TherapeuticsMD, Inc.
Form 424B2
July 30, 2014
Table of Contents

Filed pursuant to Rule 424(b)(2)
Registration No. 333-186189
Registration No. 333-197699

Prospectus Supplement

to Prospectus dated February 5, 2013

8,565,310 Shares

TherapeuticsMD, Inc.

Common Stock

We are offering 8,565,310 shares of our common stock, par value $0.001 per share.

Our common stock is listed on the NYSE MKT under the symbol TXMD. The last reported sale price of our common stock on the NYSE MKT on July 29, 2014 was $4.67 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors on page S-8 of this prospectus supplement and page 5 of the accompanying prospectus to read about factors you should consider before buying shares of our common stock.

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

	Per Share	Total
Public offering price	$ 4.67	$ 39,999,998

Underwriting discounts	$ 0.30355	$ 2,600,000
Proceeds, before expenses, to us	$ 4.36645	$ 37,399,998

The underwriters have the option to purchase up to an additional 1,284,796 shares of common stock from us at the public offering price less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on August 4, 2014.

Goldman, Sachs & Co.

Noble Financial Capital Markets

Prospectus Supplement dated July 30, 2014.

Table of Contents

TABLE OF CONTENTS

	Page
Prospectus Supplement	
About this Prospectus Supplement	S-ii
Prospectus Supplement Summary	S-1
Risk Factors	S-8
Cautionary Statement About Forward Looking Information	S-34
Use of Proceeds	S-36
Dilution	S-37
Material U.S. Federal Income Tax Considerations For Non-U.S. Holders of Common Stock	S-38
Underwriting	S-42
Legal Matters	S-46
Experts	S-46
Incorporation of Certain Information by Reference	S-47
Where You Can Find More Information	S-48
Prospectus	
About this Prospectus	ii
Prospectus Summary	1
Risk Factors	5
Where You Can Find More Information	6
Forward-Looking Statements	7
Incorporation of Certain Information by Reference	8
Prospectus Supplements	9
Ratio of Earnings to Fixed Charges	9
Dilution	9
Use of Proceeds	10
Securities We May Offer	10
Description of Common Stock	11
Description of Preferred Stock	13
Description of Debt Securities	17
Description of Depositary Shares	29
Description of Warrants	32
Description of Purchase Contracts	35
Description of Units	36
Certain Provisions of Nevada Law and our Charter and Bylaws	38
Legal Ownership of Securities	41
Plan of Distribution	45
Legal Matters	47
Experts	47

We have not authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do

so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of the respective dates of such documents.

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

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

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, 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. 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

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 herein and therein, 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-001HR, our oral combination of progesterone and estradiol; TX-002HR, our oral progesterone alone; TX-003HR, our oral estradiol alone; and TX-004HR, our vaginal suppository estradiol alone. We are currently conducting phase 3 clinical trials for TX-001HR and TX-002HR; and we currently intend to begin a phase 3 clinical trial for TX-004HR in the third quarter of 2014. We have no current plans to conduct clinical trials for TX-003HR.

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 clinical 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

Table of Contents

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.

Pipeline of our Hormone Therapy Drug Candidates

TX-001HR

TX-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 and sleep disturbances 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.

On September 5, 2013, we began enrollment of the REPLENISH trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, 6 months and 12 months. We intend to enroll approximately 1,750 patients at approximately 80 sites. We currently anticipate that enrollment in the REPLENISH Trial will be complete during the fourth quarter of 2014 and that results of the trial will be reported during the fourth quarter of 2015.

TX-002HR

TX-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. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of

Table of Contents

TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we temporarily suspended enrollment in the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. We intend to update the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if approved by the FDA, will allow us to ease the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol that we intend to propose.

TX-004HR

TX-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, which represents a 20% annual growth rate over the past five years.

We currently intend to begin a multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. Based on discussions with the FDA, we expect to conduct a single 12 week study, evaluating three different doses of estradiol: 4 mcg, 10 mcg and 25 mcg. The FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level. The study has been designed to include four primary endpoints: the reduction of vaginal pH levels to less than 5.0, an increase in superficial cells, a decrease in parabasal cells and the improvement of dyspareunia. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The trial is designed to enroll approximately 800 patients across approximately 60 to 80 sites. We currently anticipate that enrollment in the trial will be complete during the second quarter of 2015 and that results of the trial will be reported during the third quarter of 2015. Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-004HR during the fourth quarter of 2015 and that such NDA would be approved by the FDA during the fourth quarter of 2016.

Early Clinical Development

Based upon leveraging our hormone platform technology, we have four early clinical projects in development, including our proposed combination estradiol and progesterone and progesterone-alone products in a topical cream form, which we refer to as TX-005HR and TX-006HR, respectively, and transdermal patch form, which we refer to as TX-007HR and TX-008HR, respectively. We recently completed a pilot pharmacokinetic, or PK, study of TX-005HR in eight patients that tested the topical administration on the upper arm of 50 mcg of estradiol and 25 mg of progesterone. The results of the PK study suggest that topical formulations of estradiol and progesterone may be possible using our proprietary solubilized forms of the compounds. We intend to file an IND with respect to TX-005HR and TX-006HR during the fourth quarter of 2014 and then commence phase 1 clinical trials. We may in the future engage with a financing partner to advance our topical cream and transdermal patch projects.

Table of Contents

We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth and premature ovarian failure.

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 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 combining estradiol and progesterone in a single formulation, 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. In the first quarter of 2014, we introduced a new prescription prenatal vitamin product under our branded vitaMedMD name as vitaPearl and under our generic Prena1 name as Prena1 Pearl. The Prena1 Pearl will replace our existing Prena1 and Prena1 Plus prescription prenatal vitamin products, which we intend to discontinue marketing during the third

Table of Contents

quarter of 2014. We plan to continue 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 drugs (based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250).

Recent Developments

Estimated Second Quarter 2014 Results

Although our final financial statements for the three months ended June 30, 2014 are not yet available, the information set forth below reflects our preliminary estimates of our results based solely upon information available to us as of the date of this prospectus supplement. The preparation of our condensed consolidated financial statements for the three months ended June 30, 2014 is ongoing and subject to adjustments, which could result in changes to the financial results set forth below. As a result, our financial results could differ materially from those set forth below. Our condensed consolidated financial statements for the three months ended June 30, 2014 will not be available until after this offering is completed and consequently will not be available to you prior to investing in this offering. There can be no assurance that the estimates set forth below will be realized and estimates are subject to risks and uncertainties, many of which are not within our control. See Cautionary Statement About Forward Looking Information.

As of the date of this prospectus supplement, we expect to report net revenues of between $3.5 million and $3.9 million for the three months ended June 30, 2014, compared to $2.1 million for the three months ended June 30, 2013. We expect to report a net loss of between $(10.5) million and $(11.3) million for the three months ended June 30, 2014, compared to a net loss of $(6.0) million for the three months ended June 30, 2013. We expect to report a net loss per share, basic and diluted, of between $(0.06) and $(0.08) for the three months ended June 30, 2014, based on a weighted average number of common shares outstanding of approximately 145,485,505, compared to a net loss per share, basic and diluted, of $(0.05) for the three months ended June 30, 2013, based on a weighted average number of common shares outstanding of 130,851,978. We expect to report cash on hand of approximately $35.6 million at June 30, 2014, compared to cash on hand of approximately $54.2 million at December 31, 2013.

Patent Allowance

In July 2014, we received Notices of Allowance from the U.S. Patent and Trademark Office for two patent applications related to our combination estradiol/progesterone drug candidate. The first allowed application, U.S. patent application 14/099,545, is directed to methods of treating a menopause symptom using our combination estradiol and progesterone formulation. The second allowed application, U.S. patent application 14/099,571, is directed to pharmaceutical compositions of our combination estradiol and progesterone formulation.

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 us	8,565,310 shares or 9,850,106 shares if the underwriters option to purchase additional shares is exercised in full.
Common stock to be outstanding immediately after this offering	154,492,283 shares
Use of proceeds	We intend to use approximately $20.0 million of the net proceeds from this offering to fund our phase 3 clinical trials of our proposed combination estradiol and progesterone drug candidate and our proposed suppository estradiol VVA product, and approximately $10.0 million of the net proceeds from this offering to fund validation and scale-up of the manufacturing processes for these products. We intend to use the remainder of the net proceeds from this offering for other clinical and formulation development, including work on our proposed topical combination estradiol and progesterone product and topical progesterone only product, other research and development and for general corporate purposes. Please see the section entitled Use of Proceeds on page S-36 of this prospectus supplement.
Risk factors	Investing in our common stock involves a high degree of risk. You should carefully read and consider the information set forth under Risk Factors on page S-8 of this prospectus supplement and page 5 of the accompanying prospectus and in the documents incorporated by reference herein and therein to read about factors you should consider before buying shares of our common stock.
Common stock symbol	Our common stock is listed on the NYSE MKT under the symbol TXMD.
Lock-Up agreements	We, our directors and executive officers have agreed with the underwriters that, without the prior written consent of Goldman, Sachs & Co., subject to certain exceptions, neither we nor our directors or executive officers will, for a period of 90 days following the date

of this prospectus supplement, offer or contract to sell any of our common stock.

Table of Contents

The number of shares of common stock to be outstanding immediately after this offering is based on 145,926,973 shares outstanding on July 25, 2014 and excludes the following as of that date:

- outstanding options representing the right to purchase a total of 16,913,128 shares of common stock at a weighted average exercise price of $1.89 per share;

- outstanding warrants representing the right to purchase a total of 14,122,127 shares of common stock at a weighted-average exercise price of $1.80 per share; and

- 15,258,759 shares of common stock reserved for future issuance under our non-qualified stock option plans.

If the underwriters option to purchase additional shares is exercised in full, we will issue and sell an additional 1,284,796 shares of our common stock and will have 155,777,079 shares outstanding after the offering.

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

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below 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 March 31, 2014, we had an accumulated deficit of approximately $90 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 property of VitaMedMD 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;

Table of Contents

- 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, such as the potential effect of high doses of folic acid masking pernicious anemia. 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 is 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 currently 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 a New Drug Application, or NDA, for any of them and even if we believe the results of our clinical trials are sufficient to support any NDA that we submit, the FDA may disagree and may not approve our NDA. In addition, even if the FDA approves one or more of our NDAs, it may do so with restrictions on the intended uses that may make commercialization of the product or products financially untenable. The failure to commercialize or obtain necessary approval for any one or more of these products would substantially harm our prospects and our business.

We may not be able to complete the development and commercialization of our 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

Table of Contents

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;
- 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. We have recently begun to conduct validation and scale-up of the manufacturing processes for our proposed combination estradiol and progesterone drug candidate and our proposed suppository estradiol VVA product and intend to use part of the net proceeds from this offering to fund such work. 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.

Table of Contents

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 begun phase 3 clinical trial of our estradiol and progesterone combination and our progesterone alone drug candidates and currently intend to begin a phase 3 clinical trial for our vaginal suppository estradiol drug candidate in the third quarter of 2014. Clinic trials are expensive, can take many years to complete and have highly uncertain outcomes. For example, we recently temporarily suspended enrollment in the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. 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. Prior to approving a new drug, the FDA generally requires that the safety and efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations the FDA approves drugs on the basis of a single well-controlled clinical trial. We believe we may be required to conduct only a single phase 3 clinical trial of each of our estradiol and progesterone combination drug candidate, our progesterone alone drug candidate and our vaginal suppository estradiol drug candidate for the treatment of VVA. However, in connection with our VVA drug candidate, the FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level, and that a trial that is merely statistically significant may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial. 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.

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 a the FDA, a data safety monitoring board or committee, or DSMB, a clinical trial site s institutional review board, 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 IRB approval at each site;

delays in identifying, recruiting and training suitable clinical investigators;

delays in recruiting suitable patients to participate in a trial;

Table of Contents

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 active pharmaceutical ingredients; 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 IRB 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.

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

Table of Contents

manner, or that the results will be reproducible. We and our CROs are required to comply with the FDA s current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid and the FDA may require us to perform additional clinical trials before approving our proposed products. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, to evaluate the safety and effectiveness compared to placebo of our 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.

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

Table of Contents

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. For example, in the past the FDA has indicated it would regulate prenatal vitamins containing greater than 0.8 mg of folic acid as a drug under the Federal Food, Drug, and Cosmetic Act. More recently the FDA indicated that there is no specified upper limit on the amount of folic acid permitted in a dietary supplement. If the FDA were to seek to regulate products with higher amounts of folic acid as drugs, it may require us to stop selling certain of our dietary supplement products and otherwise adversely affect our business. If we are slow or unable to adapt to any 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

Table of Contents

holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA s 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.

Table of Contents

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 Pharma Nutrition, or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars and functional foods in the dietary supplement category, to supply approximately 98% of our vitaMedMD products. In certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells. 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.

Table of Contents

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;
- 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. A new non-hormonal product, Brisdelle, produced by Noven Pharmaceuticals, was approved by the FDA for treatment of vasomotor symptoms in June 2013. 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,

Table of Contents

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.

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.

Table of Contents

The availability of generic products at lower prices than branded products may also substantially reduce the likelihood of reimbursement for branded products, such as our 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, in light of the history of product liability claims related to other hormone replacement therapy products, 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, failures to warn of dangers inherent in the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or 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

Table of Contents

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 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

Table of Contents

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;

- 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

Table of Contents

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 were 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. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock-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 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 ability to utilize net operating loss carryforwards may be limited.

As of December 31, 2013, we had net operating loss carryforwards, or NOLs, of approximately $37 million available to offset future taxable income through 2033. These NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce or eliminate our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, imposes limitations on a corporation s ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percent over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of our common stock in this offering or in the future, or a combination thereof. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382, which may result in expiration of a portion of our NOLs before utilization.

Table of Contents

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;

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 June 30, 2014, we had 90 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

Table of Contents

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 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.

Table of Contents

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;
- 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 U.S. Patent and Trademark Office, or 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.

Table of Contents

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 drug 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 applications that exist in the areas of hormone therapy, including compounds, formulations, treatment methods and synthetic processes, which 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;

Table of Contents

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 intend to submit NDAs for our hormone therapy drug candidates, assuming that the clinical data justify submission, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA s prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA s publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product s listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

Table of Contents

If we cannot certify that all of the patents listed in the Orange Book for the approved products referenced in the NDAs for each of our hormone therapy drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA s Orange Book for approved products referenced in the NDAs for each of our hormone therapy drug candidates could have a serious and significant adverse effect on the timing for obtaining approval of our hormone therapy drug candidates. For example, at least one approved product that may be referenced in our 505(b)(2) application as a reference product for our vaginal suppository estradiol product currently lists unexpired patents in the Orange Book.

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.

Table of Contents

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

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

Risks Related to 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;

Table of Contents

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;

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 March 31, 2014, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 71.3% 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. In addition, pursuant to a Securities Purchase Agreement dated September 26, 2012, we granted certain of our stockholders the right, expiring in October 2015, if they elect, to purchase on the same terms as in any offering of our common stock, a number of shares

of common stock that is sufficient to maintain their respective pro rata ownership percentage of our common stock.

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.

Table of Contents

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.

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 will experience immediate and substantial dilution in the book value per share of the common stock you purchase and may experience further dilution in the future as a result of equity offerings and other issuances of our common stock of other securities.

The offering price of our common stock being offered is substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate substantial dilution of $4.14 in net tangible book value per share from the price you paid. For a further description of the dilution that you will experience immediately after this offering, see the section titled Dilution.

Table of Contents

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.

As of July 25, 2014, there were outstanding options representing the right to purchase a total of 16,913,128 shares of our common stock at a weighted average exercise price of $1.89 per share, outstanding warrants representing the right to purchase a total of 14,122,127 shares of our common stock at a weighted-average exercise price of $1.80 per share and 15,258,759 shares of our 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 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.

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

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways with which you may not agree or that do not yield a favorable return. We intend to use the net proceeds from the sale of the shares of common stock under this prospectus supplement to fund our phase 3 clinical trials of our proposed combination estradiol and progesterone drug candidate and our proposed suppository estradiol VVA product, for other clinical and formulation development, including work on our proposed topical combination estradiol and progesterone product, other research and development and for general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products, and technologies. Although we have no specific agreements, commitments or understandings with respect to any acquisition, we evaluate acquisition opportunities and engage in related discussions with other companies from time to time. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

Table of Contents

CAUTIONARY STATEMENT 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, 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;

the influence of extensive and costly government regulation;

the effect of governmental regulations on our business;

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

the concentration of 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

USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock that we are offering will be approximately $37.2 million, or approximately $42.8 million if the underwriters exercise in full their option to purchase additional shares, based on the public offering price of $4.67 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use approximately $20.0 million of the net proceeds from this offering to fund our phase 3 clinical trials of our proposed combination estradiol and progesterone drug candidate and our proposed suppository estradiol VVA product, and approximately $10.0 million of the net proceeds from this offering to fund validation and scale-up of the manufacturing processes for these products. We intend to use the remainder of the net proceeds from this offering for other clinical and formulation development, including work on our proposed topical combination estradiol and progesterone product and topical progesterone only product, other research and development and for general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products, and technologies. Although we have no specific agreements, commitments or understandings with respect to any acquisition, we evaluate acquisition opportunities and engage in related discussions with other companies from time to time.

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

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

Table of Contents

DILUTION

Our net tangible book value as of March 31, 2014 was approximately $44,767,418, or $0.31 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of March 31, 2014. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 8,565,310 shares of our common stock in this offering at the public offering price of $4.67 per share and after deducting the underwriting discounts and commissions and estimated offering expenses we must pay, our as adjusted net tangible book value as of March 31, 2014 would have been approximately $81.9 million, or $0.53 per share. This represents an immediate increase in net tangible book value of $0.22 per share to existing stockholders and immediate dilution in net tangible book value of $4.14 per share to new investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

Public offering price per share		$ 4.67
Net tangible book value per share as of March 31, 2014	$ 0.31	
Increase per share attributable to new investors	$ 0.22	
As adjusted net tangible book value per share after this offering		$ 0.53
Dilution per share to new investors in this offering		$ 4.14

If the underwriters exercise in full their option to purchase 1,284,796 additional shares of common stock at the public offering price of $4.67 per share, the as adjusted net tangible book value after this offering would be $0.57 per share, representing an increase in net tangible book value of $0.26 per share to existing stockholders and immediate dilution in net tangible book value of $4.10 per share to new investors purchasing our common stock in this offering.

The above discussion and table are based on 145,067,060 shares outstanding on March 31, 2014 and exclude the following as of that date:

- outstanding options representing the right to purchase a total of 16,511,006 shares of common stock at a weighted average exercise price of $1.66 per share;
- 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
- 16,299,423 shares of common stock reserved for future issuance under our non-qualified stock option plans.

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

the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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), 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 federal alternative minimum, unearned income Medicare contribution or estate taxation or 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;

persons who have elected to mark securities to market;

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

S corporations;

controlled foreign corporations;

passive foreign investment companies; and

U.S. expatriates.

Table of Contents

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

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

Distributions on Shares of our Common Stock

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 any distributions of cash or property on our common stock (other than certain distributions of stock which may be made free of tax), or effect a redemption that is treated for tax purposes as a distribution, 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. A non-U.S. holder s adjusted tax basis in a share of common stock is generally the purchase price of the share, reduced by the amount of any distributions constituting a return of capital with respect to that share.

Subject also to the discussions below under the headings, Information Reporting and Backup Withholding and Legislation Relating to Foreign Accounts, any 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 IRS Form W-8BEN-E (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.

Table of Contents

Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. The certification requirements described above also may require a non-U.S. holder to provide its U.S. taxpayer identification number. You should consult your tax adviser regarding the certification requirements for non-U.S. persons.

Gain on Sale or Other Disposition of Common Stock

Subject to the discussions below under the headings Information Reporting and Backup Withholding and Legislation Relating to Foreign Accounts, 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 (including a redemption, but only if the redemption would be treated as a sale or exchange rather than a distribution for U.S. federal income tax purposes) 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;

- 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 recognized during the taxable year of the disposition, 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.

Generally, a corporation is a USRPHC only if the fair market value of its United States real property interests (as defined in the Internal Revenue Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. 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 (within the meaning of Section 897(c)(3) of the Internal Revenue Code), 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.

Table of Contents

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 generally will be subject to backup withholding at the then applicable rate 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, IRS Form W-8BEN-E or IRS Form W-8ECI, or other applicable form (or applicable successor form), 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. Additional rules relating to information reporting requirements and backup withholding with respect to payments of the proceeds from the disposition of shares of our common stock are as follows:

If the proceeds are paid to or through the U.S. office of a broker, the proceeds generally will be subject to backup withholding and information reporting, unless the non-U.S. holder certifies under penalties of perjury (usually on IRS Form W-8BEN or W-8BEN-E) that the non-U.S. holder is not a U.S. person or otherwise establishes an exemption.

If the proceeds are paid to or through a non-U.S. office of a broker that is not a U.S. person and is not a foreign person with certain specified U.S. connections (a U.S. related person), information reporting and backup withholding generally will not apply.

If the proceeds are paid to or through a non-U.S. office of a broker that is a U.S. person or a U.S. related person, the proceeds generally will be subject to information reporting (but not to backup withholding), unless the non-U.S. holder certifies under penalties of perjury (usually on IRS Form W-8BEN or W-8BEN-E) that the non-U.S. holder is not a U.S. person.

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

Certain provisions of the Internal Revenue Code and related guidance, commonly referred to as FATCA, 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, generally, (1) such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or (2) such institution is compliant under an applicable intergovernmental agreement (which agreement may impose substantially similar requirements on such institution as would have been imposed under an agreement with the U.S. government, as described in (1) above). FATCA will generally 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 non-financial foreign entity unless such entity properly 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. Other types of holders of our common stock may also have to

provide certain documentation or certifications to avoid withholding pursuant to FATCA on payments of dividends on our common stock or payments of gross proceeds of a sale or other disposition of our common stock. Under certain transition rules, any obligation under this legislation to withhold 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

The Company and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co. is the representative of the underwriters.

Underwriters	Number of Shares
Goldman, Sachs & Co.	7,708,779
Noble Financial Capital Markets	856,531
Total	8,565,310

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,284,796 shares from the Company to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by the Company. Such amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase 1,284,796 additional shares.

Paid by the Company

	No Exercise	Full Exercise
Per Share	$ 0.30355	$ 0.30355
Total	$ 2,600,000	$ 2,990,000

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus supplement. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.18213 per share from the public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters right to reject any order in whole or in part.

The Company and the Company s directors and officers has agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus supplement continuing through the date 90 days after the date of this prospectus supplement, except with the prior written consent of the representative. This agreement does not apply to any existing employee benefit plans.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A covered short

Table of Contents

position is a short position that is not greater than the amount of additional shares for which the underwriters option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover 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 additional shares pursuant to the option described above. Naked short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such 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 common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the Company s stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the NYSE MKT, in the over-the-counter market or otherwise.

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), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

(a) to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;

(c)

to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or

(d) in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

Table of Contents

For the purposes of this provision, the expression an offer of shares to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

United Kingdom

Each 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 FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA would not, if the Issuer was not an authorized person, apply to the Issuer; 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 in, from or otherwise involving the United Kingdom.

Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares 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 in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person, or any person pursuant to Section 275(1A), 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 shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) 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

Table of Contents

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 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it 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 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 Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

The Company estimates that its share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $242,500.

The Company has agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and 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 assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Greenberg Traurig, LLP, Las Vegas, Nevada. Certain legal matters relating to this offering will be passed upon for the underwriters by Ropes & Gray LLP, Boston, Massachusetts.

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.

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 supplement and the accompanying prospectus. Information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and accompany prospectus automatically updates and supersedes previously filed information as applicable.

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

Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.

Definitive Proxy Statement on Schedule 14A, as filed with the SEC on April 17, 2014.

Current Report on Form 8-K filed with the SEC on June 11, 2014.

Current Report on Form 8-K filed with the SEC on March 21, 2014.

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

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

WHERE YOU CAN FIND MORE INFORMATION

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

The accompanying 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. The accompanying prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC s Internet website.

Table of Contents

PROSPECTUS

$125,000,000

Common Stock

Preferred Stock

Debt Securities

Depositary Shares

Warrants

Purchase Contracts

Units

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

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

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

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

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

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

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

The date of this prospectus is February 5, 2013

Table of Contents

TABLE OF CONTENTS

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

Table of Contents

ABOUT THIS PROSPECTUS

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

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

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

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

Table of Contents

PROSPECTUS SUMMARY

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

Our Company

We are a specialty pharmaceutical company focused on creating safe and effective branded prescription, generic prescription, and over-the-counter (non-prescription) products targeted exclusively for women. We are focused on the clinical trials for and commercialization of three advanced hormone therapy products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. These proposed hormone therapy products, which contain estrogen and progestin alone or in combination, are being tested to provide equivalent efficacy at lower doses, enabling an enhanced side effect profile compared with competing products. These proposed hormone therapy products have received Investigational New Drug application, or IND, acceptance by the U.S. Food and Drug Administration, or FDA. We plan to begin phase 3 clinical trials of these proposed products in 2013. We intend to leverage and grow our current marketing and sales organization to commercialize these products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, preterm birth, vulvo and vaginal atrophy, and premature ovarian failure. The oral progestin market was approximately $400 million in 2011 U.S. sales; the estrogen market was approximately $800 million in 2011 U.S. sales; and the combination Progestin/Estrogen market was $600 million in 2011 U.S. sales.

As we continue the clinical development of our proposed hormone therapy products, we continue to market and expand our branded prescription, generic prescription, and over-the-counter product lines consisting of prenatal vitamins, over-the-counter prenatal vitamins, vegan docosahexaenoic acid, or DHA, iron supplements, Vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD name and our generic prescription prenatal vitamins products under our BocaGreenMD Prena1 name. All of our prenatal vitamins are gluten, sugar, and lactose free. We believe our product attributes result in greater patient acceptance and satisfaction than competitive products while offering the highest quality and patented ingredients.

Our sales model focuses on the 4Ps : patient, provider, pharmacist, and payor. We market and sell our current products through a direct national sales force of approximately 40 full-time professionals that calls on healthcare providers in the obstetrics and gynecologic, or OB/GYN, market space as well as through our website to consumers. We strive to demonstrate to physicians that recommending our products enable them to realize office efficiencies and patient and payor cost savings over competitive products, strategies, and distribution models. In addition, our products offer healthcare providers an alternative to patients to meet their individual nutritional and financial requirements related to co-pay and cost of care considerations. We also believe that our combination of branded, generic, and over-the-counter lines allows physicians, women, and payors cost-effective alternatives for top quality care. We supply our prescription products to consumers through retail pharmacies. We supply our over-the-counter products either directly to consumers via the Internet and phone sales followed by home shipment as well as through physicians who then sell them to their patients. Our fully staffed customer care center uses current customer relationship management technologies to respond to healthcare providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders through our auto-ship feature.

Table of Contents

Our Strategy

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

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

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

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

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

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

- introducing new products to build upon the introduction of our first three prescription products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012, as well as our proposed hormone therapy products consisting of a bioidentical oral combination of progesterone and estradiol product, an oral progesterone product, and a suppository vulvar and vaginal atrophy estradiol product. Early pharmacokinetic, or PK, studies on our HT products indicate achievement of 80-125% comparability of the reference listed drugs approved by the FDA for the combined progestin and estrogen product.

Our Offices

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487. Our telephone number is (561) 961-1911. The Company maintains websites at *www.therapeuticsmd.com*, *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.

The Securities That May Be Offered

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

2

Table of Contents

Common Stock

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

Preferred Stock

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

Debt Securities

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

The senior and subordinated debt securities will be issued under an indenture between us and a trustee. We have summarized the general features of the debt securities to be governed by the indenture. The indenture has been filed as an exhibit to the registration statement of which this prospectus forms a part. We encourage you to read the indenture. Instructions on how you can get copies of this document are provided in the section entitled Where You Can Find More Information on page 6 of the prospectus.

Depositary Shares

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

Table of Contents

Warrants

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

Purchase Contracts

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

Units

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

Table of Contents

RISK FACTORS

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

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

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

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

Table of Contents

FORWARD-LOOKING STATEMENTS

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

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

Table of Contents

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

this prospectus.

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

TherapeuticsMD, Inc.

Attention: Corporate Secretary

951 Broken Sound Parkway NW, Suite 320

Boca Raton, Florida 33487

(561) 961-1911

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

Table of Contents

PROSPECTUS SUPPLEMENTS

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

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

RATIO OF EARNINGS TO FIXED CHARGES

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

DILUTION

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

- the net tangible book value per share of our equity securities before and after the offering;
- the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and
- the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.

Table of Contents

USE OF PROCEEDS

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

SECURITIES WE MAY OFFER

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

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

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

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

Table of Contents

DESCRIPTION OF COMMON STOCK

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

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

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

Voting Rights

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

Dividends

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

Preemptive Rights

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

Redemption

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

Table of Contents

Liquidation Rights

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

Options and Other Stock-Based Rights

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

Listing

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

Transfer Agent and Registrar

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

Table of Contents

DESCRIPTION OF PREFERRED STOCK

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

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

Terms of Preferred Stock

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

- the title and stated value of the preferred stock;
- the number of shares of preferred stock to be issued and the offering price of the preferred stock;
- any dividend rights;
- any dividend rates, periods, or payment dates, or methods of calculation of dividends applicable to the preferred stock;
- the date from which distributions on the preferred stock will accumulate, if applicable;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into our common stock, including the conversion price (or manner of calculation thereof);
- any right to convert the preferred stock into a different type of security;
- any voting rights attributable to the preferred stock;

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

any terms of redemption;

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

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

any listing of the preferred stock on any securities exchange;

Table of Contents

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

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

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

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

Rank

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

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

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

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

Distributions

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

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

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

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

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

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

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

Table of Contents

Voting Rights

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

Liquidation Preference

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

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

Conversion Rights

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

Redemption

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

Registrar and Transfer Agent

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

Table of Contents

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

Table of Contents

DESCRIPTION OF DEBT SECURITIES

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

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

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

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

General

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

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

- the title of the debt securities;
- the series designation and whether they are senior securities, senior subordinated securities, or subordinated securities;
- the aggregate principal amount of the debt securities and any limit on the aggregate amount of the series of debt securities;

Table of Contents

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

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

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

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

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

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

any subordination provisions or limitations relating to the debt securities;

any sinking fund requirements;

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

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

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

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

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

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

the currency of denomination of the debt securities;

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

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

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

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

Table of Contents

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

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

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

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

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

any restrictions on transfer, sale, or other assignment;

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

any provisions relating to any guarantee of the debt securities;

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

any depositaries, interest rate calculation agents, exchange rate calculation agents, or other agents with respect to the debt securities.

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

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

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

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

Payments and Paying Agents

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

Table of Contents

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

Form, Transfer, and Exchange

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

Certificated Debt Securities

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

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

Global Debt Securities and Book-Entry System

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

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

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

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

Table of Contents

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

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

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

No Protection in the Event of a Change in Control

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

Covenants

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

Merger, Consolidation, and Sale of Assets

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

- either (a) the company is the surviving entity or (b) the successor person is a corporation, partnership, trust, or other entity organized and validly existing under the laws of any U.S. domestic jurisdiction and expressly assumes our obligations on the debt securities and under the indenture;
- immediately after giving effect to the transaction, no event of default, and no event that, after notice or lapse of time, or both, would become an event of default, will have occurred and be continuing under the indenture; and
- certain other conditions that may be set forth in the applicable prospectus supplement are met.

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

Table of Contents

Events of Default Under the Indenture

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

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

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

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

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

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

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

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

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

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

22

Table of Contents

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

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

- our failure to pay the principal of, and interest and any additional amounts on, any debt security; or
- a covenant or provision contained in the indenture that cannot be modified or amended without the consent of the holders of each outstanding debt security affected by the default.

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

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

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

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

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

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

Modification of Indenture and Waiver

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

23

Table of Contents

Changes Requiring the Unanimous Approval

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

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

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

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

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

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

change the place of payment on a debt security;

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

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

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

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

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

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

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

Changes Not Requiring Approval of Debt Holders

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

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

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

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

Table of Contents

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

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

to establish additional series of debt securities;

to secure previously unsecured debt securities;

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

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

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

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

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

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

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

Defeasance of Debt Securities and Certain Covenants in Certain Circumstances

Legal Defeasance

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

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

Table of Contents

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

Defeasance of Certain Covenants

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

The conditions include, among others, the following:

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

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

Covenant Defeasance and Events of Default

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

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

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

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

Guarantees

Our payment obligations under any series of debt securiti