

TherapeuticsMD, Inc.  
Form 424B3  
March 12, 2013

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Filed Pursuant to Rule 424(b)(3)  
Registration No. 333-185156

Prospectus Supplement No. 1 dated March 12, 2013  
(To Prospectus dated December 12, 2012)

3,953,489 Shares

Common Stock

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This Prospectus Supplement supplements and amends the Prospectus dated December 12, 2012 (the "Prospectus"), relating to the resale of up to 3,953,489 outstanding shares of common stock of TherapeuticsMD, Inc. (the "Company") by the selling stockholders identified in the Prospectus.

This Prospectus Supplement is being filed to include the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2012, filed by the Company with the Securities and Exchange Commission on March 12, 2013 (the "Form 10-K"). The Form 10-K is attached hereto.

This Prospectus Supplement is not complete without, and may not be delivered or utilized except in connection with the Prospectus, including any supplements and amendments thereto. This Prospectus Supplement should be read in conjunction with the Prospectus, which is to be delivered with this Prospectus Supplement. This Prospectus Supplement is qualified by reference to the Prospectus, except to the extent that the information in this Prospectus Supplement updates or supersedes the information contained in the Prospectus, including any supplements and amendments thereto.

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See "Risk Factors" beginning on page 5 of the Prospectus to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of the Prospectus. Any representation to the contrary is a criminal offense.

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The date of this Prospectus Supplement is 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):

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

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(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,” “expect,” and “may be,” or the 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 use