TherapeuticsMD, Inc.
Form 10-K
March 05, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

S ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

Commission File Number 000-16731

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

6800 Broken Sound Parkway NW

Third Floor

Boca Raton, Florida 33487

(561) 961-1900

(Address, including zip code, and telephone number,

including area code, of Principal Executive Offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	NYSE MKT

Securities registered pursuant to Section 12(g) of the Act: None.

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

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

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

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

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

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

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

(Do not check if a smaller reporting company)

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

The aggregate market value of common stock held by nonaffiliates of the registrant (91,907,740 shares) based on the closing price of the registrant's common stock as reported on NYSE MKT on June 28, 2013, which was the last business day of the registrant's most recently completed second fiscal quarter, was $278,462,272. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors, or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 3, 2014, there were outstanding 145,017,060 shares of the registrant's common stock, par value $0.001 per share.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement for its 2014 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2013.

THERAPEUTICSMD, INC.

ANNUAL REPORT ON FORM 10-K

Fiscal Year Ended December 31, 2013

TABLE OF CONTENTS

---

vitaMedMD®, TherapeuticsMD®, and BocaGreenMD® are registered trademarks of our company. This Annual Report also contains trademarks and trade names of other companies.

This Annual Report includes market and industry data that we obtained from periodic industry publications, third-party studies and surveys, government agency sources, filings of public companies in our industry, and internal company surveys. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the foregoing industry and market data to be reliable at the date of the report, this information could provide to be inaccurate as a result of a variety of matters.

Statement Regarding Forward-Looking Information

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

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

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

PART I

Item 1. *Business*

Overview

Our Company

We are a women's health care product company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins and cosmetics.

We have obtained U.S. Food and Drug Administration, or FDA, approval of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our hormone therapy drug candidates: TX 12-001HR, our oral combination of progesterone and estradiol; TX 12-002HR, our oral progesterone alone; TX 12-003HR, our oral estradiol alone; and TX 12-004HR, our suppository estradiol alone.

Hormone Therapy Market

The menopause hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. On November 27, 2013, the Drug Quality and Security Act became law and the FDA was given additional oversight over compounding pharmacies. We believe FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals, when produced and sold by compounding pharmacies are not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies approximate $1.5 billion

per year and the FDA-approved market approximates $625 million per year. Our phase 3 trials are intended to establish an indication of the safety and efficacy of our bioidentical drug candidates at specific dosage levels. We intend our hormone therapy drug candidates, if approved, to provide hormone therapies with well characterized safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bioidentical market. This is based on our belief that our drug candidates will offer advantages in terms of demonstrated safety and efficacy consistency in the hormone dose, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains than custom order or formulation by individual compounders.

Pipeline of our Hormone Therapy Drug Candidates

TX 12-001HR

TX 12-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman’s body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone the biologically identical or bioidentical to the estradiol and progesterone produced by the ovaries, would be approved for use in a single combined product. According to Source Healthcare Analytics, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately $625 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-002HR

TX 12-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may be effective at lower dosages. According to Source Healthcare Analytics, the total FDA-approved market for oral progestin was approximately $364 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-003HR

TX 12-003HR is a natural estradiol formulation. This hormone therapy drug candidate would be chemically identical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. According to Source Healthcare Analytics, the total FDA-approved market for oral estradiol was approximately $130 million in U.S. sales for the 12 months ended December 31, 2013.

TX-12-004HR

TX 12-004HR is a vaginal suppository estradiol drug candidate for the treatment of vulvar and vaginal atrophy, or VVA, in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure inferring a greater probability of dose administration to the target tissue and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. According to Source Healthcare Analytics, the total FDA-approved market for VVA treatment was approximately $1 billion in U.S. sales for the 12 months ended December 31, 2013.

Preclinical Development

Based upon leveraging our hormone platform technology, we have seven preclinical projects that include development of our proposed combination estradiol and progesterone and progesterone-alone products in a topical cream and transdermal patch form. We plan to advance these projects into the next stages of development as financial and personnel resources become available. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to South Healthcare Analytics, the total FDA-approved menopause-related market for estrogen alone and in combination was approximately $3.3 billion in U.S. sales for the 12 months ended December 31, 2013.

Current Products

As we continue the clinical development of our hormone therapy drug candidates, we continue to market our prescription and over-the-counter dietary supplement and cosmetic product lines, consisting of prenatal vitamins, iron supplements, vitamin D supplements, natural menopause relief products, and cosmetic stretch mark creams under our vitaMedMD® brand name and duplicate formulations of our prescription prenatal vitamin products, also referred to as "generic" formulations, under our BocaGreenMD® Prena1™ name. All of our prenatal vitamins are gluten-, sugar-, and lactose-free. We believe our product attributes result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality and patented ingredients.

Industry and Market

Health Care and Pharmaceutical Market

According to EvaluatePharma® World Preview report, the pharmaceutical industry experienced an unprecedented decline in worldwide prescription drug sales in 2012. Worldwide prescription drug sales fell by 1.6% to $714 billion in 2012, with the United States representing about 36% of the market. Loss of patent protection on a number of blockbuster brands and fiscal austerity affecting Eurozone countries (compounded by a weak euro compared to the dollar) contributed to this unprecedented contraction. In total, $38 billion of sales were lost as a result of expired patent protection, including drugs such as Lipitor and Plavix. According to the report, this anomaly is not expected to continue and sustained sales growth should start returning at the end of 2013 at an average rate of 3.8% per annum between 2012 and 2018.

In terms of numbers of new drug approvals in the United States, 2012 was the best year since 1997 when the Pfizer drug, Lipitor, was approved. But perhaps more important than the large number of approvals in 2012 (45 versus 35 in 2011), quality was also significantly better than in previous years, as judged by analysts' consensus expectations of sales five-year post launch. Looking ahead, EvaluatePharma expects this positive dynamic to continue, with 2013 being another good year for new drug approvals.

Women's Health Care Market

According GBI Research (a provider of industry-leading business intelligence solutions on a global basis) report "Women's Health Therapeutic Market through 2018", the women's health therapeutics market is one of the most attractive markets in the global pharmaceutical industry. Hormone therapy, gynecological disorders, and musculoskeletal disorders in women are the prime areas of focus in the women's health therapeutics market. The women's health therapeutics market in the United States was valued at $12.5 billion in 2011. Revenues are projected to increase to $15.1 billion in 2018 at a compound and growth rate of 2.7%. This can be attributed to the launch of new drug molecules.

Hormone Therapy Market

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. It is defined as the final menstrual period and is confirmed when a woman has not had her period for 12 consecutive months. Hormone therapy is the only government-approved treatment in the United

States and Canada for relief of menopausal symptoms. These symptoms are caused by the reduced levels of circulating estrogen as the ovarian production shuts down. The symptoms include hot flashes, night sweats, sleep disturbances, and vaginal dryness. According to Source Healthcare Analytics, prescriptions for hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis generated total sales of over $3.8 billion on over 36 million prescriptions for the 12 months ended December 31, 2013. Oral hormone therapy accounted for $1.8 billion on 23 million prescriptions over the same time period.

Prescriptions for menopausal hormone therapy in the United States dropped significantly following the Women's Health Initiative, or WHI, study in 2002 that found that subjects using estrogen plus synthetic progestin had, among other things, a greater incidence of coronary heart disease, breast cancer, stroke, and pulmonary embolism. A number of additional studies regarding the benefits and risks of hormone therapy have been conducted over the last decade since the WHI results were first published. In general, recommendations for hormone therapy use are to be judged on an individual basis, and the FDA recommends that women with moderate to severe menopausal symptoms who want to try menopausal hormone therapy for relief use it for the shortest time needed and at the lowest effective dose.

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

Hormone Therapy Products

Estrogen (with or without a progestin) is the most effective treatment for menopause-related vasomotor symptoms according to the North American Menopause Society, or NAMS. Sales of total oral, transdermal and suppositories for Estrogen (with and without a progestin) hormone therapy products were approximately $3.3 billion for the 12 months ended December 31, 2013. That was up approximately 7% over the comparable 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, which are produced in a variety of forms, including oral tablets or capsules, skin patches, gels, emulsion, or vaginal suppositories and creams.

Estrogen-Only Therapies

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

Estrogen-only therapy, or ET, is used primarily 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 ET were approximately $2.7 billion for the 12-month period ended December 31, 2013, according to Source Healthcare Analytics.

ET is also used for vulvar and vaginal atrophy, which has a variety of indications, including vaginal dryness, vaginal itching and irritation, painful intercourse, painful urination, and other symptoms. Sales of ET for vulvar and vaginal atrophy were approximately $1 billion for the 12-month period ended December 31, 2013, according to Source Healthcare Analytics.

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

Progestin-Only Therapies

Progestins include the naturally occurring hormone progesterone and a number of synthetic progestin compounds that have progestational activity. These agents are used for a variety of indications and conditions, but most often, progestins are used either alone or in combination with an estrogen for hormonal contraception and to prevent endometrial hyperplasia from unopposed estrogen in hormone therapy. Progestins alone are also used to treat women with secondary amenorrhea in order to create withdrawal bleeding in these women who have not had regular menses. Progestins are also used to treat dysfunctional uterine bleeding and endometriosis. Progesterone has also been used to

prevent threatened or recurrent pregnancy loss and for the prevention of preterm birth. Progestins have also been used in fertility treatments. Progestins have also been used as a palliative measure for metastatic endometrial carcinoma and in the treatment of renal and breast carcinoma.

Estrogen/Progestin Combination Products

Progestins are used in combination with estrogen in post-menopausal women with uteruses to avoid an increase in the incidence of endometrial hyperplasia. This is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that, after one year, the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. In accordance with FDA recommendations, doctors typically recommend that a menopausal or post-menopausal 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 FDA-approved estrogen/progestin combinations were approximately $625 million in the United States for the 12-month period ended December31, 2013.

Limitations of Existing Estrogen/Progestin Therapies

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

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

Prenatal Vitamin Market

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

There are hundreds of prenatal vitamins available, with both prescription and OTC (non-prescription) choices. According to Source Healthcare Analytics, there were approximately 7.7 million prescriptions for prenatal vitamins sold for a total of approximately $314 million for the 12 months ended July 31, 2013, with sales between branded and generic products split nearly evenly. According to the 2012 Gallup Target Market Report on Prenatal Vitamins, supplement use has been fairly constant overall between 2008 and 2011. However, shifts have occurred in terms of types used, with the trend toward OTC prenatal vitamins and away from prescription prenatal vitamins. During this same period, the use of OTC products surpassed the use of prescription products, largely driven by increased use among women currently pregnant.

Our Business Model

We are a women's health care product company focused on creating and commercializing products targeted exclusively for women, including products specifically for pregnancy, childbirth, nursing, pre-menopause, menopause, and post-menopause. We intend to use our current prescription and over-the-counter dietary supplement

and cosmetic product lines, consisting of prenatal vitamins, iron supplements, vitamin D supplements, natural menopause relief products, and stretch mark creams, as the foundation of our business platform. If approved and commercialized, our hormone therapy drug candidates will allow us to enter the $3.8 billion hormone therapy market, based on 2013 total sales of the hormone therapy market, according to Source Healthcare Analytics.

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

Our sales model focuses on the “4Ps”: patient, provider, pharmacist, and payor. We market and sell our current dietary supplement and cosmetic products primarily through a direct national sales force of approximately 30 full-time professionals that calls on health care providers in the OB/GYN market space as well as through our website directly to consumers. In addition, our products allow health care providers to offer an alternative to patients to meet their individual nutritional and financial requirements related to co-payment and cost-of-care considerations and help patients realize cost savings over competing products. We also believe that our combination of branded, generic, and over-the-counter lines offers physicians, women, and payors cost-effective alternatives for top-quality care. We supply our prescription dietary supplement products to consumers through retail pharmacies. We market our over-the-counter products either directly to consumers via our website and phone sales followed by direct shipment to their homes or offices or through physicians who then re-sell them to their patients. Our fully staffed customer care center uses current customer relationship management software to respond to health care providers, pharmacies, and consumers via incoming and outgoing telephone calls, e-mails, and live-chat. We also facilitate repeat customer orders for our non-prescription products through our website’s auto-ship feature.

As health care becomes increasingly consumer driven, patients are seeking more information, control, and convenience, which places additional time and financial pressures on physicians, and as a result, physicians are looking for improved ways to provide better service to their patients. A recent study by IMS Health Inc. concluded 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 health care products, including our hormone therapy drug candidates, if approved.

  - Our hormone therapy drug candidates are designed to use the lowest effective dose for the shortest duration.

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

- We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.

- We believe health care providers are able to offer alternatives to patients that meet the patient’s individual nutritional and financial requirements and help patients realize cost savings over competing products.

-

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

- Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

Our Growth Strategy

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

Exclusive Focus on Women's Health Issues. We plan to focus exclusively on women's health issues to enable us to build long-term relationships with women as they move through their life cycles of birth control, pregnancy, child birth, and pre- and post- menopause.

Focus on Hormone Therapy Products. We plan to focus on the development, clinical trials, and commercialization of hormone therapy products designed to (1) alleviate the systems of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and (2) demonstrate equivalent clinical efficacy at lower doses, enabling an enhanced side effect profile compared with competing products.

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

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

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

Geographical Expansion. We plan to expand our geographic market and sales team to cover the entire country by increasing our current 36 sales territories to 60 sales territories in the next 18 months.

Introducing New Products. We plan to introduce a new prescription prenatal vitamin product under our branded vitaMedMD name and our generic Prena1 name in the first quarter of 2014, as well as the development of our hormone therapy drug candidates consisting of a (1) bioidentical oral combination of progesterone and estradiol product, (2) an oral progesterone product, and (3) a suppository vulvar and vaginal atrophy estradiol product. Early pharmacokinetic, or PK, studies of our combination estradiol and progesterone drug candidate demonstrate that the product is bioequivalent to the reference listed drug (based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250).

Our Current Product Lines

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

In March 2012, we launched our first prescription-only prenatal vitamin, vitaMedMD Plus Rx, with subsequent launches of our second prescription-only prenatal vitamin, vitaMedMD One Rx, in April 2012 and our third prescription-only prenatal vitamin, vitaMedMDRediChew™, Rx in May 2012. In the fourth quarter 2012, our

BocaGreenMD Prena1 line brand was launched and our first products include three prescription products Prena1 Plus, Prena1, and Prena1 Chew, which are duplicate, or "generic" formulations, of our vitaMedMD-branded prescription prenatals. In the first quarter of 2014, we will introduce vitaPearl, a prescription prenatal vitamin. This "complete prenatal in one tiny pearl" features a unique, proprietary combination of FOLMAX™, FePlus™, and pur-DHA™. Our product line is detailed below.

vitaMedMD Plus (Prenatal Women's Multivitamin + DHA™)

vitaMedMD Plus Prenatal is a once-daily, two pill combo pack that contains a complete multivitamin with 16 essential vitamins and minerals and 300 mg of plant based DHA, and is Vegan and Kosher certified. Based on recent medical and scientific research, we have optimized many of the nutrients found in *vitaMedMD* Plus. All minerals, including iron, zinc, and copper, are chelated to improve absorption.

vitaMedMD One Prenatal Multivitamin

vitaMedMD One is a single-dose daily multivitamin that provides 14 vitamins and minerals and 200 mg of vegetarian, plant-based DHA. 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 DHA 300 mg capsule. Quatrefolic® is a registered trademark of Gnosis S.P.A. All minerals, including iron, zinc, and copper, are chelated to improve absorption.

vitaMedMD One Rx Prenatal Multivitamin

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

vitaMedMD RediChew™ Rx Prenatal Multivitamin

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

vitaMedMD Iron 21/7

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

vitaMedMD Menopause Relief with Lifenol® Plus Bone Support

vitaMedMD Menopause Relief with Lifenol® Plus Bone Support offers a natural treatment for hot flashes, night sweats, and mood disturbances. Each single tablet dosage delivers 120 mg of Lifenol®, a well-studied female hops

extract recognized for its potency and support in alleviating hot flashes, plus plant phytoestrogens. It also includes calcium and vitamin D3 for added bone support.

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

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

vitaMedMD Signature Collection Stretch Mark Body Cream

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

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's DHA.

BocaGreenMD Prena1

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

BocaGreenMD Prena1 Chew

BocaGreenMD Prena1 Chew is a prescription-only, single daily easy-to-chew, vanilla-flavored, chewable tablet well-suited for women planning a pregnancy and those with difficulty swallowing tablets or capsules or when nausea or morning sickness make taking tablets or capsules difficult.

All *BocaGreenMD* Prena1 multivitamins contain a combination of folic acid and Quatrefolic and are available by prescription only.

Our Hormone Therapy Drug Candidates

We have obtained FDA approval of our IND applications to conduct clinical trials for four of our proposed products: TX 12-001HR, our oral combination of progesterone and estradiol; TX 12-002HR, our oral progesterone alone; TX 12-003HR, our oral estradiol alone; and TX 12-004HR, our estradiol alone vaginal suppository.

TX 12-001HR

TX 12-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The drug candidate is chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone, the biologically identical or bioidentical to the estradiol and progesterone produced by the ovaries, would be approved for use in a single combined product. According to Source Healthcare Analytics, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately $625 million in U.S. sales for the 12 months ended December 31, 2013.

We conducted a PK study of Therapeutics' TX 12-001HR to demonstrate that our drug candidate is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 80% to 125%. The study compared our combined capsule TX 12-001HR of 2 mg estradiol and 200 mg of progesterone to 2 mg of Estrace® and 200 mg of Prometrium®.

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

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

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

On September 5, 2013, we began enrollment of patients in the REPLENISH Trial, a phase 3 clinical trial designed to measure the safety and effectiveness in treating the symptoms of menopause and protecting the endometrium.

TX 12-002HR

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages.

In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness in treating secondary amenorrhea. According to Source Healthcare Analytics, the total FDA-approved market for oral progestin was approximately $364 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-003HR

TX 12-003HR is a natural estradiol formulation. This hormone therapy drug candidate would be chemically identical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. According to Source Healthcare Analytics, the total FDA-approved market for oral estradiol was approximately $130 million in U.S. sales for the 12 months ended December 31, 2013.

TX 12-004HR

TX 12-004HR is a vaginal suppository estradiol drug candidate for the treatment of vulvar and vaginal atrophy, or VVA, in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be as effective as the traditional treatments for VVA and that it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. In August 2013, we initiated a phase 1 clinical trial for VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance. Based upon our phase 1 results, we believe we have a rapidly acting product that differs substantially from the reference listed drug Vagifem® sold by Novo Nordisk. According to Source Healthcare Analytics, the total FDA-approved market for VVA treatment was approximately $1 billion in U.S. sales for the 12 months ended December 31, 2013.

Preclinical Development

Based upon leveraging our hormone platform technology, we have seven preclinical projects that include development of our proposed combination estradiol and progesterone and progesterone-alone products in a topical cream and transdermal patch form. We plan to advance these projects into the next stages of development as financial and personnel resources become available. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to South Healthcare Analytics, the total FDA-approved menopause-related market for estrogen alone and in combination was approximately $3.3 billion in U.S. sales for the 12 months ended December 31, 2013.

Sales and Marketing

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

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

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

We believe our sales force has developed strong relationships and partnerships in the OB/GYN market to sell our current products. We have also established relationships with some of the largest OB/GYN practices their respective markets. By delivering additional products through the same sales channel, we believe we can leverage our already deployed assets to increase our sales and achieve profitability. We intend to leverage and grow our current marketing and sales organization to commercialize our drug candidates in the United States assuming the successful completion of the FDA regulatory process.

Online Commerce

A vast majority of our over-the-counter product sales are completed online. The Internet has continued to increase its influence over communication, content, and commerce. We believe several factors will contribute to this continuing 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 continues to grow, the majority of products are still purchased directly by the consumer locally at traditional stores. As this division 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.

Competition

The pharmaceutical industry is subject to intense competition and is characterized by extensive research efforts and rapid technological change. Competition in our industry occurs in a variety of areas, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost, and developing new products to provide benefits superior to those of existing products. There are many companies, including generic manufacturers, drug compounding pharmacies, and large pharmaceutical companies, that have significantly greater financial and other resources than we do. In addition, academic and other research institutions could be engaged in research and development efforts for the indications targeted by our products.

Seasonality

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

Products in Development

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

Raw Materials for Our Products

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

Availability of and Dependence Upon Suppliers

We currently obtain approximately 98% of our vitaMedMD products from Lang Pharma Nutrition, or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars, and functional foods in the dietary supplement category. As a result, we are dependent on Lang for the manufacture of most of our products. We believe the terms of our agreements with Lang are competitive with other suppliers and manufacturers. Although we anticipate continuing our relationship with Lang, we believe that we could obtain similar terms with other suppliers to provide the same services. We have experienced no difficulties in obtaining the products we need in the amounts we require and do not anticipate those issues in the future.

Manufacturing of Our Products

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

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

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

Quality Control for Our Products

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

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

Distribution of our Products

We use a variety of distribution channels dependent upon product type. We sell our prescription dietary supplement products to patients through their pharmacies. Since the launch of our prescription products, in addition to third-party logistics providers, we use some of the same national and regional distributors as other pharmaceutical companies, including Cardinal, McKesson, AmerisourceBergen, H.D. Smith, and Smith Drug. Wholesaler product inventory is monitored daily and sales out is monitored weekly. National and regional retail chain pharmacies are also an area of focus to make sure our products are purchased and dispensed properly. We sell our OTC products directly to consumers via our website and phone sales and the products are shipped directly from us to the consumer's home or office. In a few instances, we sell OTC product to physicians who then sell the products directly to their patients.

Customer Service

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

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

Our Return Policy

We sell our prescription products through third-party logistics providers, major distributors, and pharmacies, all of whom may return a product within six months prior to or after the expiration date of the product. Once customers buy a product from the pharmacy, the product may not be returned. Non-prescription customers may return or exchange our products for any reason by returning the product within 30 days of receipt. We will refund the entire purchase price, less shipping. The customer is responsible for the cost of returning the products to us, except in cases in which 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.

Research and Development

Our product development programs are concentrated in the area of advanced hormone therapy pharmaceutical products. We engage in programs to provide alternatives to the non-FDA approved compounded bioidentical market for hormone therapy. Our programs seek to bring new products to market in unique delivery systems or formats that enhance the effectiveness, safety, and reliability of existing hormone therapy alternatives.

We intend our hormone therapy drug candidates, if approved, to provide an alternative to the non-FDA approved compounded bioidentical market based on our belief that our drug candidates will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

Our research and development expenses were $13.6 million in 2013, $4.5 million in 2012, and $0.1 million in 2011.

Intellectual Property

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

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

As we continue to develop proprietary intellectual property, we will expand our protection by applying for patents on future technologies. 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.

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

Government Regulation

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

Pharmaceutical Regulation

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

- completion or reference of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA’s Good Laboratory Practice, or GLP, regulations;

- submission to the FDA of an IND, which the FDA must allow to become effective before human clinical trials may begin and must be updated annually;

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication; and

- submission to the FDA of an NDA after completion of all pivotal clinical trials.

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

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

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

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

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

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

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities in which the drug product will be formulated and its active pharmaceutical ingredient, or API, will be produced, it may issue an approval letter or, instead, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and

manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

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

505(b)(2) Applications

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

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

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

Marketing Exclusivity

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

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

Dietary Supplement and Cosmetic Regulation

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

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

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

The FDA or other agencies could take actions against products or product ingredients that in its determination present an unreasonable health risk to consumers that would make it illegal for us to sell such products. In addition, the FDA

could issue consumer warnings with respect to the products or ingredients in such products. Such actions or warnings could be based on information received through FDCA-mandated reporting of serious adverse events. The FDCA requires that reports of serious adverse events be submitted to the FDA, and based in part on such reports, the FDA has issued public warnings to consumers to stop using certain third party dietary supplement products.

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

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

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

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

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

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

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

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

Other U.S. Health Care Laws and Compliance Requirements

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

- The federal health care 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 health care programs, such as Medicare and Medicaid.

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

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

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care 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 health care 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 health care 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 health care laws and regulations could be costly. Although we believe that our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other health care laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from third party payor programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians, providers, or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded health care 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 that 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.

Employees

As of December 31, 2013, we had 69 full-time employees, four of whom are executive officers. Additionally, from time to time, we hire temporary contract employees. None of our employees are covered by a collective bargaining agreement, and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike, or dispute. We consider our relationship with our employees to be good.

Our History

On October 3, 2011, we changed our name to TherapeuticsMD, Inc. On October 4, 2011, we closed a reverse merger with VitaMedMD, LLC, a Delaware limited liability company, or VitaMed, pursuant to which (1) all outstanding membership units of VitaMed were exchanged for shares of our common stock (2) all outstanding VitaMed options and warrants were exchanged and converted into options and warrants to purchase shares of our common stock, and (3) VitaMed became our wholly owned subsidiary. 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.

We were incorporated in Utah in 1907 under the name Croff Mining Company. 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, or the Exchange Act. As a result of the spin-off, Croff was a "shell company" under the rules of the Securities and Exchange Commission, or the SEC. In July 2009, Croff (i) closed a transaction to acquire America's Minority Health Network, Inc. as a wholly owned subsidiary, (ii) ceased being a shell company, and (iii) experienced a change in control in which the former stockholders of America's Minority Health Network, Inc. acquired control of our company. On 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.

Available Information

We are a Nevada corporation. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmd.com*, *www.vitamedmdrx.com*, and *www.bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites is not incorporated by reference into this Annual Report or in any other report or document we file with the SEC.

We file reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any other filings required by the SEC. Through our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The public may read and copy any materials we file with, or furnish to, the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (*www.sec.gov*) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Executive Officers

The following table sets forth certain information regarding our executive officers as of December 31, 2013:

Name	Age	Position
Robert G. Finizio	43	Chief Executive Officer
John C.K. Milligan, IV	51	President and Secretary
Daniel A. Cartwright	56	Chief Financial Officer, Vice President of Finance, and Treasurer
Mitchell L. Krassan	48	Executive Vice President and Chief Strategy Officer

Robert G. Finizio has served as Chief Executive Officer and a director of our company since October 2011. As co-founder of VitaMed, Mr. Finizio served as its Chief Executive Officer and a director from April 2008 to October 2011. Mr. Finizio has 16 years of successful early stage company development experience in the health care industry. Mr. Finizio co-founded and served from August 2001 to February 2008 as President of Care Fusion, LLC and then as Chief Executive Officer of CareFusion, Inc., which was acquired by Cardinal Health, Inc. Mr. Finizio's early business experience was with Omnicell, Inc. (formerly known as Omnicell Technologies, Inc.) and Endoscopy Specialists, Inc. in the healthcare IT and surgical space, respectively. Mr. Finizio earned a B.A. from the University of Miami.

John C.K. Milligan, IV has served as President, Secretary, and a director of our company since October 2011. From December 2008 to October 2011, Mr. Milligan served as President and Director of VitaMed. Prior to VitaMed, Mr. Milligan co-founded CareFusion, LLC, serving as President and General Manager from August 2001 to February 2008, and then as President and Chief Operating Officer of CareFusion, Inc. From 1997 to 2001, Mr. Milligan was Vice President, Sales and Operations for Omnicell, Inc., a provider of pharmaceutical supply chain management systems and services. Prior to Omnicell, Mr. Milligan also held executive management positions at Serving Software Inc. and HBO & Co., both subsequently acquired by McKesson Corporation. Mr. Milligan is a graduate of the U.S. Naval Academy.

Daniel A. Cartwright has served as Chief Financial Officer, Vice President of Finance, and Treasurer of our company since October 2011. From July 2011 to October 2011, Mr. Cartwright served as Chief Financial Officer of VitaMed. From May 1996 to July 2011, Mr. Cartwright served as Chief Financial Officer and Executive Vice President of Circle F Ventures, LLC, an Arizona venture capital firm that made investments in more than 50 companies. During the same period, Mr. Cartwright served as Chief Financial Officer and Treasurer of Fleming Securities, formerly a registered broker dealer involved with raising capital for public and private companies. From 1993 to 1996, Mr. Cartwright served as Chief Financial Officer of American Wireless Systems, Inc., a provider of entertainment video services. Mr. Cartwright currently serves as a member of the board of directors of Primetrica, Inc., a private information research company for the telecommunications industry, and formerly served on the board of directors of Antenna Technologies Company, Inc. and WEB Corp. Mr. Cartwright earned his B.S. in Accounting from Arizona State University.

Mitchell L. Krassan has served as Executive Vice President and Chief Strategy Officer of our company since October 2011. From April 2010 to October 2011, Mr. Krassan served as Chief Strategy and Performance Officer of VitaMed. Mr. Krassan has been a partner with EquiMark Limited, a private investment partnership, since October 1997. From November 1994 to July 1997, Mr. Krassan served as Chief Financial Officer and Chief Operating Officer of The Reich Group/Telespectrum Worldwide, a fully integrated direct marketing firm that provided clients expertise in market research and analysis, strategic planning, marketing, creative, and production services, telemarketing and database development. The Reich Group became a leading company in a roll-up and $180 million initial public offering of Telespectrum Worldwide. Mr. Krassan earned a B.S. in Accounting from University of Maryland, received his certification as a CPA in the state of Maryland, and earned his M.B.A. in Management from New York University.

Non-Executive Officers

Dr. Brian Bernick has served as Chief Clinical Officer of our company since November 2012 and has served as a director of our company since October 2011. Dr. Bernick also has served as the Chief Medical Officer of our company from February 2012 until 2013. As co-founder of VitaMed, Dr. Bernick served on VitaMed’s board of directors from April 2008. Dr. Bernick is a practicing and board certified obstetrician/gynecologist with 20 years of clinical medical experience. Dr. Bernick is the past Chairman of the Department of Obstetrics and Gynecology at Boca Raton Regional Hospital and has served as a member of its Medical Executive Board. He has served on the board of directors of the Palm Beach Medical Society and VitalMD Group Holding, LLC, the largest physician-owned and managed group of

obstetricians/gynecologists in Florida covering more than 250 physicians/practices. Dr. Bernick is an Associate Professor of Medicine at Florida Atlantic University and provides medical education in conjunction with Emory University and Florida Atlantic University School of Nursing and Medicine. Dr. Bernick earned a B.A. in economics from Northwestern University and a doctorate in medicine from the University of Chicago Medical School. He completed his residency at the University of Pennsylvania.

Julia Amadio has served as Chief Product Officer of our company since January 16, 2012. Ms. Amadio has a 25-year background in general management and leading pharmaceutical marketing and product development organizations. From June 2011 to January 2012, Ms. Amadio was President of JMA Consulting, LLC, her own consulting company that she formed in 2008. From June 2009 to May 2011, she served as Global Vice President of Marketing for MeadWestvaco Healthcare Division. Previously, Ms. Amadio was President of a start-up, Patients' & Consumers' Pharma, in 2007. She was Vice President of Marketing & Marketing Services with Daiichi Pharmaceutical from 2004 to 2006; Vice President of Aventis Pharmaceutical from 1997 to 2004; Senior Director, New Products Women's Health at Wyeth from 1991 to 1997; and started her career at J&J's McNeil Pharmaceutical. Ms. Amadio is an active member and leader in the Healthcare Businesswomen's Association. She was an adjunct lecturer at St. Joseph's University in the pharmaceutical MBA program and authored a chapter on Marketing, Market Research and insights in the book Pharmaceutical Development for Woman (Wiley & Sons). Ms. Amadio earned a B.S. in Accounting from St. Joseph's University and a Masters in Business Administration from Drexel University.

Dr. Joel Krasnow has served as the Chief Scientific Officer of our company since December 2013. Dr. Krasnow has 15 years of pharmaceutical industry experience in clinical development and medical affairs. Mr. Krasnow was Chief Safety Officer for Intarcia Therapeutics in 2013. From 2010 to 2012, Dr. Krasnow served as Vice-President and Chief Medical Officer of Eisai Pharmaceuticals, Frontier Business Unit. He led the Actemra® (tocilizumab) and Boniva® (ibandronate sodium) development teams at Roche Pharmaceuticals, resulting in several global product approvals between 2006 to 2010. From 2004 to 2006, Dr. Krasnow led the global development team at Novartis for Zometa® (zoledronic acid), resulting in multiple regulatory approvals. Dr. Krasnow's experience as a Medical Director in women's health includes the development of contraceptive, hormone replacement, and fertility treatments while at Organon. In a medical affairs capacity at Pharmacia/Pfizer, Dr. Krasnow worked with Activella® (estradiol/norethindrone acetate), Vagifem® (estradiol vaginal tablets), Depo-Provera (medroxyprogesterone acetate injectable suspension), and Detrol® (tolterodine tartrate). Dr. Krasnow pursued his residency training in OB-GYN at the University of Chicago; a fellowship in Reproductive Endocrinology at Baylor College of Medicine; and was on faculty in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Pittsburgh from 1991 to 1996. After receiving a Masters of Business Administration from the University of Pittsburgh, Dr. Krasnow worked in the healthcare practice at Deloitte Consulting.

Dr. Sebastian Mirkin has served as the Chief Medical Officer of our company since November 2013. Dr. Mirkin has more than 15 years of experience and leadership in clinical development and medical affairs in Women's Health in global pharmaceutical companies. From October 2009 to November 2013, Dr. Sebastian was Clinical Lead and Global Clinical Lead of Women's Health, Clinical Research at Pfizer. From October 2005 to October 2009, he was Director and Senior Director, Clinical Research, Women's Health at Wyeth, and from October 2004 to October 2005 was Global Lead Medical Services, Women's Health at Organon. Dr Mirkin oversaw the development and successful marketing authorization of several novel medicines, including Duavee®, Conbriza®, Lybrel®, and Premarin Vaginal Cream® in the United States, Europe, and Japan. Dr. Mirkin holds a Doctor in Medicine degree from National University, Argentina. Trained in Obstetrics/Gynecology, Dr. Mirkin completed his fellowship in Reproductive Medicine at The Jones Institute of Reproductive Medicine in Norfolk, Virginia, USA.

Jason Spitz has served as Vice President - Marketing of our company since December 2011. Mr. Spitz has a 24-year career in marketing, advertising, and general management experience in pharmaceutical and biopharmaceutical

markets. From June 2008 to December 2010, Mr. Spitz served as Managing Director, Oncology & Hematology at Beacon Healthcare Communications, a company specializing in pharmaceutical and health care advertising. From September 2004 to June 2008, he served as General Manager, Canada and Commercial Strategy and Development at MGI Pharma (later acquired by Eisai, Inc.), a company specializing in oncology and cancer supportive care products. From February 2004 to September 2004, he served as Vice President of Marketing and Sales at Aesgen, Inc., a company specializing in cancer products and drug delivery systems that was acquired by MGI Pharma. Mr. Spitz began his career at Schering Plough as a sales representative, rising within the organization over 15 years to lead a global pharmaceutical franchise. Mr. Spitz earned his Bachelor of Business Administration in Marketing from The University of Texas at Austin and his Master of Business Administration in Pharmaceutical Studies from Fairleigh Dickinson University.

Michael Donegan has served as Vice President – Finance of our company since April 2013. Mr. Donegan has a 23-year background in accounting and finance. From August 2012 to April 2013, Mr. Donegan served as an independent consultant exclusively for our company, where he conceptualized, designed and executed our Sarbanes-Oxley 404 compliance program. From August 2007 to August 2012, Mr. Donegan served as an independent consultant designing and implementing Sarbanes-Oxley 404 compliance programs for various non-accelerated filers and executed on pre-designed Sarbanes-Oxley 404 compliance programs for certain large accelerated filers. From January 2005 to August 2007, Mr. Donegan served as an independent consultant exclusively for Tyco International, where he enhanced and executed the Sarbanes-Oxley 404 compliance model with their corporate headquarters group. From November 2001 to December 2004, Mr. Donegan was Manager of Financial Systems at Tyco International at its global headquarters. From 1994 to 2001, Mr. Donegan held various positions in the global consolidation/SEC Reporting group at Sensormatic Electronics Corporation culminating with the acquisition of Sensormatic Electronics Corporation by Tyco International in the fall of 2001 when he was the Manager of Financial Systems. Mr. Donegan began his career at Ernst & Young, LLP where he worked in both the audit and tax departments. Mr. Donegan earned his Bachelor of Science in Accounting and his Master of Accounting from the University of Florida.

Christian Bloomgren has served as Vice President - Sales of our company since June 2011. Mr. Bloomgren has 14 years of leadership experience in the pharmaceutical, bio-technology, and diagnostic industry. From 2005 to 2011, Mr. Bloomgren served as Region Manager at ViaCell, Inc., a biotechnology company dedicated to enabling the widespread application of human cells as medicine, later acquired by PerkinElmer, Inc. While at ViaCell, Mr. Bloomgren built a successful national sales channel and helped lead the Specialty Diagnostics business. From 2000 to 2002, Mr. Bloomgren served as a specialty Account Manager at Eli Lilly & Co. and from 2002 to 2005 as District Manager at KV Pharmaceutical. Mr. Bloomgren served as an Officer in the United States Air Force and holds a Bachelor of Science degree from California State University and a Master of Science degree from Troy State University.

Marlan Walker has served as Corporate and Intellectual Property Counsel since June 2013. Mr. Walker’s experience is focused in the life science industries, including long-term portfolio strategy and management, patent preparation and prosecution, contract negotiation and drafting, life-cycle management, and Hatch-Waxman. After law school, he took a position at Greenberg Traurig LLP in August 2005. In March of 2009, he moved to Luce Forward Hamilton & Scripps. Mr. Walker accepted an in-house position as Intellectual Property Counsel for Medicis Pharmaceutical Corp. in June 2011, which was acquired by Valeant Pharmaceutical International, Inc. in December 2012. In February 2013, Mr. Walker accepted a position at Kilpatrick Townsend & Stockton, but chose to move in-house again in June 2013, when he accepted a position at our company. Mr. Walker graduated from Arizona State University’s Sandra Day O’Conner College of Law with his J.D. in 2004, and an LL.M. in Intellectual Property Law at The George Washington University Law School in 2005. He holds a Master’s Degree in Molecular Biology and a Bachelor of Science degree, both earned from Brigham Young University.

Risk Factors

Item 1A. *Risk Factors*

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with all of the information included in this Annual Report before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition, or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

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

We have incurred recurring net losses, including net losses of $28 million, $35, and $13 million for the years ended December 31, 2013, 2012, and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of approximately $81 million. We have generated limited revenue and have funded our operations to date primarily from public and private sales of equity and private sales of debt securities. We expect to incur substantial additional losses over the next several years as our research, development, and clinical trial activities increase, especially those related to our hormone therapy drug candidates. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our hormone therapy drug candidates. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

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

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

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

We currently derive all of our revenue from sales of women's health care products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, natural menopause relief, and scar reduction creams. While

sales of our vitamin products grew from 2010 through 2013, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic copies of our prescription dietary supplement products;
- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;
- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in health care laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal health care programs;
- the impact or efficacy of any price increases we may implement in the future;
- changes to our label and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

If revenue from sales of our existing prescription and over-the-counter dietary supplements and cosmetics does not continue or increase, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects, or we may not be able to commence or continue clinical trials to seek approval for and commercialize our hormone therapy drug candidates or any other products we may choose to develop in the future.

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

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

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

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

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

We need substantial amounts of cash to complete the clinical development of our hormone therapy drug candidates. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We do not currently have any committed external source of funds. We will attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, or other means, or a combination of

any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
- seek collaborators for our hormone therapy drug candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and
- license, potentially on unfavorable terms, our rights to our hormone therapy drug candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

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

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

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

Three hormone therapy drug candidates are currently in various stages of clinical testing. We have recently begun phase 3 clinical trial of our estradiol and progesterone combination and our progesterone alone drug candidates. Clinic trials are expensive, can take many years to complete, and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies

in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our hormone therapy drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

- delays in obtaining regulatory approval to commence a trial;

- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

- imposition of a clinical hold because of safety or efficacy concerns by DSMB, the FDA, or IRB, or us;

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

- delays in obtaining required institutional review board approval at each site;

- delays in identifying, recruiting, and training suitable clinical investigators;

- delays in recruiting suitable patients to participate in a trial;

- delays in having patients complete participation in a trial or return for post-treatment follow-up;

- clinical sites dropping out of a trial to the detriment of enrollment;

- time required to add new sites;

- delays in obtaining sufficient supplies of clinical trial materials, including suitable API; or

- delays resulting from negative or equivocal findings of DSMB for a trial.

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

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

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

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

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

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

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

30

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

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

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

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

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

new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

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

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMPs regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

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

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

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture our existing women's health care products. For example, we depend on Lang to supply approximately 98% of our vitaMedMD products. We also rely on third-party contract manufacturing organizations, or CMOs to supply our hormone therapy drug candidates for use in the conduct of our clinical trials. We rely on these third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We do not have long-term contracts for the commercial supply of our products or our hormone therapy drug candidates. We intend to pursue long-term manufacturing agreements, but we may not be able to negotiate such agreements on acceptable terms, if at all.

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

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

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

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

- the clinical indications for which our hormone therapy drug candidates are approved, if at all;
- acceptance by physicians and payors of each product as safe and effective treatment;
- the cost of treatment in relation to alternative treatments, including numerous generic drug products;
- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;

- limitations or warnings contained in a product's FDA-approved labeling; and

- prevalence and severity of adverse side effects.

Even if the medical community accepts that our products are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. We cannot assure you that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our products, including, in particular our hormone therapy drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

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

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

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

Market acceptance and sales of our products, including any hormone therapy drug candidates, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors generally do not cover over-the-counter products, and coverage for vitamins and dietary supplements varies. We cannot be sure that coverage and reimbursement will be available for our products, including any hormone therapy drug candidates, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our existing dietary supplement products or successfully commercialize our hormone therapy drug candidates.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in

any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products, including our hormone therapy drug candidates, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education 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. Among other measures, PPACA imposes increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect PPACA will have on federal reimbursement policies in general or on our business specifically, the PPACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted, or what impact they may have on us if they are adopted.

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

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

We face an inherent risk of product liability claims as a result of the marketing of our current products and the clinical testing of our hormone therapy drug candidates despite obtaining appropriate informed consents from our clinical trial participants, and we will face an even greater risk if we obtain FDA approval and commercialize our hormone therapy drug candidates in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, 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 hormone therapy drug candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our products or hormone therapy drug candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional restrictions;
- product recalls or withdrawals;
- decreased demand for our products or products that we may develop in the future;
- loss of revenue;

- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- exhaustion of any available insurance and our capital resources; and
- a decline in our stock price.

Although we maintain general liability insurance of up to $10 million in the aggregate and clinical trial liability insurance of $10 million in the aggregate for our hormone therapy drug candidates, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects.

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

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

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

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

We are subject to extensive and costly government regulation.

The products we currently market, including the vitamins and cosmetic creams, and the pharmaceutical products we are developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of our hormone therapy drug candidates to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal health care program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations, and financial condition.

PPACA also imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to health care providers and ownership of their stock by health care providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value, or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and will be required to report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock-based compensation that vests over time. The value to employees of stock-based compensation will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific, and medical teams may terminate their employment with us on short notice. We do not have employment agreements with a number of our key employees. As a result, most employees are employed on an at-will basis, which means that any of these employees could leave our employment at any time, with or without notice, and may go to work for a competitor. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, and financial condition. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled scientific and medical personnel.

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

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

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

commercialize drug candidates will be limited.

Our success is tied to our distribution channels.

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. However, over 98% of our product shipments since inception were to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. Our business would be harmed if any of these customers refused to distribute our products or refused to purchase our products on commercially favorable terms to us.

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

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

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

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

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

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

We may initiate product recalls or withdrawals, or may be subject to regulatory enforcement actions that could negatively affect our business.

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

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

As of December 31, 2013, we had 69 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our hormone therapy drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

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

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

Risks Related to our Intellectual Property

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

We plan to seek to obtain market exclusivity for our hormone therapy drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also be seeking marketing exclusivity and may be in various stages of development, including some more advanced than us. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our hormone therapy drug candidates, and materially adversely affect our business, financial condition, and results of operations.

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

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

These risks include the possibility of the following:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were not the first inventors to file patent applications for these technologies in the United States or were not the first to file patent applications directed to these technologies abroad;
- we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;
- future drug candidates may not be patentable;
- others will claim rights or ownership with regard to patents and other proprietary rights that we hold or license;
- delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; and
- we may fail to timely apply for patents on our technologies or products.

While we apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our hormone therapy drug candidates. In addition, if third parties file patent applications in the technologies that also claim technology to

which we have rights, we may have to participate in interference, derivation, or other proceedings with the USPTO or foreign patent regulatory authorities to determine our rights in the technologies, which may be time-consuming and expensive. Moreover, issued patents may be challenged during in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

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

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

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

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

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. We are aware of numerous third-party U.S. and non-U.S. issued patents and pending applications that exist in the areas of hormone therapy, including compounds, formulations, treatment methods, and synthetic processes, that may be applied towards the synthesis of hormones. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third-party patents and pending applications of which we are currently unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot ever know with certainty the nature or existence of every third-party patent filing. We cannot provide assurances that we or our partners will be free to manufacture or market our drug candidates as planned or that we or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

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

- infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies or future products unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- any delay in commencement of our phase 3 clinical trials for our hormone therapy drug candidates;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our hormone therapy drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our hormone therapy drug candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate clinical supply for our hormone therapy drug candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners' commercialization efforts;

- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by us or our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;

- increases in our common stock available for sale upon expiration of lock-up agreements;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

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

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

At December 31, 2013, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 77% of our common stock on an as converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting for future periods as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

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

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

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

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

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

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

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

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

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our corporate headquarters is located in Boca Raton, Florida, where we lease 17,686 square feet of space. The primary functions performed at this location are executive, administrative, accounting, treasury, marketing, and human resources.

We believe that our current facility is in good working order and is capable of supporting our operations for the foreseeable future.

Item 3. *Legal Proceedings*

From time to time, we are involved in litigation and proceedings in the ordinary course of our business. We are not currently involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

Item 4. *Mine Safety Disclosures*

Not applicable.

PART II

Item 5. *Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities*

Market Information on Common Stock

Since April 23, 2013, our common stock has been listed on the NYSE MKT under the symbol "TXMD." Prior to that time, our common stock was quoted on the OTCQB. The following table sets forth for the periods indicated the high and low bid or sales prices of our common stock on the OTCQB and the NYSE MKT, as applicable. The below quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. Prices listed in 2011 are historic prices that have been adjusted to reflect the 1:100 reverse split that was effective on October 3, 2011.

	High	Low
2013		
Fourth Quarter	$5.50	$2.86
Third Quarter	$3.18	$2.03
Second Quarter	$3.23	$1.73
First quarter	$3.70	$1.65
2012		
Fourth quarter	$3.50	$1.25
Third quarter	$3.60	$2.61
Second quarter	$2.84	$2.06
First quarter	$2.50	$1.43
2011		
Fourth quarter	$1.70	$0.51
Third quarter	$4.00	$1.00
Second quarter	$7.00	$1.00
First quarter	$10.00	$2.00

On March 3, 2014, the closing sale price of our common stock was $6.75 per share. On March 3, 2014, there were approximately 324 record holders and approximately 3,103 beneficial owners of our common stock.

Dividends

Historically, we have not paid dividends on our common stock, and we currently do not intend to pay any dividends on our common stock in the foreseeable future. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations, and capital requirements as well as other factors deemed relevant by our board of directors.

Performance Graph

The following line graph compares cumulative total shareholder return for the five years ended December 31, 2013 for (i) our common stock; (ii) NASDAQ Pharmaceutical Index; and (iii) Peer Group (includes: Acorda Therapeutics, Inc., AMAG Pharmaceuticals, Inc., Amarillo Biosciences Inc., Arena Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Cadence Pharmaceuticals Inc., Dendreon Corporation, Dyax Corporation, Exelixis, Inc., Halozyme Therapeutics, Inc., Orexigen Therapeutics, Inc., Spectrum Pharmaceuticals, Inc., and VIVUS Inc.). The graph assumes $100 invested on December 31, 2009 and includes reinvestment of dividends. Measurement points are at the last trading day of the fiscal years ended December 31, 2009, 2010, 2011, 2012, and 2013. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

The following line graph compares cumulative total shareholder return for the period beginning when we became listed on the NYSE MKT exchange (April 23, 2013) and ended December 31, 2013 for (i) our common stock; (ii) NASDAQ Pharmaceutical Index; and (iii) our Peer Group (includes: Acorda Therapeutics, Inc., AMAG Pharmaceuticals, Inc., Amarillo Biosciences Inc., Arena Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Cadence Pharmaceuticals Inc., Dendreon Corporation, Dyax Corporation, Exelixis, Inc., Halozyme Therapeutics, Inc., Orexigen Therapeutics, Inc., Spectrum Pharmaceuticals, Inc., and VIVUS Inc.). The graph assumes $100 invested on December 31, 2009 and includes reinvestment of dividends. Measurement points are April 23, 2013 and the last trading day of the fiscal years ended December 31, 2013. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

The performance graphs shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. The performance graphs will not be deemed incorporated by reference into any filing of our company under the Exchange Act or the Securities Act.

Item 6. *Selected Financial Data*

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this Annual Report. The consolidated statements of operations for the years ended December 31, 2013, 2012, and 2011 and the consolidated balance sheet data as of December 31, 2013, 2012, and 2011 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the year ended December 31, 2010, and the consolidated balance sheet data as of December 31, 2010, are derived from the audited consolidated financial statements of VitaMed, our predecessor, included in this Annual Report. The consolidated statements of operations for the period April 2, 2009 (inception) through December 31, 2009, and the consolidated balance sheet data as of December 31, 2009, are derived from the audited consolidated financial statements of AMHN, Inc., our predecessor, not included in this Annual Report.

	Year Ended December 31,				
	2013	2012	2011	2010 (Restated)	2009 (Restated)
	(in thousands, except share data)				
Consolidated Statements of Operations Data:					
Revenue, net	$8,776	$3,818	$2,088	$ 1,242	$ 221
Gross profit	6,816	2,470	1,141	556	205
Operating expenses:					
Sales, general, and administration	19,015	14,070	6,406	3,335	1,471
Research and development	13,551	4,492	107	65	23
Depreciation and amortization	58	56	55	23	4
Total operating expense	32,624	18,618	6,568	3,423	1,498
Operating loss	(25,808)	(16,148)	(5,427)	(2,867)	(1,293)
Other income (expense)	(2,611)	(18,972)	(7,486)		5
Net loss	$(28,419)	$(35,120)	$(12,913)	$ (2,867)	$ (1,288)
Net loss per share, basic and diluted	$(0.22)	$(0.38)	$(0.21)	$ (0.07)	$ (0.05)
Weighted average number of common shares outstanding	127,570	91,630	62,516	38,289	27,424
Consolidated Balance Sheet Data (at end of period)					
Total assets	$62,016	$5,926	$1,439	$ 1,197	$ 585
Total liabilities	$7,318	$7,359	$3,151	$ 233	$ 102
Total stockholders surplus (deficit)	$54,698	$(1,433)	$(1,712)	$ 964	$ 484

Other Data:					
Capital expenditures	$480	$273	$38	$ 27	$ 102
Working Capital (deficit) (end of period)	$52,085	$1,015	$(1,914)	$ 826	$ 361

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion and analysis in conjunction with the information set forth under "Selected Consolidated Financial and Other Data" and our consolidated financial statements and the notes to those financial statements included elsewhere in this Annual Report. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially from those contained in or implied by any forward-looking statements as a result of various factors, including the risks and uncertainties described under "Risk Factors" elsewhere in this Annual Report.

Company Overview

We are a women's health care product company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins and cosmetics.

Results of Operations

Comparison of Years Ended December 31, 2013, 2012, and 2011:

Year ended December 31, 2013 compared with year ended December 31, 2012

	Year Ended December 31,		
	2013	2012	Change
	(000s)		
Revenue	$8,776	$3,818	$4,958

Cost of goods sold	1,960	1,348	612
Operating expenses	32,624	18,618	14,006
Operating loss	(25,808)	(16,148)	(9,660)
Financing Costs	(1,504)	—	(1,504)
Interest expense	(1,166)	(1,905)	739
Other income (expense) net	59	(42)	101
Loss on extinguishment of debt	—	(10,308)	10,308
Beneficial conversion feature	—	(6,717)	6,717
Net loss	$(28,419)	$(35,120)	$(6,701)

Revenue

Revenue for year ended December 31, 2013 increased by approximately $4,958,000, or 130%, compared with the year ended December 31, 2012. This increase was directly attributable to additional products sold and an increase in the average sales price of each product, increase in the number of physicians writing prescriptions for our products, the productivity of our sales force, and the new prescription products introduced in 2012.

Cost of Goods Sold

Cost of goods sold increased by approximately $611,000, or 45%, for the year ended December 31, 2013 compared with the year ended December 31, 2012. Our gross margins increased to 78% in 2013 compared to 65% in 2012. The gross margin change was primarily attributable to the increase in average sales price of products sold and product mix of prescription and OTC products.

Operating Expenses

Our principal operating costs included the following items as a percentage of total operating expenses.

	Year Ended December 31,	
	2013	2012
Human resource costs	33%	39 %
Sales and marketing, excluding human resource costs	15%	24 %
Production design and development costs	41%	24 %
Professional fees and consulting	4 %	6 %
Other	7 %	7 %

Operating expenses increased by approximately $14,006,000, or 75%, for the year ended December 31, 2013 from year ended December 31, 2012 as a result of the following items:

	(000s)
Increase in product research and development costs	$9,059

Increase in human resource costs	3,333
Increase in sales and marketing, excluding human resource costs	582
Increase in professional and consulting	79
Increase in all other operating expenses	953
	$14,006

Research and development costs increased by approximately $9,059,000, primarily as a result of the commencement of phase 3 clinical trials for TX 12-001HR as well as the preparation for phase 3 clinical trials for TX 12-002HR, and phase 3 clinical trials for TX 12-004HR.

Human resource related costs, including salaries and benefits, increased by approximately $3,333,000, primarily as a result of an increase in amortization of non-cash compensation totaling approximately $3,152,000 related to employee stock options issued during 2013 and 2012.

Sales and marketing costs increased approximately $582,000, primarily as a result of expanded marketing, advertising, education, and training. In addition, we increased spending in the areas of travel, product samples, and commissions. We also incurred added costs associated with our new product distribution channels introduced in 2013.

Financing Costs

Financing costs increased approximately $1,504,000 resulting from the amortization of costs associated with warrants granted in 2013 in connection with a $10,000,000 revolving line of credit.

Interest Expense

Interest expense decreased approximately $739,000, primarily as a result of the retirement of debt issued during 2012.

Year ended December 31, 2012 compared with year ended December 31, 2011

	Year Ended December 31,		
	2012	2011	Change
	(000s)		
Revenue	$3,818	$2,088	$1,730
Cost of goods sold	1,348	947	401
Operating expenses	18,618	6,568	12,050
Operating loss	(16,148)	(5,427)	(10,721)
Loss on extinguishment of debt	(10,308)	7,390	(2,918)
Beneficial conversion feature	(6,717)	-0-	(6,717)
Interest expense	(1,905)	(64)	(1,841)
Other expense, net	(42)	(32)	(10)
Net loss	$(35,120)	$(12,913)	$(22,207)

Revenue

Revenue for year ended December 31, 2012 increased by $1,730,000, or 83%, from the year ended December 31, 2011. This increase was directly attributable to the introduction of our prescription prenatal product line and the use of various pharmaceutical distribution sources.

Cost of Goods Sold

Consistent with our increase in revenue, cost of goods sold increased by $401,000, or 42%, for the year ended December 31, 2012 compared with the year ended December 31, 2011. Our gross margins increased to 65% in 2012 compared to 55% in 2011. This change is primarily attributed to the fact that our 2012 revenue consisted of prescription and OTC products in contrast to revenue in prior years that consisted exclusively of OTC products. Our prescription products offer more favorable margins than those of our OTC products.

Operating Expenses

Our principal operating costs included the following items as a percentage of total operating expenses.

	Year Ended December 31,	
	2012	2011
Human resource costs	39%	48 %
Sales and marketing, excluding human resource costs	24%	33 %
Production design and development costs	24%	2 %
Professional fees and consulting	6 %	7 %
Other	7 %	10 %

Operating expenses increased by $12,050,000, or 184%, for year ended December 31, 2012 from year ended December 31, 2011 as a result of the following items:

	(000s)
Increase in product research and development costs	$4,385
Increase in human resource costs	4,155
Increase in sales and marketing, excluding human resource costs	2,238
Increase in professional and consulting	719
Increase in all other operating expenses	553
	$12,050

53

During 2012 we began the development of drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. The increase in our product research and development costs was primarily attributable to these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of providing clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. We have obtained FDA acceptance of our IND applications to conduct clinical trials for four drug candidates and have commenced or intend to commence clinical trials for three of those products.

Human resource related costs, including salaries and benefits, increased by approximately $4,155,000, primarily as a result of an increase in amortization of non-cash compensation totaling approximately $1,678,000 related to employee stock options issued during 2012 and 2011, and an increase of 19 employees in 2012.

Sales and marketing costs increased approximately $2,238,000, primarily as a result of expanded marketing, advertising, education, and training. In addition, we increased spending in the areas of travel, product samples, and commissions. We also incurred added costs associated with our new product distribution channels introduced in 2012.

Professional fees increased approximately $719,000 primarily because of an increase in legal fees of approximately $442,000 arising from contract and patent services, costs related to our September 2012 private placement, and public filings. We incurred additional accounting and audit costs of approximately $101,000 as a result of SEC reporting and additional requirements related to Sarbanes-Oxley. Consulting costs also increased by approximately $176,000 as a result of the introduction of new pharmacy-sold products, as well as enhanced SEC reporting.

Loss on Extinguishment of Debt

In February 2012, we issued promissory notes in the aggregate of approximately $2,700,000 and granted warrants for the purchase of an aggregate of 9,000,000 shares of our common stock, or the February 2012 Funding. In connection with the February 2012 Funding, we received $1,000,000 and the surrender of certain other promissory notes totaling $1,700,000. We determined that the resulting modification of these notes was substantial in accordance with Accounting Standards Certification 470-50, *Modifications and Extinguishments*. As such, the modification was accounted for as an extinguishment and restructuring of the debt and the fair value of the warrants granted of approximately $10,505,000 was recognized as loss on the extinguishment of debt. The relative fair value of the promissory notes was estimated to be $1,500,000 by calculating the present value of future cash flows discounted at a market rate of return for comparable debt instruments. We recognized a reduction in loss of extinguishment of debt in the amount of $197,000, which represented the difference between the net carrying amount of the February 2012 Funding and its fair value.

Beneficial Conversion Feature

Beneficial conversion feature of approximately $6,717,000 consisted of non-cash costs associated with the conversion of approximately $1,055,000 in debt into 2,775,415 shares of our common stock. As a result of this conversion, we recognized $6,717,000 in non-cash costs related to a beneficial conversion feature.

Interest Expense

Interest expense increased approximately $1,841,000, primarily as a result of amortization of debt discount associated with promissory notes we issued during 2012.

Year ended December 31, 2011 compared with year ended December 31, 2010

	Year Ended December 31,		
	2011	2010	Change
	(000s)		
Revenue	$2,088	$1,242	$846
Cost of goods sold	947	556	391
Operating expenses	6,568	3,553	3,015
Operating loss	(5,427)	(2,867)	(2,560)
Loss on extinguishment of debt	(7,390)	-0-	(7,390)
Other expense, net	(96)	-0-	(96)
Net loss	$(12,913)	$(2,867)	$(10,046)

Revenue

Revenue for year ended December 31, 2011 increased by $846,000, or approximately 68.1%, from the year ended December 31, 2010. This increase was directly attributable to the increase in the number of sales territories and the associated increase in number of sales people in those territories.

Cost of Goods Sold

Cost of goods sold increased $391,000, or approximately 70.3%, for the year ended December 31, 2011 compared with the year ended December 31, 2010. Approximately 96.9% of this increase was due to an increase in the amount of product sold and approximately 3.1% of the increase was related to product mix. Our costs of individual products did not change for year ended December 31, 2011 compared with 2010.

Operating Expenses

Our principal operating costs included the following items as a percentage of total operating expenses.

	Year Ended December

	31, 2011	2010
Human resource costs	48 %	48 %
Sales and marketing, excluding human resources cost	33 %	31 %
Professional fees and consulting	7 %	4 %
Product design and development costs	2 %	2 %
Other	10 %	15 %

Operating expenses increased by $3,015,000, or 84%, for year ended December 31, 2011 from year ended December 31, 2010 as a result of the following items:

	(000s)
Increase in human resource costs	$1,411
Increase in sales and marketing	1,094
Increase in professional and consulting	318
Increase in product design and development costs	42
Increase in all other	150
	$3,015

Human resource related costs increased by approximately $1,411,000 primarily due to the addition of employees in 2011. We had 49 employees at December 31, 2011, which increased from 25 for the comparable date in the prior year.

Sales and marketing costs increased $1,094,000 because of the increase in both sales territories and sales personnel during 2011.

Professional fees increased approximately $318,000, primarily due to an increase in legal fees arising from contract and patent services as well as due diligence related to our merger with VitaMed in October 2011. We incurred additional accounting and audit costs related to audits for 2010 and 2011 as required by our merger with VitaMed. Consulting cost also increased as a result of opening new sales territories and the additional resources needed to complete the merger.

During 2011, we made improvements to products and packaging, which increased costs by a nominal amount.

Rent and occupancy costs increased slightly as a result of repairs and maintenance and other ancillary costs. Non-cash compensation costs increased as a result of the additional options granted in 2011.

Loss on Extinguishment of Debt

On October 18, 2011, we and two noteholders entered into debt conversion agreements and converted the $210,000 principal amount of their convertible notes into 20,000,000 shares of our common stock valued at $7,600,000.

Other Expense, net

Other non-operating expense increased by $96,000 for the year ended December 31, 2011 over the prior fiscal year, primarily as a result of the addition of interest expense not incurred during 2010.

Liquidity and Capital Resources

We have funded our operations primarily through the private placement of equity, debt securities, and public offerings of our common stock. For the three year period ending December 31, 2013, we received $12 million in net proceeds from the issuance of debt securities and $88 million in net proceeds from the issuance of shares of our common stock. As of December 31, 2013, we had cash and cash equivalents totaling $54 million, however, 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 believe that our existing cash and cash equivalents will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. 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 shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. 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. Additionally, we may have to grant licenses on terms that may not be favorable to us.

We need substantial amounts of cash to complete the clinical development of our hormone therapy drug candidates. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of Sources and (Uses) of Cash

	Year Ended December 31,		
	2013	2012	2011
Net cash flows used in operating activities	$ (20,768,069)	$ (12,737,326)	$ (4,966,596)
Net cash flows used in investing activities	$ (583,561)	$ (272,506)	$ (37,636)
Net cash flows provided by financing activities	$ 73,989,416	$ 14,436,885	$ 4,707,714

Operating Activities

The use of cash in all periods resulted primarily from our net loss adjusted for non-cash charges and changes in components of working capital. The increase of $8 million in cash used in operating activities for the year ended December 31, 2013 in comparison to prior year was due primarily to research and development, sales, general and administrative costs. These were offset by $9 million in sales.

The increase of $8 million in cash used in operating activities for the year ended December 31, 2012 compared with the comparable period in the prior year was due to research and development, and sales, general and administrative costs. These were offset by $4 million in sales.

Investing Activities

The use of cash in all periods reflects patent costs, security deposits, and purchase of property and equipment. The increase of $300,000 in cash used in investing activities for the year ended December 31, 2013 compared with the comparable period in the prior year was due to patent costs and purchase of property and equipment.

The increase of $200,000 in cash used in investing activities for the year ended December 31, 2012 compared with the comparable period in the prior year was due to patent costs and purchase of property and equipment.

Financing Activities

Financing activities represent the principal source of our cash flow.

Our financing activities for the year ended December 31, 2013 provided net cash of $74 million.

On March 14, 2013, we entered into an underwriting agreement. The net proceeds to us from this offering was approximately $45 million, after deducting underwriting discounts and commissions and other offering expenses. In addition, under the terms of the underwritten offering, we granted the underwriters a 30-day option to purchase additional shares of our common stock. On April 12, 2013, the underwriters exercised their option to purchase 1,954,587 shares of our common stock, and we received net proceeds of approximately $3 million after deducting underwriting discounts and commissions and other offering expenses. On September 25, 2013, we entered into an underwriting agreement. The net proceeds to us from this offering was approximately $30 million, after deducting underwriting discounts and commissions and other offering expenses. In March 2013, we repaid approximately $5 million in notes and credit lines.

Our financing activities for the year ended December 31, 2012 provided net cash of $14 million.

In September 2012, we entered into a Securities Purchase Agreement with multiple investors, relating to the issuance and sale of our common stock in a private placement to raise approximately $8 million in net proceeds. During 2012, we issued notes in the aggregate amount of approximately $9 million to multiple parties, of which approximately $2 million was repaid.

Our financing activities for the year ended December 31, 2011 provided net cash of $5 million. During 2011, we entered into a securities purchase agreement with an investor, relating to the issuance and sale of our common stock in a private placement to raise approximately $1 million in net proceeds. Our predecessor company sold membership units prior to our merger for approximately $1 million of net proceeds. In 2011, we issued notes in the aggregate amount of approximately $3 million.

Critical Accounting Estimates and New Accounting Pronouncements

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. We consider an accounting estimate to be critical if

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have a material impact on our results of operations or financial condition.

We base our estimates and judgments on our experience, our current knowledge, our beliefs of what could occur in the future, our observation of trends in the industry, information provided by our customers, and information available from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have identified the following accounting policies and estimates as those that we believe are most critical to our financial condition and results of operations and that require our most subjective and complex judgments in estimating the effect of inherent uncertainties: share-based compensation expense and income taxes.

Revenue Recognition. We recognize revenue on arrangements in accordance with ASC 605, Revenue Recognition. We recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed, and collectability is reasonably assured.

Over-the-Counter Products

We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound shipping and handling fees in sales and bill them upon shipment. We include shipping expenses in cost of sales. A majority of our customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce customers. We recognize our revenue from OTC sales, net of returns, sales discounts, and eCommerce fees.

Prescription Products

We sell our name brand and generic prescription products primarily through drug wholesalers and retail pharmacies. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, and rebates.

We accept returns of unsalable product from customers within a return period of six months prior to and following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture. Given the limited history of our prescription products, we currently cannot reliably estimate expected returns of the prescription products at the time of shipment. Accordingly, we defer recognition of revenue on prescription products until the right of return no longer exists, which occurs at the earlier of the time the prescription products are dispensed through patient prescriptions or expiration of the right of return.

We maintain various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The consumer rebate program is designed to enable the end user to return a coupon to us. If the coupon qualifies, we send a rebate check to the end user. We estimate the allowance for consumer rebates based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis.

Research and Development Expense. We rely on the services of external contract research organizations, or CRO's, to facilitate our clinical studies. Certain of these CRO's require us to make payments based on agreed-upon terms, which may include payments in advance of a study starting date. We capitalize these advance payments into prepaid expense when paid. We expense these nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed rather than when the payment is made. As a result, we amortize certain of these amounts based on factors relating to the progress of our clinical studies. These factors include successful enrollment of patients, expected duration of studies, and completion of clinical trial milestones. On a quarterly basis we re-assess the factors by which these advanced payments are expensed. If these factors change we adjust these prepaid balances accordingly.

Share-Based Compensation. We periodically issue stock options and warrants to employees and non-employees in non-capital raising transactions for services and for financing costs. We account for stock option and warrant grants

issued and vesting to employees based on the authoritative guidance provided by the Financial Accounting Standards Board whereas the value of the awards are measured on the date of grant and recognized over the vesting period. We account for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the Financial Accounting Standards Board whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Non-employee stock-based compensation charges generally are amortized over the vesting period on a straight-line basis. In certain circumstances where there are no future performance requirements by the non-employee, option grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date. Determining the fair value of share-based awards at the measurement date requires judgment, including estimating the expected term that stock options and warrants will be outstanding prior to exercise and the associated volatility. We estimate the fair value of options granted using the Black-Scholes-Merton valuation model. The expected life of the options used in this calculation is the period the options are expected to be outstanding and has been determined based on the simplified method in accordance with guidance provided by SEC Staff Accounting Bulletin 07 (ASC 718-10-S99). Expected stock price volatility is based on the historical volatility of the stock of peer entities whose stock prices were publicly available for a period approximating the expected life. We use the historical volatility of peer entities due to the lack of sufficient historical data or our stock prices. The risk-free interest rate is based on the implied yield available on US Treasury zero-coupon issues approximating the expected life. We believe that these assumptions are "critical accounting estimates" because significant changes in the assumptions used to develop the estimates could materially affect key financial measures including net income/(loss).

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate income taxes in each of the jurisdictions in which we operate. We determine provision for income taxes using the asset and liability approach to account for income taxes. We record current liability for the estimated taxes payable for the current year. We record deferred tax assets and liabilities for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates in effect for the year in which the timing differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of changes in tax rates or tax laws is recognized in the provision for income taxes in the period that includes the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount more-likely-than-not to be realized. Changes in valuation allowances will flow through the statement of operations unless related to deferred tax assets that expire unutilized or are modified through translation, in which case both the deferred tax asset and related valuation allowance are similarly adjusted. Where a valuation allowance was established through purchase accounting for acquired deferred tax assets, any future change will be credited or charged to income tax expense.

The determination of our provision for income taxes requires significant judgment, the use of estimates, and the interpretation and application of complex tax laws. In the ordinary course of our business, there are transactions and calculations for which the ultimate tax determination is uncertain. In spite of our belief that we have appropriate support for all the positions taken on our tax returns, we acknowledge that certain positions may be successfully challenged by the taxing authorities. We determine the tax benefits more likely than not to be recognized with respect to uncertain tax positions. Although we believe our recorded tax assets and liabilities are reasonable, tax laws and regulations are subject to interpretation and inherent uncertainty; therefore, our assessments can involve both a series of complex judgments about future events and rely on estimates and assumptions. Although we believe these estimates and assumptions are reasonable, the final determination could be materially different than that which is reflected in our provision for income taxes and recorded tax assets and liabilities.

New Accounting Pronouncements

In July, 2013, the FASB issued Accounting Standards Update, or ASU, No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*, or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in ASU No. 2013-11 do not require new recurring disclosures. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in ASU No. 2013-11 are not expected to have a material impact on our consolidated financial statements.

In July 2012, the FASB issued ASU No. 2012-02, *Testing Indefinite-Lived Intangible Assets for Impairment*, or ASU 2012-02. ASU 2012-02 gives entities an option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the long-lived intangible assets are impaired. If, based on its qualitative assessment, an entity concludes that it is more likely than not that the fair value of an indefinite lived intangible asset is less than its carrying amount, quantitative impairment testing is required. However, if an entity concludes otherwise, quantitative impairment testing is not required. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. ASU 2012-02 is not expected to have a material impact on our financial position or results of operations.

In December 2011, the FASB issued ASU No. 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities*, or ASU 2011-11. ASU 2011-11 enhances current disclosures about financial instruments and derivative instruments that are either offset on the statement of financial position or subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset on the statement of financial position. Entities are required to provide both net and gross information for these assets and liabilities in order to facilitate comparability between financial statements prepared in conformity with GAAP and financial statements

prepared on the basis of International Financial Reporting Standards. ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those years. ASU 2011-11 is not expected to have a material impact on our financial position or results of operations.

We do not believe there would have been a material effect on the accompanying consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Off-Balance Sheet Arrangements

As of December 31, 2013, 2012 and 2011 we had no material off-balance sheet arrangements.

In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions, which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our drug candidates, use of such drug candidates, or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we have no liabilities recorded for these provisions as of December 31, 2013, 2012 or 2011.

In the normal course of business, we may be confronted with issues or events that may result in a contingent liability. These generally relate to lawsuits, claims, environmental actions or the actions of various regulatory agencies. We consult with counsel and other appropriate experts to assess the claim. If, in our opinion, we have incurred a probable loss as set forth by accounting principles generally accepted in the United States, an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements.

Effects of Inflation

For each of the fiscal years ended December 31, 2013, 2012, and 2011, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual cash obligations as of December 31, 2013 is as follows:

	Payments Due By Period (in thousands)			
	Total	**Less than 1 Year**	**1-3 Years**	**4-5 Years**
Operating Lease Obligations	1,766	316	1,147	303

Seasonality

The specialty pharmaceutical industry component of women's health is not subject to seasonal sales fluctuation.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

We had cash and cash equivalents totaling $54 million as of December 31, 2013. We hold our cash in money market funds and the primary objective of our investment policy is to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are held at fair value.

Item 8. *Financial Statements and Supplementary Data*

Reference is made to the financial statements, the notes thereto, and the report thereon, commencing on page F-1 of this Annual Report, which financial statements, notes, and report are incorporated herein by reference.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

Not applicable.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(f) or 15d-15(f)) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2013, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

The management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, the management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework. The Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on the management's assessment, we believe that our internal controls over financial reporting were effective as of December 31, 2013.

Rosenberg Rich Baker Berman & Company, an independent registered public accounting firm , has audited the consolidated financial statements included in this Annual Report; and, as part of its audit, has issued an attestation

report, included herein, on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, misstatements, errors, and instances of fraud, if any, within our company have been or will be prevented or detected. Further, internal controls may become inadequate as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

Item 9B. *Other Information*

Not applicable.

PART III

Item 10. *Directors, Executive Officers, and Corporate Governance*

The information required by this Item relating to our directors and corporate governance is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2014 Annual Meeting of Stockholders**.** The information required by this Item relating to our executive officers is included under the caption "Executive Officers" within Item 1.

Item 11. *Executive Compensation*

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2014 Annual Meeting of Stockholders.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this Item is incorporated by reference to the definitive Proxy Statement to be filed pursuant to Regulations 14A of the Exchange Act for our 2014 Annual Meeting of Stockholders.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required by this Item is incorporated herein by reference to the definitive Proxy Statements to be filed pursuant to Regulation 14A of the Exchange Act for our 2014 Annual Meeting of Stockholders.

Item 14. *Principal Accountant Fees and Services*

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regular 14A of the Exchange Act for our 2014 Annual Meeting of Stockholders.

PART IV

Item 15. *Exhibits and Financial Statement Schedules*

(a) **Financial Statements and Financial Statements Schedules**

(1) Financial Statements are listed in the Index to Consolidated Financial Statements on page F-1 of this Annual Report.

(2) No financial statement schedules are included because such schedules are not applicable, are not required, or because required information is included in the consolidated financial statements or notes thereto.

(b) **Exhibits**

Exhibit	Date	Description
2.1	July 6, 2009	Agreement and Plan of Reorganization among Croff Enterprises, Inc., AMHN Acquisition Corp., America's Minority Health Network, Inc., and the Major Shareholders§[1]
2.2	June 11, 2010	Agreement and Plan of Reorganization among AMHN, Inc., SHN Acquisition Corp., Spectrum Health Network, Inc., and the Sole Shareholder of Spectrum Health Network, Inc.[2]
2.3	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization[3]
2.4	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC[4]
3.1	September 15, 2009	Articles of Amendment to Articles of Incorporation (to change name to AMHN, Inc.)[5]
3.2	July 27, 2009	Certificate of Merger of AMHN Acquisition Corp., with and into America's Minority Health Network, Inc.[6]
3.3	December 27, 2007	Articles of Amendment to Articles of Incorporation of Croff Enterprises, Inc. (to increase authorized common shares from 20,000,000 to 50,000,000)[3]
3.4	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada[7]
3.5	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada[7]
3.6	August 29, 2011	Certificate of Amendment and Restatement of Articles of Incorporation of AMHN, Inc. (to change name and increase authorized shares)[8]
3.7	n/a	Bylaws of AMHN, Inc.[9]
4.1	September 26, 2012	Form of Securities Purchase Agreement [10]
4.2	n/a	Form of Certificate of Common Stock[11]
10.1	November 9, 2010	Demand Promissory Note to Philip M. Cohen for $210,000[12]
10.2	April 18, 2011	Convertible Promissory Note to First Conquest Investment Group, L.L.C. for $105,000[12]
10.3	April 18, 2011	Convertible Promissory Note to Energy Capital, LLC for $105,000[12]
10.4	May 7, 2011	Sales Representative Agreement between AMHN, Inc. and Mann Equity, LLC[12]
10.5	July 9, 2009	Lease Agreement between Liberty Property Limited Partnership and VitaMedMD, LLC[13]
10.6	September 8, 2011	Stock Purchase Agreement between AMHN, Inc. and Pernix Therapeutics, LLC[14]
10.7	September 8, 2011	Lock-Up Agreement between AMHN, Inc. and Pernix Therapeutics, LLC[14]
10.8	n/a	Form of Common Stock Purchase Warrant [13]
10.9*	n/a	Form of Non-Qualified Stock Option Agreement [13]
10.10	September 2011	Form of Convertible Promissory Note[15]
10.11	September 20, 2011	Financing Agreement between Lang Naturals, Inc. and VitaMedMD, LLC[16]
10.12	October 18, 2011	Debt Conversion Agreement between the Company and Energy Capital, LLC[17]
10.13	October 18, 2011	Debt Conversion Agreement between the Company and First Conquest Investment Group, LLC[17]
10.14		Consulting Agreement among VitaMedMD, LLC, the Company, and Lang Naturals, Inc.[17]

	October 23, 2011	
10.15	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc.(17)
10.16	October 23, 2011	Lock-Up Agreement between the Company and Lang Naturals, Inc. (17)
10.17	November 3, 2011	Software License Agreement between vitaMedMD, LLC and Pernix Therapeutics, LLC(18)

Exhibit	Date	Description
10.18	November 2011	Form of Promissory Note [19]
10.19	February 24, 2012	Note Purchase Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson[20]
10.20	February 24, 2012	Form of Secured Promissory Note[20]
10.21	February 24, 2012	Security Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson[20]
10.22	February 24, 2012	Form of Common Stock Purchase Warrant[20]
10.26	April 17, 2012	Master Services Agreement between the Company and Sancilio and Company, Inc.[21]
10.27**	May 17, 2012	Consulting Agreement between the Company and Sancilio and Company, Inc. [21]
10.28*	November 8, 2012	Form of Employment Agreement[22]
10.29	January 31, 2013	Multiple Advance Revolving Credit Note, issued to Plato & Associates, LLC[23]
10.30	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC[23]
10.31*	May 8, 2013	Agreement to Forfeit Non-Qualified Stock Options between the Company and Robert G. Finizio[24]
10.32	May 7, 2013	Consulting Agreement between the Company and Sancilio and Company, Inc. [24]
10.33	May 16, 2013	Lease between the Company and 6800 Broken Sound LLC[25]
10.34*	n/a	Amended and Restated 2012 Stock Incentive Plan[26]
10.35*	n/a	2009 Long Term Incentive Compensation Plan, as amended[27]
21.00	December 31, 2012	Subsidiaries of the Company[21]
23.1	March 5, 2014	Consent of Rosenberg Rich Baker Berman & Company
31.1	March 5, 2014	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
31.2	March 5, 2014	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1	March 5, 2014	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	March 5, 2014	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS †	n/a	XBRL Instance Document
101.SCH †	n/a	XBRL Taxonomy Extension Schema Document
101.CAL †	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF †	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB †	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE †	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

* Indicates a contract with management or compensatory plan or arrangement.

** Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

† Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

(1) Filed as an exhibit to Form 8-K filed with the Commission on July 10, 2009 and incorporated herein by reference.

(2) Filed as an exhibit to Form 8-K filed with the Commission on June 14, 2010 and incorporated herein by reference.

(3) Filed as an exhibit to Form 10-K for the year ended December 31, 2007 filed with the Commission on May 1, 2008 and incorporated herein by reference.

(4) Filed as an exhibit to Form 8-K filed with the Commission on July 21, 2011 and incorporated herein by reference.

(5) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2009 filed with the Commission on November 16, 2009 and incorporated herein by reference.

(6) Filed as an exhibit to Form 10-K for the year ended December 31, 2009 filed with the Commission on March 17, 2010 and incorporated herein by reference.

(7) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2010 filed with the Commission on August 3, 2010 and incorporated herein by reference.

(8) Filed as an exhibit to Definitive 14C Information Statement filed with the Commission on September 12, 2011 and incorporated herein by reference.

(9) Filed as an exhibit to Definitive 14C Information Statement filed with the Commission on June 29, 2010 and incorporated herein by reference.

(10) Filed as an exhibit to Form 8-K filed with the Commission on October 2, 2012 and incorporated herein by reference.

(11) Filed as an exhibit to Form S-3 filed with the Commission on January 25, 2013 and incorporated hereby by reference.

(12) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2011 filed with the Commission on May 19, 2011 and incorporated herein by reference.

(13) Filed as an exhibit to Form 8-K filed with the Commission on October 11, 2011 and incorporated herein by reference.

(14) Filed as an exhibit to Form 8-K filed with the Commission on September 14, 2011 and incorporated herein by reference.

(15) Filed as an exhibit to Form 8-K/A filed with the Commission on November 22, 2011 and incorporated herein by reference.

(16) Filed as an exhibit to Form 8-K/A filed with the Commission on February 2, 2012 and incorporated herein by reference.

(17) Filed as an exhibit to Form 8-K filed with the Commission on October 24, 2011 and incorporated herein by reference.

(18) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2011 filed with the Commission on November 7, 2011 and incorporated herein by reference.

(19) Filed as an exhibit to Form 8-K filed with the Commission on November 23, 2011 and incorporated herein by reference.

(20) Filed as an exhibit to Form 8-K filed with the Commission on February 24, 2012 and incorporated herein by reference.

(21) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2012 filed with the Commission on August 9, 2012 and incorporated herein by reference.

(22) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2012 filed with the Commission on November 13, 2012 and incorporated herein by reference.

(23) Filed as an exhibit to Form 8-K filed with the Commission on February 6, 2013 and incorporated herein by reference.

(24) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2013 filed with the Commission on May 10, 2013 and incorporated herein by reference.

(25) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2013 filed with the Commission on August 7, 2013 and incorporated herein by reference.

(26) Filed as an exhibit to Form 8-K filed with the Commission on August 22, 2013 and incorporated herein by reference.

(27) Filed as an exhibit to Registration Statement on Form S-8 filed with the Commission on October 15, 2013 and incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THERAPEUTICSMD, INC.

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer

Date: March 5, 2014

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	**Capacity**	**Date**
/s/ Robert G. Finizio Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	March 5, 2014
/s/ John C.K. Milligan, IV John C.K. Milligan, IV	President, Secretary, Director	March 5, 2014
/s/ Daniel A. Cartwright Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	March 5, 2014
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman	March 5, 2014
/s/ Brian Bernick Brian Bernick	Director	March 5, 2014
/s/ Cooper C. Collins Cooper C. Collins	Director	March 5, 2014
/s/ Robert V. LaPenta, Jr. Robert V. LaPenta, Jr.	Director	March 5, 2014

/s/ Nicholas Segal Nicholas Segal	Director	March 5, 2014
/s/ Jules Musing Jules Musing	Director	March 5, 2014
/s/ Randall Stanicky Randall Stanicky	Director	March 5, 2014

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of TherapeuticsMD, Inc.

We have audited the accompanying consolidated balance sheets of TherapeuticsMD, Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three year period ended December 31, 2013. TherapeuticsMD Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of TherapeuticsMD, Inc. as of December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), TherapeuticsMD Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 5, 2014 expressed an unqualified opinion on the effectiveness of TherapeuticsMD, Inc.'s internal control over financial reporting.

/s/ Rosenberg Rich Baker Berman & Company

Somerset, New Jersey

March 5, 2014

F-2

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of TherapeuticsMD, Inc.

We have audited TherapeuticsMD, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). TherapeuticsMD Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, TherapeuticsMD, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows of TherapeuticsMD, Inc., and our report dated March 5, 2014 expressed an unqualified opinion on those consolidated financial statements.

/s/ Rosenberg Rich Baker Berman & Company

Somerset, New Jersey

March 5, 2014

THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	2012
ASSETS		
Current Assets:		
Cash	$54,191,260	$1,553,474
Accounts receivable, net of allowance for doubtful accounts of $26,555 and $42,048, respectively	1,690,753	714,425
Inventory	1,043,618	1,615,210
Other current assets	2,477,715	751,938
Total current assets	59,403,346	4,635,047
Fixed assets, net	61,318	65,673
Other Assets:		
Prepaid expense	1,750,455	953,655
Intangible assets	665,588	239,555
Security deposit	135,686	31,949
Total other assets	2,551,729	1,225,159
Total assets	$62,016,393	$5,925,879
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$2,114,217	$1,641,366
Deferred revenue	1,602,580	1,144,752
Other current liabilities	3,601,189	833,654
Total current liabilities	7,317,986	3,619,772
Long-Term Liabilities:		
Notes payable, net of debt discount of $0 and $1,102,680, respectively	—	3,589,167
Accrued interest	—	150,068
Total long-term liabilities	—	3,739,235
Total liabilities	7,317,986	7,359,007
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 250,000,000 shares authorized; 144,976,757 and 99,784,982 issued and outstanding, respectively	144,977	99,785

Additional paid in capital	135,086,056	50,580,400
Accumulated deficit	(80,532,626)	(52,113,313)
Total stockholders' equity	54,698,407	(1,433,128)
Total liabilities and stockholders' equity	$62,016,393	$5,925,879

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2013	2012	2011
Revenues, net	$8,775,598	$3,818,013	$2,088,177
Cost of goods sold	1,959,597	1,348,113	947,112
Gross profit	6,816,001	2,469,900	1,141,065
Operating expenses:			
Sales, general, and administrative	19,014,837	14,069,701	6,406,197
Research and development	13,551,263	4,492,362	107,241
Depreciation and amortization	58,145	56,260	54,845
Total operating expense	32,624,245	18,618,323	6,568,283
Operating loss	(25,808,244)	(16,148,423)	(5,427,218)
Other income and (expense)			
Miscellaneous income	34,544	3,001	6,392
Interest income	27,234	—	—
Financing costs	(1,503,922)	—	—
Interest expense	(1,165,981)	(1,905,409)	(64,380)
Loan guaranty costs	(2,944)	(45,036)	(38,159)
Loss on extinguishment of debt	—	(10,307,864)	(7,390,000)
Beneficial conversion feature	—	(6,716,504)	—
Total other income (expense)	(2,611,069)	(18,971,812)	(7,486,147)
Loss before taxes	(28,419,313)	(35,120,235)	(12,913,365)
Provision for income taxes	—	—	—
Net loss	$(28,419,313)	$(35,120,235)	$(12,913,365)
Net loss per share, basic and diluted	$(0.22)	$(0.38)	$(0.21)
Weighted average number of common shares outstanding	127,569,731	91,630,693	62,516,461

The accompanying footnotes are an integral part of these consolidated financial statements.

F-5

THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2010	55,487,321	$55,487	$4,988,637	$(4,079,713)	$964,411
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	165,879	166	(255,919)	—	(255,753)
Shares issued in private placement, net of cost	5,551,589	5,552	1,701,448	—	1,707,000
Shares issued in exchange for debt	21,681,958	21,682	8,217,455	—	8,239,137
Shares issued for exercise of options	92,057	92	17,158	—	17,250
Options issued as compensation	—	—	183,355	—	183,355
Warrants issued for services	—	—	190,280	—	190,280
Warrants issued for loan guaranty costs-related parties	—	—	93,969	—	93,969
Warrants issued for financing costs	—	—	45,362	—	45,362
Warrants issued for financing costs-related parties	—	—	9,338	—	9,338
Warrants issued as compensation-related party	—	—	7,158	—	7,158
Net loss	—	—	—	(12,913,365)	(12,913,365)
Balance, December 31, 2011	82,978,804	82,979	15,198,241	(16,993,078)	(1,711,858)
Shares issued in private placement, net of cost	3,953,489	3,954	7,891,531	—	7,895,485
Shares issued in exchange for debt	2,775,415	2,775	1,051,882	—	1,054,657
Shares issued for exercise of options	1,931,788	1,932	189,068	—	191,000
Shares issued for exercise of warrants	8,145,486	8,145	3,093,855	—	3,102,000
Options issued as compensation	—	—	1,832,061	—	1,832,061
Warrants issued for financing costs	—	—	13,014,784	—	13,014,784
Warrants issued for services	—	—	1,563,620	—	1,563,620
Warrants issued as compensation-related party	—	—	36,284	—	36,284
Warrants issued for cash	—	—	400	—	400
Cancellation of warrants issued for loan guaranty costs-related parties	—	—	(7,830)	—	(7,830)
Beneficial ownership feature	—	—	6,716,504	—	6,716,504

Net loss	—	—	—	(35,120,235)	(35,120,235)
Balance, December 31, 2012	99,784,982	99,785	50,580,400	(52,113,313)	(1,433,128)
Shares issued in private placements, net of cost	45,116,352	45,117	78,605,236	—	78,650,353
Shares issued for exercise of options	75,423	75	30,835	—	30,910
Employee Share Based Compensation	—	—	3,254,083	—	3,254,083
Warrants issued for financing costs	—	—	1,711,956	—	1,711,956
Warrants issued for services	—	—	867,262	—	867,262
Warrants issued as compensation-related party	—	—	36,284	—	36,284
Net loss	—	—	—	(28,419,313)	(28,419,313)
Balance, December 31, 2013	144,976,757	$144,977	$135,086,056	$(80,532,626)	$54,698,407

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2013	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(28,419,313)	$(35,120,235)	$(12,913,365)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	—	—	(255,753)
Depreciation	47,883	27,484	25,686
Amortization of intangible assets	10,262	28,776	29,159
Provision for doubtful accounts	(15,493)	40,548	1,500
Loss on extinguishment of debt	—	10,307,864	7,390,000
Beneficial conversion feature	—	6,716,504	—
Amortization of debt discount	1,102,680	1,604,240	28,719
Stock based compensation	3,207,238	1,868,345	190,513
Amortization of deferred financing costs	1,451,934	—	25,980
Stock based expense for services	636,917	338,457	22,630
Loan guaranty costs	2,944	45,036	38,159
Changes in operating assets and liabilities:			
Accounts receivable	(1,068,619)	(728,253)	(16,409)
Inventory	571,592	(1,027,137)	29,996
Other current assets	(1,386,319)	42,281	(346,822)
Other assets	(565,706)	—	—
Accounts payable	472,851	1,334,855	188,876
Deferred revenue	457,828	1,144,752	—
Accrued expenses and other current liabilities	2,875,320	639,157	594,535
Other liabilities	(150,068)	—	—
Net cash flows used in operating activities	(20,768,069)	(12,737,326)	(4,966,596)
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs, net of abandoned costs	(439,034)	(206,101)	(8,870)
Payment of security deposit	(103,737)	—	—
Purchase of property and equipment	(40,790)	(66,405)	(28,766)
Net cash flows used in investing activities	(583,561)	(272,506)	(37,636)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	78,650,353	7,895,485	1,000,000
Proceeds bank line of credit	500,000	—	300,000
Proceeds from exercise of options	30,910	191,000	17,250

Proceeds from notes and loans payable	—	8,700,000	2,684,160
Proceeds from sale of warrants	—	400	—
Proceeds from notes and loans payable-related parties	—	—	300,000
Proceeds from sale of membership units, net of expenses	—	—	707,000
Repayment of bank line of credit	(500,000)	(300,000)	—
Repayment of notes payable-related party	—	(200,000)	(100,696)
Repayment of notes payable	(4,691,847)	(1,850,000)	(200,000)
Net cash flows provided by financing activities	73,989,416	14,436,885	4,707,714
Increase in cash	52,637,786	1,427,053	(296,518)
Cash, beginning of period	1,553,474	126,421	422,939
Cash, end of period	$54,191,260	$1,553,474	$126,421
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$212,853	$17,253	$696
Cash paid for income taxes	$—	$—	$—
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:			
Warrants issued for financing	$1,711,956	$2,509,537	$148,668
Warrants issued for services	$462,196	$1,532,228	$190,280
Warrants exercised in exchange for debt and accrued interest	$—	$3,102,000	$—
Shares issued in exchange for debt and accrued interest	$—	$1,054,658	$849,137
Notes payable issued for accrued interest	$—	$15,123	$—

The accompanying footnotes are an integral part of these consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has two wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company organized on May 13, 2008, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation incorporated on January 10, 2012, or BocaGreen. Unless the context otherwise requires, TherapeuticsMD, VitaMed, and BocaGreen collectively are sometimes referred to as “our company,” “we,” “our,” or “us.”

Nature of Business

We are a women’s healthcare product company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture (through third parties) and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics.

Agreement and Plan of Merger with VitaMed

On July 18, 2011, we entered into an Agreement and Plan of Merger with VitaMed and our newly formed wholly owned subsidiary. In connection with the acquisition, our subsidiary merged with and into VitaMed with VitaMed surviving the merger. The merger became effective upon the filing of the Certificate of Merger with the Secretary of State of the State of Delaware on October 4, 2011. In preparation for and prior to the closing of the Merger, we completed the following required corporate actions:

- a reverse split of our 16,575,209 issued and outstanding shares of our common stock, par value $0.001 per share, or the Common Stock, on a ratio of 1-for-100. As a result of the reverse split, each share of Common Stock outstanding on the July 28, 2011 record date, without any action on the part of the holder thereof, became one one-hundredth of a share of Common Stock. The reverse split decreased the number of outstanding shares of our Common Stock by approximately 99%, resulting in 165,856 shares outstanding after the reverse split. The effectuation of the reverse split did not result in a change in the relative equity position or voting power of our shareholders;

- an increase in the number of shares of our Common Stock authorized for issuance to 250,000,000;

- a change in the name of our company to TherapeuticsMD, Inc.; and

- an amendment to our 2009 Long Term Incentive Compensation Plan to increase the number of shares of our Common Stock reserved for issuance thereunder to 25,000,000.

On the effective date of the merger, we acquired 100% of VitaMed in exchange for shares of our Common Stock.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Exchange of Securities

On the effective date of the merger, all outstanding membership units of VitaMed were exchanged for shares of our Common Stock. In addition, all outstanding options and warrants to purchase VitaMed membership units were exchanged for and converted into options and warrants to purchase shares of our Common Stock. Pursuant to the conversion ratio in the merger, we issued 58,407,331 shares of our Common Stock in exchange for the outstanding VitaMed membership units, reserved an aggregate of 10,119,796 shares of our Common Stock for issuance upon the exercise of the VitaMed options, and reserved an aggregate of 1,472,916 shares of our Common Stock for issuance upon the exercise of the warrants. After giving effect to the reverse split, and taking into consideration the 58,407,331 shares issued in exchange for the membership units, the number of shares of our Common Stock issued and outstanding as of the effective date of the merger was 58,573,187, of which the former members of VitaMed owned approximately 99%. All shares of our Common Stock issued in exchange for the VitaMed membership units and issuable upon exercise of the options and warrants were subject to a lock-up agreement for a period of 18 months from the effective date of the merger, and on a limited basis for 12 months thereafter.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of our company and our wholly owned subsidiaries, VitaMed and BocaGreen. All material intercompany balances and transactions have been eliminated in consolidation.

Cash

We maintain cash at financial institutions that at times may exceed federally insured limits. We have never experienced any losses related to these funds. All of our non-interest bearing cash balances were fully insured at December 31, 2012 and 2011, resulting from the temporary federal program in effect from December 31, 2010 through December 31, 2012. Under this program, there was no limit to the amount of insurance for eligible accounts.

Beginning January 1, 2013, insurance coverage reverted to $250,000 per depositor at each financial institution, at which time our non-interest bearing cash balances again exceeded federally insured limits.

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card charge-backs and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due for more than 90 days to be delinquent. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off as increase in allowance for doubtful accounts when received. To the extent data we use to calculate these estimates does not accurately reflect bad debts; adjustments to these reserves may be required.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Inventories

Inventories represent packaged nutritional products and supplements and raw materials, which are valued at the lower of cost or market using the average-cost method. The costs of manufacturing the prescription products associated with the deferred revenue (as discussed in Revenue Recognition) are recorded as deferred costs and are included in inventory, until such time as the related deferred revenue is recognized.

Fixed Assets

Equipment

We state equipment at cost, net of accumulated depreciation. We charge maintenance costs, which do not significantly extend the useful lives of the respective assets, and repair costs to operating expense as incurred. We compute depreciation using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years.

Leasehold Improvements

We state improvements at cost, net of accumulated depreciation. We compute depreciation using the straight-line method over the remaining term of the lease.

Intangible Assets

Patent and Trademarks

We have adopted the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 350, *Intangible-Goodwill and Other*, or ASC 350. Capitalized patent costs, net of accumulated amortization, include legal costs incurred for patent applications. In accordance with ASC 350, once a patent is granted, we amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, we write-off any capitalized patent costs at that time. We review intangible assets for impairment annually or when events or circumstances indicate that their carrying amount may not be recoverable. Our first patent was granted in the year ended December 31, 2013.

Impairment of Long-Lived Assets

We review the carrying values of property and equipment and long-lived intangible assets for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. Such events or circumstances include the following:

- significant declines in an asset's market price;
- significant deterioration in an asset's physical condition;
- significant changes in the nature or extent of an asset's use or operation;
- significant adverse changes in the business climate that could impact an asset's value, including adverse actions or assessments by regulators;
- accumulation of costs significantly in excess of original expectations related to the acquisition or construction of an asset;
- current-period operating or cash flow losses combined with a history of such losses or a forecast that demonstrates continuing losses associated with an asset's use; and
- expectations that it is more likely than not that an asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

If impairment indicators are present, we determine whether an impairment loss should be recognized by testing the applicable asset or asset group's carrying value for recoverability. This test requires long-lived assets to be grouped at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities, the determination of which requires judgment. We estimate the undiscounted future cash flows expected to be generated from the use and eventual disposal of the assets and compare that estimate to the respective carrying values in order to determine if such carrying values are recoverable. This assessment requires the exercise of judgment in assessing the future use of and projected value to be derived from the eventual disposal of the assets to be held and used. In our assessments, we also consider changes in asset utilization, including the temporary idling of capacity and the expected timing for placing this capacity back into production. If the carrying value of the assets is not recoverable, then we record a loss for the difference between the assets' fair value and respective carrying value. We determine the fair value of the assets using an "income approach" based upon a forecast of all the expected discounted future net cash flows associated with the subject assets. Some of the more significant estimates and assumptions include market size and growth, market share, projected selling prices, manufacturing cost, and discount rate. We base estimates upon historical experience, our commercial relationships, market conditions, and available external information about future trends. We believe our current assumptions and estimates are reasonable and appropriate. Unanticipated events and changes in market conditions, however, could affect such estimates, resulting in the need for an impairment charge in future periods.

Fair Value of Financial Instruments

Our financial instruments consist primarily of accounts receivable, accounts payable, accrued expenses, and short-term debt. The carrying amount of accounts receivable, accounts payable, and accrued expenses approximates their fair value because of the short-term maturity of such instruments and are considered Level 1 assets under the fair value hierarchy. We use interest rates that are currently available to us for issuance of short- and long-term debt with similar terms and remaining maturities to estimate the fair value of our short- and long-term debt, which would be considered Level 3 inputs under the fair value hierarchy.

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by ASC 820, *Fair Value Measurements and Disclosures.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3).

Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1	unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2	quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
Level 3	unobservable inputs for the asset or liability.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At December 31, 2013, 2012, and 2011, we had no assets or liabilities that were valued at fair value on a recurring basis.

Income Taxes

With the advent of the Merger, we determined that VitaMed would become the sole focus of our company and previous business performed by our predecessor was discontinued. Because of these events, deferred income taxes are determined by calculating the loss from operations of our company starting October 4, 2011.

We account for income taxes under the asset and liability method. We recognize deferred tax assets and liabilities for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the related temporary differences are expected to be recovered or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates when the rate change is enacted. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized.

In accordance with ASC 740, *Income Taxes*, we recognize the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. We measure recognized uncertain income tax positions using the largest amount that has a likelihood of being realized that is greater than 50%. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur. At December 31, 2013, 2012, and 2011 we had no uncertain income tax positions.

We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. At December 31, 2013 and 2012, we had no tax positions relating to open tax returns that were considered to be uncertain.

Our tax returns are subject to review by the Internal Revenue Service three years after they are filed. Currently, years filed after 2010 are subject to review.

Share-Based Compensation

In December 2004, the FASB issued ASC 718, *Compensation – Stock Compensation*, or ASC 718. Under ASC 718, companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include options, restricted stock, restricted stock units, performance-based awards, share appreciation rights, and employee share purchase plans. As such, compensation cost is measured on the date of grant at fair value. We amortize such compensation amounts, if any, over the respective vesting periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, that requires the input of highly complex and subjective variables, including the expected life of the award and our expected stock price volatility over a period equal to or greater than the expected life of the award.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Equity instruments ("instruments") issued to anyone other than employees are recorded on the basis of the fair value of the instruments, as required by ASC 718. ASC 505, *Equity Based Payments to Non-Employees*, or ASC 505, defines the measurement date and recognition period for such instruments. In general, the measurement date is when either (a) a performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in ASC 505.

We recognize the compensation expense for all share-based compensation granted based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense on a straight-line basis over the employee's requisite service period.

Debt Discounts

Costs incurred from parties that are providing long-term financing, which include warrants issued in connection with the underlying debt, are reflected as a debt discount based on the relative fair value of the debt and warrants to the total proceeds. We generally amortize discounts over the life of the related debt using the effective interest rate method.

Revenue Recognition

We recognize revenue on arrangements in accordance with ASC 605, *Revenue Recognition*. We recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed, and collectability is reasonably assured.

Over-the-Counter Products

We generate OTC revenue from product sales primarily to retail consumers. We recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We include outbound

shipping and handling fees in sales and bill them upon shipment. We include shipping expenses in cost of sales. A majority of our customers pay for our products with credit cards, and we usually receive the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to sales. We provide an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce customers. We recognize our revenue from OTC sales, net of returns, sales discounts, and eCommerce fees.

Prescription Products

We sell our name brand and generic prescription products primarily through drug wholesalers and retail pharmacies. We recognize revenue from prescription product sales, net of sales discounts, chargebacks, and rebates.

We accept returns of unsalable product from customers within a return period of six months prior to and following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture. Given the limited history of our prescription products, we currently cannot reliably estimate expected returns of the prescription products at the time of shipment. Accordingly, we defer recognition of revenue on prescription products until the right of return no longer exists, which occurs at the earlier of the time the prescription products are dispensed through patient prescriptions or expiration of the right of return.

We maintain various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The consumer rebate program is designed to enable the end user to return a coupon to us. If the coupon qualifies, we send a rebate check to the end user. We estimate the allowance for consumer rebates based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Shipping and Handling Costs

We expense all shipping and handling costs as incurred. We include these costs in cost of sales on the accompanying consolidated financial statements.

Advertising Costs

We expense advertising costs when incurred. Advertising costs were $11,739, $65,944 and $19,480 during the years ended December 31, 2013, December 31, 2011 and December 31, 2012, respectively.

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal counsel. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future R&D activities were $2,091,809 and $189,375 for years ended December 31, 2013 and December 31, 2012, respectively. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

Earnings Per Share

We calculate earnings per share, or EPS, in accordance with ASC 260, *Earnings Per Share*, which requires the computation and disclosure of two EPS amounts: basic and diluted. We compute basic EPS based on the weighted-average number of shares of Common Stock outstanding during the period. We compute diluted EPS based on the weighted-average number of shares of our Common Stock outstanding plus all potentially dilutive shares of our Common Stock outstanding during the period. Such potentially dilutive shares of our Common Stock consist of options and warrants. Potentially dilutive shares of our Common Stock representing 29,926,241, 25,926,987, and 13,647,788 shares of our Common Stock for 2013, 2012, and 2011, respectively, were excluded from the calculation of diluted earnings per share for these periods because their effect would have been anti-dilutive due to the net loss reported by us.

Use of Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenue, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates, including those related to contingencies, on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ, at times in material amounts, from these estimates under different assumptions or conditions.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Recently Issued Accounting Pronouncements

In July, 2013, the FASB issued Accounting Standards Update, or ASU, No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*, or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in ASU No. 2013-11 do not require new recurring disclosures. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in ASU No. 2013-11 are not expected to have a material impact on our consolidated financial statements.

In July 2012, the FASB issued ASU No. 2012-02, *Testing Indefinite-Lived Intangible Assets for Impairment*, or ASU 2012-02. ASU 2012-02 gives entities an option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the long-lived intangible asset are impaired. If, based on its qualitative assessment, an entity concludes that it is more likely than not that the fair value of an indefinite lived intangible asset is less than its carrying amount, quantitative impairment testing is required. However, if an entity concludes otherwise, quantitative impairment testing is not required. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. ASU 2012-02 is not expected to have a material impact on our financial position or results of operations.

In December 2011, the FASB issued ASU No. 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities*, or ASU 2011-11. ASU 2011-11 enhances current disclosures about financial instruments and derivative instruments that are either offset on the statement of financial position or subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset on the statement of financial position. Entities are required to provide both net and gross information for these assets and liabilities in order to facilitate comparability between financial statements prepared in conformity with GAAP and financial statements prepared on the basis of International Financial Reporting Standards. ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those years. ASU 2011-11 is not expected to have a material impact on our financial position or results of operations.

We do not believe there would have been a material effect on the accompanying consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Reclassifications

Certain 2012 amounts have been reclassified to conform to current year presentation.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – INVENTORY

Inventory consists of the following:

	December 31,	
	2013	2012
Finished product	$621,679	$1,124,739
Raw material	250,943	380,000
Deferred costs	170,996	110,471
TOTAL INVENTORY	$1,043,618	$1,615,210

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31,	
	2013	2012
Prepaid R&D costs	$1,267,588	$189,375
Prepaid consulting	530,596	432,216
Deferred financing costs	260,022	
Other receivable – related party	249,981	
Prepaid other	169,528	127,403
Prepaid guaranty costs		2,944
TOTAL OTHER CURRENT ASSETS	$2,477,715	$751,938

NOTE 5 – FIXED ASSETS

Fixed assets consist of the following:

	December 31,	
	2013	2012
Equipment	$108,458	$67,668
Furniture and fixtures	46,625	46,625
Leasehold improvements		11,980
	155,083	126,273
Accumulated depreciation	(93,765)	(60,600)
TOTAL FIXED ASSETS	$61,318	$65,673

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was $45,145, $27,484 and $25,686, respectively. In December 2013, accumulated depreciation was reduced by $11,980 associated with leasehold improvements of our previously leased office property.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 –PREPAID EXPENSE

Prepaid expense consists of the following:

	December 31,	
	2013	2012
Prepaid R & D costs	$824,221	$953,655
Prepaid manufacturing costs	899,000	
Accreted prepaid costs	27,234	
TOTAL PREPAID EXPENSE	$1,750,455	$953,655

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of December 31, 2013 and December 31, 2012:

	December 31, 2013			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$31,951	$ (499)	$31,452	15.8
Development costs for corporate website	91,743	(89,661)	2,082	0.3
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents	572,726	—	572,726	n/a
Multiple trademarks for vitamins/supplements	59,328	—	59,328	n/a
Total	$755,748	$ (90,160)	$665,588	

	December 31, 2012			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA ® software patent	$23,722	$ 0	$23,722	0
Development costs for corporate website	91,743	(77,159)	14,584	1.3
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents	180,194	—	180,194	n/a
Multiple trademarks for vitamins/supplements	21,055	—	21,055	n/a
Total	$316,714	$ (77,159)	$239,555	

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The intangible asset related to development costs for corporate website is amortized over 36 months, which is the prescribed life for software and website development costs. The intangible asset related to OPERA® is amortized using the straight-line method over the estimated remaining useful life of 16 years, which is the life of the intellectual property patents. During the year ended December 31, 2013, there was no impairment recognized.

Amortization expense was $13,001, $28,776, $29,159 for the years ended December 31, 2013, 2012, and 2011, respectively. Estimated amortization expense for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2014	$ 4,080
2015	$ 1,997
2016	$ 1,997
2017	$ 1,997
2018	$ 1,997

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	December 31,	
	2013	2012
Accrued payroll and commission costs	$941,313	$397,210
Accrued financing costs	850,000	
Accrued vacation	256,920	114,899
Allowance for wholesale distributor fees	306,303	107,784
Accrued legal and accounting expense	224,550	90,000
Accrued lab research	536,574	
Accrued clinical trial costs	129,208	
Allowance for coupons and returns	126,233	53,002
Other accrued expenses[(1)]	230,088	70,759
TOTAL OTHER CURRENT LIABILITIES	$3,601,189	$833,654

(1) In June 2008, we declared and paid a special dividend of $0.40 per share of our Common Stock to all shareholders of record as of June 10, 2008, of which $41,359 remained unclaimed by certain shareholders at December 31, 2013 and 2012.

NOTE 9 – NOTES PAYABLE

Issuance and Payment of Multiple Advance Revolving Credit Note

On January 31, 2013, we entered into a business loan agreement with Plato and Associates, LLC, or Plato, for a Multiple Advance Revolving Credit Note, or the Revolving Credit Note. The Revolving Credit Note allowed us to draw down funding up to a $10,000,000 maximum principal amount, at a stated interest rate of 6% per annum. Plato was able to make advances to us from time to time under the Revolving Credit Note at our request, which advances were of a revolving nature and were able to be,made, repaid, and made from time to time. Interest payments were due and payable on the tenth day following the end of each calendar quarter in which any interest was accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Revolving Credit Note, together with all accrued interest and other amounts payable under the Revolving Credit Note, if any, was due and payable on February 24, 2014. The Revolving Credit Note was secured by substantially all of our assets. On each of February 25 and March 13, 2013, $200,000 was drawn against the Revolving Credit Note. On March 21, 2013, we repaid $401,085, including accrued interest, and there was no balance outstanding under the Revolving Credit Note as of December 31, 2013 and February 24, 2014 when it expired. As additional consideration for the Revolving Credit Note, we granted to Plato a warrant to purchase 1,250,000 shares of our Common Stock at an exercise price $3.20 per share (see NOTE 10 for more details).

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Borrowing under Business Loan Agreement and Promissory Note, as amended

In March 2011, VitaMed entered into a business loan agreement with First United Bank for a $300,000 bank line of credit for which personal guarantees and cash collateral were required. Personal guarantees and cash collateral limited to $100,000 each were provided by Robert Finizio and John Milligan, officers of our Company, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of our Company. The bank line of credit accrued interest at the rate of 3.02% per annum based on a year of 360 days and was due on March 1, 2012. We negotiated a one-year extension with First United to the bank line of credit, which was executed on March 19, 2012. Under the extension, borrowings bear interest at a rate of 2.35% and are due on March 1, 2013. On November 13, 2012, the outstanding balance of $299,220 was repaid in full, and we amended the line of credit to reflect a $100,000 bank line of credit. In accordance with the amended line of credit, the personal guarantee and cash collateral limited to $100,000 provided by the Reich Family Limited Partnership remained in place, while the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. In February 2013, we borrowed $100,000 from First United Bank under the amended bank line of credit. The amended bank line of credit required a personal guarantee and cash collateral limited to $100,000, which was provided by Reich Family Limited Partnership. On April 25, 2013, we re-paid $100,735, which represented the principal and interest that was due under the amended bank line of credit. On May 1, 2013, the amended bank line of credit expired and was not renewed. Accordingly, the personal guarantee was canceled, and the cash collateral was refunded to the Reich Family Limited Partnership. During the years ended December 31, 2013, 2012, and 2011, we paid $735, $7,366, and $5,650, respectively, of interest expense, which are included in interest expense on the accompanying consolidated financial statements.

Issuance of Promissory Notes

In January and February 2012, we issued 6% promissory notes in the aggregate principal amount of $900,000, due March 1, 2012. As discussed below in Issuance and Settlement of February 2012 Notes, these promissory notes were modified on February 24, 2012 through the issuance of secured promissory notes.

Issuance and Settlement of February 2012 Notes

On February 24, 2012, we issued promissory notes, the February 2012 Notes, to an individual and an entity, or the Parties, both of which are stockholders of our company, in the principal amount of $1,358,014 and $1,357,110, respectively, and granted warrants to purchase an aggregate of 9,000,000 shares of our Common Stock pursuant to the

terms of a Note Purchase Agreement, dated February 24, 2012. We received an aggregate of $1,000,000 of new funding from the Parties upon issuance of the February 2012 Notes and related warrants and surrender by the Parties of certain promissory notes, which we previously issued in the aggregate amount of $1,700,000 plus the aggregate accrued interest of $15,124 (collectively known as the “Prior Notes”). Under the February 2012 Notes, we borrowed an additional $3,000,000 from the Parties during March, April, and May 2012.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

We granted 5,685,300 warrants in consideration of the modification of the Prior Notes and 3,314,700 warrants with the February Funding. We determined that the resulting modification of the Prior Notes was substantial in accordance with ASC 470-50, *Modifications and Extinguishments.* As such the modification was accounted for as an extinguishment and restructuring of the debt, and the 5,685,300 warrants issued in consideration of the modification were expensed (see Warrant Activity During 2012 in NOTE 10 for more details). The fair value of the Prior Notes was estimated by calculating the present value of the future cash flows discounted at a market rate of return for comparable debt instruments to be $1,517,741, resulting in a debt discount of $197,383 and recognized a loss on extinguishment of debt of $10,307,864, which represented the fair value of the 5,685,300 warrants net of the difference between the carrying amount of the Prior Notes and their fair value as of the date of the modification on the accompanying consolidated financial statements.

On June 19, 2012, we settled an aggregate amount of $3,102,000 of principal and accrued interest of the February 2012 Notes in exchange for the exercise of warrants to purchase 8,145,486 shares of our Common Stock. As discussed below in Issuance and Payment of June 2012 Notes, the remaining balance of $2,691,847 of the February 2012 Notes was modified on June 19, 2012 through the issuance of secured promissory notes, or the June 2012 Notes (see NOTE 10 for more details).

Issuance and Payment of June 2012 Notes

On June 19, 2012, we issued secured promissory notes, or the June 2012 Notes, to the Parties in the principal amounts of $2,347,128 and $2,344,719, respectively, pursuant to the terms of a Note Purchase Agreement. In connection with the June 2012 Notes, the Parties surrendered the remaining balance of the February 2012 Notes in the aggregate amount of $1,347,128 and $1,344,719, respectively, which sums included principal and accrued interest through June 19, 2012, and we received an aggregate of $2,000,000 of new funding from the Parties, or the June Funding. The principal amount of each of the June 2012 Notes, plus any additional advance made to us thereafter, together with accrued interest at the annual rate of 6%, was due in one lump sum payment on February 24, 2014. As security for our obligations under the June 2012 Notes, we entered into a Security Agreement and pledged all of our assets, tangible and intangible, as further described therein. We also granted warrants to purchase an aggregate of 7,000,000 shares of our Common Stock in connection with the June Funding. On March 21, 2013, we repaid $4,882,019, including accrued interest, leaving a balance of $21,595 in accrued interest as of March 31, 2013 on the June 2012 Notes. On April 25, 2013, the balance of accrued interest was paid in full.

Issuance and Payment of Additional Notes in 2012

In August and September 2012, we issued 6% promissory notes in the amount of $1,600,000 due on October 1, 2012, which due date was subsequently extended. These notes were paid in full in October 2012.

In September 2012, we issued a 6% promissory note for $200,000 due on October 15, 2012. This note was paid in full in October 2012.

Conversion of July 2011 Secured Notes

In July 2011, VitaMed issued two senior secured promissory notes, or the Secured Notes, each in the amount of $500,000 and also entered into a security agreement under which VitaMed pledged all of its assets to secure the obligation. The Secured Notes were assumed by us upon the merger and bore interest at the rate of 6% per annum, were due on the one year anniversary thereof, and were convertible into shares of our Common Stock at our option. We were permitted to satisfy the obligation underlying the Secured Notes by delivering such number of shares of our Common Stock calculated by dividing the then-outstanding principal balance by the Share Price. For purposes of the Secured Notes, the “Share Price” meant the lower of the most recent price at which we offered and sold shares of our Common Stock (not including any shares of our Common Stock issued upon the exercise of options and/or warrants or upon the conversion of any convertible securities) or the five-day average closing bid price immediately preceding the date of conversion. On June 19, 2012, we reached an agreement to convert the outstanding amount of the Secured Notes, representing principal and accrued interest through June 19, 2012, of $1,054,647 into an aggregate of 2,775,415 shares of our Common Stock at $0.38 per share. This resulted in a beneficial conversion feature of $6,716,504 as recorded in other income and expense on the accompanying consolidated financial statements. For the years ended December 31, 2012 and 2011, we recorded an aggregate of $33,204 and $21,453, respectively, as interest expense on the accompanying consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Issuance of VitaMed Promissory Notes

In June 2011, VitaMed issued promissory notes, or the VitaMed Notes, in the aggregate principal amount of $500,000. In connection with the VitaMed Notes, we granted warrants to purchase an aggregate of 613,718 shares of our Common Stock. The VitaMed Notes were assumed by us upon the merger and bore interest at a rate of 4% per annum and were due at the earlier of (i) the six month anniversary of the date of issuance and (ii) such time as VitaMed received the proceeds of a promissory note(s) issued in an amount of not less than $1,000,000, or the Funding. Upon the closing of the Funding in July 2011, as more fully described above in Conversion of July 2011 Secured Notes, two of the VitaMed Notes in the aggregate of $200,000 were paid in full. By mutual agreement, the remaining VitaMed Notes in the aggregate of $300,000 were extended. In October 2011, one of the VitaMed Notes for $50,000 was paid in full, and, by mutual agreement, certain of the VitaMed Notes in the aggregate amount of $100,000 were converted into 266,822 shares of our Common Stock at $0.38 per share, which represented the fair value of the shares of our Common Stock on the date of conversion. In June 2012, a VitaMed Note held by an unaffiliated individual was paid in full, including $2,160 in accrued interest. The remaining VitaMed Notes, held by Mr. Milligan and by BF Investment Enterprises, Ltd., which is owned by Brian Bernick, a director of our company, in the aggregate amount of $100,000, were extended to October 15, 2012. On October 4, 2012, we re-paid the outstanding VitaMed Notes in full, including $5,341 in accrued interest.

In September and October 2011, VitaMed issued convertible notes, or the VitaMed Convertible Notes, in the aggregate amount of $534,160. The VitaMed Convertible Notes bore interest at the rate of 4% per annum and were due December 1, 2011. On November 18, 2011, we entered into Debt Conversion Agreements with the holders of VitaMed Convertible Notes, pursuant to which we converted the principal and accrued interest of the VitaMed Convertible Notes into 1,415,136 shares of our Common Stock at $0.38 per share, which represented the fair value of the shares of our Common Stock on the date of conversion.

In December 2011, we issued 4% promissory notes to Mr. Finizio and Mr. Milligan for an aggregate of $100,000 due March 1, 2012. These promissory notes were subsequently extended by mutual agreement to June 1, 2012. In June 2012, we paid the promissory note held by Mr. Finizio in full, including $888 in accrued interest. Mr. Milligan’s promissory note was extended to October 15, 2012. On October 4, 2012, we paid Mr. Milligan’s promissory note in full, including $1,519 in accrued interest.

For the years ended December 31, 2012 and 2011, we recorded an aggregate of $6,344 and $2,390, respectively, as interest expense on the accompanying consolidated financial statements.

F-21

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

At December 31, 2013, we had 10,000,000 shares of preferred stock, par value $0.001, authorized for issuance, of which no shares of preferred stock were outstanding.

Common Stock

At December 31, 2013, we had 250,000,000 shares of Common Stock authorized for issuance, of which 144,976,757 shares of our Common Stock were issued and outstanding.

Issuances During 2013

Pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission, or the SEC, on March 14, 2013, we entered into an underwriting agreement with Jefferies LLC, or Jefferies, as the representative of the underwriters named therein, or the Jefferies Underwriters, relating to the issuance and sale of 29,411,765 shares of our Common Stock. The price to the public in the offering was $1.70 per share, and the Jefferies Underwriters agreed to purchase the shares of our Common Stock from us pursuant to the underwriting agreement at a price of $1.58 per share. The net proceeds to us from this offering was approximately $45.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, under the terms of the underwriting agreement, we granted the Jefferies Underwriters a 30-day option to purchase up to an additional 4,411,765 shares of our Common Stock. The offering closed on March 20, 2013. On April 12, 2013, the Jefferies Underwriters exercised their option to purchase an additional 1,954,587 shares of our Common Stock to cover over-allotments. We issued these shares to the Jefferies Underwriters on April 18, 2013 and received proceeds of approximately $3.1 million, net of expenses.

On September 25, 2013, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated, as the representative of the underwriters named therein, or the Stifel Underwriters, relating to the issuance and sale of 13,750,000 shares of our Common Stock. The price to the public in the offering was $2.40 per share, and the Stifel Underwriters agreed to purchase the shares of our Common Stock from us pursuant to the underwriting agreement at a price of $2.23 per share. The net proceeds to us from this offering were approximately $30.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering closed on September 30, 2013.

During 2013 certain individuals exercised their right to purchase shares of our Common Stock. Options to purchase an aggregate of 75,423 shares of our Common Stock were exercised for approximately $31,000. These shares of our Common Stock were issued in part in reliance upon an exemption from the registration provisions of the Securities Act of 1933, or the Act, provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder.

Issuances During 2012

During 2012, certain individuals exercised their right to purchase shares of our Common Stock. These shares were issued in reliance upon an exemption from the registration provisions of the Act provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder.

- Options to purchase an aggregate of 1,691,393 shares of our Common Stock were exercised for $191,000.
- Using the cashless exercise feature, options to purchase an aggregate of 240,395 shares of our Common Stock were exercised.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

During June 2012, we settled $3,102,000 in principal and accrued interest of the February 2012 Notes in exchange for the Parties' exercise of a portion of the related warrants for an aggregate of 8,145,486 shares of our Common Stock. The shares were issued in reliance upon an exemption from the registration provisions of the Act provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder. During June 2012, we and the Parties also agreed to convert a portion of the February 2012 Notes, and principal and accrued interest through June 19, 2012, totaling $1,054,647, into 2,775,415 shares of our Common Stock at $0.38 per share. The shares were issued in reliance upon an exemption from the registration provisions of the Act provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder.

In September 2012, we entered into a Securities Purchase Agreement with multiple investors, relating to the issuance and sale of our Common Stock in a private placement. The private placement closed on October 2, 2012, through which we sold an aggregate of 3,953,489 shares of our Common Stock at $2.15 per share, for an aggregate purchase price of $8,500,001. In connection with the private placement, Jefferies served as our exclusive placement agent. Jefferies' compensation for the transaction was a cash fee of $552,500. We also paid legal fees and expenses of the investors in the aggregate of $52,016, resulting in net proceeds to us from the private placement of $7,895,485. The shares were issued in reliance upon the exemptions from registration under the Act provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder. The shares were issued directly by us and did not involve a public offering. The investors were "accredited investors" as that term is defined in Rule 501 of Regulation D and acquired our Common Stock for investment only and not with a present view toward, or for resale in connection with, the public sale or distribution thereof. Pursuant to the terms of the Securities Purchase Agreement, we agreed to file a registration statement covering the resale of these shares, which we filed on November 27, 2012.

Issuances During 2011

In December 2011, a former director of VitaMed, exercised options to purchase 92,057 shares of our Common Stock for an aggregate exercise price of $17,250.

In October and November 2011, we converted principal and accrued interest in the aggregate of $849,137 into shares of our Common Stock totaling 20,266,822 and 1,415,136, respectively (as more fully described in NOTE 9).

On October 5, 2011, we entered into a Stock Purchase Agreement with Pernix Therapeutics, LLC, a Louisiana limited liability company, or Pernix. Pursuant to the terms of the Stock Purchase Agreement, Pernix agreed to purchase

2,631,579 shares of our Common Stock at a purchase price of $0.38 per share for a total purchase price of $1,000,000. Pernix is a related party. For further details, see NOTE 12

On October 3, 2011, we effected a reverse split of our 16,575,209 issued and outstanding shares of Common Stock on a ratio of 1- for -100, resulting in 165,856 shares issued and outstanding thereafter.

Warrants

As of December 31, 2013, we had warrants outstanding to purchase an aggregate of 14,293,499 shares of our Common Stock with a weighted-average contractual remaining life of 3.9 years, and exercise prices ranging from $0.24 to $3.20 per share, resulting in a weighted average exercise price of $1.79 per share.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the warrant.

Warrant Activity During 2013

In January 2013, we granted warrants to purchase 1,250,000 shares of our Common Stock in connection with the issuance of the Revolving Credit Note, or the Plato Warrant, (see NOTE 9). The Plato Warrant has an exercise price of $3.20 per share. The Plato Warrant vested on October 31, 2013 and may be exercised prior to its expiration on January 31, 2019. The Plato Warrant, with a fair value of approximately $1,711,956, was valued on the date of the issuance using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. At December 31, 2013, $260,022 was reported as deferred financing costs included in other current assets in the accompanying consolidated balance sheet and is being amortized over the life of the Plato Note. As of December 31, 2013, $1,451,934 was recorded as financing costs on the accompanying consolidated financial statements.

In May 2013, we entered into a consulting agreement with Sancilio & Company, Inc., or SCI, to develop drug platforms to be used in hormone replacement drug products, or the Drug Products. These services include support of our efforts to successfully obtain U.S. Federal Drug Administration, or FDA, approval for the Drug Products, including a vaginal capsule for the treatment of vulvar and vaginal atrophy. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of our Common Stock that were to be granted pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the agreement, we agreed to grant to SCI a warrant to purchase 850,000 shares of our Common Stock at $2.01 per share that has vested or will vest, as applicable, as follows:

1. 283,333 shares were earned on May 11, 2013 upon successful filing of the IND application with the FDA for the Drug Product for an estradiol-based product in a softgel vaginal capsule for the treatment of vulvar and vaginal atrophy; however, pursuant to the terms of the agreement, the shares did not vest until June 30, 2013. The fair value of $405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of the vesting using a term of five years; a volatility of 45.89%; risk free rate of 1.12%; and a dividend yield of 0%. We recorded the entire $405,066 as non-cash compensation in the accompanying consolidated financial statements;

2. 283,333 shares vested on June 30, 2013. The fair value of $462,196 for these shares was determined by using the Black-Scholes Model on the date of the vesting using a term of five years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. At December 31, 2013 we had $154,068 recorded as prepaid expense-short term

and $308,128 recorded as prepaid expense-long term in the accompanying consolidated financial statements. During the year ended December 31, 2013, we recorded $77,034 as non-cash compensation in the accompanying consolidated financial statements; and

3. 283,334 shares will vest upon the receipt by us of any final FDA approval of a Drug Product that SCI helped us design. It is anticipated that this event will not occur before December 2015.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Warrant Activity During 2012

In February 2012, we issued an aggregate of 5,685,300 Warrants in connection with the modification of certain existing promissory notes, or the Modification Warrants, and warrants for the purchase of an aggregate of 3,314,700 shares of our Common Stock in connection with the issuance of the February 2012 Notes, or the February 2012 Warrants (see NOTE 9). Both the Modification Warrants and the February 2012 Warrants are exercisable at $0.38 per share. The Modification Warrants have a fair value of $10,505,247, and the February 2012 Warrants have a fair value of $6,124,873. Fair value was determined on the date of the issuance using a term of five years; a volatility of 44.5%; risk free rate of 0.89%; and a dividend yield of 0%. We recorded the fair value of the Modification Warrants as part of the loss on extinguishment of debt in the accompanying consolidated financial statements. The relative fair value of the February 2012 Warrants of $859,647 was recorded as debt discount. As a result of the surrender of the February 2012 Notes on June 19, 2012, we expensed the remaining unamortized debt discount.

In March 2012, we issued an aggregate of 31,000 Warrants to five unaffiliated individuals for services rendered. These Warrants were valued on the date of the issuance using a term of five years; a volatility of 44.81%; risk free rate of 1.04%; and a dividend yield of 0%; we recorded $29,736 as consulting expense in the accompanying consolidated financial statements.

In May 2012, we issued an aggregate of 1,300,000 Warrants to an unaffiliated entity for services to be rendered over approximately five years beginning in May 2012. Services provided are to include (a) services in support of our drug development efforts, including services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain New Drug Approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The Warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. At December 31, 2013, we had $360,528 reported as prepaid expense-short term and $593,127 recorded as prepaid expense-long term. During the year ended December 31, 2013 and the year ended December 31, 2012, we recorded $360,528 and $218,045, respectively as non-cash compensation in the accompanying consolidated financial statements. The contract will expire upon the commercial manufacture of a drug product. Based on the review, we have determined that the process will take approximately five years. As a result, we are amortizing the $1,532,228 over five years.

In June 2012, we granted aggregate of 7,000,000 Warrants in connection with the issuance of the June 2012 Notes, or the June 2012 Warrants, (see NOTE 9). Of the June 2012 Warrants issued, 6,000,000 are exercisable at $2.00 per share and 1,000,000 are exercisable at $3.00 per share. The fair value of the June 2012 Warrants of $9,424,982 was determined on the date of the issuance using a term of five years; a volatility of 44.64%; risk free rate of 0.75%; and a dividend yield of 0%. The relative fair value of the June 2012 Warrants of $1,649,890 was determined by using the relative fair value calculation method on the date of the issuance. Of the $1,649,890, $547,210 was amortized to interest expense in 2012 and as a result of the repayment of the associated debt on March 21, 2013, we amortized the remaining unamortized debt discount of $1,102,680 to interest expense.

In June 2012, we issued an aggregate of 1,500 Warrants to three unaffiliated individuals for services rendered. The Warrants were valued on the date of the issuance using a term of five years; a volatility of 44.78%; risk free rate of 0.72%; and a dividend yield of 0%. A total of $1,656 was recorded as consulting expense in the accompanying consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Warrant Activity During 2011

In December 2011, we issued 500 Warrants with a fair value of $338 to an unrelated individual for consulting services covered under a three-month agreement. The Warrants were valued on the date of the issuance using a term of 10 years; volatility of 51.83%; risk free rate of 0.91%; and a dividend yield of 0%. The Warrants vested immediately. As of December 31, 2011, of the $338 fair value, $15 was recorded as non-cash compensation and $323 was recorded as prepaid expense on the accompanying consolidated financial statements.

In October 2011, we issued 600,000 Warrants with a fair value of $133,045 to an officer of our company for services performed. The Warrants were valued on the date of the issuance using an exercise price of $0.38; a term of 10 years; volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Warrants vest over a 44-month period beginning on November 21, 2011 (or 13,636 shares for months 1-43 and 13,652 shares for month 44). For the years ended December 31, 2013, 2012 and 2011, we recognized $36,284, $36,284 and $7,158, as non-cash compensation in the accompanying consolidated financial statements.

In December 2011, we issued 184,211 Warrants with a fair value of $25,980 to an unrelated entity for consulting services covered under a two month agreement. The Warrants were valued on the date of the issuance using an exercise price of $0.38; a term of five years; volatility of 41.04%; risk free rate of 1.08%; and a dividend yield of 0%. For the year ended December 31, 2011, the $25,980 fair value was recorded as financing expense.

In December 2011, VitaMed entered into a two-year consulting agreement with an entity providing help to evaluate improvements to existing products and new products as well as services, including research, design, compliance, scientific and regulatory affairs, and commercialization of products. As compensation, the consultant received 800,000 fully vested and non forfeitableWarrants. The Warrants were valued on the date of the issuance using an exercise price of $0.38; a term of 10 years; a volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Warrant vested immediately. The fair value of the warrants was $177,394 at the date of grant and was amortized to research and development expense over the life of the agreement which is when the research and development activities were performed. During the years ended December 31, 2013, 2012 and 2011, we recognized $71,688, $95,582 and $10,124, respectively, in research and development expenses related to this agreement.

In July 2011, VitaMed also entered into a one-year consulting agreement with the same consultant, whereby Consultant would assist in the design, development, and distribution efforts of VitaMed’s initial product offering. As

compensation, the Consultant received 200,000 fully vested non forfeitable VitaMed Warrants (or a Warrant for 245,485 shares pursuant to the Conversion Ratio). The VitaMed Warrant was valued on the date of the grant at $12,548 using an exercise price of $0.41; a term of five years; a volatility of 39.44%; risk free rate of 1.56%; and a dividend yield of 0%. The Warrant vested immediately. The fair value of the warrants was $12,548 at the date of grant and was amortized to research and development expense over the life of the agreement which is when the research and development activities were performed. During the years ended December 31, 2013, 2012 and 2011, we recognized $0, $6,936 and $5,612 respectively, in research and development expenses related to this agreement. In June 2011, VitaMed issued promissory notes, or the VitaMed Notes, in the aggregate of $500,000 with 500,000 accompanying VitaMed Warrants (or Warrants for an aggregate of 613,718 shares of our Common Stock taking into account the merger). The VitaMed Warrants were valued on the date of the issuance using an exercise price of $0.41; a term of five years; a range of volatility from 39.13% to 39.15%; risk free rate ranging from 1.38-1.65%; and a dividend yield of 0%. The Warrants vested immediately. Although the fair value was $30,993, using the appropriate accounting treatment, $28,719 was recorded as debt discount and fully amortized during 2011 with the amortized amount recorded as interest expense on the accompanying consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In March 2011, VitaMed entered into a business loan agreement with First United for a $300,000 line of credit for which personal guarantees and cash collateral were required. Personal guarantees and cash collateral limited to $100,000 each were provided by Mr. Finizio, Mr. Milligan, and Reich Family Limited LP (See NOTE 9 for more details). In consideration for the personal guarantees and cash collateral, VitaMed issued an aggregate of 499,998 VitaMed Warrants (or Warrants for an aggregate of 613,713 shares of our Common Stock taking into account the merger). The ten-year Warrants vested at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of $0.24 per share. On November 13, 2012, the outstanding balance was repaid in full and business loan agreement was amended to reflect a $100,000 bank line of credit. As part of the amended line of credit, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. In accordance with the terms of the Warrants, Warrants previously issued to Mr. Finizio and Mr. Milligan were amended to reflect the amount vested prior to the date of the amended line of credit (179,000 each). At December 31, 2013, an aggregate of 562,571 Warrants were vested. The Warrants, with a fair value of $93,969 ($86,139 after adjusting for the effect of the amended line of credit), were valued on the date of the issuance using a term of 10 years; a volatility of 47.89%; risk free rate of 3.48%; and a dividend yield of 0%. For the years ended December 31, 2013, 2012 and 2011, $2,944, $45,036 and $38,159, respectively was recorded as loan guaranty costs in other income and expense on the accompanying consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Summary of our Warrant activity and related information for 2011-2013

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2010				
Issued	3,057,627	$ 0.36	7.9	$3,483,691
Exercised				
Expired				
Cancelled				
Balance at December 31, 2011	3,057,627	$ 0.36	7.9	$3,483,691
Issued	17,332,500	$ 1.26	4.3	$31,891,150
Exercised	(8,145,486)	$ 0.38		
Expired				
Cancelled	(51,142)	$ 0.24		
Balance at December 31, 2012	12,193,499	$ 1.63		$17,971,994
Issued	2,100,000	$ 2.72	4.8	$5,232,500
Exercised				
Expired				
Cancelled				
Balance at December 31, 2013	14,293,499	$ 1.79	3.9	$48,932,777
Vested and Exercisable at December 31, 2013	13,764,710	$ 1.81	3.9	$46,840,559

As of December 31, 2013, we had warrants outstanding with exercise prices ranging from $0.24 to $3.20 per share. As of December 31, 2013, unamortized costs associated with warrants totaled approximately $1,599,000.

The weighted average fair value per share of warrants issued and the assumptions used in the Black-Scholes Model during the years ended December 31, 2013, 2012 and 2011 are set forth in the table below.

	2013	2012	2011
Weighted average fair value	$2.83	$2.05	$0.16
Risk-free interest rate	0.88-1.12 %	0.72-1.04 %	0.91-3.48 %

Volatility	44.29-45.89%	44.64-44.81%	39.13-51.83%
Term (in years)	5-6	5	5-10
Dividend yield	0.00 %	0.00 %	0.00 %

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term.

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our estimated volatility is an average of the historical volatility of the stock prices of peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the historical volatility of peer entities due to the lack of sufficient historical data of our stock price during 2011-2013.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Options to Purchase Common Stock of the Company

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created shareholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares authorized for issuance thereunder. Prior to the merger, no awards had been issued under the 2009 Plan. As of December 31, 2013 there were 13,632,742 shares of our Common Stock issued under the 2009 Plan.

On February 23, 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. There are 10,000,000 shares of our Common Stock authorized for issuance thereunder. As of December 31, 2013, there were 2,650,000 shares issued under the 2012 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The assumptions used in the Black-Scholes Model during the years ended December 31, 2013 are set forth in the table below.

	2013		2012		2011	
Risk-free interest rate	0.65-1.71	%	0.61-2.23	%	0.91-2.54	%
Volatility	33.35-45.76	%	40.77-46.01	%	37.92-40.48	%
Term (in years)	5-6.25		5-6.25		5.5-6.25	
Dividend yield	0.00	%	0.00	%	0.00	%

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the expected life. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our estimated volatility is an average of the historical volatility of the stock prices of our peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the

historical volatility of our peer entities due to the lack of sufficient historical data on our stock price. The average expected life is based on the contractual term of the option using the simplified method.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A summary of activity under the 2009 and 2012 Plans and related information for 2011-2013 follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2010				
Granted[(1)]	10,682,218	$ 0.16	7.6	$14,188,484
Exercised	(92,057)	$ 0.19		
Expired				
Cancelled				
Balance at December 31, 2011	10,590,161	$ 0.16	7.6	$14,067,649
Granted	5,121,250	$ 2.80	9.7	$1,737,530
Exercised	(1,931,788)	$ 0.13		
Expired				
Cancelled	(46,135)			
Balance at December 31, 2012	13,733,488	$ 1.16	7.7	$26,804,117
Granted	2,583,677	$ 3.31	9.8	$4,920,981
Exercised	(75,423)			
Expired	(250)			
Cancelled	(608,750)			
Balance at December 31, 2013	15,632,742	$ 1.44	7.2	$58,878,132
Vested and Exercisable at December 31, 2013	11,282,627	$ .80	6.5	$48,321,930

[(1)]This includes (i) VitaMed Options granted between October 2008 and December 31, 2010 for an aggregate of 7,639,722 Units, of which 16,000 were canceled prior to conversion (or Options for 9,357,561 shares per the Conversion Ratio), (ii) VitaMed Options granted between January 1, 2011 and October 3, 2011 for an aggregate of 621,000 Units (or Options for 762,235 shares per the Conversion Ratio) and (iii) Options granted between October 4, 2011 and December 31, 2011 for an aggregate of 562,422 shares. The terms and conditions of the VitaMed Options were reflected in the replacement Options including the number of shares vested.

At December 31, 2013, our outstanding options had exercise prices ranging from $0.10 to $4.67 per share.

Share-based compensation expense for options recognized in our results for the years ended December 31, 2013, 2012, and 2011 ($3,200,655, $1,832,061, and $183,355, respectively) is based on awards vested and we estimated no forfeitures. ASC 718-10 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates.

At December 31, 2013, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $3,921,000, which is expected to be recognized over a weighted-average period of 1.3 years. No tax benefit was realized due to a continued pattern of operating losses. At December 31, 2012 and 2011, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $4,391,000 and $244,000, respectively.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In December 2013, we issued a restricted stock unit, or the RSU, under our 2012 Plan to an officer for the purchase of 50,000 shares of our Common Stock. The RSU will vest on April 1, 2014 and has a fair value of $233,500. As of December 31, 2013, we recorded $53,428 of non-cash compensation.

NOTE 11 – INCOME TAXES

For the years ended December 31, 2013, 2012 and 2011, there was no provision for income taxes, current or deferred.

At December 31, 2013, we have a federal net operating loss carry forward of approximately $37,000,000 available to offset future taxable income through 2033.

At December 31, 2013, 2012, and 2011, we have state net operating loss carryforwards of approximately $35,000,000 available to offset future losses through 2033. We established valuation allowances equal to the full amount of the deferred tax assets because of the uncertainty of the utilization of the operating losses in future periods. We periodically assess the likelihood that we will be able to recover the deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income.

Our deferred tax asset and liability as presented in the accompanying consolidated financial statements consist of the following:

	2013	2012	2011
Deferred Income Tax Assets:			
Net operating losses	$14,773,537	$5,920,861	$748,404
R&D Credit	547,511	186,346	
Total deferred income tax asset	15,321,048	6,107,207	748,404
Valuation allowance	(15,321,048)	(6,107,207)	(748,404)
Deferred Income Tax Assets, net	$-0-	$-0-	$-0-

Our provision for income taxes differs from applying the statutory U.S. federal income tax rate to the income before income taxes. The primary differences result from deducting certain expenses for financial statement purposes but not for federal income tax purposes.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A reconciliation between taxes computed at the federal statutory rate and the consolidated effective tax rate is as follows:

	2013	2012	2011
Federal statutory tax rate	35.0 %	35.0 %	35.0 %
State tax rate, net of federal tax benefit	5.8 %	5.5 %	-0- %
Adjustment in valuation allowances	(32.4)%	(18.2)%	(5.8)%
Permanent and other differences	(8.4)%	(22.3)%	(29.2)%
Provision (Benefit) for Income Taxes	-0- %	-0- %	-0- %

NOTE 12 – RELATED PARTIES

Loan Guaranty

In March 2011, VitaMed entered into a business loan agreement with First United for a $300,000 line of credit for which personal guarantees and cash collateral were required. Personal guarantees and cash collateral limited to $100,000 each were provided by Mr. Finizio, Mr. Milligan, and Reich Family Limited Limited Partnership. See NOTES 9 and 10 for more details.

Loans from Affiliates

In June 2011, VitaMed issued promissory notes, or the VitaMed Notes, in the aggregate principal amount of $500,000, of which $100,000 was sold to affiliates. In June 2012, the affiliate notes were extended to October 15, 2012 (one held by Mr. Milligan for $50,000 and one for $50,000 held by BF Investments, LLC, which is owned by Brian Bernick, a member of the board of directors of our company. On October 4, 2012 these VitaMed Promissory Notes were paid in full including $5,341 in accrued interest.

In December 2011, we issued 4% promissory notes to Mr. Finizio and Mr. Milligan and for an aggregate of $100,000 ($50,000 each) with original due dates of March 1, 2012. These promissory notes were extended by mutual agreement

to June 1, 2012. In June 2012, the VitaMed Promissory Note held by Mr. Finizio was paid in full, including $888 in accrued interest. Mr. Milligan's VitaMed Promissory Note was extended to October 15, 2012. On October 4, 2012 this VitaMed Notes was paid in full including $1,519 in accrued interest.

Lock Up Agreements

As required by the terms of the merger agreement with VitaMed dated July 18, 2011, we entered into Lock-Up Agreements with stockholders covering the aggregate of 70,000,000 shares of our Common Stock issued pursuant to the merger or reserved for issuance pursuant to stock options and warrants. Each stockholder agreed that during a lock-up period from the date of the lock-up agreements until 18 months thereafter they would not make or cause any sale of our common stock. After the completion, each stockholder agreed not to sell or dispose of more than 2.5% of the stockholder's aggregate Common Stock or shares reserved for issuance under stock options and warrants per quarter over the following 12-month period, or the Dribble Out Period. Upon the completion of the Dribble Out Period, the Agreements will terminate.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Purchases by Related Parties

During 2013, 2012, and 2011, we sold our products to Dr. Brian Bernick, a director of our company, in the amounts of $0, $2,632 and $20,669, respectively, while $0, $1,272 and $0 of receivables related thereto remained outstanding at December 31, 2013, 2012 and 2011, respectively.

Agreements with Pernix Therapeutics, LLC

On February 29, 2012, Cooper C. Collins, President and largest shareholder of Pernix Therapeutics, LLC, or Pernix, was elected to serve on our board of directors. We closed a stock purchase agreement with Pernix on October 5, 2011. From time to time, we have entered into agreements with Pernix in the normal course of business. All such agreements are reviewed by independent directors or a committee consisting of independent directors. During the years ended December 31, 2013, 2012, and 2011, we made purchases of approximately $0, $404,000 and $19,000, respectively, from Pernix. At December 31, 2013, 2012, and 2011, there were amounts due Pernix of approximately $46,000, $308,000 and 19,000 outstanding, respectively.

Additionally, there were amounts due to us from Pernix for legal fee reimbursement relating to a litigation matter pursuant to a license and supply agreement, in the amounts of $249,981 and $0 for the periods ending December 31, 2013 and December 31, 2012, respectively.

Warrants assigned to Related Party

In June 2012, a warrant to purchase 100,000 shares of our Common Stock was assigned to the son of the Chairman of our board of directors by a non-affiliated third party.

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 98%, 76%, and 95% of our purchases supplied from one vendor for the years ended December 31, 2013 2012, and 2011, respectively.

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. Revenue generated from sales to three customers, Cardinal Health, Inc., Amerisource Bergen, and McKesson Corporation accounted for 79%, 63% and 42% of our recognized revenue for years ended December 31, 2013, 2012, and 2011, respectively.

For the years ended December 31, 2013 and 2012, 64% and 28% of our recognized revenue and 97% and 98% of our deferred revenue was generated from sales to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. We did not sell to these customers in prior years.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Operating Lease

We lease administrative office space in Boca Raton, Florida pursuant to a 63 month non-cancelable operating lease commencing on July 1, 2013 and expiring on September 30, 2018. The lease stipulates, among other things, average base monthly rents of $30,149 (inclusive of estimated operating expenses) and sales tax, for a total future minimum payments over the life of the lease of $1,899,414.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The straight line rental expense related to our current lease totaled $180,894 for the six months ended December 31, 2013 offset by rent income of $32,963. The rental expense related to our prior lease which expired June 30, 2013 totaled $60,168 for the six months ended June 30, 2013, and $106,315 and $122,752 for the years ended December 31, 2012 and 2011, respectively.

As of December 31, 2013, future minimum rental payments are as follows:

Years Ending December 31,	
2014	$316,039
2015	371,240
2016	382,377
2017	393,848
2018	302,748
Total minimum lease payments	1,766,252
Noncancelable sub-lease income	(38,956)
Net minimum lease payments	$1,727,296

NOTE 15 – SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal years 2013 and 2012 is as follows:

	2013 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$1,537	$2,081	$2,295	$2,863
Gross profit	$1,157	$1,617	$1,646	$2,396
Net loss	$(6,376)	$(6,009)	$(7,673)	$(8,361)
Loss per common share, basic and diluted	$(0.06)	$(0.05)	$(0.06)	$(0.06)

	2012 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$722	$819	$1,036	$1,241

Gross profit	$386	$447	$729	$908
Net loss	$(13,290)	$(11,850)	$(4,253)	$(5,727)
Loss per common share, basic and diluted	$(0.16)	$(0.14)	$(0.04)	$(0.06)

NOTE 16 – SUBSEQUENT EVENTS

On January 6, 2014, options for 390,000 shares of stock were granted to certain members of our Board of Directors under the 2012 Plan for their services to be rendered in 2014. The options were granted for a period of 10 years at an exercise price equal to the closing price at the date of grant, and vest on December 31, 2014.