UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): January 25, 2013

TherapeuticsMD, Inc.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**000-16731**	**87-0233535**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

951 Broken Sound Parkway NW, Suite 320
Boca Raton, FL 33487
(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1911

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

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

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

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

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

Item 8.01. Other Events.

TherapeuticsMD, Inc. (the "Company") is providing certain information as an update to the information provided in the Company's previous periodic filings with the Commission to reflect recent business developments in advance of filing a Registration Statement on Form S-3 in connection with a shelf offering.

Exhibit 99.1 contains the Company's updated business description and risk factors and is incorporated herein by reference. This Current Report on Form 8-K, including the exhibit, should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2011 as well as the Company's other filings with the Commission. There is no change to the Company's previously reported consolidated financial position or cash flows.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Business and Risk Factor Update for TherapeuticsMD, Inc.

SIGNATURES

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

Date: January 25, 2013

THERAPEUTICSMD, INC.

By: /s/Robert G. Finizio
Robert G. Finizio, Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Business and Risk Factor Update for TherapeuticsMD, Inc.

Exhibit 99.1

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

Special Note Regarding Forward-Looking Statements

This document contains forward-looking statements. All statements other than statements of historical fact contained in this document, including statements regarding our future operating results and financial position, business strategy, and plans and objectives of management for future operations, are forward-looking statements. In many cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of these terms or other similar expressions.

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

- our operating losses incurred since inception and anticipated for the foreseeable future;
- our ability to continue as a going concern;
- our ability to maintain or increase sales of our products;
- our products may not have the healthful effects intended;
- our ability to commercialize our proposed advanced hormone replacement therapies;
- our ability to obtain additional financing;
- our lack of experience in bringing a drug to regulatory approval;
- the uncertainty of results from our clinical trials;
- delays, suspensions, or discontinuation of our clinical trials;
- our reliance on third-parties to conduct our clinical trials and research and development;
- the effects of laws, regulations, and enforcement;
- our dependence on third-party manufacturers;
- our ability to gain and retain market acceptance for our products;
- the competitive nature of the industries in which we conduct our business;
- the availability of reimbursement for our products;
- the impact of product liability lawsuits;
- unfavorable publicity or lack of customer acceptance;
- our use of hazardous or biological materials in violation of applicable law;

- our reliance on our executive officers and key personnel;
- our ability to expand our direct sales force;
- our dependence on certain customers and distribution channels;
- our ability to maintain optimal inventory levels;
- our response to changing consumer preferences and demand;
- product recalls;
- our inability to manage our growth;
- the conduct of our employees;
- our ability to protect our intellectual property and not infringe on the intellectual property of others; and
- our ability to establish and maintain proper internal controls and comply with the financial reporting obligations of the SEC and Sarbanes-Oxley.

Readers are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on these forward-looking statements. All of the forward-looking statements we have included in this document are based on information available to us on the date of this document. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as otherwise required by law.

BUSINESS

Introduction

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

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

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

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 economy or 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 and Medicaid Services, the total national spending on prescription drugs, both private and public, from retail outlets reached $259 billion in 2010, or approximately ten percent of all national healthcare spending. Total national spending on prescription drugs, both private and public, from retail outlets “increased on average by about 10 percent a year from 1998 through 2009 — faster than the average 6.7 percent 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 Health Market

The U.S. Census Bureau projects that there were approximately 150 million women and 146 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, greater rates of health problems, 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, or HT, 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 ending June 30, 2012, prescriptions for either treatment of menopause symptoms or prevention of osteoporosis generated total sales of over $3.2 billion on 37.5 million prescriptions. Oral hormone therapy accounted for $1.7 billion on 25.8 million prescriptions over the same time period.

Prescriptions for menopausal hormone therapy in the United States have dropped significantly since 2002 with the results of the Women's Health Initiative, or WHI, study that found that subjects using estrogen plus 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 HT 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 41.5 million women in the United States between the ages of 45 and 64 in 2010, projected to increase slightly (2.4%) to 42.5 million in 2015 and maintaining at approximately 43 million until 2030, 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 $2.34 billion for the twelve months ending June 2012. That was up 4.9% 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.

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. 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 estimate that approximately 70% to 80% of estrogen usage is for the treatment of vasomotor symptoms, while the other 20% to 30% is prescribed mainly 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 United States 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 therapy 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, the European Journal of Obstetrics, Gynecology and Reproductive Biology in 1999, and Clinical Endocrinology in 1994, demonstrated efficacy based on increases in bone mineral density. Epidemiological and some fracture prevention studies, such as those published in the American Journal of Obstetrics and Gynecology in 1989 and the New England Journal of Medicine in 1980, also have demonstrated a decrease in fractures resulting from increases in bone density associated with estrogen therapy.

Progestin-Only Therapies

The progestins include the naturally occurring hormone progesterone and a number of synthetic 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. Progesterone has also been used in fertility treatments. Progestins have 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. 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 ending June 2012, up 3.3% over the same time period a year prior. The segment is still dominated by products in the Premarin® family that constituted 56% of that market segment.

Limitations of Existing Estrogen/Progestin Therapies

The most commonly prescribed progestin (medroxyprogesterone acetate) 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 lower LDL cholesterol.

One of the most widely prescribed progestin is the naturally occurring progesterone, 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 begin taking a prenatal vitamin as the recommended standard of care. Prenatal vitamins are 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 brand and generic prenatal vitamins available, with both prescription and over-the-counter (non-prescription), or OTC, choices. According to Source Healthcare Analytics, there were 9.4 million prescriptions for prenatal vitamins sold for a total of $370 million for the 12 months ended June 30, 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. Since 2008, the use of OTC products is now larger than prescription products, largely driven by increased use among women currently pregnant.

Our Business Model

We are a specialty pharmaceutical company focused on creating safe and effective prescription, over-the-counter (non-prescription), or OTC, and generic products targeted exclusively for women, including products specifically for pregnancy, childbirth, nursing, pre-menopause, and menopause. We intend to use our current product line, including prescription and over-the-counter prenatal vitamins, over-the-counter multivitamins, vegan DHA, iron supplements, Vitamin D supplements, natural menopause relief products, and scar tissue and stretch mark creams, as the foundation of our business platform. If commercialized, our proposed hormone therapy products will allow us to enter the $3 billion hormone therapy market segment, based on 2011 total sales of the hormone therapy market according to Health Source 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 nutritional supplements, and other products under our vitaMedMD name and our generic prescription prenatal vitamins products under our BocaGreenMD Prena1 name. We believe that our vitaMedMD™ brand name has become a recognized name for high quality and effective women's healthcare, while our BocaGreenMD Prena1™ products will provide physicians, women, and payors with a lower cost alternative. 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 products 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 to consumers. We strive to demonstrate to physicians that recommending our products enable them to realize office efficiencies and patient and payor cost savings over competitive products strategies, and distribution models. In addition, our products offer health care providers an alternative to patients to meet their individual nutritional and financial requirements related to co-pay and cost of care considerations. We also believe that our combination of branded, generic, and over-the-counter lines allows physicians, women, and payors cost-effective alternatives for top quality care. We supply our prescription products to consumers through retail pharmacies. We supply our over-the-counter products either directly to consumers via the Internet and phone sales followed by home shipment as well as through physicians who then sell them to their patients. Our fully staffed customer care center uses current customer relationship management technologies to respond to health care providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders through our auto-ship feature.

As healthcare becomes increasingly consumer driven, patients are seeking more information, control, and convenience, which place 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 deliver the most efficacious outcomes by using the lowest effective dose for the shortest duration.

- We believe our product attributes will result in greater patient 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 we are able to show health care provider practices, that by recommending our products, they are able to realize office efficiencies and patient cost savings over prescribing competing products. In addition, health care providers are able to offer alternatives to patients that meet the patients' individual nutritional and financial requirements.

- Health care provider practices that choose to dispense our over-the-counter products directly to their patients through their offices earn revenue from the sale of the products.

- Our statistical data indicates that our direct interaction with patients through supplemental patient education achieves a high level of patient compliance.

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

Marketing Emphasis. We plan to maintain an emphasis on large group OB/GYN practices that provide opportunities to large patient bases and that are receptive to the data and savings we provide that facilitate them in negotiating contracts with insurance companies.

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

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

Our 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 prenatal vitamins, 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 name and our generic prescription prenatal vitamins products 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 third launch of *vitaMedMD™ RediChew™ Rx* in May 2012. In the fourth quarter 2012, our *BocaGreenMD™* brand was launched and our first products include three generic prescription products *Prena1™ Plus*, *Prena1™* and *Prena1™ Chew*. Our product line is detailed below.

vitaMedMD™ Plus (Prenatal Women's Multi-vitamin + 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 the latest 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 and tolerability. The 300mg 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, minerals, and 200 mg of vegetarian, plant-pure life's DHA,™ which is 100% fish-free with no ocean-borne contaminants, such as mercury or polychlorinated biphenyis, 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™ 300mg capsule. (Quatrefolic® is a registered trademark of Gnosis S.P.A.) All minerals, including iron, zinc, and copper, are chelated to improve absorption and tolerability.

vitaMedMD™ One Rx Prenatal Multivitamin

vitaMedMD™ One Rx is a prescription-only product with a single-dose daily multivitamin containing Quatrefolic, the fourth generation folate, and 200 mg of vegetarian, plant-pure life's DHA, which is 100% fish-free with no ocean-borne contaminants such as mercury and PCBs. Each convenient, easy-to-swallow softgel features fourteen minerals, vitamins and 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, the fourth generation folate, 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 a doctor-recommended iron replacement supplement with a unique 3-weeks-on/1-week-off dosing schedule that helps maximize absorption and enhances 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 E, 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 solution for hot flashes, night sweats, and mood disturbances. Each single tablet dosage delivers 120 mg of Lifenol®, a patented, 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. This product offers women a natural alternative to hormone therapy.

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 doctor-formulated 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. *vitaMedMD™ Vitamin D3 50,000 IU and Vitamin D3 2,000 IU* are used in the dietary management of Vitamin D deficiency and should be used under medical supervision. We believe *vitaMedMD™* Vitamin D3 50,000 IU and Vitamin D3 2,000 IU are ideal for pregnant, breastfeeding, and menopausal women needing 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. Backed by clinical and scientific testing, *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™ Prena1 Plus

BocaGreenMD™ Prena1 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'sDHA.

BocaGreenMD™ Prena1

BocaGreenMD™ Prena1 is a prescription-only, convenient single-dose softgel with 14 vitamins, minerals and 200 mg of plant-based life's DHA.

BocaGreenMD™ Prena1 Chew

BocaGreenMD™ Prena1 Chew is a prescription-only, single daily easy to chew, vanilla-flavored, chewable tablet ideal 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 Prena1 multivitamins contain a combination of folic acid and Quatrefolic and are available by prescription only.

Our Proposed Hormone Therapy Products

Our three proposed hormone therapy products have received IND acceptance by the FDA. Our goal is to improve bioavailability of our progestin when used alone or in combination with estrogen over current marketed and FDA approved options. Early PK studies on our HT products indicate achievement of 80-125% comparability of the reference listed drugs approved by the FDA for the combined progestin and estrogen product. We hope to begin phase 3 trials in the first half of 2013. Progestins and estrogens are clearly 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' TX12001HR

Therapeutics' TX12001HR is a drug candidate that will be a combination product for post-menopausal women with an intact uterus. It will be indicated for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness. 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 will 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 biodentical hormones would be approved for use in a single combined product.

Therapeutics' TX12002HR

Therapeutics' TX12002HR is a drug candidate that will be a progestin product indicated for treatment of secondary amenorrhea. It is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product will be chemically identical to the hormones that naturally occur in a women's body. We believe it will be similarly effective but at lower dosages.

Therapeutics' TX12003HR

Therapeutics' TX12003HR is a drug candidate that will be an estrogen product indicated 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. This can be used for women with and without a uterus. It is an estradiol product, chemically bio-identical to the hormones that naturally occur in a women's body.

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

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 in the country. By delivering additional products through the same sales channel, we can leverage our already deployed assets to increase our sales and improve 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. According to Forrester Research, U.S. online retail sales increased 12.2% from 2010 to 2011. Forrester projects online retail sales to grow at a 10% compound annual growth rate, to $278.9 billion by 2015. 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 propriety 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 manufacturers maintain 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 over 80% of our products from Lang Naturals, Inc., or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven™ products, including medical foods, nutritional supplements, beverages, bars, and functional foods in the dietary supplement category; 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 products are manufactured and regulated by the same FDA quality standards (Controls Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements for FDA 21 CFR Part 110/111 CGMP Regulations, or CFR 111,) and current good manufacturing practices, or cGMP, as prescription nutritional therapies. In addition, we conduct two additional unrequired certificates of analysis on every lot to ensure quality, and 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 not have a material adverse effect on our business.

We plan to use third-party manufacturers to source key raw materials and manufacture and package our commercial products. The FDA must issue marketing clearance and deem a manufacturer acceptable under cGMP regulations before production of bulk proprietary or finished pharmaceuticals for commercial sale may begin. Accordingly, we intend to engage only those third-party contract manufacturers that have consistently shown the ability to satisfy these requirements.

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 the latest FDA regulations. To ensure the highest quality, our manufacturing operations are audited by AIB International, Inc., or AIB, 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 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. In addition, our manufacturers are hazard analysis critical control point certified which is a systematic preventive approach for food and pharmaceutical safety that addresses physical, chemical and biological hazards as a means of prevention rather than finished product inspection.

Distribution of our Products

We use a variety of distribution channels dependent upon product type. We sell our prescription 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 the Internet 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 product 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 technologies 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 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 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 constantly seeking ways to protect our intellectual property through registrations in relevant jurisdictions.

We have several patents pending with the United States Patent and Trademark Office, or USPTO. 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 numerous U.S. trademark registrations and have 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, as formal clinical studies have in most instances not been conducted by us to validate the intended health benefits of our products, we are generally prohibited by the FDA 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

The products we are currently marketing do not specifically require FDA approval, but we are subject to federal and state consumer protection laws, including laws protecting the privacy of consumer non-public information and regulations prohibiting unfair and deceptive acts and trade practices. In particular, under federal and state financial privacy laws and regulations, we must provide

- notice to consumers of our policies on sharing non-public information with third parties;
- advance notice of any changes to our policies; and
- with limited exceptions, provide consumers the right to prevent sharing of their non-public personal information with unaffiliated third parties.

We received acceptance of the INDs for our proposed hormone therapy products, TX12002HR, TX12003HR and TX12001HR, from the FDA on June 29, 2012, August 23, 2012, and August 30, 2012, respectively. We plan to file NDAs via 21 CRF Part 314 and utilize previously available data in support of our drug candidates' approval. We anticipate the FDA will require us to perform further studies evaluating blood levels of the drug candidate after dosing to prove the correlation of dosage strengths (phase 1). In addition, phase 3 clinical trials for secondary amenorrhea versus placebo will be required for TX12002. TX12003 will be required to undergo phase 3 studies of vasomotor symptoms compared to placebo. In regards to TX12001, we will be required to do phase 3 studies for vasomotor symptoms versus placebo and an endometrial protection study.

All of our products are subject to extensive regulation in the United States. The FDA enforces the Federal Food, Drug and Cosmetic Act, or FDCA, and related regulations, which govern the identity, purity, quality, strength, and composition of dietary supplements and regulate the formulation, manufacture, packaging, labeling, holding, sale, and distribution of dietary supplements, foods, and OTC and prescription drugs, and prohibit the sale of misbranded and adulterated dietary supplements and dietary supplements that by the intention of the manufacturer or distributor or label or labeling claims are unapproved new drugs.

The Federal Trade Commission, or FTC, enforces the Federal Trade Commission Act, or FTCA, and related regulations which govern the advertising and advertising acts and practices associated with the promotion and sale of these products. The U.S. Postal Inspection Service enforces federal laws governing fraudulent use of the mail. Regulation of certain aspects of the dietary supplement business at the federal level is also governed by the Consumer Product Safety Commission, or CPSC, (*e.g.*, concerning the presence of adulterated substances, such as toxic levels of lead or iron, that render products unsafe for consumption and require an ordered recall), the Department of Agriculture (*e.g.*, for products that are intended for ingestion as dietary supplements for animals) and the Environmental Protection Agency (*e.g.*, in the methods of disposal used for certain dietary ingredients, such as colloidal silver). Federal and state anti-kickback statutes, the Ethics in Patient Referrals Act, false claims statutes and the Health Insurance Portability and Accountability Act, or HIPPA, also apply to our business.

The FDCA has been amended several times affecting provisions that concern dietary ingredients and dietary supplements, including by the Dietary Supplement Health and Education Act of 1994, or DSHEA. DSHEA formally defined what may be sold as a dietary supplement, defined statements of nutritional support and the conditions under which they may lawfully be used, and included provisions that permit the FDA to regulate manufacturing practices and labeling claims peculiar to dietary supplements. "Dietary supplements" are defined as vitamins, minerals, herbs, other botanicals, amino acids, and other dietary substances that are used to supplement the diet, as well as concentrates, constituents, extracts, metabolites, or combinations of such dietary ingredients. Generally, under DSHEA, dietary ingredients that were on the market before October 15, 1994 may be used in dietary supplements without notifying the FDA. However, a "new" dietary ingredient (*i.e.*, a dietary ingredient that was 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 having been "chemically altered." A new dietary ingredient notification must provide the FDA with evidence of a "history of use or other evidence of safety," which establishes 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 new dietary ingredient can be marketed. There can be no assurance that the FDA will accept evidence purporting to establish the safety of any new dietary ingredients that we may want to market and the FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients.

Increased FDA enforcement could lead the FDA to challenge dietary ingredients already on the market as "illegal" under the FDCA because of the failure to file a new dietary ingredient notification or because the substance may be one found to be the subject of an investigational new drug application for which clinical trials have commenced and been publicized.

The FDA generally prohibits labeling a dietary supplement with any "health claim" (*i.e.*, any statement associating a nutrient with prevention, but not treatment, of a disease or health-related condition), unless the claim is pre-approved by the FDA. The FDA prohibits disease treatment claims entirely when made for a dietary supplement; however, "statements of nutritional support," including so-called "structure/function claims" are permitted to be included in labeling for dietary supplements without FDA pre-approval. 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 the structure, function or well-being of the body, but such statements may not state that a dietary supplement will reduce the risk or incidence of a disease unless such claim has been reviewed and approved by the FDA. A company that uses a statement of nutritional support in labeling must possess evidence substantiating that the statement is truthful and not misleading. Such statements must be submitted to the FDA no later than 30 days after first marketing the product with the statement and must be accompanied by the following FDA mandated label disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." There can be no assurance that the FDA will not determine that a particular statement of nutritional support that we want to use is an unacceptable disease claim or an unauthorized nutrient-disease relationship claim otherwise permitted with FDA approval as a "health claim." Such a determination might prevent the use of such a claim.

In addition, DSHEA provides that certain "third-party literature," such as a reprint of a peer-reviewed scientific publication linking a particular dietary ingredient with health benefits, may "in connection with the sale of a dietary supplement to consumers" be exempt from labeling regulation. However, the FDA has adopted an "intent to use" doctrine whereby such literature, even if exempt from labeling, may nonetheless form the basis for an agency determination that the literature in context reveals a company's intent to sell a dietary ingredient or dietary supplement as a drug, thereby rendering the supplement an unlawful, unapproved new drug. Because the "intent to use" doctrine is predicated on a subjective assessment of all facts and circumstances associated with the promotion and sale of a dietary supplement, we cannot know whether any particular piece of literature otherwise exempt from labeling will be deemed by the FDA unlawful for use in association with the sale of the dietary ingredient or dietary supplement.

As authorized by the FDCA, the FDA has adopted and is implementing Good Manufacturing Practices, or GMPs, specifically for dietary supplements. These GMPs impose extensive process controls on the manufacture, holding, labeling, packaging, and distribution of dietary supplements. They require that every dietary supplement be made in accordance with a master manufacturing record; that each step in the manufacture, holding, labeling, packaging, and distribution be defined with written standard operating procedures, monitored, and documented; and that any deviation in manufacture, holding, labeling, packaging, or distribution be contemporaneously documented, assessed by a quality control expert, and corrected through documented corrective action steps (whether through an intervention that restores the product to the specifications in the master manufacturing record or to document destruction of the non-conforming product). The GMPs are designed to ensure documentation, including testing results that confirm the identity, purity, quality, strength, and composition of dietary supplements. In addition, GMPs require a company to make and keep written records of every product complaint that is related to GMPs. The written record of the product complaint must include the following: the name and description of the dietary supplement; the batch, lot, or control number of the dietary supplement, if available; the date the complaint was received and the name, address, or telephone number of the person making the complaint, if available; the nature of the complaint, including, if known, how the product was used; the reply to the complainant, if any; and findings of the investigation and follow-up action taken when an investigation is performed. The regulations directly affect all that manufacture the dietary supplements we sell. The FDA may deem any dietary supplement adulterated, whether presenting a risk of illness or injury or not, based on a failure to comply with any one or more process controls in the GMP regulations. If deemed adulterated, a dietary supplement may not be lawfully sold and may have to be recalled from the market. It is possible that the FDA will find one or more of the process controls implemented by us, by our contract manufacturers, or by those whose dietary supplements we sell to be inadequate and, thus, requiring corrective action, requiring any one or more of the dietary supplements we sell to be unlawful for sale, or resulting in a judicial order that may impair our ability to manufacture, market, and sell dietary supplements.

The FDA also requires adverse event reporting notices on labels and serious adverse event reporting for all supplements and drugs. An “adverse event” is defined by statute to include “any health-related event associated with the use of a dietary supplement that is adverse.” All adverse events and medication errors are reported to the FDA on a voluntary basis. An IND sponsor must report all adverse events expected or unexpected in an Annual report to the Agency within 60 days of IND acceptance anniversary. Only serious adverse events must be reported to the FDA on a seven-day reporting basis. A “serious adverse event” is an adverse event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above.

The regulation of medical foods and dietary supplements may increase or become more restrictive in the future. There can be no assurance that, if more stringent statutes are enacted for dietary supplements, or if more stringent regulations are promulgated, we will be able to comply with such statutes or regulations without incurring substantial expense.

The FDA regulates the formulation, manufacturing, packaging, labeling, and distribution of OTC and prescription drug products pursuant to a “monograph” system that specifies active drug ingredients that are generally recognized as safe and effective for particular uses. If an OTC or prescription drug is not in compliance with the applicable FDA monograph, the product generally cannot be sold without first obtaining FDA approval of a new drug application, which can be a long and expensive procedure. The homeopathic drugs that we sell are regulated as prescription or non-prescription drugs. These products must generally meet the standards set forth in the Homeopathic Pharmacopeia of the United States and claims made for them must not deviate from those contained in specific homeopathic treatises recognized by the FDA as appropriate for use. If these requirements are not met, the FDA can consider the products unapproved new drugs and prohibit their sale.

The FDA has broad authority to enforce the provisions of the FDCA concerning medical foods, dietary supplements, and drugs, including powers to issue a public “warning letter” to a company to quarantine and prohibit the sale of products deemed adulterated or misbranded, to publicize information about illegal products, to request a voluntary recall of illegal products from the market, to request that the Department of Justice initiate a seizure action, to pursue an injunction action or a criminal prosecution in U.S. courts, and to seek disgorgement from a federal court of all proceeds received from the sale of products deemed misbranded or adulterated. For instance, the FDA recently announced that any unapproved new drug introduced after September 19, 2011 will be subject to immediate enforcement action, without prior notice and without regard to the enforcement priorities set out in CPG 440.100. The FDA will continue to apply the enforcement priorities established in 2006. These give a higher priority to enforcement actions involving drugs in certain high-risk categories, such as drugs that pose a potential safety risk or lack evidence of effectiveness.

The FTC exercises jurisdiction over the advertising of medical foods, dietary supplements, and drugs. 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.

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 reimbursed under the Medicare and 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.

- 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 our regulatory counsel has assisted us in establishing business practices 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 exclusions 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.

Legal Proceedings

We are party to various legal actions arising in the ordinary course of business, including actions related to our intellectual property. While it is not feasible to determine the actual outcome of these actions at this time, we do not believe that these matters, including those described below, will have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

Aceto Corporation

On November 13, 2012, Aceto Corporation filed a lawsuit against our company in the United States District Court for the Southern District of Florida. The lawsuit alleges, among other things, that we are improperly obtaining certain products containing Quatrefolic and improperly using the related trademarks that we have acquired pursuant to a sub-license agreement with Pernix Therapeutics Holdings, Inc., or Pernix. Cooper C. Collins, a member of our Board of Directors, is the President, Chief Executive Officer, and a director of Pernix. The lawsuit seeks to enjoin us from using the Quatrefolic products and trademarks, in addition to unspecified actual and punitive damages. We filed a motion to dismiss on January 2, 2013. Based on our assessment, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

Avion Pharmaceuticals, LLC

On November 30, 2012, Avion Pharmaceuticals, LLC, or Avion, filed a lawsuit against our company in the United States District Court for the Northern District of Georgia. The lawsuit alleges, among other things, unfair competition and trademark infringement against Avion's "Prenate" trademarks based on the use of our Prena1 branded products which we launched in November 2012. The lawsuit seeks to enjoin us from using the Prena1 name, in addition to unspecified actual and punitive damages. We filed an answer and counterclaim on January 17, 2013. Based on our assessment, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

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 bocagreenmd.com.

Properties

On July 9, 2009, we entered into a 45-month lease for approximately 7,130 square feet of office space for our principal executive offices. Over the term of this lease, we will pay an average monthly cost of $9,352, which includes base rent, common area fees, taxes, and insurance. Terms of this lease provide for an extension for an additional two-year period. The primary functions performed at our corporate headquarters are accounting, marketing, human resources, product development oversight, product sales, and fulfillment. We believe that the leased premises are suitable and adequate to meet our current needs.

Employees

As of September 30, 2012, we had 62 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 shareholders 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 October 3, 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 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.

Market, Industry, and Other Data

Unless otherwise indicated, information contained herein concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various sources, on assumptions that we have made that are based on those data and other similar sources, and on our knowledge of the markets for our products. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the "Risk Factors" sections in our filings with the Commission. These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

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 $2.9 million and $12.9 million for the years ended December 31, 2010 and 2011, respectively, and $29.4 million for the nine months ended September 30, 2012. As of September 30, 2012, we had an accumulated deficit of approximately $46.4 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 firms, in their audit reports related to our financial statements for the years ended December 31, 2011 and 2010, expressed substantial doubt about our ability to continue as a going concern.

As a result of our continued losses, our independent registered public accounting firms have included an explanatory paragraph in their reports on our financial statements for the years ended December 31, 2011 and 2010, 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 firms 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 2010 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 versions of our prescription 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, 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 prescription and over-the-counter, or OTC, revenue from sales of our existing products do 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 commercialize our proposed hormone therapy products or other product candidates.

If our products do not have the healthful effects intended, our business may suffer.

Although many of the ingredients in our current products are vitamins, minerals, and other substances for which there is a long history of human consumption, they contain innovative ingredients or combinations of ingredients. Although we believe all of such products and the combinations of ingredients in them are safe when taken as directed, the products could have certain side effects if not taken as directed or if taken by a consumer that has certain medical conditions. In addition, such products have been proven to be more effective when taken in accordance with certain instructions, which include certain dietary restrictions. Therefore, such products may not be effective if such instructions are not followed. 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. 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 three 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 commercialize our three 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. Although we have received Investigational New Drug applications acceptance by the FDA for our proposed hormone replacement therapy products, we may not be able to complete the development, obtain necessary FDA approval, or commercialize any of these proposed products. 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. We currently estimate the cost of our research and development activities through the completion of our phase 3 trials will be approximately $18.0 million for TX12001HRT, will be approximately $7.0 million for TX12002HRT, and will be approximately $8.0 million for TX12003HRT. 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 have currently 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 New Drug Applications, or 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, or it may require that we conduct additional clinical or manufacturing validation studies, which may be costly, 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 or application 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 our proposed hormone therapy 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.

Our proposed hormone therapy products are currently in various stages of clinical testing, which is expensive, can take many years to complete, and have a highly uncertain outcome. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug or inadequate adherence by patients or investigators to clinical trial protocols. If clinical trials for any of our proposed hormone therapy products fail to demonstrate safety and efficacy compared to placebo according to FDA guidelines, the FDA will not approve that proposed product 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.

Our planned phase 3 trials for our proposed hormone therapy products may be more expensive and time consuming than we currently expect. FDA regulations require phase 3 trials for any drug for which an NDA is submitted. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than we have, have suffered significant setbacks in phase 3 clinical trials. The failure to obtain positive results in any of our phase 3 clinical trials could seriously impair the development prospects, and even prevent regulatory approval, of our proposed hormone therapy products.

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 or delayed 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;
- 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 data safety monitoring board, or 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 Data Safety Monitoring Board or the Institutional Review Board 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 clinical trials, and we may experience delays in obtaining or may be unsuccessful in obtaining regulatory approval for or commercialize our proposed hormone therapy products if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We have relied, and plan to continue to rely, on various CROs to recruit patients, 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 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, 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 we cannot control whether or not they will devote sufficient time and resources to our on-going clinical, non-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. 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 impact our ability to meet our desired clinical development timelines. 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 health 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 impact the cost, timing, and completion of the clinical trials for our proposed hormone therapy products.

In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as impose more stringent product labeling and post-marketing testing and other requirements.

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

Even if we obtain regulatory approval for 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 impose ongoing requirements for potentially costly post-approval studies 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 phase 4 trials could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about side effects or efficacy of a product. For example, the labeling ultimately approved for our proposed hormone therapy products, if any, may include restrictions on use. 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. Therefore, our proposed hormone therapy products will also be subject to ongoing FDA requirements governing the 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 and other 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 proposed hormone therapy products and other products. Accordingly, new data about our proposed hormone therapy products and other products could negatively impact 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 proposed hormone therapy products or other products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our proposed hormone therapy products or other 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 current good manufacturing practices, or cGMP 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 Risk Evaluation and Mitigation Strategy. 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 Veteran's 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;
- suspend 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
- 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.

We rely on third parties for our research and development efforts. We may be unable to obtain regulatory approval for or commercialize our product candidates if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We do not have the resources to independently conduct research and development activities; therefore, we rely on third parties, such as CROs, to conduct all of our research and development activities and expect to continue to do so in the future. Because we rely on such third parties, we have less direct control over those activities and cannot assure you that the research will be done properly or in a timely manner, or that the results will be reproducible. 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. In addition, our CROs are not our employees and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they devote sufficient time and resources to our on-going programs. Switching or adding additional CROs involves additional cost and requires 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 impact our ability to meet our desired clinical development timelines and can increase our costs significantly. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

Our dependence upon third parties for the manufacture and supply of our existing women's health 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 health products or our proposed hormone therapy products for use in the conduct of our clinical trials. We employ the services of third parties to manufacture our products for sale and to supply the finished product for the clinical trials for our proposed hormone therapy products. These third parties manufacture the products according to our specifications under our proprietary rights. Although we do not have long-term contracts for the commercial supply of our products or our proposed hormone therapy products, we intend to eventually pursue long-term manufacturing agreements. However, 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. We do not control the manufacturing process of our existing products or our proposed hormone therapy products and are completely dependent on these third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of the products. 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, 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 third-party manufacturers give greater priority to the supply of other products over our products and product candidates 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 women's health products, including any of our proposed hormone therapy products that are 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 the product is approved;
- acceptance by physicians and payors of each product as a 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 pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our products, including any proposed hormone therapy that are approved, face intense competition, including from major multinational pharmaceutical 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.

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 approved hormone therapy products, will depend on 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 drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for our products, including any approved hormone therapy products. Also, we 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 with our existing products or 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 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 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 cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products 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 that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. The goal of PPACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our products. Members of the U.S. Congress and some state legislatures are seeking to overturn at least portions of the legislation, and we expect they will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

The availability of numerous generic products at lower prices than branded products, such as our proposed hormone therapy products if they were approved for commercial introduction, may also substantially reduce the likelihood of reimbursement for such products. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

We face an inherent risk of product liability as a result of the clinical testing of our proposed hormone therapy products despite obtaining appropriate informed consents from our clinical trial participants, and will face an even greater risk if we commercialize our proposed hormone therapy products in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or proposed hormone therapy products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in any of the following:

- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls or withdrawals;
- labeling, marketing, or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or proposed products; and
- a decline in our stock price.

Although we maintain general liability insurance of up to $10.0 million in the aggregate and clinical trial liability insurance of $10.0 million in the aggregate for our proposed hormone therapy products, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects.

Our business may be affected by unfavorable publicity or lack of consumer acceptance.

We are highly dependent upon consumer acceptance of the safety, efficacy, and quality of our products, as well as similar products distributed by other companies. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention, and other publicity about product use. A product may be received favorably resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or any of our particular products and may not be consistent with earlier favorable research or publicity. A future research report or publicity that is perceived by our consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates consumption of our product or any other similar product with illness or other adverse effects, or that questions the benefits of our product or a similar product, or that claims that such products are ineffective could have a material adverse effect on our business, reputation, financial condition or results of operations.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological, and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state, and local laws and regulations in the United States govern the use, manufacture, storage, handling, and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing, and disposing of these materials (all of which only occur at third-party sites operated by our contractors) comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. We also cannot predict the impact on our business of new or amended environmental laws or regulations, or any changes in the way existing and future laws and regulations are interpreted or enforced. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources, and we do not carry liability insurance covering the use of hazardous materials. If we fail to comply with applicable requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs, or capital expenditures for control equipment or operational changes necessary to achieve or maintain compliance. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which adversely affect our business, financial condition, results of operations, and prospects.

We are subject to extensive and costly government regulation.

Pharmaceutical products, including the vitamins we are currently selling and hormone therapy drugs we are currently developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. If any products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling products. Our failure to comply with these regulations could result in significant fines or the inability of our product candidates to obtain and maintain regulatory approval, which would have a materially adverse effect on our business, financial condition, results of operations and prospects.

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

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock options that vest over time. The value to employees of stock options will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific, and medical teams may terminate their employment with us on short notice. We do not have employment agreements with a number of our key employees. As a result, most employees are employed on an at-will basis, which means that any of these employees could leave our employment at any time, with or without notice, and may go to work for a competitor. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, and financial condition. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled scientific and medical personnel.

Any failure to adequately expand a direct sales force will impede our growth.

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets in which we do business. While there presently exists a high rate of unemployment, if we are unable to hire and develop sufficient numbers of productive sales personnel our business prospects could suffer.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and longer histories than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we offer. If we are unable to continue to attract and retain high-quality personnel, our ability to commercialize drug candidates will be limited.

Our success is tied to our distribution channels.

We sell our prescription products to wholesale drug distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. We do not promote our products to these customers, and they do not determine product demand. However, over 96% of our product shipments since inception were to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. Our business would be harmed if any of these customers refused to distribute our products or refused to purchase our products on commercially favorable terms to us.

A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our reputation and subject us to financial losses.

Our ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. In some instances, our products have unique ingredients used under license arrangements. If our manufacturers are unsuccessful in obtaining raw materials, if we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and brands could be harmed, and physicians may be less likely to recommend our products in the future, each of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Our success depends on how efficiently we respond to changing consumer preferences and demand.

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences. We may not be able to respond in a timely or commercially appropriate manner to these changes. Our failure to accurately predict these trends could negatively impact our inventory levels, sales, and consumer opinion of us as a source for the latest product. The success of our new product offerings depends upon a number of factors, including our ability to achieve the following:

- accurately anticipate customer needs;
- innovate and develop new products;
- successfully commercialize new products in a timely manner;
- competitively price our products in the market;
- procure and maintain products in sufficient volumes and in a timely manner; and
- differentiate our product offerings from those of our competitors.

If we do not introduce new products, make enhancements to existing products, or maintain the appropriate inventory levels to meet customers' demand in a timely manner, our business, results of operations, and financial condition could be materially and adversely affected.

We may be subject to product recalls that could negatively affect our business.

We may be subject to product recalls, withdrawals, or seizures if any of the products we formulate, manufacture, or sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal, or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and could materially and adversely affect our business, financial condition, and results of operations.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2012, we had 62 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our proposed hormone therapy products and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately, or to disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to our Intellectual Property

Another party could develop hormone products and achieve FDA regulatory exclusivity in the United States before we do, potentially preventing our ability to commercialize our proposed hormone therapy products and other products in development.

We have and will continue to seek to obtain various forms of exclusivity for our proposed hormone therapy products and other products in development, including FDA regulatory exclusivity. To the extent that patent protection is not available or has expired, FDA regulatory exclusivity may be the only available form of exclusivity available for our proposed hormone therapy products and other products in development. The process of obtaining regulatory approvals can be lengthy. The FDA also has substantial discretion to require additional testing, to delay or withhold registration and marketing approval, and to otherwise preclude distribution and sale of product. At the same time, potentially competitive products may be in various stages of development, some of which may have been filed for approval with the FDA. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may achieve FDA approval and exclusivity before we do, which could delay our ability to obtain necessary regulatory approvals, result in lost market opportunities with respect to our proposed hormone therapy products and other products, and materially adversely affect our business, financial condition, and results of operations.

If our efforts to protect the proprietary nature of the intellectual property related to our proposed hormone therapy products and other products are not adequate, we may not be able to compete effectively in our market

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent positions as well as our ability to maintain adequate protection of other intellectual property for our proposed hormone therapy products and other products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent positions of pharmaceutical companies are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action, and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the recently adopted America Invents Act of 2011, may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged, discovered to have been issued on the basis of insufficient or incorrect information, or held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude other competitors from developing or designing around these patents;
- we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were not the first to file patent applications for these inventions;

- we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;

- future product candidates may not be patentable;

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

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

- we may fail to timely apply for patents on our technologies or products.

While we apply for patents covering our technologies and products, as we deem appropriate, many pharmaceutical companies and university and research institutions already have filed patent applications or have received patents in our areas of product development**.** These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our proposed hormone therapy products**.** In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the U.S. Patent and Trademark Office, or USPTO, or applicable foreign patent regulatory authorities, as applicable, to determine our rights in the invention, which may be time-consuming and expensive. Moreover, issued patents may be challenged during post-grant proceedings brought by a third party or the USPTO, or in foreign countries, or in the courts. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our proposed hormone therapy products or other product candidates may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to our patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as "at risk" launches to challenge our patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent us or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the areas of hormone replacement therapy, including compounds, formulations, treatment methods, and synthetic processes that may be applied towards the synthesis of hormones. We cannot provide assurances that we or our partners will be free to manufacture or market our product candidates as planned, or that we or our licensors' and partners' patents will not be opposed or litigated by third parties. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry generally. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations, and prospects, including the following:

- infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management's attention from our business;

- substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;

- a court prohibiting us from selling or licensing our technologies or future products unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; and

- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes, or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our product candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

We may be required to file lawsuits or take other actions to protect or enforce our patents or the patents of our licensors, which could be expensive and time consuming.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions, or other interim proceedings or developments to be negative, the price of our common stock could be adversely affected. The occurrence of any of the above could adversely affect our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of certain information, the value of our products and technology could be materially adversely affected.

We also rely on trade secrets, know-how, and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers, and collaborators. We cannot, however, ensure that these protective arrangements will be honored by third parties, and we may not have adequate remedies if these arrangements are breached. In addition, enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, or technological advancements is expensive, time-consuming, and uncertain. Non-U.S. courts are sometimes less willing than U.S. courts to protect this information. Moreover, our trade secrets, know-how, and technological advancements may otherwise become known or be independently developed by competitors in a manner providing us with no practical recourse against the competing parties. If any such events were to occur, they could adversely affect our business, financial condition, results of operations, and prospects.

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

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

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include the following:

- any delay in commencement of our phase 3 clinical trials for our proposed hormone therapy products;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our proposed hormone therapy products and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our proposed hormone therapy products;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate product supply for our proposed hormone therapy products or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners' commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;

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

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

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

In addition, the stock market in general, and the OTCQB Bulletin Board and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

At December 31, 2012, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 70% of our common stock on an as-if converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to deliver a report that assesses the effectiveness of our internal control over financial reporting for the year ending December 31, 2012. Our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2012.

If we conclude that our internal control over financial reporting is not effective, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effect on our operations because there is presently no precedent available by which to measure compliance adequacy. As a consequence, we may not be able to complete our remediation process in time to meet our deadline for compliance with Section 404 of the Sarbanes-Oxley Act. Also, there can be no assurance that we will not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. The presence of material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results.

If we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the value of their stock.

Some provisions of our charter documents and Nevada law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if an acquisition would benefit our stockholders, and could also make it more difficult to remove our current management. These provisions in our certificate of incorporation and bylaws include the following:

- authorizing the issuance of "blank check" preferred that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;

- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

In addition, we are subject to Nevada's Combination with Interested Stockholders Statute (Nevada Law Sections 78.411 - 78.444) which prohibits an "interested stockholder" from entering into a "combination" with the corporation, unless certain conditions are met. An "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10% or more of the corporation's capital stock entitled to vote.