TherapeuticsMD, Inc.
Form 424B5
July 29, 2014
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The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed pursuant to Rule 424(b)(5)
Registration No. 333-186189
Registration No. 333-197699

Subject to Completion. Dated July 29, 2014.

Prospectus Supplement

to Prospectus dated February 5, 2013

$40,000,000

TherapeuticsMD, Inc.

Common Stock

We are offering 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 28, 2014 was $4.55 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	$	$
Underwriting discounts	$	$
Proceeds, before expenses, to us	$	$

The underwriters have the option to purchase up to an additional $6,000,000 of 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 , 2014.

Goldman, Sachs & Co.

Noble Financial Capital Markets

Prospectus Supplement dated July , 2014.

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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.

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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.

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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

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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

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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.

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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

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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.

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The Offering

Common stock offered by us	shares or shares if the underwriters option to purchase additional shares is exercised in full.
Common stock to be outstanding immediately after this offering	shares
Use of proceeds	We intend to use approximately $ 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 $ 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.

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The number of shares of common stock to be outstanding immediately after this offering is based on 145,896,287 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 shares of our common stock and will have 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.

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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;

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- 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

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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.

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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;

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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

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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

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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

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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.

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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.

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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