, such prospectus supplements may add, update, or change information contained in this prospectus to the extent permitted by the Securities Act of 1933, as amended, or the Securities Act. You should read both this prospectus and any prospectus supplement together with additional information described under the heading Where You Can Find More Information.

We and the selling stockholders have not authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

The selling stockholders are offering to sell, and seeking offers to buy, the securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus and the information in the incorporated documents is only accurate as of their respective dates, regardless of the time of delivery of this prospectus or of any sale of the common stock. Neither the delivery of this prospectus, nor any sale made hereunder, will under any circumstances create any implication that there has been no change in our affairs since the date hereof or that the information contained herein or incorporated by reference herein is correct as of any time subsequent to the date of such information.

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. Unless otherwise indicated, the terms TherapeuticsMD, we, us, our, and our company refer to TherapeuticsMD, Inc.

Our Business

We are a womens 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 vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products.

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

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

Our sales model focuses on the 4Ps : patient, provider, pharmacist, and payor. We market and sell our current dietary supplement and cosmetic products primarily through a direct national sales force of approximately 30 full-time professionals that calls on healthcare providers in the obstetrics and gynecologic market space as well as through our website directly to consumers. In addition, our products allow healthcare providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded, generic, and over-the-counter lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription dietary supplement products to consumers through retail pharmacies. We market our

over-the-counter products either directly to consumers via our website and phone sales followed by home shipment or through physicians who then re-sell

Table of Contents

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:

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

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

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

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

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

Our Offices

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmd.com*, *www.vitamedmdrx.com*, and *bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

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, 2012, which is incorporated by reference in this prospectus, as well as the risk factors and other information contained in or incorporated by reference in the applicable prospectus supplement and any related free writing prospectus. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus or in the applicable prospectus supplement or any related free writing prospectus. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements that involve risks and uncertainties. These forward-looking statements are not historical facts but rather are based on current expectations, estimates, and projections about our industry, our beliefs, our 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. You should not place undue reliance on these forward-looking statements, which reflect our view only as of the date of this prospectus, and we undertake no obligation to update these forward-looking statements in the future. In many cases, you can identify forward-looking statements by terms such as may, should, expects, plans, anticipates, could, intends, target, projects, contemplates, b predicts, potential, or continue or the negative of these terms or other similar expressions.

The forward-looking statements contained in this prospectus reflect our views as of the date of this prospectus 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 under the caption Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which is incorporated by reference in this prospectus. Some of the key factors that could cause actual results to differ from our expectations include the following:

- our operating losses incurred since inception and anticipated for the foreseeable future;
- our ability to continue as a going concern;
- our ability to maintain or increase sales of our products;
- the ability of our products to produce the intended effects;
- our ability to develop and commercialize our proposed advanced hormone therapies;

our estimates regarding our capital requirements;

our lack of experience in bringing a drug to regulatory approval;

the uncertainty of results from our clinical trials;

delays, suspensions, or discontinuation of our clinical trials;

our reliance on third-parties to conduct our clinical trials and research and development;

the effects of laws, regulations, and enforcement;

our dependence on third-party manufacturers;

Table of Contents

our expectations with respect to the potential commercial value of our proposed products;

the competitive nature of the industries in which we conduct our business;

the availability of reimbursement from government authorities and health insurance companies for our products;

the impact of product liability lawsuits;

unfavorable publicity or lack of customer acceptance;

our ability to use hazardous or biological materials in compliance with applicable law;

our ability to gain and retain market acceptance for our products;

our reliance on our executive officers and key personnel;

our ability to expand our direct sales force;

our dependence on certain customers and distribution channels;

our ability to maintain optimal inventory levels;

our response to changing consumer preferences and demand;

product recalls, withdrawals, or safety alerts;

our inability to manage our growth;

the conduct of our employees;

our ability to protect our intellectual property and not infringe on the intellectual property of others; and

our ability to establish and maintain proper internal controls and comply with the financial reporting obligations of the SEC and Sarbanes-Oxley Act of 2002.

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 this prospectus are based on information available to us on the date of this prospectus. 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.

USE OF PROCEEDS

We will not receive any of the proceeds from the offer and sale of the securities by the selling stockholders. The selling stockholders will receive all of the proceeds from this offering, if any.

Table of Contents

SELLING STOCKHOLDERS

This prospectus relates to the possible resale by certain of our stockholders of up to 12,000,000 shares of our common stock that were issued on October 4, 2011 in connection with a reverse merger, or the Merger, pursuant to an Agreement and Plan of Merger, dated as of July 18, 2011, among our company, VitaMed Acquisition, LLC, a Delaware limited liability company and wholly owned subsidiary of our company, and VitaMedMD, LLC, a Delaware limited liability company. The Merger is described in greater detail in our Current Report on Form 8-K filed with the SEC on October 11, 2011.

The identity of any selling stockholder, including any material relationship between us, our affiliates or predecessors, and a selling stockholder within the last three years, the number of shares of our common stock held by a selling stockholder before and after the offering, the number of shares of common stock to be offered by a selling stockholder, and the percentage of our shares of common stock held by a selling stockholder before and after the offering will be set forth in a prospectus supplement to this prospectus.

Selling stockholders may not sell any shares of our common stock pursuant to this prospectus until we have identified the selling stockholders and the shares being offered for resale by the selling stockholder in a subsequent prospectus supplement. However, selling stockholders may sell or transfer all or a portion of their shares of our common stock pursuant to any available exemption from the registration requirements of the Securities Act.

PLAN OF DISTRIBUTION

The securities being offered by this prospectus may be sold by a selling stockholder in one or more of the following ways:

to or through underwriters or dealers;

directly to one or more purchasers;

through agents;

through a combination of any of those methods of sale; or

through any other methods described in a prospectus supplement.

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 sales;

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 the selling stockholders;

any discounts or concessions allowed or reallowed or paid to dealers; and

any securities exchanges on which such securities may be listed.

The selling stockholders may sell 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

at negotiated prices.

Table of Contents

Unless otherwise indicated in the applicable prospectus supplement, if underwriters are used 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. Underwriters with whom the selling stockholders have a material relationship may be used, and if so, the applicable prospectus supplement will name the underwriter and the nature of any such relationship. The selling stockholders 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. The selling stockholders 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 the selling stockholders 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 the selling stockholders. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

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 Securities Exchange Act of 1934, as amended, or 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 transactions involve 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 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-allotment transactions, 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 NYSE MKT or otherwise and, if commenced, may be discontinued at any time.

Table of Contents

Underwriters, dealers, and agents may be entitled under agreements entered into with us or a selling stockholders to indemnification by us or the selling stockholders against certain civil liabilities, including liabilities under the Securities Act, or to contribution by us or the selling stockholders with respect to payments they may be required to make in respect of these liabilities thereof. If required, the prospectus supplement will describe the terms and conditions of such indemnification or contribution. Underwriters, dealers, and agents and their affiliates may be customers of, engage in transactions with, or perform services for us, our subsidiaries, or one or more of the selling stockholders in the ordinary course of business for which they receive compensation.

LEGAL MATTERS

The validity of the securities offered hereby has been passed upon for us by Greenberg Traurig, LLP, Phoenix, Arizona.

EXPERTS

The consolidated financial statements as of and for the years ended December 31, 2012 and December 31, 2011 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2012 incorporated by reference in this prospectus and in the registration statement have been so included in reliance on the reports of Rosenberg Rich Baker Berman & Company, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in accounting and auditing.

The consolidated financial statements as of and for the year ended December 31, 2010 incorporated by reference in this prospectus and in the registration statement have been so included in reliance on the report of Parks & Company, LLC, an independent registered public accounting firm, incorporated herein by reference herein, given on the authority of such firm as experts in accounting and auditing.

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 filed 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, 2012.
- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2013, June 30, 2013, and September 30, 2013.
- Current Reports on Form 8-K filed with the SEC on January 25, 2013, February 6, 2013, March 15, 2013, April 23, 2013, May 16, 2013, August 22, 2013, September 24, 2013, September 25, 2013 (two reports filed), and December 18, 2013.
- The description of our common stock included under the heading Description of Common Stock in the prospectus forming a part of the Registration Statement on Form S-3 (File No. 333-186189), as filed on January 25, 2013, including exhibits, which description has been incorporated by reference in Item 1 of the Registration Statement on Form 8-A (File No. 001-00100), as filed on April 22, 2013, including any amendment or report filed for the purpose of updating such description.

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 this prospectus and prior to the termination of the offering covered by this prospectus or any prospectus supplement.

You may request a copy of these documents, which will be provided to you at no cost, by contacting us as follows:

TherapeuticsMD, Inc.

Attention: Corporate Secretary

6800 Broken Sound Parkway NW, Third Floor

Boca Raton, Florida 33487

(561) 961-1900

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 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, 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

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly, and current reports, proxy statements, and other information with the SEC. You 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*. The SEC s website contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

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. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. For further information with respect to our company and the securities offered by this prospectus, as well as the exhibits and schedules to the registration statement, we refer you to the registration statement, those exhibits and schedules, and to the information incorporated by reference in this prospectus. 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 website.

Table of Contents

9,000,000 Shares

Common Stock

PROSPECTUS SUPPLEMENT

Joint Book-Running Managers

Jefferies **Stifel**

Co-Managers

Cowen and Company **Mizuho Securities**

Prospectus Supplement dated March 20, 2014