TherapeuticsMD, Inc.
Form 8-K
July 30, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE**

**SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): July 29, 2014**

**TherapeuticsMD, Inc.**

**(Exact Name of Registrant as Specified in its Charter)**

| **Nevada** | **001- 00100** | **87-0233535** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**6800 Broken Sound Parkway NW, Third Floor**

**Boca Raton, FL 33487**

**(Address of Principal Executive Office) (Zip Code)**

**Registrant s telephone number, including area code: (561) 961-1900**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2 below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01. Other Events.**

On July 30, 2014, TherapeuticsMD, Inc., a Nevada corporation, filed a prospectus supplement with the Securities and Exchange Commission under its effective shelf registration statements on Form S-3 (the Prospectus ) pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended (the Securities Act ). The discussion below contains certain updated disclosures regarding the Company s business included the Prospectus. Unless the context otherwise requires, all references in this Current Report on Form 8-K to TherapeuticsMD, TXMD, Company, our company, 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. vitaMedMD®, TherapeuticsMD®, and BocaGreenMD® are registered trademarks of our company.

**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

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

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.

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. 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.

## 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 contained in our other filings with the SEC. 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;

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. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our hormone therapy drug candidates, generating revenue from these proposed products and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our hormone therapy drug candidates, which would materially adversely affect our business and could potentially cause us

to cease operations.

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

Three hormone therapy drug candidates are currently in various stages of clinical testing. We have 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;

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

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

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.

***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.

***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,

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.

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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

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

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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

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

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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 the future. 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.

***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

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.

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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.

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;

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.

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.

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***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;

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.

***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.

**Cautionary Statement About Forward Looking Information**

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 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 this Current Report on Form 8-K, including statements regarding our future operating results and financial position, business strategy, and plans and objectives of management for future operations, are forward-looking statements. In many cases, you can identify forward-looking statements by terms such as may, should, expects, plans, anticipates, could, intends, target, projects, believes, estimates, predicts, potential, or continue or the negative of these terms or other similar expressions.

The forward-looking statements contained in this Current Report on Form 8-K reflect our views as of the date of this Current Report on Form 8-K about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances that may cause our actual results, performance, or achievements to differ significantly from those expressed or implied in any forward-looking statement. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future events, results, performance, or achievements. A number of important factors could cause actual results to differ materially from those indicated by the forward-looking statements, including, without limitation, those factors described under the heading Risk Factors in this Current Report on Form 8-K. 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;

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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 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 Current Report on Form 8-K 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 Current Report on Form 8-K 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 this Current Report on Form 8-K by these cautionary statements.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 30, 2014

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright
Name: Daniel A. Cartwright
Title: Chief Financial Officer