

TherapeuticsMD, Inc.  
Form 10-K  
March 12, 2013

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, DC 20549**

**Form 10-K**

S ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2012

**Commission File Number 000-16731**

**TherapeuticsMD, Inc.**

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

Nevada 87-0233535  
(State or Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification No.)

**951 Broken Sound Parkway NW**

**Suite 320**

**Boca Raton, Florida 33487**

**(561) 961-1911**

*(Address, including zip code, and telephone number,*

*including area code, of Principal Executive Offices)*

**Securities registered pursuant to Section 12(b) of the Exchange Act:** None

**Securities registered pursuant to Section 12(g) of the Exchange Act:**

Common Stock, Par Value \$0.001 per share  
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of common stock held by nonaffiliates of the registrant (40,348,071 shares) based on the closing price of the registrant's common stock as reported on OTCQB on June 29, 2012, which was the last business day of the registrant's most recently completed second fiscal quarter, was \$112,974,599. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors, or 10% beneficial owners are, in fact, affiliates of the registrant.

As of February 28, 2013, there were outstanding 99,784,982 shares of the registrant's common stock, par value \$0.001 per share.

### **Explanatory Note**

The registrant meets the "accelerated filer" requirements as of the end of its 2012 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the registrant (as a smaller reporting company transitioning to a larger reporting company system based on its public float as of June 30, 2012) is not required to satisfy the larger reporting company requirements until its first quarterly report on Form 10-Q for the 2013 fiscal year and is thus eligible to check both the "Accelerated Filer" and "Smaller Reporting Company" boxes on the cover of this Form 10-K.

**THERAPEUTICSMD, INC.**

**ANNUAL REPORT ON FORM 10-K**

**Fiscal Year Ended December 31, 2012**

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### **Statement Regarding Forward-Looking Information**

This Annual Report on Form 10-K contains forward-looking statements. For example, statements regarding our financial position, business strategy, product development, and other plans and objectives for future operations, and assumptions and predictions about future product demand, research and development, marketing, expenses and sales are all forward-looking statements. These statements may be found in the items of this Annual Report entitled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as in this Annual Report generally. These statements are generally accompanied by words such as “intend,” “anticipate,” “believe,” “estimate,” “potential(ly),” “continue,” “forecast,” “predict,” “plan,” “may,” “will,” “could,” “would,” “should,” “ex” negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, research and product development uncertainties, regulatory policies and approval requirements, competition from other similar businesses, market and general economic factors, and the other risks discussed in Item 1A of this Annual Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this Annual Report in the section entitled “Risk Factors” which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. We do not undertake, and specifically decline any obligation, to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

## **PART I**

### **Item 1. *Business***

#### **Introduction**

#### **Our Company**

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy, or HT, pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for three proposed products and intend to begin clinical trials for two of those products. We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed products once we have been successful in raising the capital required to complete these trials, and we may file an IND to begin clinical studies of our proposed suppository vulvar and vaginal atrophy estradiol product later in 2013. We intend to leverage and grow our current marketing and sales organization to commercialize these proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, vulvar and vaginal atrophy, and premature ovarian failure. During the 12 months ended June 30, 2012, the total FDA-approved menopause-related progestin market was approximately \$400 million in U.S. sales; the total FDA-approved menopause-related estrogen market was approximately \$2.3 billion in U.S. sales; and the total FDA-approved menopause-related combination progestin/estrogen market was approximately \$600 million in U.S. sales.

The hormone therapy market includes two segments: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies are approximately \$1.5 billion per year. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA approved

compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders. Compounders are currently under a substantial amount of national scrutiny due to recent widely published incidents involving patient death and illness. The FDA also may take action to cause compounders to cease the production of products that would be deemed copies of our FDA-approved products.

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



Our sales model focuses on the “4Ps”: patient, provider, pharmacist, and payor. We market and sell our current dietary supplement and cosmetic products primarily through a direct national sales force of approximately 40 full-time professionals that calls on healthcare providers in the OB/GYN market space as well as through our website directly to consumers. In addition, our products allow health care providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded, generic, and over-the-counter lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription dietary supplement products to consumers through retail pharmacies. We market our over-the-counter products either directly to consumers via our website and phone sales followed by home shipment or through physicians who then re-sell them to their patients. Our fully staffed customer care center uses current customer relationship management software to respond to health care providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders for our non-prescription products through our website’s auto-ship feature.

## **Industry and Market**

### *Healthcare and Pharmaceutical Market*

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

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

### *Women’s Healthcare Market*

The U.S. Census Bureau estimates that there were approximately 157 million women and 152 million men living in the United States in 2010. Women are major consumers of health care services, negotiating not only their own health

care but often managing care for their family members as well. Their reproductive health needs and greater health care spending and longer life spans as compared with men make women's relationships with the health care system complex.

### *Hormone Therapy Market*

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

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

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

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

### *Hormone Therapy Products*

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

### *Estrogen-Only Therapies*

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

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

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

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

### *Progestin-Only Therapies*

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

### *Estrogen/Progestin Combination Products*

Progestins are used in combination with estrogen in women with uteruses to avoid an increase in the incidence of endometrial hyperplasia. This is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that, after one year, the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. In accordance with FDA recommendations, doctors typically recommend that a menopausal or postmenopausal woman who has a uterus take estrogen plus a progestin, either as a combination drug or as two separate drugs. Source Healthcare Analytics estimates that sales of estrogen/progestin combinations were approximately \$519.1 million in the United States for the 12 months ended June 2012, up approximately 3.2% over the same time period a year prior. The segment is still dominated by products in the Premarin® family that constituted approximately 56% of that market segment.

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

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

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

with natural progesterone.

### *Prenatal Vitamin Market*

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

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

### **Our Business Model**

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

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

Our sales model focuses on the “4Ps”: patient, provider, pharmacist, and payor. We market and sell our current dietary supplement and cosmetic products primarily through a direct national sales force of approximately 40 full-time professionals that calls on healthcare providers in the OB/GYN market space as well as through our website directly to consumers. In addition, our products allow health care providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded, generic, and over-the-counter lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription dietary supplement products to consumers through retail pharmacies. We market our over-the-counter products either directly to consumers via our website and phone sales followed by home shipment or through physicians who then re-sell them to their patients. Our fully staffed customer care center uses current customer relationship management software to respond to health care providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders for our non-prescription products through our website’s auto-ship feature.

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

- We believe we will offer physicians a comprehensive product line of women’s healthcare products, including our proposed hormone therapy products, if approved.
- Our proposed hormone therapy products are designed to use the lowest effective dose for the shortest duration.

We believe the attributes of our dietary supplements will result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality products incorporating patented ingredients, such as Quatrefolic®, chelated iron and life’s DHA™. All of our prenatal vitamins are gluten, sugar, and lactose free.

- We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.
- We believe health care providers are able to offer alternatives to patients that meet the patient's individual nutritional and financial requirements and help patients realize cost savings over competing products.



- Health care provider practices that choose to dispense our OTC products directly to their patients through their offices could earn revenue from the sale of the products.
- Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

## **Our Growth Strategy**

Our goal is to become the women's healthcare company recommended by 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) provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products.

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

*Marketing Emphasis.* We plan to maintain an emphasis on large group OB/GYN practices that provide opportunities to reach large patient bases and that are receptive to the data and savings we provide.

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

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

*Introducing New Products.* We plan to introduce new products to build upon the introduction of our first three prescription prenatal vitamin products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012, as well as the development of our proposed hormone therapy products consisting of a (1) bioidentical oral combination of progesterone and estradiol product, (2) an oral progesterone product, and (3) a suppository vulvar and vaginal atrophy estradiol product. Early pharmacokinetic, or PK, studies of our proposed combination estradiol and progesterone drug demonstrate that the product is bioequivalent to the reference listed drug (based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250).

## **Our Products**

We offer a wide range of products targeted for women's health specifically associated with pregnancy, child birth, nursing, post-child birth, and menopause, including prescription and over-the-counter prenatal vitamins, vegan DHA, iron supplements, vitamin D supplements, natural menopause relief products, and scar tissue and cosmetic stretch mark creams under our vitaMedMD brand name and duplicate formulations of our prescription prenatal vitamin products, referred to as "generic" formulations, under our BocaGreenMD Prena1 name.

In March 2012, we launched our first prescription-only prenatal vitamin, *vitaMedMD™ Plus Rx*, with subsequent launches of our second prescription-only prenatal vitamin, *vitaMedMD™ One Rx*, in April 2012 and our third prescription-only prenatal vitamin, *vitaMedMD™ RediChew™ Rx* in May 2012. In the fourth quarter 2012, our *BocaGreenMD™* brand was launched and our first products include three prescription products *Prena1™ Plus*, *Prena1™*, and *Prena1™ Chew*, which are duplicate, or “generic” formulations of our *vitaMedMD*-branded prescription prenatals. Our product line is detailed below.

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

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

*vitaMedMD™ One Prenatal Multivitamin*

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

*vitaMedMD™ Plus Rx Prenatal Multivitamin*

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

*vitaMedMD™ One Rx Prenatal Multivitamin*

*vitaMedMD™ One Rx* is a prescription-only product with a single-dose daily multivitamin that provides 14 vitamins and minerals, Quatrefolic®, and 200 mg of vegetarian, plant-based life's DHA™.

*vitaMedMD™ RediChew™ Rx Prenatal Multivitamin*

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

*vitaMedMD™ Iron 21/7*

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

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

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

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

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

*vitaMedMD™ Stretch Mark Body Cream*

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

*vitaMedMD™ Scar Reduction Body Cream*

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

*BocaGreenMD™ Prenal Plus*

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

*BocaGreenMD™ Prenal*

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

*BocaGreenMD™ Prenal Chew*

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

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

## Our Proposed Hormone Therapy Products

The FDA has permitted us to begin clinical testing of three of our proposed hormone therapy products. We also may seek FDA acceptance to conduct a clinical trial for the fourth drug candidate later in 2013. Our goal is to improve bioavailability of our progesterone when used alone or in combination with estrogen over currently marketed and FDA-approved options. Early PK studies of our proposed combination estradiol and progesterone drug demonstrate that it is bioequivalent to the reference listed drug (based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.8000 to 1.2500). We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed drugs once we have been successful in raising the capital required to complete these trials, and we may file an IND to begin clinical studies of our proposed suppository vulvar and vaginal atrophy estradiol product later in 2013. Progestins and estrogens are well-understood by both the FDA and health care providers. Although regulatory testing results cannot be guaranteed, we are optimistic that the clinical trials for our proposed hormone products will achieve our goals. Our proposed hormone therapy products are detailed below. We are currently planning to focus our efforts on relief of vasomotor symptoms associated with menopause, but will also be considering the treatment and prevention of osteoporosis and other conditions of hypoestrogenism.

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

*Therapeutics' TX 12-001HR* is a drug candidate consisting of a combination of estradiol and progesterone. We are developing the product for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. We are planning to conduct the necessary safety study to show protection against endometrial hyperplasia over a 12-month duration, at the lowest effective combination dosage. The product will be chemically identical to the hormones that naturally occur in a women's body, namely estradiol and progesterone, and would be packaged as both a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily), as well as a sequentially-combined regimen (where the estrogens are taken daily and the progesterone is taken in combination for two weeks of every month). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for *Therapeutics' TX 12-001HR* to be approximately \$20 to \$25 million.

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

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

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

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



*Therapeutics' TX 12-002HR*

*Therapeutics' TX 12-002HR* is a progesterone drug candidate under development for treatment of secondary amenorrhea. It is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a women's body. We believe it would be similarly effective but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for *Therapeutics' TX 12-002HR* to be approximately \$5 to \$8 million.

*Therapeutics' TX 12-003HR*

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

*Other Programs*

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

**Sales and Marketing**

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

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

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

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

### *Online Commerce*

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

### *Retail Commerce*

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

### **Seasonality**

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

### **Products in Development**

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

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

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

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

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

### **Manufacturing of Our Products**

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

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

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

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

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

Our manufacturers' quality and production standards are designed to meet or exceed current FDA regulations. To ensure the highest quality, our manufacturing operations are audited by AIB International, Inc., or AIB, among others, for independent cGMP certification. AIB is an independent, not-for-profit organization that offers programs and services to augment and support the work of regulatory officials around the country, including standards development, product testing and certification, and onsite audits and inspections. The manufacturing facilities we primarily use are also ISO 9001 certified, which is a family of standards related to quality management systems and are designed to help organizations ensure they meet the needs of customers.

### **Distribution of our Products**

We use a variety of distribution channels dependent upon product type. We sell our prescription dietary supplement products to patients through their pharmacies. Since the launch of our prescription products, in addition to third-party logistics providers, we use some of the same national and regional distributors as other pharmaceutical companies, including Cardinal, McKesson, AmerisourceBergen, H.D. Smith and Smith Drug. Wholesaler product inventory is monitored daily and sales out is monitored weekly. National and regional retail chain pharmacies are also an area of

focus to make sure our products are purchased and dispensed properly. We sell our OTC products directly to consumers via our website and phone sales and the products are shipped directly from us to the consumer's home. In a few instances, we sell OTC product to physicians, who then sell the products directly to their patients.

## **Customer Service**

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

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

## **Our Return Policy**

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

## **Our Quality Guarantee**

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

- ensure the potency and quality of our vitamin products;
- help health care providers and payors by delivering information on patient compliance and satisfaction;
- provide a 30-day money back guarantee for all of our OTC products; and
- ensure a safe, secure online shopping experience through our encrypted website.

We value frequent communication with and feedback from our customers in order to continue to improve our offerings and services.

## **Intellectual Property**

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

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

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



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

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

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

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

## **Government Regulation**

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

## **Pharmaceutical Regulation**

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

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

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

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

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

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

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

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

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product will be formulated and its API will be produced, it may issue an approval letter or, instead, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical

trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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

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

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

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

We intend to submit NDAs for our proposed hormone therapy products, assuming that the clinical data justify submission, under section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. In regards to *TX 12-001HR*, we will be required to conduct Phase 3 studies for vasomotor symptoms versus placebo and an endometrial protection study.

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

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

### *Marketing Exclusivity*

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

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

### *Dietary Supplement and Cosmetic Regulation*

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

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

published in final form. Moreover, Congress can amend the dietary supplement provisions of the FDCA to impose additional restrictions on labeling and marketing of dietary supplements. Such action would have material adverse impact on our business and growth prospects.

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

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



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

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

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

Our cosmetic products, such as our topical creams, are also subject to regulation by the FDA. Such products and their ingredients do not require premarket approval prior to sale, but are subject to specific labeling regulations. While the FDA has not promulgated specific cGMPs for the manufacture of cosmetics, the FDA has provided guidelines for cosmetic manufacturers to follow to ensure that their products are neither misbranded nor adulterated.

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

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

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

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

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

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.

The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

• Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable

health information.

The federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.

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

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

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

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

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

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

services could result in significant additional taxes on our business. These taxes could have an adverse effect on our results of operations.

## **Our Offices**

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

## **Employees**

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

## **Our History**

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

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

## **Item 1A. Risk Factors**

### **Risks Related to Our Business**

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

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



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

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

We currently derive all of our revenue from sales of our women's health products, and our failure to maintain or increase sales of these products would have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

We currently derive all of our revenue from sales of women's health products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, natural menopause relief, and scar reduction creams. While sales of our vitamin products grew from 2011 through 2012, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- 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 healthcare laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal healthcare 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 in order to seek approval for and commercialize our proposed hormone therapy products or any other products we may choose to develop in the future.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 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 the data safety monitoring board, or DSMB, the FDA, an 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 institutional review board approval at each site;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredient, or API; or
- delays resulting from negative or equivocal findings of the DSMB for a trial.

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

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

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

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

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



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

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

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

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

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



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

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

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

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's Good Manufacturing Practice, or 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 Health Care Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- 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 healthcare programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

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

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

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

In addition, regulatory requirements could pose barriers to the manufacture of our products, including our proposed hormone therapy products. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers must be approved by the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party CMO. All of our existing

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

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

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

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

- the clinical indications for which our proposed hormone therapy products 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 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 proposed hormone therapy products, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.



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

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

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

Market acceptance and sales of our products, including any proposed hormone therapy products, will depend on coverage and reimbursement policies and may be affected by 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 proposed hormone therapy products, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our existing dietary supplement products or successfully commercialize our proposed hormone therapy products.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the 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 proposed hormone therapy products, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement