

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

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

**Form 10-K**

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

For the fiscal year ended December 31, 2012

**Commission File Number 000-16731**

**TherapeuticsMD, Inc.**

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

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

**951 Broken Sound Parkway NW**

**Suite 320**

**Boca Raton, Florida 33487**

**(561) 961-1911**

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

*including area code, of Principal Executive Offices)*

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

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

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

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

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

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

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

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

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

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

(Do not check if a smaller reporting company)

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

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

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

### **Explanatory Note**

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

**THERAPEUTICSMD, INC.**

**ANNUAL REPORT ON FORM 10-K**

**Fiscal Year Ended December 31, 2012**

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

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

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

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

## **PART I**

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

#### **Introduction**

#### **Our Company**

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

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

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

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



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

## **Industry and Market**

### *Healthcare and Pharmaceutical Market*

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

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

### *Women’s Healthcare Market*

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

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

### *Hormone Therapy Market*

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

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

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

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

### *Hormone Therapy Products*

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

### *Estrogen-Only Therapies*

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

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

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

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

### *Progestin-Only Therapies*

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

### *Estrogen/Progestin Combination Products*

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

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

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

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

with natural progesterone.

### *Prenatal Vitamin Market*

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

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

### **Our Business Model**

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

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

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

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

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

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

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



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

## **Our Growth Strategy**

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

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

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

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

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

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

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

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

## **Our Products**

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

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

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

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

*vitaMedMD™ One Prenatal Multivitamin*

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

*vitaMedMD™ Plus Rx Prenatal Multivitamin*

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

*vitaMedMD™ One Rx Prenatal Multivitamin*

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

*vitaMedMD™ RediChew™ Rx Prenatal Multivitamin*

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

*vitaMedMD™ Iron 21/7*

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

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

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

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

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

*vitaMedMD™ Stretch Mark Body Cream*

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

*vitaMedMD™ Scar Reduction Body Cream*

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

*BocaGreenMD™ Prenal Plus*

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

*BocaGreenMD™ Prenal*

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

*BocaGreenMD™ Prenal Chew*

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

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

## Our Proposed Hormone Therapy Products

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

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

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

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

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

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

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



*Therapeutics' TX 12-002HR*

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

*Therapeutics' TX 12-003HR*

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

*Other Programs*

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

**Sales and Marketing**

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

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

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

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

### *Online Commerce*

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

### *Retail Commerce*

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

### **Seasonality**

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

### **Products in Development**

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

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

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

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

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

### **Manufacturing of Our Products**

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

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

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

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

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

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

### **Distribution of our Products**

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

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

### **Customer Service**

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

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

## **Our Return Policy**

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

## **Our Quality Guarantee**

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

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

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

## **Intellectual Property**

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

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

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



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

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

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

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

## **Government Regulation**

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

## **Pharmaceutical Regulation**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### *Marketing Exclusivity*

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

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

### *Dietary Supplement and Cosmetic Regulation*

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

health information.

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

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

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

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

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

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

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

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

## **Our Offices**

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

## **Employees**

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

## **Our History**

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

We need substantial amounts of cash to complete the clinical development of our proposed hormone therapy products. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We do not currently have any committed external source of funds. We will attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

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

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

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

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

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

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

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

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

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

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the data safety monitoring board, or DSMB, the FDA, an Institutional Review Board, or IRB, or us;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

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

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

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

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

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

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



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

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

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

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

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



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

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

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

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's Good Manufacturing Practice, or cGMPs, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products, including our proposed hormone therapy products, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement 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 proposed hormone therapy products, 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 proposed hormone therapy products 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 proposed hormone therapy products in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or proposed hormone therapy products, 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:

- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to our reputation;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls or withdrawals;
- labeling, marketing, or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or proposed hormone therapy products; 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 proposed hormone therapy products, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects.

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

We are highly dependent upon consumer acceptance of the safety 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 proposed hormone therapy products 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 healthcare 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 healthcare 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 healthcare 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 healthcare programs that are false or fraudulent;

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

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

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare 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 healthcare providers and ownership of their stock by healthcare 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 will be required to begin data collection on August 1, 2013 and 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 healthcare 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 options that vest over time. The value to employees of stock options will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

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

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

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

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

***Our success is tied to our distribution channels.***

We sell our prescription 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, 2012, 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 product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our proposed hormone therapy products, 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 proposed hormone therapy products and other products in development.*

We plan to seek to obtain market exclusivity for our proposed hormone therapy products 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 proposed hormone therapy products, and materially adversely affect our business, financial condition, and results of operations.

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

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

These risks include the possibility of the following:

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

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

If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our proposed hormone therapy products or 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 our patent rights.



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

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

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. 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, if at all. 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 product 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 product 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 product candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product 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; and

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

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

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

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

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

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

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

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

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

## Risks Related to Ownership of Our Common Stock

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

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

- any delay in commencement of our Phase 3 clinical trials for our proposed hormone therapy products;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our proposed hormone therapy products and any adverse development or perceived adverse development with respect to the FDA’s review of the NDAs, including the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our proposed hormone therapy products;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate clinical supply for our proposed hormone therapy products or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners’ commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;

- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;

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

In addition, the stock market in general, and the OTCQB Bulletin Board, and the NYSE MKT, on which we have applied for listing, 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 February 28, 2013, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 78% of our common stock on an as-if converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***If we fail to 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 to deliver a report that assesses the effectiveness of our internal control over financial reporting for the year ended December 31, 2012. Our independent registered public accounting firm is also required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ended December 31, 2012. 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. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

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

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



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

Provisions in our 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 the corporation, unless certain conditions are met. An “interested stockholder” is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10% or more of the corporation’s capital stock entitled to vote.

***We have applied to list our common shares for trading on the NYSE MKT. If our application is not approved, the liquidity and market price of our common stock could decrease.***

We have applied to list our common shares for trading on the NYSE MKT. We have not yet been informed that our common shares will be listed on the NYSE MKT, and can provide no assurance that our NYSE MKT listing application will be approved. If our listing application is not approved by the NYSE MKT, our shares would continue to be listed on the OTCQB, which could adversely affect the market price and liquidity of our common stock. Therefore, our failure to become listed on the NYSE MKT or another established national securities exchange and subsequently maintain such listing would have a material adverse effect on the value of your investment in our company.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. *Properties***

On July 9, 2009, we entered into a 45-month lease for approximately 7,130 square feet of office space in Boca Raton, Florida for our principal executive offices. Over the term of this lease, we will pay an average monthly cost of \$9,352, which includes base rent, common area fees, taxes, and insurance. The primary functions performed at our corporate headquarters are accounting, marketing, human resources, product development oversight, product sales, and fulfillment. The lease expires May 31, 2013 and we believe we will be able to extend the lease in a manner adequate to meet our current needs.

**Item 3. *Legal Proceedings***

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

*Aceto Corporation*

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

*Avion Pharmaceuticals, LLC*

On November 30, 2012, Avion Pharmaceuticals, LLC, or Avion, filed a lawsuit against TherapeuticsMD and BocaGreen in the United States District Court for the Northern District of Georgia. The lawsuit alleges, among other things, unfair competition and trademark infringement against Avion's "Prenate" trademarks based on the use of our BocaGreen's Prenal branded products which were launched in November 2012. The lawsuit seeks to enjoin BocaGreen from using the Prenal name, in addition to unspecified actual and punitive damages. We filed an answer and counterclaim on January 17, 2013, as amended on February 27, 2013. Based on our initial assessment of currently available information, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

**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**

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

	High	Low
2013		
First quarter (through March 6, 2013)	\$3.70	\$3.00
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	\$3.50	\$.50
Second quarter	\$7.00	\$1.20
First quarter	\$10.00	\$2.00

On December 31, 2012, the closing sale price of our common stock was \$3.10 per share. On December 31, 2012, there were approximately 346 record holders and approximately 500 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.

**Item 6. *Selected Financial Data***

Not required.

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

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy, or HT, pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for three proposed products and intend to begin clinical trials for two of those products. We plan to begin Phase 3 clinical trials of our estradiol and progesterone combination and progesterone-alone proposed products once we have been successful in raising the capital required to complete these trials.

The hormone therapy market includes two segments: an FDA-approved drug market and a non-FDA-approved drug market supplied by compounding pharmacies. FDA-approved products are easily measured and monitored, while non-FDA-approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA-approved compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

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

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

## **Results of Operations**

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

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	Year Ended		Change
	December 31,		
	2012	2011	
	(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 of 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 fiscal 2012 from fiscal 2011 as a result of the following items:

(000s)



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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

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

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	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 resource 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 fiscal 2011 from fiscal 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 incurred recurring net losses, including net losses of \$35.1 million and \$12.9 million for the years ended December 31, 2012 and 2011, respectively. Net cash outlays from operations and capital expenditures were \$13.0 million and \$5.0 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had an accumulated deficit of approximately \$52.1 million and a stockholders' deficit of \$1.4 million. We have generated limited revenue and have funded our operations to date primarily from private sales of equity and debt securities. We expect to incur substantial additional losses in the near term as our research, development, and clinical trial activities increase, especially those related to our proposed hormone therapy products. As a result, profitability will elude us unless we successfully commercialize our products, in particular, our proposed hormone therapy products. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices or refinance existing debt obligations on terms unfavorable to us. Such circumstances could compel us to merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

We need substantial amounts of cash to complete the clinical development of our proposed hormone therapy products. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We do not currently have any committed external source of funds. We will attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, other necessary means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
-

seek collaborators for our proposed hormone therapy products at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and

• license, potentially on unfavorable terms, our rights to our proposed hormone therapy products that we otherwise would seek to develop or commercialize ourselves.

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

On March 7, 2012 we filed a Prospectus Supplement for an underwritten public offering of our common stock with anticipated gross proceeds of \$50 million. The securities being offered by us are pursuant to a shelf registration statement previously filed with the SEC and January 25, 2013, which the SEC declared effective on February 5, 2013. 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.

*Cash and Cash Equivalents*

During the years ended December 31, 2012 and 2011, our cash liquidity increased (decreased) as follows:

	(000s)
At December 31, 2012	\$ 1,554
At December 31, 2011	126
Increase in cash and cash equivalents	\$ 1,428

	(000s)
At December 31, 2011	\$ 126
At December 31, 2010	423
Decrease in cash and cash equivalents	\$ (297 )

The increase (decrease) in cash and cash equivalents consisted of the following components for the years ended December 31:

	(000s)	
	2012	2011
Proceeds from notes payable and line of credit	\$ 8,700	\$ 3,284
Proceeds from issuance of equity securities	7,896	1,707
Proceeds from exercise of stock options	191	17
Sources of cash and cash equivalents	16,787	5,008
Cash used in operating activities	12,737	4,967
Repayment of debt	2,350	301
Cash used in other investing activities	206	8
Cash used to purchase equipment	66	29
Uses of cash and cash equivalents	15,359	5,305
Increase (decrease) in cash and cash equivalents	\$ 1,428	\$ (297 )

During the year ended December 31, 2012, working capital increased by \$2.9 million as follows:

	December 31,	
	2012	2011
	(000s)	Change



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Current assets	\$4,527	\$1,237	\$3,290
Current liabilities	3,512	3,151	361
Working capital (deficit)	\$1,015	\$(1,914)	\$2,929

*Primary Sources of Cash*

Between January and September 2012, we received funds from the sale of promissory notes in the aggregate of \$8,700,000, of which \$1,800,000 was repaid with funds generated by our October 2012 private placement discussed below.

In October 2012, we sold 3,953,489 shares of our common stock in a private placement, resulting in aggregate net proceeds of \$7,896,000.

In January, July, and August 2012, we received funds from the exercise of options to purchase 1,931,788 shares of our common stock at an aggregate exercise price of \$191,000.

## Recent Financing Transactions

### *Issuance of Promissory Notes*

In August and September 2012, we sold 6% promissory notes for an aggregate of \$1,600,000 due on October 1, 2012, which due date was subsequently extended. The notes were paid in full in October 2012.

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

### *Issuance, Modification and Settlement of February 2012 Notes*

On February 24, 2012, we sold and issued promissory notes, or the February 2012 Notes, to an individual and an entity, whom we refer to as the Parties, both of which are shareholders of our company, in the principal base amount of \$1,358,014 and \$1,357,110 respectively, and granted warrants for the purchase of our common stock in the aggregate of 9,000,000 shares (4,500,000 to each Party), or the February 2012 Warrants, pursuant to the terms of a note purchase agreement also dated February 24, 2012. As consideration for the February 2012 Notes and the February 2012 Warrants, we received an aggregate of \$1,000,000 of new funding from the Parties, or the February Funding, and the Parties surrendered certain promissory notes previously issued by us in the amount of \$1,700,000 plus accrued interest of \$15,124. The February 2012 Warrants included 5,685,300 shares in consideration of the modification of these surrendered notes and 3,314,700 shares in consideration of the February Funding. See Note 9 – Notes Payable in the financial statements included in this Form 10-K for more details.

Under the February 2012 Notes, the Parties loaned us an additional \$3,000,000 during March, April, and May 2012.

On June 19, 2012, we settled \$3,102,000 in principal and interest of the February 2012 Notes in exchange for the Parties' exercise of a portion of the February 2012 Warrants for an aggregate of 8,145,486 shares. As discussed below, 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.

### *Issuance of June 2012 Notes*

On June 19, 2012, we sold and issued the June 2012 Notes to the Parties in the principal base amounts of \$2,347,128 and \$2,344,719, respectively, pursuant to the terms of a note purchase agreement. As consideration for the June 2012 Notes, the Parties surrendered the remaining balance of the February 2012 Notes in the aggregate amounts of \$1,347,128 and \$1,344,719, respectively (which sums included principle and 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 base amount of each of the June 2012 Notes, plus any additional advances made to us thereafter, together with accrued interest at the annual rate of 6%, is due in one lump sum payment on February 24, 2014. As security for our obligations under this note purchase agreement and the June 2012 Notes, we entered into a security agreement and pledged all of our assets, tangible and intangible, as further described therein. We granted warrants for the purchase of an aggregate of 7,000,000 shares of common stock with the June Funding. See Note 9 – Notes Payable and Note 10 – Stockholders' Equity – Warrants in the financial statements included in this Form 10-K for more details.

#### *March 2011 Bank Line of Credit*

In March 2011, we entered into a Business Loan Agreement and Promissory Note with First United Bank for a \$300,000 bank line of credit, or the Bank LOC, for which a personal guarantee and cash collateral was 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. In consideration for the personal guarantees and cash collateral, warrants for an aggregate of 613,713 shares of common stock were granted. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. We negotiated a one-year extension to the Bank LOC with First United Bank, which was executed on March 19, 2012, or Bank LOC Extension. The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and First United Bank amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit, or the Amended Bank LOC. In accordance with the Amended Bank LOC, the personal guarantees and cash collateral were removed for Messrs. Finizio and Milligan. The Amended Bank LOC accrues interest at the rate of 2.35% and is due on May 1, 2013. At December 31, 2012, the outstanding principle balance of the Amended Bank LOC was \$0.

*Repayment of VitaMed Promissory Notes*

In June 2011, VitaMed sold promissory notes, or the VitaMed Promissory Notes, in the aggregate principal amount of \$500,000. In consideration for the VitaMed Promissory Notes, warrants for an aggregate of 613,718 shares of our common stock were granted. The VitaMed Promissory Notes bear interest at the 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 or notes issued in an amount of not less than \$1,000,000. Upon the closing of the such funding in July 2011, two of the VitaMed Promissory Notes in the aggregate of \$200,000 were paid in full. By mutual agreement, the remaining VitaMed Promissory Notes in the aggregate of \$300,000 were extended. In October 2011, one of the VitaMed Promissory Notes for \$50,000 was paid in full. By mutual agreement, VitaMed Promissory Notes in the aggregate of \$100,000 were converted into 266,822 shares of our common stock at \$0.38 per share, which represents the fair value of the shares on the date of conversion. In June 2012, a VitaMed Promissory Note held by an unaffiliated individual was paid in full including \$2,160 in accrued interest. The remaining VitaMed Promissory Notes in the aggregate of \$100,000 were extended to October 15, 2012 (one held by Mr. Milligan for \$50,000 and one for \$50,000 held by BF Investments, LLC, an entity owned by Brian Bernick, a member of our Board of Directors). These VitaMed Promissory Notes were paid in full in October 2012.

In December 2011, we sold 4% promissory notes to Messrs. Finizio and Milligan 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 and subsequently paid in full in October 2012.

*Private Placement*

On September 26, 2012, we entered into a securities purchase agreement, or the Purchase Agreement, with multiple investors relating to the issuance and sale of our common stock in a private placement. This private placement closed on October 2, 2012, through which we sold an aggregate of 3,953,489 shares of common stock at \$2.15 per share for an aggregate purchase price of \$8,500,001. We plan to use the net proceeds from the sale of these shares for research and development of our drug candidates, working capital, and general corporate purposes.

In connection with the private placement, Jefferies LLC served as our exclusive placement agent. We also incurred legal fees and expenses for the private placement investors, resulting in net proceeds to us of \$7,895,485.

These shares were issued in reliance upon the exemptions from registration under the Securities Act of 1933, as amended, provided by Section 4(2) and Rule 506 of Regulation D promulgated thereunder. The shares were issued

directly by us and did not involve a public offering or general solicitation. The investors in the private placement were “accredited investors” as that term is defined in Rule 501 of Regulation D and acquired the shares for investment only and not with a present view toward, or for resale in connection with, the public sale or distribution thereof.

As part of the Purchase Agreement, we agreed to file a registration statement covering the resale of these shares. We were required to use our best efforts to effect the registration no later than 90 days from October 2, 2012. Our registration statement on Form S-1 was declared effective by the SEC on December 12, 2012.

*Credit Line for \$10 Million*

On January 31, 2013, we issued a Multiple Advance Revolving Credit Note, the Note, to Plato and Associates, LLC, or Plato. The Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum (the “Stated Interest Rate”). Plato may make advances to us from time to time under the Note at our request. Such advances will be of a revolving nature and may be repaid and made from time to time. Interest payments are due and payable on the tenth day following the end of each calendar quarter in which any interest is accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Note, together with all accrued interest and other amounts payable under the Note, if any, will be due and payable on February 24, 2014. The default interest rate under the Note will be a per annum rate equal to the Stated Interest Rate plus eight percentage points (the “Default Interest Rate”), and the principal amount outstanding under the Note will bear interest at the Default Interest Rate upon the occurrence of an event of default as specified in the Note, including, our nonpayment of amounts due under the Note or our failure to comply with any provision of the Note, among others.

As additional consideration for the Note, we issued to Plato a warrant (the “Warrant”) to purchase 1,250,000 shares of our common stock at an exercise price \$3.20 per share. The Warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to the January 31, 2019 expiration date of the Warrant.

*Public Offering of Common Stock*

On March 7, 2013, we announced that we intend to offer up to \$50 million of shares of our common stock in an underwritten public offering. The shares are being offered by us pursuant to our shelf registration statement on Form S-3, previously filed with the SEC on January 25, 2013 and declared effective by the SEC on February 5, 2013. There can be no assurance as to whether or when the offering will be completed, or as to the actual size or terms of the offering. If completed, we intend to use the proceeds of the offering for general corporate purposes, including funding our Phase 3 clinical trials of our proposed hormone therapy products, other research and development, securing manufacturing technology and capacity, and working capital. We also intend to use the net proceeds from this offering to repay the June 2012 Notes.

**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.

*Share-Based Compensation Expense.* We calculate share-based compensation expense for option awards and warrant issuances (“Share-based Awards”) based on the estimated grant/issue-date fair value using the Black-Scholes-Merton option pricing model (“Black-Scholes Model”), and recognize the expense on a straight-line basis over the vesting period, net of estimated forfeitures. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the vesting period of the Share-based Award in determining the fair value of Share-based Awards. Although we believe our assumptions used to calculate share-based compensation expense are reasonable, these assumptions can involve complex judgments about future events, which are open to interpretation and inherent uncertainty. In addition, significant changes to our assumptions could significantly impact the amount of expense recorded in a given period.

*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 2012, FASB issued Accounting Standards Update (“ASU”) No. 2012-02, “*Testing Indefinite-Lived Intangible Assets for Impairment*” (“ASU 2012-02”). ASU 2012-02 gives entities an option to first assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that the indefinite-lived intangible asset 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*” (“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 U.S. GAAP and financial statements prepared on the basis of International Financial Reporting Standards (“IFRS”). ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. ASU 2011-11 is not expected to have a material impact on our financial position or results of operations.

In September 2011, the FASB issued ASU No. 2011-08 *Intangibles – Goodwill & Other* (“ASU 2011-08”), which updates the guidance in Accounting Standards Codification (“ASC”) Topic 350, *Intangibles – Goodwill & Other* (“ASC Topic 350”). The amendments in ASU 2011-08 permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than fifty percent. If, after assessing the totality of events or circumstances, an entity determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. The amendments in ASU 2011-08 include examples of events and circumstances that an entity should consider in evaluating whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. However, the examples are not intended to be all-inclusive and an entity may identify other relevant events and circumstances to consider in making the determination. The examples in this ASU 2011-08 supersede the previous examples under ASC Topic 350 of events and circumstances an entity should consider in determining whether it should test for impairment between annual tests, and also supersede the examples of events and circumstances that an entity having a reporting unit with a zero or negative carrying amount should consider in determining whether to perform the second step of the impairment test. Under the amendments in ASU 2011-08, an entity is no longer permitted to carry forward its detailed calculation of a reporting unit’s fair value from a prior year as previously permitted under ASC Topic 350. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of ASU 2011-08 did not have a material impact on our financial position or results of operations.

In May 2011, the FASB issued ASU 2011-04 (“ASU 2011-04”), which updated the guidance in ASC Topic 820, *Fair Value Measurement*. The amendments in ASU 2011-04 generally represent clarifications of Topic 820, but also include some instances where a particular principle or requirement for measuring fair value or disclosing information about fair value measurements has changed. ASU 2011-04 results in common principles and requirements for measuring fair value and for disclosing information about fair value measurements in accordance with U.S. GAAP and IFRS. The amendments in ASU 2011-04 are to be applied prospectively. For public entities, the amendments are effective for interim and annual periods beginning after December 15, 2011. The adoption of ASU 2011-04 did not have a material impact on our financial position or results of operations.

We do not believe there would be a material effect on the accompanying 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, 2012, 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 that, 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 the indemnified parties for losses suffered or incurred by the indemnified parties with respect to our product candidates, use of such product 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, 2012.

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**

During the periods for which financial information is presented, our business and operations have not been materially affected by inflation.

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

Not required.

**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 on Form 10-K, which financial statements, notes, and report are incorporated herein by reference.

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

None.

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**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 the Company's 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 that date, our disclosure controls and procedures were effective.

*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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness as 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.

The management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. 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, 2012.

Our internal control over financial reporting as of December 31, 2012 has been audited by Rosenberg Rich Baker Berman & Company, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this Annual Report on Form 10-K. Its report is also included on page F-3 of this Annual Report on Form 10-K.

## Changes in Internal Controls Over Financial Reporting

To remediate the material weaknesses in our internal control over financial reporting disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, in the fourth quarter of 2012, we enlisted additional experts and advisors to assist with the closing of the books and financial statement preparation processes. These consultants and advisors are certified public accountants proficient in the areas of SEC reporting, generally accepted accounting principles (GAAP) and tax accounting procedures. With the help of these qualified experts, we conducted a review of existing accounting and reporting policies and procedures and, where necessary, designed, documented and implemented improvements and additions to our policies and procedures for accounting and financial reporting with respect to the requirements and application of both generally accepted accounting principles in the United States and guidelines of the Securities and Exchange Commission. In procuring the services of these experts we were able to enhance our finance organization and control framework particularly as it relates to the segregation of duties of accounting and financial analyses and other post-closing procedures.

Except as otherwise disclosed above, there were no other changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

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

The table below lists all current executive officers and directors of our company. All executive officers serve at the discretion of the Board of Directors. The term of office of each of our directors continues until our next annual meeting of stockholders or until his successor is duly elected and qualified.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Robert G. Finizio	42	Chief Executive Officer, Director
John C.K. Milligan, IV	50	President, Secretary, Director
Daniel A. Cartwright	55	Chief Financial Officer, Vice President of Finance, Treasurer
Mitchell L. Krassan	47	Executive Vice President, Chief Strategy Officer
Brian Bernick, M.D.	44	Chief Medical Officer, Director
Tommy G. Thompson	71	Chairman
Samuel A. Greco	61	Director
Cooper C. Collins	33	Director
Robert V. LaPenta, Jr.	44	Director
Nicholas Segal	30	Director

*Robert G. Finizio* has served as Chief Executive Officer and a director of our company since October 2011. As co-founder of our VitaMed subsidiary, 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 healthcare 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. We believe Mr. Finizio's intimate knowledge and experience with all aspects of the business, operations, opportunities, and challenges of our company and experience with early stage company development in the healthcare industry provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. 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. We believe Mr. Milligan's significant

experience in creating, developing and guiding growth-oriented healthcare companies and knowledge of our business provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. 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.

*Dr. Brian Bernick* has served as a director of our company since October 2011. Dr. Bernick also has served as the Chief Medical Officer of our company since February 2012. As co-founder of VitaMed, Dr. Bernick served on VitaMed's board of directors from its inception. 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 the recipient of several national and regional awards including the American Medical Association Foundation's Leadership Award and was recognized by both Super Doctors and National Consumers Survey for being in the top 5% of doctors. 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. We believe Dr. Bernick's experience in the OB/GYN field gives him an understanding of sales channels and the needs and requirements of our customers and provides the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. 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.

*Tommy G. Thompson* has served as the Chairman of the Board of Directors of our company since May 2012. As the former Secretary of the U.S. Department of Health & Human Services, or HHS, from February 2001 to January 2005, Secretary Thompson served as the nation's leading advocate for the health and welfare of all Americans. Secretary Thompson is the former Independent Chairman of the Deloitte Center for Health Solutions and is a former partner of the international law firm of Akin Gump Strauss Hauer & Feld LLP, or Akin Gump. At the Deloitte Center for Health Solutions and at Akin Gump, Secretary Thompson built on his efforts at HHS to work toward developing solutions to the health care challenges facing American families, businesses, communities, states, and the nation as a whole. As the Governor of Wisconsin from January 1987 to February 2001, Secretary Thompson was perhaps best known for his efforts to revitalize the Wisconsin economy, for his national leadership on welfare reform, and for his work toward expanding healthcare access across all segments of society. Secretary Thompson also serves as Chairman of CareView Communications, Inc. [OTCQB: CRVW], and serves as a member of the board of directors for the following public companies: C. R. Bard, Inc. [NYSE: BCR], Centene Corporation [NYSE: CNC], United Therapeutics Corporation [NASDAQ: UTHR], and Cytori Therapeutics, Inc. [NASDAQ: CYTX]. Secretary Thompson also served as a member of the boards of directors of PURE Bioscience, Inc. [NASDAQ: PURE] from February 2006 to August 2009, SpectraScience, Inc. [OTCBB: SCIE] from September 2007 to December 2009, AGA Medical Holdings, Inc. [NASDAQ: ASAM ] from August 2005 to November 2010, and CNS Response, Inc.

[OTCBB: CNSO.OB] from September 2009 to March 2010. We believe Secretary Thompson's experience in public service, particularly his services and knowledge related to the healthcare industry as a whole, makes him well suited to be a director of our company. He received both his B.S. and his J.D. from the University of Wisconsin-Madison.

*Samuel A. Greco* has served as a director of our company since February 2012. Mr. Greco has served as Chief Executive Officer of CareView Communications, Inc. since September 2007 and as a director of CareView since February 2009 [OTCQB: CRVW]. CareView is an information technology provider to the healthcare industry. Mr. Greco has spent over 30 years in hospital administration, beginning at an independent city hospital and progressing to Senior Vice President of Financial Operations at Columbia/HCA Healthcare Corporation, the industry's largest operator of healthcare facilities. Over the past 10 years, Mr. Greco has provided consulting services to hospital management companies. He was instrumental in the development of the CareView System™. We believe Mr. Greco's experience in the healthcare industry and knowledge of supply chain strategies, vendor partnering, and logistics management provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. Greco earned his B.A. in Accounting from Bryant College and is a frequent speaker at various healthcare symposiums.

*Cooper C. Collins* has served as a director of our company since February 2012. Mr. Collins has served as the President, Chief Executive Officer, and a director of Pernix Therapeutics Holdings, Inc. [NASDAQ: PTX] since the close of the merger between Pernix and Golf Trust of America, Inc. in March 2010. Mr. Collins joined Pernix in 2002. Pernix is a specialty pharmaceutical company focused on the sales, marketing, and development of branded and generic pharmaceutical products primarily for the pediatric market. He was appointed a director of Pernix in January 2007, Pernix's President in December 2007, and Pernix's Chief Executive Officer in June 2008. From December 2005 to December 2007, Mr. Collins served as Vice President of Business and Product Development of Pernix and as Pernix's Territory Manager from December 2003 to December 2005. Mr. Collins was employed for three years by the National Football League franchise, The New Orleans Saints, in its media relations department. We believe Mr. Collins' specialty pharmaceutical company knowledge and executive experience provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. While on a football scholarship, Mr. Collins received a B.A. from Nicholls State University, where he later received an M.B.A.

*Robert V. LaPenta, Jr.* has served as a director of our company since February 2012. Since August 2011, Mr. LaPenta has served as a partner of Aston Capital, a private equity investment firm with a current focus on investments in the aerospace, defense, and intelligence markets. Prior to Aston Capital, Mr. LaPenta served as Vice President of Mergers and Acquisitions and Corporate Strategy for L-1 Identity Solutions, Inc., or L-1, provider of technology, products, systems and solutions, and services that protect and secure personal identities and assets. From April 2007 through July 2011, Mr. LaPenta assisted L-1 senior management in identifying acquisition candidates and investments while assisting in due diligence, structuring, valuation, execution, and related financing. Prior to L-1, Mr. LaPenta spent 13 years as an institutional equity trader focused on healthcare sector trading for both customer and proprietary accounts. From February 2003 to March 2007, Mr. LaPenta served as Managing Director, Co-Head of Equity Trading at Banc of America Securities LLC where he managed capital commitment, proprietary trading, and risk management within cash trading. Prior to Banc of America Securities, he served as Director or Vice President of Equity Trading with Credit Suisse First Boston, PaineWebber, Inc., and Salomon Smith Barney, Inc. Previously, as a Senior Associate at Coopers & Lybrand LLP, Mr. LaPenta assisted with auditing, consulting, due diligence, and SEC reporting. Mr. LaPenta is Co-Investment Manager of a \$250 million family/friends/partners asset portfolio consisting of individual equities, fixed income, equity options, hedge fund strategies, private equity, and alternative investments. He is an active participant and fund raiser for New York City's W. 63rd Street YMCA, Turn the Corner Foundation, and numerous other charities. Mr. LaPenta has recently been added to the board of directors of Revolution Lighting Technologies, Inc. [NASDAQ: RVLN], a public company engaged in the design, manufacture, marketing and installation of LED lighting systems. We believe Mr. LaPenta's diverse investing background, capital markets

knowledge, and his relationships within the financial community provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. Mr. LaPenta graduated in 1991 from Boston College with a B.A. in Accounting and Finance and is a registered CPA (inactive) in the State of New York.

*Nicholas Segal* has served as a director of our company since February 2012. Since June 2007, Mr. Segal has served as a director of Seavest Capital Partners, a private investment company that invests in early and growth-stage companies, primarily in the education, healthcare, consumer technology, and media sectors. Representing investments of Seavest, Mr. Segal previously served on the board of directors of VitaMed prior to its acquisition by our company. Mr. Segal serves on the board of directors of AutoSquad Corporation, a private company specializing in online tire sales and installation directly to the consumer. He also serves as a member of the board of directors of Tout Industries, Inc., a private company with a new social media platform. Mr. Segal founded and currently serves as Chief Executive Officer of Polar Generation, LLC, an early-stage consumer products company. Prior to joining Seavest, Mr. Segal served as a senior analyst in the Finance and Business Development group at ESPN from September 2004 to April 2007. We believe Mr. Segal's broad base of knowledge in technologies and products directed to the consumer market provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our Board of Directors. He graduated with a B.A. from Duke University in 2004.

*Non-Executive Officers*

*Julia Amadio* has served as Chief Product Officer of our company since January 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, a consulting company that she formed in 2008. From June 2009 to May 2011, she served as Global Vice President of Marketing for MeadWestvaco's 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 Co., Ltd. from 2004 to 2006, Vice President of Aventis Pharmaceutical Inc. from 1997 to 2004, Senior Director, New Products Women's Health at Wyeth from 1991 to 1997, and started her career at Johnson & Johnson'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 M.B.A. 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 an M.B.A. from Drexel University.

*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, Inc. (later acquired by Eisai Co., Ltd.), 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, which was acquired by MGI Pharma. Mr. Spitz began his career at Schering-Plough Corporation as a sales representative, rising within the organization over 15 years to lead a global pharmaceutical franchise. Mr. Spitz earned his B.B.A. in Marketing from The University of Texas at Austin and his M.B.A. in Pharmaceutical Studies from Fairleigh Dickinson University.

*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, biotechnology, 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. From 2000 to 2002, Mr. Bloomgren served as a specialty Account Manager at Eli Lilly and Company and from 2002 to 2005 as District Manager at KV Pharmaceutical. Mr. Bloomgren served as an officer in the U.S. Air Force and holds a B.S. degree from California State University and an M.S. degree from Troy State University.

There are no arrangements or understandings between our officers and directors and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there are no arrangements, plans, or understandings as to whether non-management stockholders will exercise their voting rights to continue to elect the current Board of Directors. There are also no arrangements, agreements, or understandings to our knowledge between non-management stockholders that may directly or indirectly participate in or influence the management of our

affairs.

### **Identification of Certain Significant Employees**

We consider the following non-executive officers to be significant employees: Julia Amadio (Chief Product Officer), Dr. Brian Bernick (Chief Medical Officer), Jason Spitz (Vice President - Marketing), and Christian Bloomgren (Vice President - Sales). An overview of their business experience is included above.

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## **Family Relationships**

There are no family relationships between any of our officers or directors.

## **Other Directorships**

Other than as indicated above, none of our directors hold or have been nominated to hold a directorship in any company with a class of securities registered pursuant to Section 12 of the Exchange Act, or subject to the requirements of Section 15(d) of the Securities Act, or any company registered as an investment company under the Investment Company Act of 1940.

## **Committees of the Board**

Our Board of Directors has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The members of each of the committees are independent directors within the meaning of NYSE MKT listing standards.

### *Audit Committee*

The purpose of the Audit Committee is to oversee our financial and reporting processes and the audits of our financial statements and to provide assistance to our Board of Directors with respect to its oversight of the integrity of our financial statements, our company's compliance with legal and regulatory matters, the independent registered public accountant's qualifications and independence, and the performance of our independent registered public accountant. The primary responsibilities of the Audit Committee are set forth in its charter and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements on behalf of our Board of Directors. The Audit Committee also selects the independent registered public accountant to conduct the annual audit of our financial statements; review the proposed scope of such audit; review accounting and financial controls with the independent registered public accountant and our financial accounting staff; and review and approve any transactions between us and our directors, officers, and their affiliates.

As of February 11, 2013, the members of the Audit Committee were Messrs. LaPenta, Jr., Greco, and Segal. Mr. LaPenta, Jr. serves as Chair. Our Board of Directors has determined that Mr. LaPenta, Jr. qualifies as an audit

committee financial expert.

*Compensation Committee*

The purpose of the Compensation Committee includes determining, or recommending to our Board of Directors for determination, the compensation of our Chief Executive Officer and other executive officers and discharging the responsibilities of our Board of Directors relating to our compensation programs.

As of February 11, 2013, the members of the Compensation Committee were Messrs. Collins and Segal. Mr. Collins serves as Chair.

*Nominating and Corporate Governance Committee*

The purpose of the Nominating and Corporate Governance Committee includes the selection or recommendation to our Board of Directors of nominees to stand for election as directors at each election of directors, the oversight of the selection and composition of committees of our Board of Directors, the oversight of the evaluations of our Board of Directors and management, the development and recommendation to our Board of Directors of a set of corporate governance principles applicable to us.

As of February 11, 2013, the members of the Nominating and Corporate Governance Committee were Messrs. Thompson and LaPenta, Jr. Mr. Thompson serves as Chair.



## **Board Policies**

### *Code of Conduct and Ethics*

Our Board of Directors has adopted a Code of Conduct and Ethics applicable to all of our directors and executive officers. This code is intended to focus the members of the Board of Directors and each executive officer on areas of ethical risk, provide guidance to directors and executive officers to help them recognize and deal with ethical issues, provide mechanisms to report unethical conduct, and help foster a culture of honesty and accountability. All members of the Board of Directors and all executive officers are required to sign this code on an annual basis.

### *Code of Ethics for the CEO and Senior Financial Officers*

Our Board of Directors has adopted a Code of Ethics for the CEO and Senior Financial Officers. This code governs the professional and ethical conduct of our financial executives, and directs that they (i) provide disclosure in the periodic reports that is complete, fair, accurate, timely, and understandable; (ii) promptly inform the Audit Committee of any significant deficiencies in internal controls or fraud by management or other employees who play a significant role in our financial reporting, disclosures, or internal controls; (iii) promptly inform the Audit Committee of any violations of the Code of Conduct and Ethics or Code of Ethics for the CEO and Senior Financial Officers, as well as any conflicts of interest involving management or other employees who play a significant role in our financial reporting, disclosures, or internal controls; and (iv) promptly inform the Audit Committee of any material violations of the laws, rules, or regulations applicable to us and operation of our business, by us or any of our agents.

### *Committee Charters, Corporate Governance Guidelines, and Codes of Ethics*

Our Board of Directors has adopted charters for the Audit, Compensation, and Nominating and Corporate Governance Committees describing the authority and responsibilities delegated to each committee by our Board of Directors. We post on our website, at [www.TherapeuticsMD.com](http://www.TherapeuticsMD.com), the charters of our Audit, Compensation, and Nominating and Corporate Governance Committees; our Corporate Governance Guidelines, Code of Conduct and Ethics, and Code of Ethics for the CEO and Senior Financial Officers, and any amendments or waivers thereto applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions; and any other corporate governance materials contemplated by SEC regulations. These documents are also available in print to any stockholder requesting a copy in writing from our corporate secretary at our executive offices set forth in this Annual Report on Form 10-K.

**Item 11. *Executive Compensation***

This section discusses the principals underlying our executive compensation policies and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers and places in perspective the data presented in the narrative and tables that follow.

**Overview**

The objectives of our compensation program for our executive officers seek to promote the creation of long-term stockholder value by tying a portion of those executives' total compensation to company and individual's performance measures that are expected to position us for long-term success in attracting, motivating, and retaining high-caliber executives with the skills necessary to achieve our business objectives in a competitive market for talent.

We use a mix of components in pursuing these objectives:

- base salary;
- annual cash bonuses;
- equity awards in the form of stock options;
- benefits and perquisites; and
- arrangements regarding compensation upon termination of employment.

Our practice has been to combine the components of our executive compensation program to align compensation with measures that correlate with the creation of long-term stockholder value and to achieve a total compensation level appropriate for our size and corporate performance. In pursuing this, we offer an opportunity for income in the event of successful corporate financial performance, matched with the prospect of less compensation in the absence of successful corporate financial performance. Our philosophy is to make a greater percentage of an employee's compensation based on our company's performance as he or she becomes more senior, with a significant portion of the compensation of our executive officers based on the achievement of our performance goals because the performance of these officers is more likely to have a direct impact on our achievement of strategic and financial goals, which are most likely to affect stockholder value. At the same time, our board of directors believes that we must attract and retain high-caliber executives, and therefore must offer a mixture of fixed and incentive compensation at levels that are attractive in light of the competitive market for senior executive talent.

Historically, our Board of Directors has reviewed the total compensation of our executive officers and the mix of components used to compensate those officers on an annual basis. In determining the total amount and mix of compensation components, our Board of Directors strives to create incentives and rewards for performance consistent with our short-term and long-term objectives. Our Board of Directors relies on its judgment about each individual rather than employing a formulaic approach to compensation decisions. Our Board of Directors has not assigned a fixed weighting among each of the compensation components. Our Board of Directors assesses each executive officer's overall contribution to our business, scope of responsibilities, and historical compensation and performance to determine annual compensation. In making compensation decisions, our Board takes into account input from its members and our Chief Executive Officer based on their experiences with other companies. We anticipate that our Compensation Committee may, from time to time as it sees fit, retain third-party executive compensation specialists in connection with determining cash and equity compensation and related compensation policies in the future.

### **Role of Our Compensation Committee**

Historically, our Board of Directors has determined and administered the compensation of our Chief Executive Officer and our Chief Financial Officer, and our Chief Executive Officer, subject to the approval of our Board of Directors, determined the compensation of our other executive officers. Currently, our Compensation Committee, formed on February 29, 2012, makes the ultimate decisions regarding executive officer compensation and share-based compensation for all of our employees. Our Chief Executive Officer and other executive officers may from time to time attend meetings of our Compensation Committee or our Board of Directors, but will have no final decision authority with respect to such compensation. Annually, our Compensation Committee will evaluate the performance of our Chief Executive Officer and determine our Chief Executive Officer's compensation in light of the goals and objectives of our compensation program. The decisions relating to our Chief Executive Officer's compensation will be made by the Compensation Committee, which will review its determinations with our Board of Directors prior to its final determination. The Chief Executive Officer is not permitted to attend those meetings of the Compensation Committee or the Board of Directors where the compensation of the Chief Executive Officer is deliberated or determined. Decisions regarding the compensation of other executive officers will be made by our Compensation Committee after considering recommendations from our Chief Executive Officer. As noted above, in the future we may engage an independent compensation consultant to assist the compensation committee in making its compensation determinations.

**Summary Compensation Table**

The following table lists the compensation of our company's principal executive officers for the years ended December 31, 2012, 2011, and 2010. The following information includes the dollar value of base salaries, bonus awards, the number of non-qualified options granted and certain other compensation, if any, whether paid or deferred. The following information includes the aggregated options issued to our executive officers pursuant to the reverse merger with VitaMed and those issued under our 2009 Long Term Incentive Compensation Plan, or LTIP and 2012 Stock Incentive Plan, or 2012 SOP.

Name and Principal Position	Year(1)	Salary (\$)	Bonus (\$)	Stock Option Awards		Non-Equity Incentive Plan Compensation (\$)	Non-Qualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
				Awards (\$)	Awards (2)	Compensation (\$)	Earnings (\$)		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Robert G. Finizio(3) Chief Executive Officer	2012	\$ 194,288	—	—	1,388,859	—	—	\$ 19,111	\$ 1,602,258
	2011	\$ 156,000	—	—	—	—	—	\$ 15,986	\$ 171,986
	2010	\$ 140,282	—	—	—	—	—	\$ 2,250	\$ 142,532
John C.K. Milligan, IV(4) President and Secretary	2012	\$ 181,404	—	—	1,263,781	—	—	\$ 18,184	\$ 1,463,369
	2011	\$ 156,000	—	—	—	—	—	\$ 25,329	\$ 181,329
	2010	\$ 144,787	—	—	—	—	—	\$ 9,554	\$ 154,341
Daniel A. Cartwright(5) Chief Financial Officer and Treasurer	2012	\$ 184,715	—	—	\$ 875,547	—	—	\$ 7,814	\$ 1,068,076
	2011	\$ 79,615	—	—	\$ 179,261	—	—	\$ 730	\$ 259,606
	2010	—	—	—	—	—	—	—	—
Mitchell L. Krassan(6) Chief Strategy Officer	2012	\$ 120,451	—	—	—	—	—	\$ 1,336	\$ 121,787
	2011	\$ 110,000	—	—	—	—	—	—	\$ 110,000
	2010	\$ 15,096	—	—	\$ 62,301	—	—	—	\$ 77,397

The compensation presented for fiscal years 2010 and a portion of 2011 was earned by our named executive (1) officers in their capacities as officers of VitaMed, prior to our company's reverse merger with VitaMed that was consummated on October 4, 2011.

(2) The valuation methodology used to determine the fair value of the options granted during the year was the Black-Scholes-Merton option-pricing model, an acceptable model in accordance with ASC 718-10. The Black-Scholes-Merton model requires the use of a number of assumptions, including volatility of the stock price,

the weighted average risk-free interest rate, and the weighted average expected life of the options. For further information, see “Note 10 – Stockholders’ Equity” included in the financial statements included in this Annual Report on Form 10-K.

This table does not include compensation received by Mr. Finizio in his capacity as a member of our Board of Directors; see “Director Compensation” below. For 2012: (i) Option awards included the issuance of non-qualified options for the purchase of 300,000 shares issued on February 27, 2012 and the issuance of non-qualified options for the purchase of 900,000 shares issued on November 30, 2012; (ii) All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf. For 2011: All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf. This table does not include the issuance of warrants for 204,571 shares issued in conjunction with the guarantee of a bank loan. For 2010: All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf.

This table does not include compensation received by Mr. Milligan in his capacity as a member of our Board of Directors; see “Directors Compensation” below. For 2012: (i) Option awards included the issuance of non-qualified options for the purchase of 300,000 shares issued on February 27, 2012 and the issuance of non-qualified options for the purchase of 800,000 shares issued on November 30, 2012; (ii) All Other Compensation includes health insurance premiums paid on Mr. Milligan’s behalf and a \$5,100 car allowance. For 2011: All Other Compensation includes \$15,987 for health insurance premiums paid on behalf of Mr. Milligan, \$5,100 paid for car allowance, and \$4,242 paid for housing allowance. This table does not include the issuance of warrants for 61,372 shares issued in conjunction with a promissory note and for 204,571 shares issued in conjunction with the guarantee of a bank loan. For 2010: All Other Compensation includes \$2,250 for insurance premiums paid on Mr. Milligan’s behalf and \$7,304 paid for housing allowance.

For 2012: (i) Option awards included the issuance of non-qualified options for the purchase of 700,000 shares issued on November 30, 2012; (ii) All Other Compensation includes health insurance premiums paid on Mr. (5) Cartwright's behalf. For 2011: (i) Option Awards include the issuance of non-qualified options for the purchase of 300,000 shares issued on October 21, 2011 and the issuance of a warrant for 600,000 shares issued on October 21, 2011. (ii) All Other Compensation includes health insurance premiums paid on behalf of Mr. Cartwright.

For 2012: All Other Compensation includes health insurance premiums paid on Mr. Krassan's behalf. For 2010: Option Awards include the issuance of non-qualified Company Options as follows: (i) Options for 73,646 (6) and 92,057 shares respectively which were originally issued on May 1, 2010 and reissued on October 4, 2011 pursuant to the Merger and (ii) options for 736,455 shares which was originally issued on September 1, 2010 and reissued on October 4, 2011 pursuant to our merger with VitaMed.

### Outstanding Equity Awards at Fiscal Year End

The table below shows equity awards currently outstanding for our company's executive officers at fiscal year ended December 31, 2012, which equity awards consist of non-qualified options issued under the LTIP. No executive officers have exercised their options. This table does not include the issuance of warrants as described elsewhere herein.

Name	Grant Date	Option Awards		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable				
(a)		(b)	(c)	(d)	(e)	(f)	
Robert F. Finizio	01/01/2009	1,472,910(1)	—	—	\$ 0.10	01/01/19	
	02/27/2012	—	300,000	(2)	\$ 2.20	02/27/22	
	04/16/2012	50,000 (3)	—	—	\$ 2.40	04/16/22	
	11/30/2012	—	900,000	(4)	\$ 3.00	11/30/22	
John C.K. Milligan, IV	01/01/2009	2,052,255(1)	—	—	\$ 0.10	01/01/19	
	02/27/2012	—	300,000	(2)	\$ 2.20	02/27/22	
	04/16/2012	75,000 (3)	—	—	\$ 2.40	04/16/22	
	11/30/2012	—	800,000	(4)	\$ 3.00	11/30/22	
Daniel A. Cartwright	10/21/2011	75,000 (5)	225,000	(5)	—	\$ 0.38	10/21/21

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	11/30/2012	—		700,000	(4)	—	\$ 3.00	11/30/22
Mitchell L. Krassan	05/01/2010	73,646	(6)	—		—	\$ 0.19	05/01/20
	05/01/2010	92,057	(6)	—		—	\$ 0.19	05/01/20
	09/01/2010	552,341	(7)	184,114	(7)	—	\$ 0.20	09/01/20



- (1) The options granted on January 1, 2009 vested monthly on the first of each month over three years.
- (2) The options granted on February 27, 2012 vest in full on the first anniversary.
- (3) The options granted on April 16, 2012 vested in full on December 31, 2012.
- (4) The options granted on November 30, 2012 vest annually on the anniversary date over three years.
- (5) The options granted on October 21, 2011 vest annually on the anniversary date over four years.
- (6) All underlying shares vested on May 1, 2011.
- (7) The options granted on September 1, 2010 vest monthly on the first of each month over three years.

### **Employment Agreements**

Robert G. Finizio has a three year employment agreement that commenced November 8, 2012, which calls for: (i) a time-based ten-year stock option (the “Time-Based Option”) granted and issued on November 30, 2012 (the “Date of Grant”) to purchase 900,000 shares of our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a performance-based ten-year stock option (the “Performance-Based Option”) in an amount to be determined, (iii) a base salary of not less than \$355,100 per year and (iv) an annual short-term incentive compensation bonus of up to 35% of the base salary, at the discretion of the Board of Directors. Mr. Finizio will receive employee benefits, vacation and other perquisites as may be determined from time to time and an automatic renewal option for one additional year. Conditions of termination call for (i) termination immediately upon death, (ii) termination upon a disability in which Mr. Finizio is unable to perform his duties for more than 180 total calendar days during any 12-month period, (iii) voluntary termination by Mr. Finizio upon a 14 calendar day prior notice, (iv) involuntary termination by our company without cause with 60-day notice (or 90-day notice when termination is due to the non-extension of the employment term by our company), (v) termination for cause, and (vi) termination for good reason wherein Mr. Finizio will have 90 days from the date of notice to terminate his employment. In addition, if our company is subject to a change in control or Mr. Finizio is terminated without cause, he will be entitled to receive severance benefits of 52 weeks salary, benefits, bonus and vesting of all options and warrants. The employment agreement contains standard provisions for confidentiality and noncompetition.

John C.K. Milligan, IV has a three year employment agreement that commenced on November 8, 2012, which calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 800,000 shares of the our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$288,100 per year, and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of the Board of Directors. Mr. Milligan will receive employee benefits, vacation and other perquisites as may be determined from time to time and an automatic renewal option for one additional year. Conditions of termination call for (i) termination immediately upon death, (ii)

termination upon a disability in which Mr. Milligan is unable to perform his duties for more than 180 total calendar days during any 12-month period, (iii) voluntary termination by Mr. Milligan upon a 14 calendar day prior notice, (iv) involuntary termination by our company without cause with 60-day notice or (90-day notice when termination is due to the non-extension of the employment term by our company), (v) termination for cause, and (vi) termination for good reason wherein Mr. Milligan shall have 90 days from the date of notice to terminate his employment. In addition, if our company is subject to a change in control or the Executive is terminated without cause, Mr. Milligan will be entitled to receive severance benefits of 52 weeks salary, benefits, bonus and vesting of all options and warrants. The employment agreement contains standard provisions for confidentiality and noncompetition.

Daniel A. Cartwright has a three year employment agreement that commenced November 8, 2012, which calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 700,000 shares of our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$257,100 per year, and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of the Board of Directors. Mr. Cartwright will receive employee benefits, vacation and other perquisites as may be determined from time to time and an automatic renewal option for one additional year. Conditions of termination call for (i) termination immediately upon death, (ii) termination upon a disability in which Mr. Cartwright is unable to perform his duties for more than 180 total calendar days during any 12-month period, (iii) voluntary termination by Mr. Cartwright upon a 14 calendar day prior notice, (iv) involuntary termination by our company without cause with 60-day notice or (90-day notice when termination is due to the non-extension of the employment term by our company), (v) termination for cause and (vi) termination for good reason wherein Mr. Cartwright will have 90 days from the date of notice to terminate his employment. In addition, if our company is subject to a change in control or Mr. Cartwright is terminated without cause, Mr. Cartwright will be entitled to receive severance benefits of 18 months salary, benefits, bonus and vesting of all options and warrants. The employment agreement contains standard provisions for confidentiality and noncompetition.

## **Post-Employment Compensation**

### *Pension Benefits*

We do not offer any defined benefit pension plans for any of our employees. We do have a 401(k) plan in which our employees may participate.

### *Potential Payments Upon Termination or Change in Control*

The tables below reflect the amount of compensation to certain of our executive officers in the event of termination of such executive's employment or a change in control. Other than as set forth below, no amounts will be paid to our named executive officers in the event of termination.

### *Severance Arrangements Upon Termination*

We have employment agreements with our executive officers as described above. The arrangements reflected in these employment agreements are designed to encourage the officers' full attention and dedication to our company currently

and, in the event of any proposed change of control, provide these officers with individual financial security. Pursuant to the employment agreements, if the executive is terminated for any reason other than for “cause,” or if he terminates his employment voluntarily for “good reason” (as such terms are defined in the employment agreements), he is entitled to receive severance for a period of 12 months in accordance with our normal payroll practices and will be eligible to receive all benefits under welfare benefit plans, practices, policies, and programs provided by us (including medical and group life plans and programs) for the same period.

Assuming these agreements were in place on December 31, 2012, if our named executive officers were terminated without cause or for good reason (as those terms are defined in the employment agreements) on December 31, 2012, they would receive the following severance over a 12-month period pursuant to their employment agreements:

<b>Name</b>	<b>Severance</b>
Robert G. Finizio	\$ 486,885
John C.K. Milligan, IV	\$ 382,030
Daniel A. Cartwright	\$ 341,730

*Severance Arrangements Upon Change of Control*

Pursuant to the employment agreements with the our executives officers as described above, if, during the one-year period following a “change of control” (as defined in the employment agreements), the executive’s employment is terminated without cause, he is entitled to receive in one lump sum payment an amount equal to the executive’s annual base salary, an amount equal to the executive’s targeted annual bonus award, an amount equal to the unpaid base salary and accrued but unused vacation pay, the full vesting of all outstanding long-term incentive awards, and a continuation of welfare benefits (healthcare, life and accidental death and dismemberment, and disability insurance) for one year.

Assuming those employment agreements were in place on December 31, 2012 and a change in control of our company occurred on December 31, 2012 and each of the executive officers listed below was terminated as a result of the change of control, our named executive officers would receive the following severance over a 12-month period pursuant to their employment letter agreements:

<b>Name</b>	<b>Severance</b>
Robert G. Finizio	\$ 516,427
John C.K. Milligan, IV	\$ 406,038
Daniel A. Cartwright	\$ 363,155

**Nonqualified Deferred Compensation**

We do not offer any deferred compensation plans for any of our named executive officers.

**Risk Management Considerations**

Our Board of Directors believes that our executive compensation program creates incentives to create long-term value while minimizing behavior that leads to excessive risk. The earnings before interest, taxes, depreciation, and amortization, or EBITDA, financial metric used to determine the amount of an executive’s company-based performance bonus has ranges that encourage success without encouraging excessive risk taking to achieve short-term results. In addition, at maximum performance levels, cash incentive compensation cannot exceed 35% of our Chief Executive Officer’s base salary and 30% of the base salary of our other executive officers. The stock options granted to our executives become exercisable over various times and remain exercisable for up to ten years from the date of grant, encouraging executives to look to long-term appreciation in equity values.

**Director Compensation**

We do not pay cash fees to directors who attend regularly scheduled and special board meetings; however, we may reimburse out-of-state directors for costs associated with travel and lodging to attend such meetings. Our directors may also be granted non-qualified options from time to time under our LTIP or 2012 SOP.

The following table and accompanying footnotes details compensation paid to our directors for services rendered for the year ended December 31, 2012.

Name (a)	Fees earned or paid in cash \$(b)	Stock Awards \$(c)	Option Awards \$(d)(1)(2)	Non-Equity Incentive Plan Compensation \$(e)	Nonqualified Deferred Compensation Earnings \$(f)	All Other Compensation \$(g)	Total \$(h)
Robert F. Finizio(3)	—	—	\$ 53,625	—	—	—	\$53,625
John C.K. Milligan, IV(4)	—	—	\$ 80,287	—	—	—	\$80,287
Brian A. Bernick, MD(5)(11)	—	—	\$ 53,625	—	—	\$ 199,036	\$252,661
Cooper Collins(6)	—	—	\$ 80,287	—	—	—	\$80,287
Robert V. LaPenta, Jr.(7)	—	—	\$ 80,287	—	—	—	\$80,287
Tommy G. Thompson(8)	—	—	\$ 80,287	—	—	—	\$80,287
Samuel A. Greco(9)	—	—	\$ 53,625	—	—	—	\$53,625
Nicholas Segal(10)	—	—	\$ 53,625	—	—	—	\$53,625

The valuation methodology used to determine the fair value of the options granted during the year was the Black-Scholes-Merton option-pricing model, an acceptable model in accordance with ASC 718-10. The

(1) Black-Scholes-Merton model requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average expected life of the options. For further information, see “Note 10 – Stockholders’ Equity” included in the financial statements included in this Annual Report on Form 10-K.

(2) Options depicted in the table above were granted to directors for serving on our Board of Directors and vested on December 31, 2012.

The amount listed does not include any compensation for services rendered as an executive officer, including: (i) options granted to Mr. Finizio in the aggregate of 2,672,910 shares during 2012 or (ii) warrants issued to Mr.

(3) Finizio in exchange for a personal bank guarantee in the aggregate of 179,000 shares during 2012. See Summary Compensation Table. On December 31, 2012, Mr. Finizio had an aggregate of 2,722,910 options and 179,000 warrants.

The amount listed does not include any compensation for services rendered as an executive officer, including: (i) options issued to Mr. Milligan in the aggregate of 3,152,255 shares during 2012 or (ii) warrants issued to Mr.

(4) Milligan in exchange for a personal bank guarantee and in connection with a promissory note in the aggregate of 240,372 shares during 2012. See Summary Compensation Table. On December 31, 2012, Mr. Milligan had an aggregate of 3,227,255 options and 240,372 warrants.

The amount listed does not include warrants issued to Dr. Bernick in connection with a promissory note in the

(5) aggregate of 61,372 shares during 2012. On December 31, 2012, Dr. Bernick had an aggregate of 1,672,190 options and 61,372 warrants.

(6) On December 31, 2012, Mr. Collins had an aggregate of 75,000 options.

(7) On December 31, 2012, Mr. LaPenta, Jr. had an aggregate of 75,000 options.

(8) On December 31, 2012, Mr. Thompson had an aggregate of 75,000 options.

(9) On December 31, 2012, Mr. Greco had an aggregate of 50,000 options.

On December 31, 2012, Mr. Segal had an aggregate of 142,057 options and 61,372 warrants. Mr. Segal owns

(10) 11.5812% of Fourth Generation Equity Partners, which has the rights to the 61,372 warrants. Mr. Segal claims ownership equal to 7,107 of these warrants.

(11) The total amount of compensation includes the options granted to Dr. Bernick for services rendered as a consultant in the aggregate of 150,000 shares during 2012 for a value of \$160,574 and consulting fees of \$38,462.

### **Compensation Committee Interlocks and Insider Participation**

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For the year ended December 31, 2011, we did not have a Compensation Committee. Upon its formation on February 29, 2012, our Compensation Committee initially consisted of three members of our Board of Directors, namely, Cooper C. Collins (Chair), Robert G. Finizio, and Nicholas Segal. Of those members, only Mr. Finizio was an officer and employee of our company. On February 11, 2013, Mr. Finizio stepped down from the Compensation Committee. No current executive officer or member of our Compensation Committee serves as a member of a board of directors or compensation committee of any entity that has one or more executive officers serving as members of our Board of Directors or Compensation Committee.



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

The following table sets forth information regarding the beneficial ownership of our common stock as of February 28, 2013 by the following:

- each of our directors and executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she, or it possesses sole or shared voting or investment power of that security, including options and warrants that are currently exercisable or exercisable within 60 days of February 28, 2013. Shares issuable pursuant to stock options, warrants, and convertible securities are deemed outstanding for computing the percentage of the person holding such options, warrants, or convertible securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o TherapeuticsMD, Inc., 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487.

Name of Beneficial Owners	Shares Beneficially Owned	
	Number	Percent <sup>(1)</sup>
Executive Officers and Directors:		
Robert G. Finizio, Chief Executive Officer and director <sup>(2)</sup>	24,163,496	23.74 %
John C.K. Milligan, IV, President, Secretary, and director <sup>(3)</sup>	9,035,645	8.82 %
Daniel A. Cartwright, Chief Financial Officer, Vice President, Finance, and Treasurer <sup>(4)</sup>	320,448	*
Mitchell L. Krassan, Executive Vice President and Chief Strategy Officer <sup>(5)</sup>	779,413	*
Brian Bernick, M.D., Chief Medical Officer and director <sup>(6)</sup>	10,854,049	10.69 %
Tommy G. Thompson, Chairman of the Board <sup>(7)</sup>	675,000	*
Samuel A. Greco, director <sup>(8)</sup>	450,000	*
Cooper C. Collins, director <sup>(9)</sup>	2,706,579	2.71 %
Robert V. LaPenta, Jr., director <sup>(10)</sup>	80,000	*
Nicholas Segal, director <sup>(11)</sup>	3,998,719	4.00 %

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All executive officers and directors as a group (10 persons) <sup>(12)</sup>	52,899,713	46.81	%
5% Stockholders:			
Robert J. Smith <sup>(13)</sup>	9,663,257	9.43	%
Steven G. Johnson <sup>(14)</sup>	9,453,149	9.22	%
FMR LLC <sup>(15)</sup>	9,128,507	9.15	%
Wellington Management Company, LLP <sup>(16)</sup>	7,386,893	7.40	%

\*Represents less than 1% of the outstanding shares of our common stock.

(1) Applicable percentage of ownership is based on 99,784,982 shares of common stock outstanding as of February 28, 2013, as adjusted for each stockholder.

(2) This amount includes (i) 22,161,586 shares directly owned by Mr. Finizio, (ii) 1,822,910 shares due to Mr. Finizio upon exercise of vested shares under options and (iii) 179,000 shares due to Mr. Finizio upon exercise of vested shares under a warrant. The percentage beneficially owned by Mr. Finizio is based on 101,786,892 shares which would be outstanding if all of Mr. Finizio's vested shares under the options and warrant were exercised.

(3) This amount includes (i) 6,368,018 shares directly owned by Mr. Milligan, (ii) 2,427,255 shares due to Mr. Milligan upon exercise of vested shares under options, and (iii) 240,372 shares due to Mr. Milligan upon exercise of vested shares under warrants. The percentage beneficially owned by Mr. Milligan is based on 102,452,609 shares which would be outstanding if all of Mr. Milligan's vested shares under the options and warrants were exercised.

(4) This amount includes (i) 75,000 shares due to Mr. Cartwright upon exercise of vested shares under options, and (ii) 245,448 shares due to Mr. Cartwright upon exercise of vested shares under a warrant. The percentage beneficially owned by Mr. Cartwright is based on 100,105,430 shares which would be outstanding if all of Mr. Cartwright's vested shares under the options and warrant were exercised.

(5) This amount includes 779,413 shares due to Mr. Krassan upon exercise of vested shares under options. The percentage of class for Mr. Krassan is based on 100,564,395 shares which would be outstanding if all of Mr. Krassan's vested shares under the options were exercised.

(6) This amount includes (i) 9,119,767 shares beneficially owned by BF Investment Enterprises, Ltd., or BF Investment, a company controlled by Dr. Bernick, (ii) 1,672,910 shares due to BF Investment upon exercise of vested shares under options and (iii) 61,372 shares due to BF Investment upon exercise of vested shares under a warrant. The percentage beneficially owned by Dr. Bernick is based on 101,519,264 shares which would be outstanding if all of BF Investment's vested shares under the options and warrant were exercised.

(7) This amount includes (i) 600,000 shares directly owned by Thompson Family Investments, LLC, an entity solely owned by Thompson Family Holdings, LLC, an entity solely owned by Mr. Thompson, and (ii) 75,000 shares due to Mr. Thompson upon exercise of vested shares under options. The percentage beneficially owned by Mr. Thompson is based on 99,859,982 shares which would be outstanding if all of Mr. Thompson's vested shares under the options were exercised.

(8) This amount includes (i) 400,000 shares directly owned by Mr. Greco, which shares are currently pledged as security for a promissory note and (ii) 50,000 shares due to Mr. Greco upon exercise of vested shares under options. The percentage beneficially owned by Mr. Greco is based on 99,834,982 shares which would be outstanding if all of Mr. Greco's vested shares under the options were exercised.

(9) This amount includes (i) 2,631,579 shares beneficially owned by Pernix Therapeutics Holdings, Inc., of which Mr. Collins is CEO, director and largest shareholder, and all of which shares have been pledged as collateral to secure a loan (Mr. Collins exercises voting control in part with the remaining directors of Pernix and disclaims beneficial ownership of the shares), and (ii) 75,000 shares due to Mr. Collins upon exercise of vested shares under options. The percentage beneficially owned by Mr. Collins is based on 99,859,982 shares, which would be outstanding if all of Mr. Collins' vested shares under the options were exercised.

(10) This amount includes (i) 5,000 shares directly owned by Mr. LaPenta and (ii) 75,000 shares due to Mr. LaPenta upon exercise of vested shares under options. The percentage beneficially owned by Mr. LaPenta is based on 99,859,982 shares which would be outstanding if all of Mr. LaPenta's vested shares under the options were exercised.

(11) This amount includes (i) 245,485 shares directly owned by Mr. Segal, and (ii) 142,057 shares due to Mr. Segal upon exercise of vested shares under an option. Mr. Segal owns 11.5812% of Fourth Generation Equity Partners, or Fourth Generation, which (i) owns 3,549,805 shares and (ii) has the right to acquire 61,372 shares upon exercise of vested shares under a warrant. Mr. Segal claims ownership equal to 411,110 shares and 7,107 vested shares under the Fourth Generation warrant. Mr. Segal disclaims beneficial ownership to the remaining shares and remaining vested shares under the warrant owned by Fourth Generation. The percentage beneficially owned by Mr. Segal is based on 99,988,411 shares which would be outstanding if all of Mr. Segal's and Fourth Generation's vested shares under options were exercised.

(12)

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This amount includes all shares directly and indirectly owned by all officers and directors and all shares to be issued directly and indirectly upon exercise of vested shares under options and warrants held by our officers and directors. The percentage beneficially owned by all officers and directors is based on 107,603,455 shares which would be outstanding if all of the officers' and directors' vested shares under options and warrants were exercised.

The information is as reported on Schedule 13D as filed February 4, 2013. This amount includes (i) 5,531,029 shares beneficially owned through Plato and Associates, LLC, or Plato, an entity solely owned by Robert J. Smith, (ii) 1,432,228 shares beneficially owned through Energy Capital, LLC, an entity solely owned by Mr. (13) Smith, and (iii) 2,700,000 shares due to Plato upon the exercise of vested warrants. The percentage beneficially owned by Plato is based on 102,484,982 shares that would be outstanding if all of Mr. Smith's shares under the vested warrants were exercised. Mr. Smith exercises voting and dispositive power over all such shares. Mr. Smith's address is 13650 Fiddlesticks Boulevard, #202-324, Ft. Myers, Florida 33912.

The information is as reported on Schedule 13D as filed February 4, 2013. This amount includes (i) 6,753,149 shares beneficially owned through SJ Capital, LLC, an entity solely owned by Steven G. Johnson, and (ii) (14) 2,700,000 shares due to Mr. Johnson upon the exercise of vested warrants. The percentage beneficially owned by Mr. Johnson is based on 102,484,982 shares which would be outstanding if all of Mr. Johnson's shares under the vested warrants were exercised. Mr. Johnson exercises voting and dispositive power over all such shares. Mr. Johnson's address is 804 Tree Haven Court, Highland Village, Texas 75077.

The information is as reported on Schedule 13G as filed February 14, 2013. Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC and a registered investment adviser, is the beneficial owner of all such shares as a result of its acting as investment adviser to various investment companies, or the Fidelity Funds. The ownership of one such Fidelity Fund, Puritan Fund, amounted to 7,722,000 shares or 7.739% of the (15) common stock outstanding. Edward C. Johnson III and FMR LLC, through its control of Fidelity Management & Research Company, each has sole power to dispose of the 9,128,507 shares owned by the Fidelity Funds. Neither FMR LLC nor Edward C. Johnson III, as Chairman of FMR LLC, has sole power to vote or direct the voting of the shares owned directly by the Fidelity Funds, which power resides with the Fidelity Funds' board of trustees. The address of FMR LLC and Puritan Fund is 82 Devonshire Street, Boston, Massachusetts 02109.

The information is as reported on Amendment No. 1 to Schedule 13G as filed February 14, 2013. The shares are beneficially owned by Wellington Management Company, LLP, in its capacity as investment adviser, for its clients. Those clients have the right to receive, or the power to direct the receipt of, dividends from, or the (16) proceeds from the sale of such shares. No such client is known to have such right or power with respect to more than five percent. Wellington Management Company, LLP has shared voting power over 5,897,322 shares and sole dispositive power over all such shares. Wellington Management Company, LLP's address is 280 Congress Street, Boston, MA 02210.

Under Rule 144 promulgated under the Securities Act, our officers, directors, and beneficial stockholders may sell up to 1% of the total outstanding shares (or an amount of shares equal to the average weekly reported volume of trading during the four calendar weeks preceding the sale) every three months provided that (i) current public information is available about our company, (ii) the shares have been fully paid for at least one year, (iii) the shares are sold in a broker's transaction or through a market-maker, and (iv) the seller files a Form 144 with the SEC.

## Equity Compensation Plans

### *2009 Long Term Incentive Compensation Plan*

In 2009, we adopted the LTIP to provide financial incentives to employees, members of the Board, and advisers and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives. The awards available under the LTIP consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, EVA awards, and other stock or cash awards as described in the LTIP. There are 25,000,000 shares authorized for issuance thereunder. The LTIP is administered by our Board of Directors, who determine (i) the persons to be granted stock options under the LTIP; (ii) the number of shares subject to each option and the exercise price of each option; (iii) whether the stock option will be exercisable at any time during the option period of ten years or whether it shall be exercisable in installments or by vesting only.

*Approval of 2012 Stock Incentive Plan*

On February 23, 2012, our Board of Directors adopted the 2012 SOP, a non-qualified plan not requiring approval by our stockholders. The 2012 SOP was designed, to serve as an incentive for retaining qualified and competent key employees, officers, directors, consultants, and advisors of our company. There are 10,000,000 shares authorized for issuance thereunder.

*Securities Authorized for Issuance under Equity Compensation Plans*

As of December 31, 2012, the following table shows the number of securities to be issued upon exercise of outstanding options under equity compensation plans approved by our shareholders, which plans do not provide for the issuance of warrants or other rights.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity Compensation Plans Approved by Shareholders	11,508,488	\$ 0.81	13,491,512
Equity Compensation Plans Not Approved by Shareholders	2,225,000	\$ 2.97	7,775,000
Total	13,733,488	\$ 1.16	21,266,512

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

## Related Transactions

Except for the transactions described below, none of our directors, officers, or principal stockholders, nor any associate or affiliate of the foregoing, have any interest, direct or indirect, in any transaction or in any proposed transaction, which materially affected us during the year ended December 31, 2012.

### *March 2011 Bank Line of Credit*

In March 2011, we entered into a Business Loan Agreement and Promissory Note with First United Bank for a \$300,000 bank line of credit, or the Bank LOC, for which a personal guarantee and cash collateral was 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. In consideration for the personal guarantees and cash collateral, warrants for an aggregate of 613,713 shares of common stock were granted. The ten-year warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter-end and have an exercise price of \$0.2444 per share. In the event that the Bank LOC is repaid prior to such date as the warrants are fully vested, we will only issue warrants for the number of shares vested through such date. As of December 31, 2012, 562,571 shares were vested under the warrants.



The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. We negotiated a one-year extension to the Bank LOC with First United Bank, which was executed on March 19, 2012, or the Bank LOC Extension. The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and First United Bank amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit, or the Amended Bank LOC. In accordance with the Amended Bank LOC, the personal guarantees and cash collateral were removed for Messrs. Finizio and Milligan. The Amended Bank LOC accrues interest at the rate of 2.35% and is due on May 1, 2013. At December 31, 2012, the outstanding principle balance of the Amended Bank LOC was \$0.

#### *Repayment of VitaMed Promissory Notes*

In June 2011, VitaMed sold Promissory Notes, or the VitaMed Promissory Notes, in the aggregate principal amount of \$500,000, including an aggregate of \$200,000 issued to certain of our directors and officers. Messrs. Milligan and Bernick and entities controlled by Messrs. Krassan and Segal were each issued VitaMed Promissory Notes for \$50,000. In consideration for the VitaMed Promissory Notes, warrants for an aggregate of 613,718 shares of our common stock were granted. The VitaMed Promissory Notes earn interest at the 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 or notes issued in an amount of not less than \$1,000,000. Upon the closing of such funding in July 2011, two of the VitaMed Promissory Notes held by unaffiliated parties in the aggregate of \$200,000 were paid in full. By mutual agreement, the remaining VitaMed Promissory Notes in the aggregate of \$300,000 were extended.

In October 2011, one of the VitaMed Promissory Notes for \$50,000 held by the entity controlled by Mr. Krassan was paid in full for \$50,696, including interest. By mutual agreement, the VitaMed Promissory Note held by the entity controlled by Mr. Segal was converted into 133,411 shares of our common stock at \$0.38 per share, which represents the fair value of the shares on the date of conversion.

In June 2012, a VitaMed Promissory Note held by an unaffiliated individual was paid in full, including \$2,160 in accrued interest. The remaining VitaMed Promissory Notes in the aggregate of \$100,000 were extended to October 15, 2012 (one held by Mr. Milligan for \$50,000 and one for \$50,000 held by BF Investments, LLC, an entity owned by Mr. Bernick), which VitaMed Promissory Notes were paid in full in October 2012.

In December 2011, we sold 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 and subsequently paid in full in October 2012.

*Lock-Up Agreements*

As required by the terms of the merger agreement with VitaMed dated July 18, 2011, we entered into a lock-up agreement with certain security holders covering the aggregate of 70,000,000 shares of our common stock issued pursuant to the merger or reserved for issuance pursuant to options and warrants. Each security holder agreed that from the date of the merger agreement until 18 months thereafter, they would not make or cause any sale of our securities. After the completion of this 18-month lock-up period, the security holders agreed not to sell or dispose of more than 2.5% of the aggregate common stock or shares reserved for issuance for options and warrants per quarter over the following 12-month period. Upon the completion of this 12-month period dribble out period, the lock up agreements will terminate.

*Agreements with Pernix Therapeutics, LLC*

We closed a stock purchase agreement with Pernix Therapeutics, LLC, or Pernix, a speciality pharmaceutical company, on October 5, 2011 pursuant to which Pernix purchased 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. The stock purchase agreement included a lock-up agreement pursuant to which, among other things, Pernix agreed that for a period of 12 months from the date of the lock-up Agreement, it would not make or cause any sale of the purchased shares. After the completion of this 12-month lock-up period, Pernix agreed not to sell or dispose of more than 5% of the shares per quarter for the following 12-month period. The President and largest shareholder of Pernix, Cooper C. Collins, was elected to serve on our Board of Directors on February 29, 2012. From time to time, we have and will continue to enter into agreements with Pernix in the normal course of business, which agreements are negotiated in arms-length transactions.

*Warrants Assigned to Related Party*

In June 2012, a 100,000 warrant was assigned to the son of the Chairman of our Board of Directors by a non-affiliated third party.

*Credit Line for \$10 Million*

On January 31, 2013, we issued a Multiple Advance Revolving Credit Note, or the Note, to Plato and Associates, LLC, or Plato, an entity solely owned by Robert J. Smith, one of our principal stockholders as of December 31, 2012. The Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum. Plato may make advances to us from time to time under the Note at our request, which advances will be of a revolving nature. Interest payments will be due and payable on a quarterly basis, commencing on April 10, 2013, and the principal balance outstanding under the Note, together with all accrued interest and other amounts payable under the Note, if any, will be due and payable on February 24, 2014. As additional consideration for the Note, we issued to Plato a warrant to purchase 1,250,000 shares of our common stock at an exercise price \$3.20 per share. This warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to its January 31, 2019 expiration date. As of March 7, 2013, we have drawn down \$200,000 on the Note.

**Director Independence**

Our Board of Directors has determined, after considering all the relevant facts and circumstances, that Messrs. Thompson, Greco, Collins, LaPenta, Jr., and Segal are independent directors, as “independence” is defined by the listing standards of the NYSE MKT, because they have no material relationship with us (either directly or as a partner, stockholder, or officer of an organization that has a relationship with us). For the year ended December 31, 2012, Mr. Finizio served as a non-independent member of the Compensation Committee and Dr. Bernick and Mr. Milligan served as non-independent members of the Nominating and Corporate Governance Committee. Messers Finizio and Milligan and Dr. Bernick stepped down from these committees on February 11, 2013.

Item 14. *Principal Accountant Fees and Services*

Aggregate fees billed to our company for the fiscal years ended December 31, 2012 and 2011 by Rosenberg Rich Baker Berman & Company, or RRBB, our independent registered public accounting firm, are as follows:

	2012	2011
Audit Fees	\$104,200	\$24,410
Audit-Related Fees	\$0	\$0
Tax Fees	\$7,500	\$3,500
All Other Fees	\$0	\$0

Fees for audit services include fees associated with the annual audit, including the audit of the effectiveness of internal control over financial reporting for 2012, the reviews of our quarterly reports and other filings with the SEC. Tax fees included the preparation of our tax returns.

### **Audit Committee Pre-Approval Policies and Procedures**

The charter of our Audit Committee provides that the duties and responsibilities of our Audit Committee include the pre-approval, or adopting procedures for pre-approval, of all audit, audit-related, tax, and other services permitted by law or applicable SEC regulations (including fee and cost ranges) to be performed by our independent auditor. Any pre-approved services that will involve fees or costs exceeding pre-approved levels will also require specific pre-approval by the Audit Committee. Unless otherwise specified by the Audit Committee in pre-approving a service, the pre-approval will be effective for the 12-month period following pre-approval. The Audit Committee will not approve any non-audit services prohibited by applicable SEC regulations or any services in connection with a transaction initially recommended by the independent auditor, the purpose of which may be tax avoidance and the tax treatment of which may not be supported by the Internal Revenue Code and related regulations.

To the extent deemed appropriate, the Audit Committee may delegate pre-approval authority to the Chairman of the Audit Committee or any one or more other members of the Audit Committee provided that any member of the Audit Committee who has exercised any such delegation must report any such pre-approval decision to the Audit Committee at its next scheduled meeting. The Audit Committee will not delegate to management the pre-approval of services to be performed by the independent auditor.

Our Audit Committee requires that our independent auditor, in conjunction with our Chief Financial Officer, be responsible for seeking pre-approval for providing services to us and that any request for pre-approval must inform the Audit Committee about each service to be provided and must provide detail as to the particular service to be provided.

All of the services provided by RRBB described above under the captions “Audit Fees,” “Audit-Related Fees,” and “Tax Fees” were approved by our Audit Committee pursuant to our Audit Committee’s pre-approval policies. All of the hours spent by RRBB in auditing our financial statements for the year ended 2012 were attributed to work performed by RRBB’s full-time, permanent employees.

## **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 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**

<b>Exhibit</b>	<b>Date</b>	<b>Description</b>
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 <sup>(1)</sup>
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. <sup>(2)</sup>

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<b>Exhibit</b>	<b>Date</b>	<b>Description</b>
2.3	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization <sup>(3)</sup>
2.4	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC <sup>(4)</sup>
3.1	September 15, 2009	Articles of Amendment to Articles of Incorporation (to change name to AMHN, Inc.) <sup>(5)</sup>
3.2	July 27, 2009	Certificate of Merger of AMHN Acquisition Corp., with and into America's Minority Health Network, Inc. <sup>(6)</sup>
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) <sup>(3)</sup>
3.4	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada <sup>(7)</sup>
3.5	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada <sup>(7)</sup>
3.6	August 29, 2011	Certificate of Amendment and Restatement of Articles of Incorporation of AMHN, Inc. (to change name and increase authorized shares) <sup>(8)</sup>
3.7	n/a	Bylaws of AMHN, Inc. <sup>(9)</sup>
4.1	September 26, 2012	Form of Securities Purchase Agreement <sup>(10)</sup>
4.2	n/a	Form of Certificate of Common Stock <sup>(11)</sup>
10.1	November 9, 2010	Demand Promissory Note to Philip M. Cohen for \$210,000 <sup>(12)</sup>
10.2	April 18, 2011	Convertible Promissory Note to First Conquest Investment Group, L.L.C. for \$105,000 <sup>(12)</sup>
10.3	April 18, 2011	Convertible Promissory Note to Energy Capital, LLC for \$105,000 <sup>(12)</sup>
10.4	May 7, 2011	Sales Representative Agreement between AMHN, Inc. and Mann Equity, LLC <sup>(12)</sup>
10.5	July 9, 2009	Lease Agreement between Liberty Property Limited Partnership and VitaMedMD, LLC <sup>(13)</sup>
10.6	September 8, 2011	Stock Purchase Agreement between AMHN, Inc. and Pernix Therapeutics, LLC <sup>(14)</sup>
10.7	September 8, 2011	Lock-Up Agreement between AMHN, Inc. and Pernix Therapeutics, LLC <sup>(14)</sup>
10.8	n/a	Form of Common Stock Purchase Warrant <sup>(13)</sup>
10.9	n/a	Form of Non-Qualified Stock Option Agreement <sup>(13)</sup>
10.10	September 2011	Form of Convertible Promissory Note <sup>(15)</sup>
10.11	September 20, 2011	Financing Agreement between Lang Naturals, Inc. and VitaMedMD, LLC <sup>(16)</sup>
10.12	October 18, 2011	Debt Conversion Agreement between the Company and Energy Capital, LLC <sup>(17)</sup>
10.13	October 18, 2011	Debt Conversion Agreement between the Company and First Conquest Investment Group, LLC <sup>(17)</sup>
10.14	October 23, 2011	Consulting Agreement among VitaMedMD, LLC, the Company, and Lang Naturals, Inc. <sup>(17)</sup>
10.15	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc. <sup>(17)</sup>
10.16	October 23, 2011	Lock-Up Agreement between the Company and Lang Naturals, Inc. <sup>(17)</sup>
10.17	November 3, 2011	Software License Agreement between VitaMedMD, LLC and Pernix Therapeutics, LLC <sup>(18)</sup>

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10.18	November 2011	Form of Promissory Note <sup>(19)</sup>
10.19	February 24, 2012	Note Purchase Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson <sup>(20)</sup>
10.20	February 24, 2012	Form of Secured Promissory Note <sup>(20)</sup>
10.21	February 24, 2012	Security Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson <sup>(20)</sup>
10.22	February 24, 2012	Form of Common Stock Purchase Warrant <sup>(20)</sup>
10.23	n/a	Audit Committee Charter*
10.24	n/a	Compensation Committee Charter*
10.25	n/a	Nominating and Corporate Governance Committee Charter*
10.26	April 17, 2012	Master Services Agreement between the Company and Sancilio and Company, Inc. <sup>(21)</sup>
10.27	May 17, 2012	Consulting Agreement between the Company and Sancilio and Company, Inc. <sup>(21)**</sup>

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Exhibit	Date	Description
10.28	November 8, 2012	Form of Employment Agreement <sup>(22)</sup>
10.29	January 31, 2013	Multiple Advance Revolving Credit Note, issued to Plato & Associates, LLC <sup>(25)</sup>
10.30	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC <sup>(25)</sup>
14.00	n/a	<u>Code of Conduct and Ethics</u> *
14.01	n/a	<u>Code of Ethics for CEO and Senior Financial Officers</u> *
14.02	n/a	<u>Insider Trading Policy</u> *
16.1	December 14, 2011	Letter to the Company from Parks & Company, LLC <sup>(23)</sup>
16.2	February 1, 2012	Letter to the SEC from Parks & Company, LLC <sup>(24)</sup>
21.1	December 31, 2012	<u>Subsidiaries of the Company</u> *
23.1	March 12, 2013	<u>Consent of Rosenberg Rich Baker Berman &amp; Company</u> *
31.1	March 12, 2013	<u>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</u>
31.2	March 12, 2013	<u>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</u>
32.1	March 12, 2013	<u>Certification pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2	March 12, 2013	<u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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 Document †
101.LAB	n/a	XBRL Taxonomy Extension Label Linkbase Document †
101.PRE	n/a	XBRL Taxonomy Extension Presentation Linkbase Document †

\* Filed herewith.

\*\* 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.

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- (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 the 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 January 25, 2012 and incorporated herein by reference.
- (24) Filed as an exhibit to Form 8-K/A filed with the Commission on February 3, 2012 and incorporated herein by reference.

(25) Filed as an exhibit to Form 8-K filed with the Commission on February 6, 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 12, 2013

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.

<b>Signature</b>	<b>Capacity</b>	<b>Date</b>
<i>/s/ Robert G. Finizio</i> Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	March 12, 2013
<i>/s/ John C.K. Milligan, IV</i> John C.K. Milligan, IV	President, Secretary, Director	March 12, 2013
<i>/s/ Daniel A. Cartwright</i> Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	March 12, 2013
<i>/s/ Tommy G. Thompson</i> Tommy G. Thompson	Chairman	March 12, 2013
<i>/s/ Brian Bernick</i> Brian Bernick	Director	March 12, 2013
<i>/s/ Samuel A. Greco</i> Samuel A. Greco	Director	March 12, 2013
<i>/s/ Cooper C. Collins</i> Cooper C. Collins	Director	March 12, 2013

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*/s/ Robert V. LaPenta, Jr.*

Robert V. LaPenta, Jr.      Director

March 12, 2013

*/s/ Nicholas Segal*

Nicholas Segal      Director

March 12, 2013

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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, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2012. TherapeuticsMD, Inc.'s management is responsible for the consolidated financial statements. Our responsibility is to express an opinion on the 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 consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated 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, 2012 and 2011, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2012 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, 2012, 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 11, 2013, expressed an unqualified opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has incurred a loss from operations of approximately \$16 million and had negative cash flow from operations of approximately \$13 million. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Rosenberg  
Rich Baker  
Berman &  
Company

Somerset, New  
Jersey  
March 11, 2013





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, 2012, 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 *Controls and Procedure*. 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, 2012, 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 balance sheets and the related statements of operations, stockholders' equity (deficit), and cash flows of TherapeuticsMD, Inc., and our report dated March 11, 2013 expressed an unqualified opinion.

/s/ Rosenberg  
Rich Baker  
Berman &

Company

Somerset, New  
Jersey  
March 11, 2013

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THERAPEUTICSMD, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current Assets:		
Cash	\$1,553,474	\$126,421
Accounts receivable, net of allowance for doubtful accounts of \$42,048 and \$1,500, respectively	606,641	26,720
Inventory	1,615,210	588,073
Other current assets	751,938	496,060
Total current assets	4,527,263	1,237,274
Fixed assets, net	65,673	26,752
Other Assets:		
Prepaid consulting	953,655	80,515
Intangible assets	239,555	62,231
Security deposit	31,949	31,949
Total other assets	1,225,159	174,695
Total assets	\$5,818,095	\$1,438,721
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$1,641,366	\$306,511
Deferred revenue	1,144,752	—
Other current liabilities	725,870	465,747
Notes payable	—	2,150,000
Notes payable, related parties	—	200,000
Accrued interest	—	28,321
Total current liabilities	3,511,988	3,150,579
Long-Term Liabilities:		
Notes payable, net of debt discount of \$1,102,680 and \$0, respectively	3,589,167	—
Accrued interest	150,068	—
Total long-term liabilities	3,739,235	—
Total liabilities	7,251,223	3,150,579
Commitments and Contingencies		
Stockholders' Deficit:		
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; 99,784,982 and 82,978,804 issued and outstanding, respectively	99,785	82,979

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Additional paid in capital	50,580,400	15,198,241
Accumulated deficit	(52,113,313)	(16,993,078)
Total stockholder' deficit	(1,433,128 )	(1,711,858 )
Total liabilities and stockholders' deficit	\$5,818,095	\$1,438,721

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

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THERAPEUTICSMMD, INC AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2012	2011
Revenues, net	\$3,818,013	\$2,088,177
Cost of goods sold	1,348,113	947,112
Gross profit	2,469,900	1,141,065
Operating expenses:		
Sales, general, and administration	14,069,701	6,406,197
Research and development	4,492,362	107,241
Depreciation and amortization	56,260	54,845
Total operating expense	18,618,323	6,568,283
Operating loss	(16,148,423)	(5,427,218 )
Other income and (expense)		
Loss on extinguishment of debt	(10,307,864)	(7,390,000 )
Beneficial conversion feature	(6,716,504 )	—
Amortization of debt discount	(1,604,240 )	(28,719 )
Interest expense	(301,169 )	(35,661 )
Loan guaranty costs	(45,036 )	(38,159 )
Other income	3,001	6,392
Total other income (expense)	(18,971,812)	(7,486,147 )
Loss before taxes	(35,120,235)	(12,913,365)
Provision for income taxes	—	—
Net loss	\$(35,120,235)	\$(12,913,365)
Net loss per share, basic and diluted	\$(0.38 )	\$(0.21 )
Weighted average number of common shares outstanding	91,630,693	62,516,461

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



THERAPEUTICSMD, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011

	Common Stock Shares	Amount	Additional Paid in Capital	Accumulated 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	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 in exercise of warrants	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 as 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 conversion 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)



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

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THERAPEUTICSMD, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,	
	2012	2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(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	27,484	25,686
Amortization of intangible assets	28,776	29,159
Provision for doubtful accounts	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	1,604,240	28,719
Stock based compensation	1,868,345	190,513
Stock based expense for services	338,457	22,630
Loan guaranty costs	45,036	38,159
Non-cash financing costs	—	25,980
Changes in operating assets and liabilities:		
Accounts receivable	(620,469 )	(16,409 )
Inventory	(1,027,137 )	29,996
Other current assets	42,281	(346,822 )
Accounts payable	1,334,855	188,876
Accrued interest	270,252	33,994
Deferred revenue	1,144,752	—
Accrued expenses and other current liabilities	261,121	560,541
Net cash flows used in operating activities	(12,737,326)	(4,966,596 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(66,405 )	(28,766 )
Patent costs, net of abandoned costs	(206,101 )	(8,870 )
Net cash flows used in investing activities	(272,506 )	(37,636 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from sale of common stock, net of costs	7,895,485	1,000,000
Proceeds from notes and loans payable	8,700,000	2,684,160
Proceeds from exercise of options	191,000	17,250
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

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Proceeds bank line of credit	—	300,000
Repayment of bank line of credit	(300,000 )	—
Repayment of notes payable-related party	(200,000 )	(100,696 )
Repayment of notes payable	(1,850,000 )	(200,000 )
Net cash flows provided by financing activities	14,436,885	4,707,714
Increase (decrease) in cash	1,427,053	(296,518 )
Cash, beginning of period	126,421	422,939
Cash, end of period	\$1,553,474	\$126,421
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	\$17,253	\$696
Cash paid for income taxes	\$—	\$—
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:		
Warrants exercised in exchange for debt and accrued interest	\$3,102,000	\$—
Warrants issued for financing	\$2,509,537	\$148,668
Warrants issued for services	\$1,532,228	\$190,280
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.

## **THERAPEUTICSMMD, INC. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

#### NOTE 1 – THE COMPANY

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

#### Agreement and Plan of Merger with VitaMed

On July 18, 2011, Therapeutics entered into an Agreement and Plan of Merger (“Merger Agreement”) by and among VitaMed and VitaMed Acquisition, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company (the “Merger Sub”), pursuant to which the Company would acquire 100% of VitaMed. The proposed acquisition was to be accomplished by the merger of Merger Sub with and into VitaMed with VitaMed being the surviving limited liability company (the “Merger”) in accordance with the Limited Liability Company Act of the State of Delaware. 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 (the “Effective Date”). In preparation of and prior to the closing of the Merger Agreement, the Company completed the following required corporate actions:

- a reverse split of the Company’s 16,575,209 issued and outstanding shares of Common Stock on a ratio of 1 for 100 (the “Reverse Split”). As a result of the Reverse Split, each share of Common Stock outstanding on July 28, 2011 (the “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 the Company’s 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 the shareholders of the Company;
- an increase of our authorized shares of Common Stock to 250,000,000;
- a change in the name of the Company to TherapeuticsMD, Inc.; and
- an amendment to the Company’s Long Term Incentive Compensation Plan to increase the authorized shares for issuance thereunder to 25,000,000.

On the Effective Date, we acquired 100% of VitaMed in exchange for the issuance of shares of the Company’s Common Stock, as more fully described below (the “Merger”). In accordance with the provisions of this triangulated merger, the Merger Sub was merged with and into VitaMed as of the Effective Date. Upon consummation of the

Merger Agreement and all transactions contemplated therein, the separate existence of the Merger Sub ceased and VitaMed became a wholly owned subsidiary of the Company.

Exchange of Securities

On the Effective Date, all outstanding membership units of VitaMed (the “Units”) were exchanged for shares of the Company’s Common Stock. In addition, all outstanding VitaMed options to purchase VitaMed membership units (the “VitaMed Options”) and all outstanding VitaMed warrants to purchase VitaMed membership units (the “VitaMed Warrants”) were exchanged and converted into options and warrants for the purchase of the Company’s Common Stock (“Company Options” and “Company Warrants,” respectively).

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 1 – THE COMPANY (continued)

Exchange of Securities (continued)

All Units, VitaMed Options and VitaMed Warrants were exchanged on a pro-rata basis for shares of the Company's Common Stock which in the aggregate totaled 70,000,000 shares, resulting in a conversion ratio calculated by the sum of all outstanding Units, VitaMed Options and VitaMed Warrants divided by 70,000,000 (the "Conversion Ratio"). Pursuant to the Conversion Ratio, the Company issued 58,407,331 shares of the Company's Common Stock in exchange for the outstanding Units, reserved for issuance an aggregate of 10,119,796 shares issuable upon the exercise of the Company Options, and reserved for issuance an aggregate of 1,472,916 shares issuable upon the exercise of the Company Warrants. After giving effect to the Reverse Split, and taking into consideration the 58,407,331 aforementioned shares issued in exchange for the Units, the number of shares of the Company's Common Stock issued and outstanding as of the Effective Date was 58,573,187, of which the former members of VitaMed owned approximately 99%. All shares of the Company's Common Stock issued in exchange for the Units, and to be issued upon exercise of the Company Options and Company Warrants, are subject to a lock-up agreement for a period of 18 months from the Effective Date.

Nature of Business

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins.

New Products

In March 2012, we launched our first prescription-only prenatal vitamin, vitaMedMD™ Plus Rx, with subsequent launches of our second prescription-only prenatal vitamin, vitaMedMD™ One Rx in April 2012, and our third prescription-only prenatal vitamin, vitaMedMD™ RediChew™ Rx in May 2012. In the fourth quarter 2012, our BocaGreenMD™ brand was launched and our first products include three prescription products Prena1™ Plus, Prena1™ and

Prena1™ Chew, which are duplicate, or “generic” formulations of our vitaMedMD-branded prescription prenatals

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Cash

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

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Cash (continued)**

Beginning 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, at which time our non-interest bearing cash balances may again exceed federally insured limits. We had no interest-bearing amounts on deposit in excess of federally insured limits at December 31, 2012 and 2011.

**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 more than 90 days to be delinquent. We write-off delinquent receivables to bad debt expense based on individual credit evaluations, results of collection efforts, and specific circumstances of the customer. Recoveries of accounts previously written off are recorded as reductions of bad debt expense when received. Historically, our bad debt expense has been limited because the majority of our trade receivables are paid via credit card. To the extent data we use to calculate these estimates does not accurately reflect bad debts; adjustments to these reserves may be required. At December 31, 2012 and 2011, we recorded an allowance for doubtful accounts of \$42,048 and \$1,500, respectively.

**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, which 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. Maintenance costs, which do not significantly extend the useful lives of the respective assets, and repair costs are charged 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. Depreciation expense totaled \$19,904 and \$23,962 for the years ended December 31, 2012 and 2011, respectively.

*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. Depreciation expense totaled \$7,580 and 1,724 for the years ended December 31, 2012 and 2011, respectively.

Intangible Assets

*Patent and Trademarks*-We have adopted the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 350 *Intangible-Goodwill and Other* (“ASC 350”). Capitalized patent costs, net of accumulated amortization, include legal costs incurred for a patent application. In accordance with ASC 350, once the 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. Intangible assets are reviewed annually for impairment or when events or circumstances indicate that their carrying amount may not be recoverable.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Intangible Assets (continued)

There was no amortization expense related to patent costs for the years ended December 31, 2012 and 2011 as patents have not yet been granted.

*Website Costs*-We expense costs incurred in the planning stage of a website, while costs incurred in the development stage are capitalized and amortized over the estimated three year life of the asset. Amortization of website development costs totaled \$28,776 and \$29,159 for the years ended December 31, 2012 and 2011, respectively.

Impairment of Long-Lived Assets

We review the carrying values of property and equipment and finite-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, but are not limited to, 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.

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. Assessments 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 a loss is recorded 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; however, unanticipated events and changes in market conditions could affect such estimates, resulting in the need for an impairment charge in future periods.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Fair Value of Financial Instruments**

Our financial instruments consist primarily of receivables, accounts payable, accrued expenses, and short-term debt. The carrying amount of receivables, 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. Interest rates that are currently available to us for issuance of short and long-term debt with similar terms and remaining maturities are used to estimate the fair value of our short and long-term debt and 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*” (“ASC 820”). 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.

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

Income Taxes

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. We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. As of December 31, 2012 and 2011, we had no tax positions relating to open tax returns that were considered to be uncertain.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Stock Based Compensation

In December 2004, the FASB issued ASC 718, *Compensation – Stock Compensation* (“ASC 718”). Under ASC 718 companies are required to measure the compensation costs of unit-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. Unit-based compensation arrangements include unit options, restricted share plans, 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. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant. We use the Black-Scholes option pricing model that requires the input of highly complex and subjective variables including the expected life of options granted and our expected stock price volatility over a period equal to or greater than the expected life of the options.

Equity instruments (“instruments”) issued to other than employees are recorded on the basis of the fair value of the instruments, as required by ASC 718. FASB ASC 505, *Equity Based Payments to Non-Employees* 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 compensation expense for all share-based payments granted based on the grant date fair value estimated in accordance with ASC 718-10, “*Share Based Payments.*” Compensation expense is generally recognized on a straight-line basis over the employee’s requisite service period.

Debt Discounts

Costs incurred with parties that are providing long-term financing, which include warrants issued 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. These discounts are generally amortized over the life of the related debt using the effective interest rate method. In

connection with debt issued during the years ended December 31, 2012 and 2011, we recorded debt discounts totaling \$2,706,920 and \$28,719, respectively. The aggregate balance of unamortized debt discount at December 31, 2012 and 2011 was \$1,102,680 and \$0, respectively. Amortization expense related to debt discounts totaled \$1,604,240 and \$28,719 for the years ended December 31, 2012 and 2011, respectively, and is included in amortization of debt discount on the accompanying consolidated financial statements.

### 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.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Revenue Recognition (continued)

Over The Counter Products

We generate OTC revenue by sales of products primarily to retail consumers. Our policy is to recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. Outbound shipping and handling fees are included in sales and are billed upon shipment. Shipping expenses are included in cost of sales. The majority of our sales are paid 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.

For the years ended December 31, 2012 and 2011, we recorded an allowance for returns of \$27,168 and \$0, respectively. We estimate the allowance for returns based on historical return activity, which is reviewed, and adjusted if necessary, on a quarterly basis.

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 and end-user 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 date of manufacture. Given the limited history of prescriptions 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. As a result of this policy, we had a deferred revenue balance of \$1,144,752 and \$0 at December 31, 2012 and 2011, respectively.

We maintain various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The 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 rebates based on industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. For the years ended December 31, 2012 and 2011, we recorded reduction to income for rebates of \$34,255 and \$0, respectively.

#### Shipping and Handling Costs

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

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Advertising Costs

We expense advertising costs when incurred. Advertising expenses totaled \$65,944 and \$19,408 during the years ended December 31, 2012 and 2011, respectively.

Research and Development Expenses

Research and development expenditures, which are expensed as incurred, totaled \$4,492,362 and \$107,241 during the years ended December 31, 2012 and 2011, respectively.

Earnings Per Share

We calculate earnings per share (“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 Common Stock outstanding plus all potentially dilutive common shares outstanding during the period. Such potential dilutive common shares consist of stock options and warrants. Potential common shares totaling 25,926,987 and 13,639,845 at December 31, 2012 and 2011, respectively, have been excluded from the diluted earnings per share calculation as they are anti-dilutive due to the net loss reported by us.

Use of Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of these financial statements requires us to make significant

estimates and judgments that affect the reported amounts of assets, liabilities, revenues, 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 are believed 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 from these estimates under different assumptions or conditions.

#### Recently Issued Accounting Pronouncements

In July 2012, FASB issued Accounting Standards Update (“ASU”) No. 2012-02, “*Testing Indefinite-Lived Intangible Assets for Impairment*” (“ASU 2012-02”). ASU 2012-02 gives entities an option to first assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that the indefinite-lived intangible asset is 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.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Recently Issued Accounting Pronouncements (continued)**

In December 2011, the FASB issued ASU No. 2011-11, “*Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities*” (“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 U.S. GAAP and financial statements prepared on the basis of International Financial Reporting Standards (“IFRS”). ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. ASU 2011-11 is not expected to have a material impact on our financial position or results of operations.

In September 2011, the FASB issued ASU No. 2011-08 *Intangibles – Goodwill & Other* (“ASU 2011-08”), which updates the guidance in Accounting Standards Codification (“ASC”) Topic 350, *Intangibles – Goodwill & Other* (“ASC Topic 350”). The amendments in ASU 2011-08 permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than fifty percent. If, after assessing the totality of events or circumstances, an entity determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. The amendments in ASU 2011-08 include examples of events and circumstances that an entity should consider in evaluating whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. However, the examples are not intended to be all-inclusive and an entity may identify other relevant events and circumstances to consider in making the determination. The examples in this ASU 2011-08 supersede the previous examples under ASC Topic 350 of events and circumstances an entity should consider in determining whether it should test for impairment between annual tests, and also supersede the examples of events and circumstances that an entity having a reporting unit with a zero or negative carrying amount should consider in determining whether to perform the second step of the impairment test. Under the amendments in ASU 2011-08, an entity is no longer permitted to carry forward its detailed calculation of a reporting unit’s fair value from a prior year as previously permitted under ASC Topic 350. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of ASU 2011-08 did not have a material impact on our financial position or results of operations.



**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Recently Issued Accounting Pronouncements (continued)

In May 2011, the FASB issued ASU 2011-04 (“ASU 2011-04”), which updated the guidance in ASC Topic 820, *Fair Value Measurement*. The amendments in ASU 2011-04 generally represent clarifications of Topic 820, but also include some instances where a particular principle or requirement for measuring fair value or disclosing information about fair value measurements has changed. ASU 2011-04 results in common principles and requirements for measuring fair value and for disclosing information about fair value measurements in accordance with U.S. GAAP and IFRS. The amendments in ASU 2011-04 are to be applied prospectively. For public entities, the amendments are effective for interim and annual periods beginning after December 15, 2011. The adoption of ASU 2011-04 did not 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 financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Reclassifications

Certain 2011 amounts have been reclassified to conform to current year presentation.

**NOTE 3 – GOING CONCERN**

The accompanying financial statements have been prepared assuming that our company will continue as a going concern. For the year ended December 31, 2012, we incurred a loss from operations of approximately \$16 million and had negative cash flow from operations of approximately \$13 million. Accumulated deficit as of December 31, 2012 was approximately \$52 million. These matters raise substantial doubt about our ability to continue as a going concern. Our plans include raising additional proceeds from debt and equity transactions and to continue to increase our sales and marketing activities; however, there are no assurances that we will be successful in these efforts. On March 7,

2013 we filed a Prospectus Supplement for an underwritten public offering of our common stock with anticipated gross proceeds of \$50 million. The securities being offered by us are pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (the "SEC") on January 25, 2013, which the SEC declared effective on February 5, 2013. The financial statements do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****NOTE 4 – INVENTORY**

Inventory consists of the following:

	December 31,	
	2012	2011
Finished product	\$1,124,739	\$588,073
Raw material	380,000	-0-
Deferred costs	110,471	-0-
<b>TOTAL INVENTORY</b>	<b>\$1,615,210</b>	<b>\$588,073</b>

**NOTE 5 – OTHER CURRENT ASSETS**

Other current assets consist of the following:

	December 31,	
	2012	2011
Prepaid consulting	\$432,216	\$95,962
Deposits with vendors	189,375	300,503
Prepaid insurance	127,403	52,611
Prepaid guaranty costs	2,944	46,984
<b>TOTAL OTHER CURRENT ASSETS</b>	<b>\$751,938</b>	<b>\$496,060</b>

**NOTE 6 – FIXED ASSETS**

Fixed assets consist of the following:

December 31,



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	2012	2011
Equipment	\$67,668	\$33,650
Furniture and fixtures	46,625	22,169
Leasehold improvements	11,980	4,049
	126,273	59,868
Accumulated depreciation	(60,600)	(33,116)
<b>TOTAL FIXED ASSETS</b>	<b>\$65,673</b>	<b>\$26,752</b>

Depreciation expense for the years ended December 31, 2012 and 2011 was \$27,484 and \$25,686, respectively.

**NOTE 7 -INTANGIBLE ASSETS**

Other assets consist of the following:

	December 31,	
	2012	2011
Patent costs	\$224,971	\$18,870
Website costs, net of amortization of \$77,159 and \$48,383 for the years ended December 31, 2012 and 2011, respectively	14,584	43,361
<b>TOTAL INTANGIBLE ASSETS</b>	<b>\$239,555</b>	<b>\$62,231</b>

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 7 – INTANGIBLE ASSETS (continued)**

Amortization expense for the years ended December 31, 2012 and 2011 was \$28,776 and \$29,159, respectively

**NOTE 8 – OTHER CURRENT LIABILITIES**

Other current liabilities consist of the following:

	December 31,	
	2012	2011
Accrued payroll	\$285,210	\$295,915
Accrued vacation	114,899	68,438
Accrued commission	112,000	-0-
Accrued legal and accounting expense	90,000	15,010
Allowance for coupons and returns	53,002	-0-
Dividends payable <sup>(1)</sup>	41,359	41,359
Other accrued expenses	29,400	45,025
<b>TOTAL OTHER CURRENT LIABILITIES</b>	<b>\$725,870</b>	<b>\$465,747</b>

<sup>(1)</sup> In June 2008, we declared and paid a special dividend of \$0.40 per share of common stock to all shareholders of record as of June 10, 2008. This amount reflects moneys remaining unclaimed by certain shareholders.

**NOTE 9 – NOTES PAYABLE**

Issuance of Promissory Notes

In January and February 2012, we issued 6% promissory notes for an aggregate of \$900,000 with due dates of March 1, 2012. As discussed below, these promissory notes were modified on February 24, 2012 through the issuance of secured promissory notes (the “February 2012 Notes”).

In August and September 2012, we issued 6% promissory notes for an aggregate of \$1,600,000 due on October 1, 2012, which due date was subsequently extended. The 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. The note was paid in full in October 2012.

#### Issuance of February 2012 Notes

On February 24, 2012, we issued and sold the February 2012 Notes to an individual and an entity (the “Parties”), both of which are stockholders of our company, in the principal amount of \$1,358,014 and \$1,357,110 respectively (the “Principal Base Amount(s)”) and granted Warrants for the purchase in the aggregate of 9,000,000 shares of our Common Stock (4,500,000 to each Party) (the “February 2012 Warrants”) pursuant to the terms of a Note Purchase Agreement (the “Note Purchase Agreement”) also dated February 24, 2012. As consideration for the February 2012 Notes and the February 2012 Warrants, we received an aggregate of \$1,000,000 of new funding from the Parties (the “February Funding”), and the Parties surrendered certain promissory notes previously issued by us in the amount of \$1,700,000 plus accrued interest of \$15,124 (collectively known as the “Prior Notes”).

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 9 – NOTES PAYABLE (continued)**

**Issuance of February 2012 Notes (continued)**

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. 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.

We determined the relative fair value of the 3,314,700 Warrants granted with the February Funding to be \$859,647 and recorded the amount as debt discount to be amortized over the term of the February 2012 Notes. As a result of the surrender of the February 2012 Notes on June 19, 2012 (see Issuance of June 2012 Notes below), we expensed the remaining unamortized debt discount. As of December 31, 2012, we recorded amortization of debt discount totaling \$859,647 related to the February 2012 Notes on the accompanying consolidated financial statements.

Under the February 2012 Notes, the Parties loaned us an additional \$3,000,000 during March, April, and May 2012.

On June 19, 2012, we settled \$3,102,000 in principal and interest of the February 2012 Notes in exchange for the exercise of 8,145,486 Common Stock purchase warrants. As discussed below, 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 (the “June 2012 Notes”).

**Issuance of June 2012 Notes**

On June 19, 2012, we issued and sold secured promissory notes (the “June 2012 Notes”) to the Parties in the principal base amounts of \$2,347,128 and \$2,344,719, respectively pursuant to the terms of a note purchase agreement (the “June 2012 Note Purchase Agreement”). As consideration for 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 interest through June 19, 2012), and we received an aggregate of \$2,000,000 of new funding from the Parties (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%, is due in one lump sum payment on February 24, 2014. As security for our obligations under the June 2012 Note Purchase Agreement and the June 2012 Notes, we entered into a Security Agreement and pledged all of our assets, tangible and intangible, as further described therein. We granted 7,000,000 Common Stock purchase warrants in connection with the June Funding.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 9 – NOTES PAYABLE (continued)**

Issuance of June 2012 Notes (continued)

We determined the relative fair value of the 7,000,000 Common Stock purchase warrants to be \$1,649,890 and recorded this amount as a debt discount to be amortized over the term of the June 2012 Notes. In conjunction with the February 2012 Notes and June 2012 Notes, as of December 31, 2012, we recorded an aggregate of \$547,210, as amortization of debt discount on the accompanying consolidated financial statements. At December 31, 2012, we reported a notes payable balance of \$3,589,167, net of debt discount of \$1,102,680 in long-term liabilities on the accompanying consolidated financial statements.

Issuance of Other Promissory Notes During 2011

On March 1, 2011, we entered into a Demand Promissory Note with our then majority stockholder wherein we could periodically borrow funds to satisfy our operational requirements. Interest accrued at 20% per annum. On October 4, 2011, this Demand Promissory Note plus accrued interest totaling \$170,152 was forgiven. The forgiveness of this related party debt was included in additional paid in capital on the accompanying financial statements.

In November and December, 2011, we sold 6% Promissory Notes for an aggregate of \$800,000 with due dates of March 1, 2012. At December 31, 2011, the outstanding principle balance of the Promissory Notes was \$800,000. As discussed above (See Issuance of February 2012 Notes, included in this Note 9) these Notes were paid in full on February 24, 2012 through the issuance of the February 2012 Notes.

Conversion of July 2011 Secured Notes

In July 2011, VitaMed sold two senior secured promissory notes (the “Secured Notes”) in the amount of \$500,000 each and also entered into a security agreement under which VitaMed pledged all of its assets to secure the obligation. The Secured Notes bear interest at the rate of 6% per annum, are due on the one year anniversary thereof, and are

convertible into shares of our Common Stock at our option. We may pay the Secured Notes by delivering such number of shares of our Common Stock as shall be determined by dividing the outstanding principal then due and owing by our Share Price. For purposes of the Secured Notes, the “Share Price” shall mean the lower of the most recent price at which we offered and sold shares of our Common Stock (not including any shares 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 and the Parties agreed to convert the Secured Notes, and according to the terms thereof, aggregated principal and interest through June 19, 2012 of \$1,054,647 was converted at \$0.38 per share into an aggregate of 2,775,415 shares of our Common Stock. This resulted in a beneficial conversion feature of \$6,716,504 as recorded in other income and expense on the accompanying condensed 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.

#### March 2011 Bank Line of Credit

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note with First United Bank (“First United”) for a \$300,000 bank line of credit (the “Bank LOC”) 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 VitaMed, and by Reich Family Limited Partnership,

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 9 – NOTES PAYABLE (continued)**

March 2011 Bank Line of Credit (continued)

an entity controlled by Mitchell Krassan, also an officer of VitaMed. In consideration for the personal guarantees and cash collateral, Common Stock purchase warrants for an aggregate of 613,713 shares were granted (see NOTE 10 for more details). The Bank LOC 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 and 1<sup>st</sup> negotiated a one-year extension to the Bank LOC which was executed on March 19, 2012 (the “Bank LOC Extension”). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and 1<sup>st</sup> United amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit (the “Amended Bank LOC”). In accordance with the Amended Bank LOC, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. During the years ended December 31, 2012 and 2011, interest expense of \$7,366 and \$5,650, respectively, was paid and is included in interest expense on the accompanying consolidated financial statements. We have made no withdrawals against the Amended Bank LOC as of December 31, 2012.

Issuance of VitaMed Promissory Notes

In June 2011, VitaMed sold Promissory Notes (the “VitaMed Promissory Notes”) in the aggregate principal amount of \$500,000. In consideration for the VitaMed Promissory Notes, Warrants for an aggregate of 613,718 shares were granted. The VitaMed Promissory Notes earn interest at the 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 (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 Promissory Notes in the aggregate of \$200,000 were paid in full. By mutual agreement, the remaining VitaMed Promissory Notes in the aggregate of \$300,000 were extended. In October 2011, one of the VitaMed Promissory Notes for \$50,000 was paid in full. Also in October 2011, by mutual agreement, VitaMed Promissory Notes in the aggregate of \$100,000 were converted into 266,822 shares of our Common Stock at \$0.38 per share, which represents the fair value of the shares on the date of conversion. In June 2012, a VitaMed Promissory Note held by an unaffiliated individual was paid in full including \$2,160 in accrued interest. The remaining VitaMed Promissory Notes in the aggregate of \$100,000 were extended to October 15, 2012 (one held by Mr. Milligan for \$50,000 and one for \$50,000 held by BF Investments, LLC (owned by Brian Bernick, a member of the board of directors of the Company)). On October 4, 2012 these VitaMed Promissory Notes were paid in full including \$5,341 in accrued interest.



In September and October 2011, VitaMed sold Convertible Promissory Notes (the “VitaMed Convertible Notes”) in the aggregate of \$534,160. The VitaMed Convertible Notes earned interest at the rate of 4% per annum and were due December 1, 2011. On November 18, 2011, we and the VitaMed Convertible Noteholders entered into Debt Conversion Agreements and 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 represents the fair value of the shares on the date of conversion.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 9 – NOTES PAYABLE (continued)**

Issuance of VitaMed Promissory Notes (continued)

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 Promissory Notes was paid 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.

Conversion of 2010 Demand Promissory Note

During 2009, a non-affiliate business consultant (the "Consultant") provided consulting services to us for \$210,000. We issued the Consultant a demand promissory note for \$210,000 dated November 9, 2010 (the "November 2010 Note"), which was subsequently assigned to non-affiliate entities (the "Noteholders"). On April 18, 2011, we and the Noteholders agreed that in exchange for the forbearance of the Noteholders not to make demand for repayment of the November 2010 Note for a minimum of 60 days, we would (i) cancel the November 2010 Note and (ii) issue two convertible promissory notes to the Noteholders in the principal amount of \$105,000, each bearing interest at the rate of 6% per annum (the "Convertible Notes"). The Convertible Notes were due on demand any time after 60 days from the date of issuance (the "Maturity Date"). At the option of the Noteholders, the Convertible Notes could be converted into shares of our Common Stock at any time after the Maturity Date at a fixed conversion price of \$0.0105 per share. The Conversion Price was not subject to adjustment at any time for any future stock split, stock combination, dividend or distribution of any kind. On October 18, 2011, we and the Noteholders entered into Debt Conversion Agreements and converted the principal of the Convertible Notes into 20,000,000 shares of our Common Stock valued at \$7,600,000. The transaction was recorded as debt settlement expense on the accompanying financial statements.

**NOTE 10 – STOCKHOLDERS' EQUITY**

As discussed in NOTE 1, on October 4, 2011, all Units were exchanged for shares of our Common Stock. In addition, all VitaMed Options and VitaMed Warrants were exchanged and converted into Company Options and Company Warrants. All Units VitaMed Options and VitaMed Warrants were exchanged on a pro-rata basis for shares of our Common Stock, which in the aggregate totaled 70,000,000 shares, resulting in a conversion ratio calculated by the sum of all Units, VitaMed Options and VitaMed Warrants divided by 70,000,000 (the "Conversion Ratio"). Pursuant to the Conversion Ratio, we issued 58,407,331 shares of our Common Stock in exchange for the Units, reserved for issuance an aggregate of 10,119,796 shares issuable upon the exercise of the Company Options, and reserved for issuance an aggregate of 1,472,916 shares issued upon the exercise of the Company Warrants.

### Preferred Stock

At December 31, 2012, we had 10,000,000 shares of Preferred Stock, par value \$0.001 authorized and none outstanding, which shares can be designated by our Board of Directors.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 10 – STOCKHOLDERS' EQUITY (continued)**

**Common Stock**

At December 31, 2012, we had 250,000,000 shares of Common Stock, \$0.001 par value authorized, with 99,784,982 shares of Common Stock issued and outstanding.

During 2012 certain individuals exercised their right to purchase shares of our Common Stock. The shares were issued in reliance upon an exemption from the registration provisions of the Securities Act of 1933 provided by Section 4(1) of the Act and Rule 144 and are covered by a Lock-Up Agreement.

Options to purchase an aggregate of 1,691,393 shares of our Common Stock were exercised for \$191,000.

Using the cashless exercise feature an aggregate of 240,395 Options were exercised, with 26,428 Options surrendered, resulting in the issuance of 240,395 shares of the Company's Common Stock.

During June 2012, we settled \$3,102,000 in principal and interest of the February 2012 Notes in exchange for the Parties' exercise of a portion of the February 2012 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 Securities Act of 1933 provided by Section 4(1) of the Securities Act of 1933 and Rule 144. During June 2012, we and the Parties also agreed to convert a portion of the February 2012 Notes, and according to the terms thereof, principal and interest through June 19, 2012 of totaling \$1,054,647 was converted at \$0.38 per share into 2,775,415 shares of our Common Stock. The shares were issued in reliance upon an exemption from the registration provisions of the Securities Act of 1933 provide by Section 4(1) of the Act and Rule 144.

In September 2012, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with multiple investors (collectively, the "Investors") relating to the issuance and sale of our Common Stock in a private placement. The Purchase Agreement was closed on October 2, 2012 (the "Closing Date") through which we sold an aggregate of 3,953,489 shares of our Common Stock (the "Shares") at \$2.15 per share for an aggregate purchase price of \$8,500,001. In connection with the private placement, Jefferies LLC ("Jefferies") served as our exclusive placement agent. Jefferies

compensation for the transaction was a cash fee of \$552,500, which is included in accounts payable in the accompanying consolidated financial statements. We also paid legal fees and expenses for the Investors in the aggregate of \$52,016, resulting in net proceeds to us of \$7,895,485. The Shares were issued in reliance upon the exemptions from registration under the Securities Act of 1933 provided by Section 4(2) and Rule 506 of Regulation D promulgated thereunder. The Shares were issued directly by us and did not involve a public offering or general solicitation. The Investors in the private placement are “Accredited Investors” as that term is defined in Rule 501 of Regulation D and acquired the Shares for investment only and not with a present view toward, or for resale in connection with, the public sale or distribution thereof. As part of the Purchase Agreement, we agreed to file a registration statement, which was filed November 27, 2012.

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.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 10 – STOCKHOLDERS’ EQUITY (continued)

Common Stock (continued)

On October 5, 2011, we closed a Stock Purchase Agreement with Pernix Therapeutics, LLC, a Louisiana limited liability company (“Pernix”). Pursuant to the terms of the Stock Purchase Agreement dated September 8, 2011, Pernix agreed to purchase 2,631,579 shares of our Common Stock (the “Shares”) at a purchase price of \$0.38 per share for a total purchase price of \$1,000,000 (“Purchase Price”). In connection with the Stock Purchase Agreement, we and Pernix entered into a Lock-Up Agreement that, among other things, restricts the sale, assignment, transfer, encumbrance and other disposition of the Shares issued to Pernix. Pursuant to the terms of the Lock-Up Agreement, Pernix agreed that for a period of 12 months from the date of the Lock-Up Agreement, it would not make or cause any sale of the Shares (the “Lock-Up Period”). After the completion of the Lock-Up Period, Pernix agreed not to sell or dispose of more than 5% of the Shares per quarter for the following 12 month period. Pernix is a related party (for further details see Note 12).

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

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

Warrants

The valuation methodology used to determine the fair value of Common Stock purchase warrants is the Black-Scholes-Merton option-pricing model (“Black-Scholes Model”), an acceptable model in accordance with ASC 718-10. 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 Common Stock purchase warrant.

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As of December 31, 2012, we had Company Warrants outstanding for an aggregate of 12,193,499 shares of our Common Stock (including the conversion of VitaMed Warrants as described above) with a weighted average contractual remaining life of 4.8 years and exercise prices ranging from \$0.24 to \$3.00, per share resulting in a weighted average exercise price of \$1.63 per share. Unamortized costs associated with Company Warrants totaled approximately \$93,000 at December 31, 2012.

During the year ended December 31, 2012, we issued the following:

	Number of Shares Under Company Warrants	Exercise Price	Exercise Term in Years	Fair Value
Debt modification	5,685,300	\$0.38	5	\$ 10,505,247
Issued with debt	10,314,700	\$0.38-\$3.00	5	15,549,855
Services	1,332,500	\$2.40-\$2.80	5	1,563,620
	17,332,500			\$27,618,722

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 10 – STOCKHOLDERS' EQUITY (continued)

Warrants Issued in Conjunction with Debt

On February 24, 2012, we issued an aggregate of 5,685,300 Warrants in connection with the modification of certain existing promissory notes (the "Modification Warrants"), and 3,314,700 Warrants with the issuance of secured promissory notes (the "February 2012 Warrants") (see NOTE 9). Both the Modification Warrants and the February 2012 Warrants are exercisable at \$0.38. The Modification Warrants' fair value of \$10,505,247 and the February 2012 Warrants' fair value of \$6,124,873 were determined by using the Black-Scholes Model on the date of the grant. Both valuations used 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. As of December 31, 2012, we recorded amortization of debt discount totaling \$859,647 related to the February 2012 Notes.

On June 19, 2012, we issued an aggregate of 7,000,000 Warrants in connection with the issuance of secured promissory notes (the "June 2012 Warrants") (see NOTE 9). Of the 7,000,000 June 2012 Warrants, 6,000,000 are exercisable at \$2.00 and 1,000,000 are exercisable at \$3.00. The fair value of the June 2012 Warrants of \$9,424,982 was determined by using the Black-Scholes Model on the date of the grant. The Warrants were valued on the date of the grant 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 grant. At December 31, 2012, \$1,102,680 was reported as debt discount and \$547,210 was recorded as amortization of debt discount on the accompanying consolidated financial statements.

Warrants Issued for Services

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 grant using a term of five years; a volatility of 44.81%; risk free rate of 1.04%; and a dividend yield of 0%; \$29,736 was recorded 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, but not limited to, 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 grant using 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, 2012 we reported \$360,528 as prepaid expense-short term, \$953,655 as prepaid expense-long term, and recorded \$218,045 as consulting expense 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.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**NOTE 10 – STOCKHOLDERS' EQUITY (continued)Warrants Issued for Services (continued)

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 grant 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.

During the year ended December 31, 2011, we issued the following:

	Number of Shares Under Company Warrants	Exercise Price	Exercise Term in Years	Fair Value
Loan guarantee	613,713	\$0.24	10	\$93,969
Loan consideration	613,718	\$0.41	5	30,993
Product consulting	1,045,485	\$0.38-\$0.41	5-10	189,942
Services	784,711	\$0.38-\$1.50	5-10	159,363
	3,057,627			\$474,267

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the "Bank LOC") for which the bank required personal guarantees and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one-year extension to the Bank LOC, which was executed on March 19, 2012 (the "Bank LOC Extension"). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The ten-year Company Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the bank loan is repaid prior to being fully vested, the Company

Warrants will be reissued only for the number of shares vested through the date of repayment. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and the bank amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit (the "Amended Bank LOC"). As part of the Amended Bank LOC, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. In accordance with the terms of the Company Warrants, the Company Warrants previously granted to Mr. Finizio and Mr. Milligan have been amended to reflect the amount vested prior to the date of the Amended Bank LOC (179,000 each). At December 31, 2012, an aggregate of 562,571 Company Warrants were vested.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 10 – STOCKHOLDERS' EQUITY (continued)

Warrants Issued for Services (continued)

The Company Warrants, with a fair value of \$93,969 (\$86,139 after adjusting for the effect of the Amended Bank LOC), were valued on the date of the grant using a term of 10 years; a volatility of 47.89%; risk free rate of 3.48%; and a dividend yield of 0%. As of December 31, 2012 and 2011, \$45,036 and \$38,159, respectively, was recorded as loan guaranty costs in other income and expense on the accompanying consolidated financial statements.

In June 2011, VitaMed issued Promissory Notes (the "VitaMed Promissory Notes") in the aggregate of \$500,000 with accompanying VitaMed Warrants for an aggregate of 500,000 shares (or Company Warrants for an aggregate of 613,718 shares pursuant to the Conversion Ratio). The VitaMed Warrants were valued on the date of the grant using 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 Company 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.

In July 2011, VitaMed entered into a one-year consulting agreement with Lang Naturals, Inc. ("Lang"), providing for Lang to assist in the design, development, and distribution efforts of VitaMed's initial product offering. As compensation, Lang received a VitaMed Warrant for 200,000 shares (or a Company 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 a term of five years; a volatility of 39.44%; risk free rate of 1.56%; and a dividend yield of 0%. The Company Warrant vested immediately. As of December 31, 2012 and 2011, \$6,936 and \$5,612, respectively was recorded as non-cash compensation on the accompanying consolidated financial statements.

In October 2011, we (i) issued a Company Warrant for 600,000 shares with a fair value of \$133,045 to an officer of the Company for services performed. The Company Warrant was valued on the date of the grant using a term of 10 years; volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Company Warrant vests 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). As of December 31, 2012 and 2011, of the \$133,045 fair value, \$36,284 and \$7,158, respectively, was recorded as non-cash compensation on the accompanying consolidated financial statements. The remaining \$89,603 will be expensed to non-cash compensation equitably over the remaining 30 months; (ii) issued a Company Warrant for

184,211 shares with a fair value of \$25,980 to an unrelated entity for consulting services covered under a two month agreement. The Company Warrant was valued on the date of the grant using a term of five years; volatility of 41.04%; risk free rate of 1.08%; and a dividend yield of 0%. As of December 31, 2011, the \$25,980 fair value was recorded as financing expense on the accompanying consolidated financial statements; and (iii), VitaMed entered into a two-year consulting agreement with Lang providing for a Lang representative to help evaluate improvements to existing products and new products as well as services, including but not limited to, research, design, compliance, scientific and regulatory affairs and commercialization of products.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**NOTE 10 – STOCKHOLDERS' EQUITY (continued)Warrants Issued for Services (continued)

As compensation, Lang received a Company Warrant for 800,000 shares. The Company Warrant was valued on the date of the grant using a term of 10 years; a volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Company Warrant vested immediately. Of the \$177,394 fair value, \$88,696 and \$17,010 was recorded as non-cash compensation and \$71,688 and \$160,384 was recorded as prepaid expense as of December 31, 2012 and 2011, respectively, on the accompanying consolidated financial statements.

In December 2011, we issued a Company Warrant for 500 shares with a fair value of \$338 to an unrelated individual for consulting services covered under a three month agreement. The Company Warrant was valued on the date of the grant using a term of 10 years; volatility of 51.83%; risk free rate of 0.91%; and a dividend yield of 0%. The Company Warrant 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.

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

	2012	2011
Weighted average fair value	\$2.05	\$0.16
Risk-free interest rate	0.72-1.04%	0.91-3.48%
Volatility	44.64-44.81%	39.13-51.83%
Term (in years)	5	5-10
Dividend yield	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.

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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 its 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 its stock price during 2001-2012.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**NOTE 10 – STOCKHOLDERS’ EQUITY (continued)Warrants Issued for Services (continued)

A summary of our Common Stock purchase warrant activity and related information for the years ended December 31, 2012 and 2011 follows:

	Number of Shares Under Company Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2010	-0-			
Granted	3,057,627	\$ 0.36	7.9	\$3,483,691
Exercised	-0-			
Expired	-0-			
Cancelled	-0-			
Balance at December 31, 2011	3,057,627	\$ 0.36	7.9	\$3,483,691
Granted	17,332,500	\$ 1.26	4.3	\$31,891,150
Exercised	(8,145,486 )	\$ 0.38		
Expired	-0-			
Cancelled	(51,142 )	\$ 0.24		
Balance at December 31, 2012	12,193,499	\$ 1.63	4.8	\$17,971,994
Vested and Exercisable at December 31, 2012	11,784,408	\$ 1.69	4.7	\$16,859,266

Stock Options

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan (the “2009 Plan”) to provide financial incentives to employees, members of the Board, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash



incentives (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, 2012 there were 11,508,488 shares issued under the 2009 Plan.

On February 23, 2012, our Board of Directors adopted the 2012 Stock Incentive Plan, a non-qualified plan not requiring approval by our stockholders (the “2012 Plan”). 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, 2012 there were 2,225,000 shares issued under the 2012 Plan.

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**THERAPEUTICSMED, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**NOTE 10 – STOCKHOLDERS' EQUITY (continued)Stock Options (continued)

A summary of activity under the 2009 and 2012 Plans and related information follows:

	Number of Shares Under Company Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2010	-0-			
Granted <sup>(1)</sup>	10,682,218	\$ 0.16	7.6	\$14,188,484
Exercised	(92,057 )	\$ 0.19		
Expired	-0-			
Cancelled	-0-			
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	-0-			
Cancelled	(46,135 )			
Balance at December 31, 2012	13,733,488	\$ 1.16	7.7	\$26,804,117
Vested and Exercisable at December 31, 2012	8,370,408	\$ 0.38	6.7	\$22,811,422

<sup>(1)</sup> 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 Company 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 Company Options for 762,235 shares per the Conversion Ratio) and (iii) Company 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 Company Options including the number of shares vested.

The weighted-average grant date fair value of Company Options granted during the years ended December 31, 2012 and 2011 was \$1.16 and \$0.16, respectively.

As of December 31, 2012 and 2011, Company Options outstanding covered an aggregate of 13,733,488 and 10,590,161 shares, respectively, with a weighted average contractual life of 7.7 and 7.6 years, respectively, and exercise prices ranging from \$2.20 to \$3.40 per share in 2012 and \$0.10 to \$1.22 per share in 2011 resulting in a weighted average exercise price of \$1.16 and \$0.16 per share, respectively.

The valuation methodology used to determine the fair value of Company Options is the Black-Scholes-Merton option-pricing model ("Black-Scholes Model"), an acceptable model in accordance with ASC 718-10. 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.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**NOTE 10 – STOCKHOLDERS' EQUITY (continued)Stock Options (continued)

The assumptions used in the Black-Scholes Model during the years ended December 31, 2012 and 2011 and are set forth in the table below.

	2012	2011
Risk-free interest rate	0.61-2.23%	0.91-2.54%
Volatility	40.77-46.01%	37.92-40.48%
Expected life (in years)	5-6.25	5.5-6.25
Dividend yield	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 its 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 its stock price during 2001-2011. The average expected life is based on the contractual term of the option using the simplified method.

Share-based compensation expense for Company Options recognized in our results for the years ended December 31, 2012 and 2011 (\$1,832,062 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, 2012 and 2011, total unrecognized estimated compensation expense related to non-vested Company Options granted prior to that date was approximately \$4,391,000 and \$244,000, respectively, which is expected to be recognized over a weighted-average period of 1.8 years. No tax benefit was realized due to a continued pattern of operating losses.

**NOTE 11- 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. Deferred income taxes are determined using the liability method for the temporary differences between the financial reporting basis and income tax basis of our assets and liabilities. Deferred income taxes are measured based on the tax rates expected to be in effect when the temporary differences are included in our tax return. Deferred tax assets and liabilities are recognized based on anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. For the years December 31, 2012 and 2011, there was no provision for income taxes, current or deferred.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****NOTE 11– INCOME TAXES (continued)**

At December 31, 2012 and 2011, we had a net operating loss carry forward of approximately \$14,900,000 and \$2,100,000 million, respectively, available to offset future taxable income through 2032.

At December 31, 2012 and 2011, we had state net operating loss carryforwards of approximately \$12,800,000 and \$25,000, respectively, available to offset future losses through 2032. 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 financial statements consist of the following:

	2012	2011
Deferred Income Tax Assets:		
Net operating losses	\$5,920,861	\$748,404
Valuation allowance	(5,920,861)	(748,404)
Deferred Income Tax Assets, net	\$-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 for federal income tax purposes.

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

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

**NOTE 12 – RELATED PARTIES**

Loan Guaranty

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the “Bank LOC”) for which the bank required personal guarantees and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one year extension to the Bank LOC which was executed on March 19, 2012 (the “Bank LOC Extension”).

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 12 – RELATED PARTIES (continued)**

Loan Guaranty (continued)

The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The Company Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the bank loan is repaid prior to being fully vested, the Company Warrants will be reissued only for the number of shares vested through the date of repayment. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and the Company and the bank amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit (the “Amended Bank LOC”). As part of the Amended Bank LOC, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. In accordance with the terms of the Company Warrants, the Company Warrants previously granted to Mr. Finizio and Mr. Milligan have been amended to reflect the amount vested prior to the date of the Amended Bank LOC (179,000 each). At December 31, 2012, an aggregate of 562,571 Company Warrants were vested.

Loans from Affiliates

In June 2011, VitaMed issued Promissory Notes (the “VitaMed Promissory Notes”) in the aggregate principal amount of \$500,000 of which \$100,000 was sold to affiliates (the “Affiliate Notes”). 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 (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 Promissory Notes was paid in full including \$1,519 in accrued interest.



Lock Up Agreements

As required by of the Merger Agreement, a Lock Up Agreement (“Agreement”) was entered into between us and security holders covering the aggregate of 70,000,000 shares of our Common Stock issued pursuant to the Merger or reserved for issuance pursuant to Company Options and Company Warrants. Each security holder agreed that from the date of the Agreement until 18 months thereafter (the “Lock-Up Period”), they would not make or cause any sale of our securities. After the completion of the Lock-Up Period, the security holder agreed not to sell or dispose of more than 2.5% of the aggregate Common Stock or shares reserved for issuance for Company Options and Company Warrants per quarter over the following 12 month period (the “Dribble Out Period”). Upon the completion of the Dribble Out Period, the Agreements shall terminate.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 12 – RELATED PARTIES (continued)**

Purchases by Related Parties

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

Agreements with Pernix Therapeutics, LLC

On February 29, 2012, Cooper C. Collins, President and largest shareholder of Pernix Therapeutics, LLC (“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 and will continue to enter 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, 2012 and 2011, we made purchases of approximately \$404,000 and \$19,000, respectively, from Pernix. At December 31, 2012 and 2011, there were amounts due Pernix of approximately \$308,000 and 19,000 outstanding, respectively.

Warrants assigned to Related Party

In June 2012, a 100,000 Company Warrant was assigned to the son of 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 76% and 95% of our purchases from one supplier for the years ended December 31, 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. For the year ended December 31, 2012, 28% of our recognized revenue 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 and distribution facilities in Boca Raton, Florida pursuant to a 45 month non-cancelable operating lease expiring in 2013. The lease stipulates, among other things, base monthly rents ranging from \$5,443 to \$5,933 over the term of the lease plus our share of monthly estimated operating expenses of \$3,500 and sales tax. The lease expires May 31, 2013 and we believe we will be able to extend the lease in a manner adequate to meet our current needs.

The rental expense related to this lease totaled \$106,315 and \$122,752 for the years ended December 31, 2012 and 2011, respectively. Future minimum rental payments through May 31, 2013 total \$29,667.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 14- COMMITMENTS AND CONTINGENCIES (continued)**

Employment Agreements

On November 8, 2012, the Compensation Committee of our Board of Directors recommended that the Board of Directors approve employment agreements with our executive officers, namely: Chief Executive Officer (Robert G. Finizio), President (John C.K. Milligan, IV) and Chief Financial Officer (Daniel A. Cartwright) (each an “Executive; together the “Executives”). Our Board of Directors approved the Employment Agreements with an effective date of November 8, 2012. With the exception of compensation, the three-year employment agreements are substantially the same with the Executives receiving employee benefits, vacation and other perquisites as may be determined from time to time and an automatic renewal option for one additional year. Conditions of termination for all employment agreements call for (i) termination immediately upon death, (ii) termination upon a disability in which the Executive is unable to perform his duties for more than 180 total calendar days during any 12-month period, (iii) voluntary termination by the Executive upon a 14 calendar day prior notice, (iv) involuntary termination by our company without cause with 60-day notice or 90-day notice when termination is due to the non-extension of the employment term by our company, (v) termination for cause and (vi) termination for good reason wherein the Executive shall have 90 days from the date of notice to terminate his employment. In addition, if we are subject to a change in control, the Executive shall be entitled to receive severance benefits as outlined therein. The employment agreements contain standard provisions for confidentiality and noncompetition.

Compensation for services rendered by Robert G. Finizio as Chief Executive Officer calls for: (i) a time-based ten-year stock option (the “Time-Based Option”) granted and issued on November 30, 2012 (“Date of Grant”) to purchase 900,000 shares of our Common Stock with the exercise price equal to the closing price of our Common Stock on the Date of Grant with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a performance-based ten-year stock option (the “Performance-Based Option”) in an amount to be determined, (iii) a base salary of not less than \$355,100 per year and (iv) an annual short-term incentive compensation bonus of up to 35% of the base salary, at the discretion of our Board of Directors.

Compensation for services rendered by John C.K. Milligan, IV as President calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 800,000 shares of our Common Stock with the exercise price equal to the closing price of our Common Stock on the Date of Grant with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$288,100 per year and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of our Board of Directors.

Compensation for services rendered by Daniel A. Cartwright as Chief Financial Officer calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 700,000 shares of our Common Stock with the exercise price equal to the closing price of our Common Stock on the Date of Grant with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$257,100 per year and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of our Board of Directors.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 14- COMMITMENTS AND CONTINGENCIES (continued)**

Employment Agreements (continued)

The employment agreements provide that as soon as reasonably practicable, we shall file a Form S-8 registration statement, subsequent to any S-1 or S-3 registration statement, to register the issuance of shares under the Time-Based Options.

In addition, should we experience a change in control, the executives are entitled to receive severance benefits in conjunction with a qualifying termination or Change in Control (“CIC”) Severance Benefits. A qualifying termination includes the occurrence of any one or more of the following events on or after the date of the announcement of a transaction which would lead to a change in control and up to 12 months following the date of the change of control shall trigger the payment of CIC Severance Benefits: (a) an involuntary termination of the Executive’s employment by us for reasons other than cause, death or disability, and (b) the voluntary termination by the Executive for Good Reason as evidenced by a Notice of Termination delivered to the us by the Executive. CIC Severance Benefits include (i) an amount equal to 1.0 to 1.5 times the Executive’s annual Base Salary established for the fiscal year in which the termination occurs, (ii) an amount equal to 1.0 to 1.5 times the Executive’s Targeted Annual Bonus Award established for the fiscal year in which the termination occurs, (iii) an amount equal to the Executive’s unpaid Base Salary and accrued but unused vacation pay through the date of termination, (iv) all outstanding long-term incentive awards shall accelerate and become fully vested, (v) a continuation of the welfare benefits of health care, life and accidental death and dismemberment, and disability insurance coverage for 1.0 to 1.5 years after the termination. The payment of the CIC Severance Benefits mentioned herein shall be paid in cash to the Executive in a single lump sum within sixty (60) days of termination.

Litigation

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

*Aceto Corporation*

On November 13, 2012, Aceto Corporation filed a lawsuit against our company in the United States District Court for the Southern District of Florida. The lawsuit alleges, among other things, that we are improperly obtaining and using the Quatrefolic product and related trademarks that we have acquired pursuant to an allegedly invalid sublicense with Pernix Therapeutics, LLC, a subsidiary of Pernix Therapeutics Holdings, Inc., or Pernix. Cooper C. Collins, a member of our Board of Directors, is the President, Chief Executive Officer, and a director of Pernix. The lawsuit seeks to enjoin us from using the Quatrefolic products and trademarks, in addition to unspecified actual and punitive damages. We filed a motion to dismiss on January 2, 2013, as amended on February 27, 2013. Based on our initial assessment of the case which is in the pre-discovery stage, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 14- COMMITMENTS AND CONTINGENCIES (continued)**

Litigation (continued)

*Avion Pharmaceuticals, LLC*

On November 30, 2012, Avion Pharmaceuticals, LLC (“Avion”), filed a lawsuit against our company in the United States District Court for the Northern District of Georgia. The lawsuit alleges, among other things, unfair competition and trademark infringement against Avion’s “Prenate” trademarks based on the use of our Prenal branded products which we launched in November 2012. The lawsuit seeks to enjoin us from using the Prenal name, in addition to unspecified actual and punitive damages. We filed an answer and counterclaim on January 17, 2013, as amended on February 27, 2013. Based on our initial assessment of the case which is in the early discovery stage, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

**NOTE 15 – SUBSEQUENT EVENTS**

Revolving Credit Note

On January 31, 2013, we issued a Multiple Advance Revolving Credit Note (the “Note”) to Plato and Associates, LLC, a Missouri limited liability company (“Plato”). The Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum (the “Stated Interest Rate”). Plato may make advances to us from time to time under the Note at our request, which advances will be of a revolving nature and may be made, repaid, and made from time to time. Interest payments shall be due and payable on the tenth day following the end of each calendar quarter in which any interest is accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Note, together with all accrued interest and other amounts payable under the Note, if any, will be due and payable on February 24, 2014. The default interest rate under the Note will be a per annum rate equal to the Stated Interest Rate plus eight percentage points (the “Default Interest Rate”), and the principal amount outstanding under the Note shall bear interest at the Default Interest Rate upon the occurrence of an event of default as specified in the Note, including, our nonpayment of amounts due under the Note or our failure to comply with any



provision of the Note, among others.

As additional consideration for the Note, we issued Plato a warrant to purchase 1,250,000 shares of our Common Stock at an exercise price \$3.20 per share (the "Warrant"). The Warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to the January 31, 2019 expiration date of the Warrant. These Warrants, with a fair value of approximately \$1.7 million, were valued on the date of the grant using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. As of March 7, 2013 we had drawn \$200,000 from this Note.

#### March 2013 Prospectus Supplement

On March 7, 2013 we filed a Prospectus Supplement for an underwritten public offering of our common stock with anticipated gross proceeds of \$50 million. The securities being offered by us are pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (the "SEC") on January 25, 2013, which the SEC declared effective on February 5, 2013. We intend to use the proceeds of the offering for general corporate purposes, including funding our Phase 3 clinical trials for our proposed hormone therapy products. Jefferies LLC is acting as sole book-running manager for the offering, and Noble Financial Capital Markets is acting as co-manager for the offering.