TherapeuticsMD, Inc.
Form 424B3
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Registration No. 333-185156

PROSPECTUS

3,953,489 Shares

Common Stock

This prospectus relates to the resale of up to 3,953,489 shares of common stock of TherapeuticsMD, Inc. ("Therapeutics"). The shares of common stock will be offered for resale by certain stockholders of Therapeutics listed in this prospectus (the "Selling Stockholders").

The shares of common stock to which this prospectus relates may be sold from time to time by and for the accounts of the Selling Stockholders named in this prospectus or in supplements to this prospectus. The Selling Stockholders may sell all or a portion of these shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices.

We will not receive any of the proceeds from the sale of the shares of common stock offered by the Selling Stockholders.

Our common stock is quoted on the OTCQB under the symbol "TXMD." On December 7, 2012, the reported closing price of our common stock on the OTCQB was $2.99 per share.

See "Risk Factors" beginning on page 5 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 this prospectus. Any representation to the contrary is a criminal offense.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the "SEC" or the "Commission") utilizing a shelf registration process. Under this shelf registration process, the Selling Stockholders may, from time to time, offer and sell shares of our common stock pursuant to this prospectus. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus supplement before making a decision whether to invest in the common stock.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus and any applicable prospectus supplement or amendment. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in our common stock. You should read this entire prospectus carefully, including "Risk Factors" and our financial statements and related notes. Unless the context otherwise requires, the terms "Therapeutics," "TXMD," "Company," "we," "us," or "our" refer to TherapeuticsMD, Inc., a Nevada corporation, and its subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation, or BocaGreen.

The Company

Our Business

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

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

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

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:

- focusing 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;

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

- maintaining a marketing emphasis on large group OB/GYN practices that provide opportunities to large patient bases and that are receptive to the data and savings we provide that facilitate them in negotiating contracts with insurance companies;

- pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and the Internet;

- expanding 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; and

- introducing new products to build upon our introduction of our first three prescription products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012 as well as our proposed hormone replacement products.

Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

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

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

- 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.

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

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

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

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

The Offering

Common stock offered by the Selling Stockholders	3,953,489 shares
Common stock outstanding	99,784,982 shares. This number does not include 10,928,695 shares of common stock reserved for issuance upon exercise of stock options and 12,244,641 shares of common stock reserved for issuance upon exercise of stock purchase warrants outstanding as of September 30, 2012.
Use of proceeds	We will not receive any of the proceeds from the sale of shares to be offered by the Selling Stockholders.
OTCQB Symbol	TXMD

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. The Company maintains websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and bocagreenmd.com. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

Summary Consolidated Financial and Other Data

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statements of operations for the years ended December 31, 2010 and 2011, and the consolidated balance sheet data as of December 31, 2010 and 2011, are derived from our audited consolidated financial statements included in this prospectus. The consolidated statement of operations for the nine months ended September 30, 2011 and 2012 and the balance sheet data as of September 30, 2012 are derived from our unaudited consolidated financial statements included in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements.

	Fiscal Year Ended December 31,		Nine Months Ended September 30,	
	2010	2011	2011	2012
	(in thousands, except share data)			
Consolidated Statements of Operations Data:				
Revenue, net	$1,242	$2,088	$1,534	$2,577
Cost of goods sold	556	947	684	1,015
Gross profit	686	1,141	849	1,562
Operating expense:				
Sales, general, and administration	3,465	6,406	3,819	9,692
Research and development	65	107	256	2,579
Depreciation and amortization	23	55	41	44
Total operating expense	3,553	6,568	4,116	12,315
Operating loss	(2,867)	(5,427)	(3,266)	(10,753)
Other income (expense)				
Loss on extinguishment of debt	–	–	–	(10,505)
Settlement of debt	–	(7,390)	–	–
Beneficial conversion feature	–	–	–	(6,717)
Amortization of debt discount	–	(29)	(18)	(1,159)
Interest expense	–	(35)	(17)	(226)
Loan guaranty costs	–	(38)	(26)	(35)
Miscellaneous income	–	6	–	2
Total other income (expense)	–	(7,486)	(61)	(18,640)
Loss before taxes	(2,867)	(12,913)	(3,328)	(29,393)
Provision for income taxes	–	–	–	–
Net loss	$(2,867)	$(12,913)	$(3,328)	$(29,393)
Net loss per share, basic and diluted:				
Net loss per share, basic and diluted	$(0.07)	$(0.21)	$(0.06)	$(0.33)
Weighted average number of common shares outstanding	38,289,463	62,516,461	57,275,797	88,892,757
Consolidated Balance Sheet Data (at end of period):				
Total assets	$1,197	$1,439	$1,222	$3,515
Total liabilities	$233	$3,151	$2,602	$7,849

Total stockholders' equity (deficit)	$964	$(1,712)	$(1,380)	$(4,334)
Other Data:				
Capital expenditures	$27	$38	$29	$157
Working capital (deficit) (at end of period)	$826	$(1,913)	$(1,526)	$(2,196)
Net cash provided by (used in)				
Operating activities	$(2,844)	$(4,967)	$(3,082)	$(8,399)
Investing activities	$(27)	$(38)	$(39)	$(489)
Financing activities	$3,171	$4,708	$2,852	$8,916

RISK FACTORS

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

Risks Related to Our Business

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

We have incurred recurring net losses, including net losses of $2.9 million and $12.9 million for the years ended December 31, 2010 and 2011, respectively, and $29.4 million for the nine months ended September 30, 2012. As of September 30, 2012, we had an accumulated deficit of approximately $46.4 million. We have generated limited revenue and have funded our operations to date primarily from private sales of equity and debt securities. We expect to incur substantial additional losses over the next several years as our research, development, and clinical trial activities increase, especially those related to our proposed hormone replacement products. As a result, we may never achieve or maintain profitability until we successfully commercialize our products, in particular, our proposed hormone replacement products. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

Our independent registered public accounting firms, in their audit reports related to our financial statements for the years ended December 31, 2011 and 2010, expressed substantial doubt about our ability to continue as a going concern.

As a result of our continued losses, our independent registered public accounting firms have included an explanatory paragraph in their reports on our financial statements for the years ended December 31, 2011 and 2010, expressing substantial doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our independent registered public accounting firms may make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we might obtain.

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

We currently derive all of our revenue from sales of women's health products, including prenatal and women's multi-vitamins, iron supplements, Vitamin D supplements, natural menopause relief, and scar reduction creams. While sales of our vitamin products grew from 2010 to 2011, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic versions of our prescription products;
    - any supply or distribution problems arising with any of our manufacturing and distribution partners;

- changed or increased regulatory restrictions or regulatory actions by the U.S. Food and Drug Administration, or FDA;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal healthcare programs;
- the impact or efficacy of any price increases we may implement in the future;
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

If prescription and over-the-counter, or OTC revenue from sales of our existing products do not continue or increase, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects, or we may not be able to commence or continue clinical trials in order to commercialize our proposed hormone replacement products or other product candidates.

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

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

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

Our future success will depend in large part on our ability to commercialize our three proposed hormone replacement products for women designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes, osteoporosis, and vaginal dryness. Although we have received Investigational New Drug applications acceptance by the FDA for our proposed hormone replacement therapy products, we may not be able to complete the development, obtain necessary FDA approval, or commercialize any of these proposed products. The failure to commercialize or obtain necessary approval for any one or more of these products would substantially harm our prospects and our business.

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

We need substantial amounts of cash to complete the clinical development of our proposed hormone replacement products. We currently estimate the cost of our research and development activities through the completion of our phase 3 trials will be approximately $18.0 million for TX12001HRT, will be approximately $6.5 million for TX12002HRT, and will be approximately $6.5 million for TX12003HRT. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We do not have currently any committed external source of funds. We will attempt to raise additional capital from the issuance of equity and/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 replacement 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 replacement products that we otherwise would seek to develop or commercialize ourselves.

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

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

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

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned New Drug Applications, or NDAs, for substantive review or may conclude after review of our data that our applications are insufficient to obtain regulatory approval of any of our proposed hormone replacement products, or it may require that we conduct additional clinical or manufacturing validation studies, which may be costly, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA or application that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our proposed hormone replacement products, generating revenue from our proposed hormone replacement 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 replacement products, which would materially adversely affect our business and could potentially cause us to cease operations.

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

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

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

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

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

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredient, or API; or
- delays resulting from negative or equivocal findings of the data safety monitoring board, or DSMB, for a trial.

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

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

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

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

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

In addition, we do not employ the personnel of our CROs, and we cannot control whether or not they will devote sufficient time and resources to our on-going clinical, non-clinical, and pre-clinical programs. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our proposed hormone replacement products that we seek to develop. As a result, our financial results and the commercial prospects for our proposed hormone replacement 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 replacement products. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations, or prospects.

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

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

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

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

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

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

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

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

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

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

We do not have the resources to independently conduct research and development activities; therefore, we rely on third parties, such as CROs, to conduct all of our research and development activities and expect to continue to do so in the future. Because we rely on such third parties, we have less direct control over those activities and cannot assure you that the research will be done properly or in a timely manner, or that the results will be reproducible. If any of our relationships with these third-parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such organizations, we cannot control whether or not they devote sufficient time and resources to our on-going programs. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines and can increase our costs significantly. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture our existing women's health products or our proposed hormone replacement products for use in the conduct of our clinical trials. We employ the services of third parties to manufacture our products for sale and to supply the finished product for the clinical trials for our proposed hormone replacement products. These third parties manufacture the products according to our specifications under our proprietary rights. Although we do not have long-term contracts for the commercial supply of our products or our proposed hormone replacement products, we intend to eventually pursue long-term manufacturing agreements. However, we may not be able to negotiate such agreements on acceptable terms, if at all.

In addition, regulatory requirements could pose barriers to the manufacture of our products, including our proposed hormone replacement products. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers must be approved by the FDA. We do not control the manufacturing process of our existing products or our proposed hormone replacement products and are completely dependent on these third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of the products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for the commercial manufacture of our existing products or our proposed hormone replacement 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 replacement products. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMP regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations, and prospects.

Finally, we also could experience manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our products and product candidates or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier of the product for our proposed hormone replacement 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 replacement products, which could impair our ability to supply our proposed hormone replacement 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 replacement products that we develop, if approved in the future, will depend upon gaining and retaining significant market acceptance of these products among physicians and payors.

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

- the clinical indications for which the product is approved;
- acceptance by physicians and payors of each product as a safe and effective treatment;

- the cost of treatment in relation to alternative treatments, including numerous generic drug products;
- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of adequate reimbursement by third parties, such as insurance companies and other health care payors, and/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 replacement 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 replacement products if approved, face significant competition from branded and generic products, and our operating results will suffer if we fail to compete effectively.

Development and awareness of our brand will depend largely upon our success in increasing our customer base. The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our products, including any proposed hormone replacement that are approved, face intense competition, including from major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. Many of these companies have greater financial and other resources, such as larger research and development staffs and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly and may be more effective in selling and marketing their products. They also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we sell or develop obsolete. As a result, our competitors may succeed in commercializing products before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If we are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed.

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

Market acceptance and sales of our products, including any approved hormone replacement products, will depend on reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for our products, including any approved hormone replacement products. Also, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete with our existing products or commercialize our proposed hormone replacement products.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

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

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

We face an inherent risk of product liability as a result of the clinical testing of our proposed hormone replacement products despite obtaining appropriate informed consents from our clinical trial participants, and will face an even greater risk if we commercialize our proposed hormone replacement 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 replacement products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in any of the following:

- decreased demand for our products or product candidates that we may develop;
- loss of revenue;
- injury to our reputation;
- withdrawal of clinical trial participants;

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

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

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

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

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

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

We are subject to extensive and costly government regulation.

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

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

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

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

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

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

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets where 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 discover, develop, and commercialize drug candidates will be limited.

Our success is tied to our distribution channels.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

If our efforts to protect the proprietary nature of the intellectual property related to our proposed hormone replacement 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 replacement 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 our 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;

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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 replacement products. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the U.S. Patent and Trademark Office, or USPTO, or applicable foreign patent regulatory authorities, as applicable, to determine our rights in the invention, which may be time-consuming and expensive. Moreover, issued patents may be challenged during post-grant proceedings brought by a third party or the USPTO, or in foreign countries, or in the courts. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we or our licensors or partners fail to obtain and maintain patent protection for our product candidates, 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 replacement products or other product candidates may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely effect our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our 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 and 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 replacement products;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our proposed hormone replacement 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 replacement products;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate product supply for our proposed hormone replacement 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 partners' commercialization efforts;
- 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 perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- developments concerning our sources of manufacturing supply and any commercialization partners;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;

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

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

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

At September 30, 2012, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 70% of our common stock on an as-if converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. All statements other than statements of historical fact contained in this prospectus, including statements regarding our future operating results and financial position, business strategy, and plans and objectives of management for future operations, are forward-looking statements. In many cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes,' "predicts," "potential," or "continue" or the negative of these terms or other similar expressions.

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

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

- the impact of product liability lawsuits;
- unfavorable publicity or lack of customer acceptance;
- our use of hazardous or biological materials in violation of applicable law;
- our reliance on our executive officers and key personnel;
- our ability to expand our direct sales force;
- our dependence on certain customers and distribution channels;
- our ability to maintain optimal inventory levels;

- our response to changing consumer preferences and demand;
- product recalls;
- our inability to manage our growth;
- the conduct of our employees;
- our ability to protect our intellectual property and not infringe on the intellectual property of others; and
- our ability to establish and maintain proper internal controls and comply with the financial reporting obligations of the SEC and Sarbanes-Oxley.

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

MARKET, INDUSTRY, AND OTHER DATA

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

USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock by the Selling Stockholders. The Selling Stockholders will pay all selling commissions and fees and expenses of their legal counsel incurred by them in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the issuance and registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, exchange fees and fees and expenses of our legal counsel and our accountants.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock has been listed on the OTCQB 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 and were not adjusted to reflect the 1:100 Reverse Split that was effective on October 3, 2011.

	High	Low
2012		
Fourth Quarter (through December 7, 2012)	$ 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	$ 0.01
Third Quarter	$ 0.04	$ 0.01
Second Quarter	$ 0.07	$ 0.01
First Quarter	$ 0.10	$ 0.02
2010		
Fourth Quarter	$ 0.15	$ 0.03
Third Quarter	$ 0.90	$ 0.06
Second Quarter	$ 1.34	$ 0.25
First Quarter	$ 1.60	$ 0.10

On December 7, 2012, the closing bid price for our common stock was $2.99 per share.

Transfer Agent

Computershare Trust Co., Inc. is the transfer agent and registrar for our common stock.

Holders

On November19, 2012, we had 346 holders of record of our common stock.

Dividend Policy

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. Some of our current debt agreements prohibit us from paying dividends without the consent of our lenders.

SELECTED CONSOLIDATED FINANCIAL AND OTHER DATA

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statements of operations for the years ended December 31, 2010 and 2011, and the consolidated balance sheet data as of December 31, 2010 and 2011, are derived from our audited consolidated financial statements included in this prospectus. The consolidated statement of operations for the nine months ended September 30, 2011 and 2012 and the balance sheet data as of September 30, 2012 are derived from our unaudited consolidated financial statements included in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements.

	Fiscal Year Ended December 31,		Nine Months Ended September 30,	
	2010	2011	2011	2012
	(in thousands, except share data)			
Consolidated Statements of Operations Data:				
Revenue, net	$1,242	$2,088	$1,534	$2,577
Cost of goods sold	556	947	684	1,015
Gross profit	686	1,141	849	1,562
Operating expense:				
Sales, general, and administration	3,465	6,406	3,819	9,692
Research and development	65	107	256	2,579
Depreciation and amortization	23	55	41	44
Total operating expense	3,553	6,568	4,116	12,315
Operating loss	(2,867)	(5,427)	(3,266)	(10,753)
Other income (expense)				
Loss on extinguishment of debt	–	–	–	(10,505)
Settlement of debt	–	(7,390)	–	–
Beneficial conversion feature	–	–	–	(6,717)
Amortization of debt discount	–	(29)	(18)	(1,159)
Interest expense	–	(35)	(17)	(226)
Loan guaranty costs	–	(38)	(26)	(35)
Miscellaneous income	–	6	–	2
Total other income (expense)	–	(7,486)	(61)	(18,640)
Loss before taxes	(2,867)	(12,913)	(3,328)	(29,393)
Provision for income taxes	–	–	–	–
Net loss	$(2,867)	$(12,913)	(3,328)	$(29,393)
Net loss per share, basic and diluted:				
Net loss per share, basic and diluted	$(0.07)	$(0.21)	$(0.06)	$(0.33)
Weighted average number of common shares outstanding	38,289,463	62,516,461	57,275,797	88,892,757
Consolidated Balance Sheet Data (at end of period):				
Total assets	$1,197	$1,439	$1,222	$3,515

Total liabilities	$233	$3,151	$2,602	$7,849
Total stockholders' equity (deficit)	$964	$(1,712)	$(1,380)	$(4,334)
Other Data:				
Capital expenditures	$27	$38	$29	$157
Working capital (deficit) (at end of period)	$826	$(1,913)	$(1,526)	$(2,196)
Net cash provided by (used in)				
Operating activities	$(2,844)	$(4,967)	$(3,082)	$(8,399)
Investing activities	$(27)	$(38)	$(39)	$(489)
Financing activities	$3,171	$4,708	$2,852	$8,916

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Company Overview

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

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

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

Our Common Stock is traded on the OTCQB under the symbol "TXMD." We maintain websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com and www.bocagreenmd.com.

Recent Developments

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, which we refer to as 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 for of an aggregate of 9,000,000 shares (4,500,000 to each Party), which we refer to as 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, which we refer to as 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 condensed consolidated financial statements as of and for the period ending September 30, 2012 included in this prospectus for more details.

Under the February 2012 Notes, the Parties loaned us an additional $2,000,000 during March, April, and May 2012.

On June 19, 2012, we settled $3,102,000 in principle 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, which we refer to as 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, which we refer to as 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 condensed consolidated financial statements as of and for the period ending September 30, 2012 included in this prospectus 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, which we refer to as 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. This extension accrues interest at the rate of 2.35% and is due on March 1, 2013. At September 30, 2012, the outstanding principle balance of the Bank LOC was $299,220.

Repayment of VitaMed Promissory Notes

In June 2011, VitaMed sold promissory notes, which we refer to as 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 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 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), 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 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.

New Products

We filed three INDs in 2012, all of which have been accepted by the FDA for hormone therapy. These proposed hormone replacement therapy products are known as TX12001HR, a combined progestin and estrogen drug candidate, TX12002HR, a progestin only drug candidate and TX12003HR, an estrogen only drug candidate. Since these INDs have been accepted by the FDA, phase 1 and 3 clinical trials may be commenced. We anticipate beginning these trials in the near future. Upon successful completion, we may seek FDA approval for these proposed hormone replacement therapy products.

On November 6, 2012, we released the following products in our BocaGreen generic prescription line:

BocaGreenMD™ Prena1 is a convenient single-dose softgel with 14 vitamins, minerals and 200 mg of plant-based life’s docosahexaenoic acid, or DHA.

BocaGreenMD™ Prena1 Plus is a comprehensive single-dose dietary supplement containing one prenatal tablet with 16 vitamins and minerals, plus one softgel with 300 mg of plant-based life'sDHA.

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

Private Placement

On September 26, 2012, we entered into a securities purchase agreement, which we refer to as 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 & Company, Inc. 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 $7,920,501.

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 are required to use our best efforts to effect the registration (including a declaration of effectiveness of this registration statement by the SEC) no later than 90 days from October 2, 2012 (120 days if reviewed by SEC). If this registration statement does not become effective on or before the required effectiveness date, we have agreed, among other things, to pay to these investors 1.5% of each investor's aggregate purchase price of the shares for each 30-day period that this registration statement is not effective, up to a maximum of 10% of such aggregate purchase price.

Employment Agreements

On November 8, 2012, our Compensation Committee recommended that the Board of Directors approve employment agreements with our executive officers, namely our Chief Executive Officer (Robert G. Finizio), President (John C.K. Milligan, IV), and Chief Financial Officer (Daniel A. Cartwright), whom we refer to as the Executives. Our Board of Directors approved these 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 our company is 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 Mr. Finizio as Chief Executive Officer calls for (i) a time-based ten-year stock option to be granted and issued on November 30, 2012 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 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 his 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 ten-year stock option to be granted and issued on November 30, 2012 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 his 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 ten-year stock option to be granted and issued on November 30, 2012 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 his base salary, at the discretion of our Board of Directors.

Results of Operations

Nine months ended September 30, 2012 compared to nine months ended September 30, 2011

	Nine Months Ended September 30,		
	2012	2011	Change
	(in thousands)		
Revenue, net	$ 2,577	$ 1,534	$ 1,043
Cost of goods sold	1,015	684	331
Operating expenses	12,315	4,117	8,198
Operating loss	(10,753)	(3,267)	(7,486)
Loss on extinguishment of debt	(10,505)	—	(10,505)
Beneficial conversion feature	(6,717)	—	(6,717)
Other income (expense), net	(1,418)	(61)	(1,357)
Net loss	$ (29,393)	$ (3,328)	$ (26,065)

Revenue and Cost of Goods Sold

Revenue for the nine months ended September 30, 2012 increased $1,043,000, or approximately 68%, from the nine months ended September 30, 2011. This increase was directly attributable to the (i) increase in the number of sales territories, (ii) the associated increase in number of sales people selling in those territories and (iii) the new prescription product introduced in March 2012. Cost of goods sold increased $331,000, or approximately 48%, for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. Cost of goods sold as a percentage of revenues was 39% and 45% for the nine months ended September 30, 2012 and 2011, respectively. Approximately 76% of this increase was due to an increase in the amount of product sold and approximately 24% of the increase was related to product mix. Our costs of individual products did not change for the nine months ended September 30, 2012 as compared to the same period in 2011.

Operating Expenses

Our principal operating costs include the following items as a percentage of total expense.

	Nine Months Ended September 30, 2012		2011	
Human resources costs, including commission, benefits and taxes	36.0	%	61.4	%
Product and design and development costs	20.9	%	6.2	%
Sales and marketing, excluding human resources costs	19.2	%	16.9	%
Professional fees for legal, accounting and consulting	8.8	%	3.4	%
Non-cash costs	10.3	%	4.0	%
Other operating expenses	4.8	%	8.1	%

Our operating expenses increased by $8.2 million (199%) as a result of the following items:

		(in thousands)
Increase in human resource costs, including commission, benefits and taxes	$	2,309
Increase in product design and development costs		2,323
Increase in sales and marketing, excluding human resource costs		1,659
Increase in non-cash costs		1,122
Increase in legal, accounting and consulting fees		669
Increase in other operating expenses		116
	$	8,198

Human resource related costs, including salaries, commission, benefits, and taxes was higher as a result of an increase of 17 employees between the two periods (approximately $1,843,000) and increased sales commissions of approximately $466,000.

Product design and development costs increased as a direct result of our new prescription prenatal products.

Professional fees increased primarily due to higher legal fees arising from contract and patent services and public company filing related costs (approximately $409,000). We experienced higher accounting and audit costs related to preparation of audits and public company filing related costs (approximately $51,000). Consulting costs were also higher as a result of new product development, opening new sales territories, and the additional resources needed for public company filings (approximately $209,000).

Sales and marketing costs increased due to the addition of new sales territories and expanded client education.

Non-cash costs were higher as the result of warrants issued for services (approximate fair value of $236,000) and additional costs related to the issuance of options (approximate fair value of $863,000).

Loss on Extinguishment of Debt

As described above, in February 2012 we issued the February 2012 Notes in the aggregate of approximately $2,700,000 and granted the February 2012 Warrants for the purchase of an aggregate of 9,000,000 shares of our common stock. As consideration for the February 2012 Notes and the February 2012 Warrants, we received $1,000,000 of new funding and the surrender of certain promissory notes previously issued by us in the aggregate amount of approximately $1,700,000. We determined that the resulting modification of the February 2012 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 February 2012 Warrants, valued at approximately $10,500,000, were expensed as loss on the extinguishment of debt. The relative fair value of the surrendered 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 on extinguishment of debt in the amount of $200,000, which represented the difference between the net carrying amount of the February Funding and its fair value. See Note 9 – Notes Payable and Note 10 – Stockholders' Equity – Warrants in the condensed consolidated financial statements as of and for the period ended September 30, 2012 included in this prospectus for more details.

Beneficial Conversion Feature

Beneficial conversion feature of approximately $6,717,000 consists of non-cash costs associated with the conversion of approximately $1,055,000 in debt into 2,775,415 shares of our common stock.

Other Income (Expense), net

Other non-operating expense increased by approximately $1,357,000 for the nine months ended September 30, 2012 in comparison to the same period in 2011 due primarily to the addition of amortization of debt discount not incurred during 2011.

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

	Year Ended December 31, 2011	2010	Change
	(in thousands)		
Revenue, net	$ 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)
Settlement of debt	(7,390)	—	(7,390)
Other expense, net	(96)	—	(96)
Net loss	$ (12,913)	$ (2,867)	$ (10,046)

Revenue and Cost of Goods Sold

Revenue for year ended December 31, 2011 increased $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 selling in those territories. Cost of goods sold increased $391,000, or approximately 70.3%, from year ended December 31, 2011 compared to the year ended December 31, 2010. Approximately 96.9% of this increase was primarily 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 as compared to 2010.

Operating Expenses

Our principal operating costs include the following items as a percentage of total expense.

	Year Ended December 31, 2011	2010
Human resources costs, including benefits	52 %	52 %
Sales and marketing	7 %	6 %
Product and design and development costs	11 %	8 %
Travel and entertainment	10 %	13 %
Professional fees for legal, accounting and consulting	7 %	4 %
Rent and other occupancy costs	5 %	8 %
Non-cash compensation	3 %	5 %
Other	5 %	4 %

Our operating expenses increased by $3.0 million (84%) as a result of the following items:

		(in thousands)
Increase in human resource costs	$	1,551
Increase in sales and marketing		257
Increase in product design and development costs		457
Increase in travel and entertainment		216
Increase in professional and consulting		318
Increase in rent and other occupancy costs		24
Increase in non-cash compensation		19
Increase in all other		173
	$	3,015

Human resource related costs (including salaries and benefits) increased by $1.6 million primarily due to an increase of 25 employees in 2011. We had 51 employees at December 31, 2011 which increased from 27 from the prior year.

Sales and marketing costs increased $0.3 million due to the increase in both sales territories and sales personnel during 2011.

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

Travel and entertainment expense increased $0.2 million as a direct result of increased activity associated with sales and training efforts.

Professional fees increased $0.3 million 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 preparation of audits for 2010 and 2011 as required for this merger. Consulting cost also increased as a result of opening new sales territories and the additional resources needed to complete the merger.

Rent and occupancy costs increased slightly as a result of repairs and maintenance and other ancillary costs.

Non-cash compensation costs increased as the result of the additional options granted in 2011.

Settlement 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 $0.1 million for the year ended December 31, 2011 in comparison to the same period in 2010 due primarily to the addition of interest expense not incurred during 2010.

Liquidity and Capital Resources

As of September 30, 2012, we had a working capital deficit of approximately $2.2 million; our accumulated deficit was approximately $46.4 million; and our stockholders' deficit was approximately $4.3 million. We began the operation of our current business plan in June 2008 and have not yet attained a level of revenue to allow us to meet our current overhead and there is no assurance that such a level can ever be achieved. We currently do not have financial resources adequate for the next 12-month period.

We are dependent upon obtaining additional financing in order to adequately fund working capital, drug development, infrastructure, manufacturing expenses, and significant marketing/investor related expenditures to gain market recognition so that we can achieve a level of revenue adequate to support our cost structure, none of which can be assured.

We expect to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our proposed products. Further, we do not have sufficient resources to develop fully any new products or product candidates unless we are able to raise substantial additional financing on acceptable terms or secure funds from new or existing partners.

We expect to increase the market penetration of our current products and expand our product base of prescription products which will necessitate an increase in inventory levels. We believe that we will be able to meet the costs of growth and public reporting with funds generated through debt and equity financing and operations.

We cannot be assured that financing will be available on favorable terms or at all. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. Additionally, these conditions may increase costs to raise capital and/or result in further dilution. Our failure to raise capital when needed would adversely affect our business, financial condition and results of operations, and could force us to reduce or cease our operations. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. These conditions raise substantial doubt about our ability to continue as a going concern. Even if we are successful in raising additional capital to meet our obligations and otherwise continue operations, our business will still require substantial additional investment that we have not yet secured.

Off Balance Sheet Arrangements

As of December 31, 2011 and September 30, 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 which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our 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, 2011 or September 30, 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.

Seasonality

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

Effects of Inflation

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

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management 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 (i) it requires assumptions to be made that were uncertain at the time the estimate was made, and (ii) 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 accounting policies and estimates 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 to be share-based compensation expense and income taxes.

Share-Based Compensation Expense. We calculate share-based compensation expense for option awards and warrant issuances based on the estimated grant/issue-date fair value using the Black-Scholes-Merton option pricing model, and recognize the expense on a straight-line basis over the vesting period, net of estimated forfeitures. This 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 options or warrants in determining the fair value of such 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. Our provision for income taxes is determined using the asset and liability approach to account for income taxes. A current liability is recorded for the estimated taxes payable for the current year. Deferred tax assets and liabilities are recorded 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 are 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.

Recent Accounting Pronouncements

There have been no material changes to our significant accounting policies as summarized in Note B – Summary of Significant Accounting Policies to our financial statements for the years ended December 31, 2011 and 2010 included in this prospectus. We do not expect that the adoption of any recent accounting pronouncements will have a material impact on our condensed consolidated financial statements.

BUSINESS

Introduction

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

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

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

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 (or 17.9% of our nation’s economy or Gross Domestic Product, or GDP, up from 7.2% of GDP in 1970 and 12.5% of GDP in

1990. In 2010, healthcare spending in the United States averaged $8,402 per person.

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

Women’s Health Market

The U.S. Census Bureau projects that there were approximately 150 million women and 146 million men living in the United States in 2010. Women are major consumers of health care services, negotiating not only their own health care but often managing care for their family members as well. Their reproductive health needs, greater rates of health problems, and longer life spans as compared with men make women’s relationships with the health care system complex.

Hormone Replacement Market

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. It is defined as the final menstrual period and is confirmed when a woman has not had her period for 12 consecutive months. Hormone therapy, or HT, is the only government-approved treatment in the United States and Canada for relief of menopausal symptoms. These symptoms are caused by the reduced levels of circulating estrogen as the ovarian production shuts down. The symptoms include hot flashes, night sweats, sleep disturbances, and vaginal dryness. According to Source Healthcare Analytics, for the 12 months ending June 30, 2012, prescriptions for either treatment of menopause symptoms or prevention of osteoporosis generated total sales of over $3.2 billion on 37.5 million prescriptions. Oral hormone replacement therapy accounted for $1.7 billion on 25.8 million prescriptions over the same time period.

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

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

There were approximately 41.5 million women in the United States between the ages of 45 and 64 in 2010, projected to increase slightly (2.4%) to 42.5 million in 2015 and maintaining at approximately 43 million until 2030, according to the 2010 National Census population figures. These women are the target market for hormone therapy to treat menopausal related symptoms.

Hormone Replacement 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 replacement therapy products were approximately $2.34 billion for the twelve months ending June 2012. That was up 4.9% over the same time period from the prior year according to Source Healthcare Analytics. The three primary hormone replacement products are estrogen, progestin, and combination of estrogen and progestin and are produced in a variety of forms, including oral tablets or capsules, skin patches, gels, emulsion, or vaginal.

Estrogen-Only Therapies

Estrogen replacement remedies the vasomotor symptoms (hot flashes and night sweats) of menopause are a direct result of the decline in estrogen levels associated with ovarian shutdown at menopause. Estrogen therapy has been used to manage these symptoms for more than 50 years. Based upon the age demographic for all women receiving prescriptions for estrogen replacement and the average age range during which women experience vasomotor symptoms, we estimate that approximately 70% to 80% of estrogen usage is for the treatment of vasomotor symptoms, while the other 20% to 30% is prescribed mainly for the prevention of osteoporosis.

Estrogen-only therapy, or ET, is used mainly in women who have had a hysterectomy and are undergoing a surgical menopause, as those women do not require a progestin to protect the uterine endometrium from proliferation. Approximately 600,000 women undergo a hysterectomy each year in the United States according to the United States Centers for Disease Control and Prevention. Sales of oral ET were approximately $864.1 million for a 12-month total at June 2012, according to Source Healthcare Analytics. That was up slightly 0.2% over the same time period a year prior, led mainly by the estradiol segment.

Estrogen replacement therapy is approved for the prevention of osteoporosis. Multiple studies conducted on various estrogen compositions, including studies published in the Journal of the American Medical Association in 2002, the European Journal of Obstetrics, Gynecology and Reproductive Biology in 1999, and Clinical Endocrinology in 1994, demonstrated efficacy based on increases in bone mineral density. Epidemiological and some fracture prevention studies, such as those published in the American Journal of Obstetrics and Gynecology in 1989 and the New England Journal of Medicine in 1980, also have demonstrated a decrease in fractures resulting from increases in bone density associated with estrogen replacement therapy.

Progestin-Only Therapies

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

Estrogen/Progestin Combination Products

Progestins are used in combination with estrogen in women with uteruses to avoid an increase in the incidence of endometrial hyperplasia. This is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that after one year the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. Doctors typically recommend that a menopausal or postmenopausal woman who has a uterus take estrogen plus a progestin, either as a combination drug or as two separate drugs. Source Healthcare Analytics estimates that sales of estrogen/progestin combinations were approximately 519.1 million in the United States for the 12 months ending June 2012, up 3.3% over the same time period a year prior. The segment is still dominated by products in the Premarin® family that constituted 56% of that market segment.

Limitations of Existing Estrogen/Progestin Therapies

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

One of the most widely prescribed progestin is the naturally occurring progesterone, known as Prometrium®, sold by Abbott Laboratories. Natural progesterone is used in combination with estrogen for hormone replacement therapy; however, we believe there are currently no FDA approved hormone replacement therapy combination products with natural progesterone.

Prenatal Vitamin Market

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

There are thousands of brand and generic prenatal vitamins available, with both prescription and over-the-counter (non-prescription), or OTC, choices. According to Source Healthcare Analytics, there were 9.4 million prescriptions for prenatal vitamins sold for a total of $370 million for the 12 months ended June 30, 2012, with sales between branded and generic products split nearly evenly. According to the 2012 Gallup Target Market Report on Prenatal Vitamins, supplement use has been fairly constant overall between 2008 and 2011. However, shifts have occurred in terms of types used, with the trend toward OTC prenatal vitamins and away from prescription prenatal vitamins. Since 2008, the use of OTC products is now larger than prescription products, largely driven by increased use among women currently pregnant.

Our Business Model

We are a specialty pharmaceutical company focused on creating safe and effective prescription, over-the-counter (non-prescription), or OTC, and generic products targeted exclusively for women, including products specifically for pregnancy, childbirth, nursing, pre-menopause, and menopause. We intend to use our current product line, including prescription and over-the-counter prenatal vitamins, over-the-counter multivitamins, vegan DHA, iron supplements, Vitamin D supplements, natural (non-hormonal) menopause relief products, and scar tissue and stretch mark creams, as the foundation of our business platform. If commercialized, our proposed hormone replacement products will allow us to enter the $3 billion hormone therapy market segment, based on 2011 total sales of the hormone therapy market according to Health Source Analytics.

Our current product line is marketed and sold by a direct national sales force that calls on healthcare providers in the OB/GYN market space, as well as through our website to consumers who have been referred to our website by physicians. We market our prescription prenatal vitamins, over-the-counter nutritional supplements, and other products under our vitaMedMD name and our generic prescription prenatal vitamins products under our BocaGreenMD Prena1 name. We believe that our vitaMedMD brand name has become a recognized name for high quality and effective women’s healthcare, while our BocaGreenMD Prena1 products will provide physicians, women, and payors with a lower cost alternative. We intend to leverage our existing relationships and distribution system to introduce our proposed hormone replacement products, if approved, which will enable us to provide a comprehensive line of women’s health care products all under one brand.

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

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

- We believe we will offer physicians a comprehensive product line of women's healthcare products, including our proposed hormone replacement products, if approved.
- Our proposed hormone replacement products are designed to deliver the most efficacious outcomes by using the lowest effective dose for the shortest duration.
- We believe our product attributes will result in greater patient acceptance and satisfaction than competitive products while offering the highest quality products incorporating patented ingredients, such as Quatrefolic®, chelated iron and life'sDHA™. All of our prenatal vitamins are gluten, sugar, and lactose free.
- We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.
- We believe we are able to show health care provider practices that by recommending our products, they are able to realize office efficiencies and patient cost savings over prescribing competing products. In addition, health care providers are able to offer alternatives to patients that meet the patients' individual nutritional and financial requirements.
- Health care provider practices that choose to dispense our over-the-counter products directly to their patients through their offices earn revenue from the sale of the products.
- Our statistical data indicates that our direct interaction with patients through supplemental patient education achieves a high level of patient compliance.
- Improved patient education, a high level of patient compliance and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

Our Growth Strategy

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

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

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

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

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.

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

Introducing New Products. We plan to introduce new products to build upon the introduction of our first three prescription products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012 as well as our proposed hormone replacement products.

Our Products

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

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

vitaMedMD™ Plus (Prenatal Women's Multi-vitamin + DHA (Combo Pack))

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

vitaMedMD™ One Prenatal Multivitamin

vitaMedMD™ One is a single dose daily multivitamin that provides 14 vitamins, minerals and 200 mg of vegetarian, plant-pure life's DHA™ which is 100% fish-free with no ocean-borne contaminants, such as mercury or 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®, a fourth generation folate, and one plant-based Life'sDHA™ 300mg capsule. (Quatrefolic® is a registered trademark of Gnosis S.P.A.) All minerals, including Iron, Zinc and Copper are chelated to improve absorption and tolerability.

vitaMedMD™ One Rx Prenatal Multivitamin

vitaMedMD™ One Rx is a prescription-only product with a single-dose daily multivitamin containing Quatrefolic, a fourth generation folate, and 200 mg of vegetarian, plant-pure life'sDHA which is 100% fish-free with no ocean-borne contaminants such as mercury and PCBs. Each convenient, easy-to-swallow softgel features fourteen minerals, vitamins and life'sDHA.

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

vitaMedMD™ Iron 21/7

vitaMedMD™ Iron 21/7 is a doctor-recommended iron replacement supplement with a unique 3-weeks-on/1-week-off dosing schedule that helps maximize absorption and enhances tolerability. It is formulated with 150 mg of chelated Iron to help improve tolerability and limit typical side effects associated with iron replacements. Each easy-to-swallow single tablet serving also includes 800 mcg of Folic Acid, plus Vitamins C and E, and Succinic Acid to aid in absorption.

vitaMedMD™ Menopause Relief with Lifenol® Plus Bone Support

vitaMedMD™ Menopause Relief with Lifenol Plus Bone Support offers a natural solution for hot flashes, night sweats and mood disturbances. Each single tablet dosage delivers 120 mg of Lifenol®, a patented, well-studied female hops extract recognized for its potency and support in alleviating hot flashes, plus plant phytoestrogens. It also includes Calcium and Vitamin D3 for added bone support. This product offers women a natural alternative to hormone replacement therapy.

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

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

vitaMedMD™ Stretch Mark Body Cream

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

vitaMedMD™ Scar Reduction Body Cream

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

BocaGreenMD™ Prena1 Plus

BocaGreenMD™ Prena1 Plus is a prescription-only comprehensive single-dose dietary supplement containing one prenatal tablet with 16 vitamins and minerals, plus one softgel with 300 mg of plant-based life’sDHA.

BocaGreenMD™ Prena1

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

BocaGreenMD™ Prena1 Chew

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

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

Our Proposed Hormone Replacement Products

Our three proposed hormone replacement therapy products have received IND acceptance by the FDA. Our goal is to improve bioavailability of our progestin when used alone or in combination with estrogen over current marketed and FDA approved options. We have begun pivotal Pharmacokinetics, or PK, studies for our proposed progestin, estrogen, and combination hormone replacement products. If the pivotal PK studies are successful, we hope to begin phase 3 trials in the first half of 2013. Progestins and estrogens are very clearly understood by both the FDA and health care providers. Although regulatory testing results cannot be guaranteed, we are optimistic that the clinical trials for our proposed hormone products will achieve our goals. Our proposed hormone replacement products are detailed below. We are currently planning to focus our efforts on relief of vasomotor symptoms associated with menopause, but will also be considering the treatment and prevention of osteoporosis and other conditions of hypoestrogenism.

Therapeutics' TX12001HR

Therapeutics' TX12001HR is a drug candidate that will be a combination product for post-menopausal women with an intact uterus, indicated for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness. We are planning to conduct the necessary safety study to show protection against endometrial hyperplasia over a 12 month duration. The product will be chemically identical to the hormones that naturally occur in a women's body, namely estradiol and progesterone, and will be packaged as both a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily), as well as a sequentially-combined regimen (where the estrogens are taken daily and the progesterone is taken in combination for two weeks of every month). If approved by the FDA, we believe this would represent the first time a combination product of these bio-identical hormones would be approved for use in a single combined product.

Therapeutics' TX12002HR

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

Therapeutics' TX12003HR

Therapeutics' TX12003HR is a drug candidate that will be an estrogen product indicated for postmenopausal women for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness. This can be used for both women with and without a uterus. It is an estradiol product, chemically bio-identical to the hormones that naturally occur in a women's body.

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

Sales and Marketing

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

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

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

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

Online Commerce

A vast majority of our over-the-counter product sales are completed online. The Internet has continued to increase its influence over communication, content, and commerce. According to Forrester Research, U.S. online retail sales increased 12.2% from 2010. Forrester projects online retail sales to grow at a 10% compound annual growth rate, to $278.9 billion by 2015. We believe several factors will contribute to this increase including convenience, expanded range of available products and services, improved security and electronic payment technology, increased access to broadband Internet connections and widespread consumer confidence and acceptance of the Internet as a means of commerce.

Retail Commerce

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

Seasonality

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

Products in Development

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

Raw Materials for Our Products

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

Availability of and Dependence Upon Suppliers

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

Manufacturing of Our Products

Our products are manufactured and regulated by the same FDA quality standards (Controls Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements for FDA 21 CFR Part 110/111 CGMP Regulations, or CFR 111,) and current good manufacturing practices, or cGMP, as prescription nutritional therapies. In addition, we conduct two additional un-required certificates of analysis on every lot to ensure quality, and we employ an outside third party to enforce rigorous quality audits.

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

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

Quality Control for Our Products

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

Our manufacturers' quality and production standards are designed to meet or exceed the latest FDA regulations. To ensure the highest quality, our manufacturing operations are audited by AIB International, Inc., or AIB, for independent cGMP certification. AIB is an independent, not-for-profit organization that offers programs and services to augment and support the work of regulatory officials around the country, including standards development, product testing and certification, and onsite audits and inspections. The manufacturing facilities we use are also ISO 9001 certified which is a family of standards related to quality management systems and are designed to help organizations ensure they meet the needs of customers. In addition, our manufacturers are hazard analysis critical control point certified which is a systematic preventive approach for food and pharmaceutical safety that addresses physical, chemical and biological hazards as a means of prevention rather than finished product inspection.

Distribution of our Products

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

Customer Service

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

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

Our Return Policy

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

Our Quality Guarantee

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

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

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

Intellectual Property

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

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

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

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

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

Generally, our nutritional product formulations are proprietary in that in designing them, we attempt to blend an optimal combination of nutrients that appear to have beneficial impact based upon scientific literature and input from physicians; however, as formal clinical studies have in most instances not been conducted by us to validate the intended health benefits of our products, we are generally prohibited by the FDA from making disease treatment and prevention claims in the promotion of our products that use these formulations.

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

Government Regulation

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

- notice to consumers of our policies on sharing non-public information with third parties;
- advance notice of any changes to our policies; and

- with limited exceptions, provide consumers the right to prevent sharing of their non-public personal information with unaffiliated third parties.

We received acceptance of the INDs for our proposed hormone replacement products, TX12002HR, TX12003HR and TX12001HR, from the FDA on June 29, 2012, August 23, 2012, and August 30, 2012, respectively. We plan to file NDAs under Section 505(b)(2) of FDCA and utilize previously available data in support of our drug candidates' approval. We anticipate the FDA will require us to perform further studies evaluating blood levels of the drug candidate after dosing to prove the correlation of dosage strengths (phase 1). In addition, phase 3 clinical trials for secondary amenorrhea versus placebo will be required for TX12002. TX12003 will be required to undergo phase 3 studies of vasomotor symptoms compared to placebo. In regards to TX12001, we will be required to do phase 3 studies for vasomotor symptoms versus placebo and an endometrial protection study.

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

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

The FDCA has been amended several times affecting provisions that concern dietary ingredients and dietary supplements, including by the Dietary Supplement Health and Education Act of 1994, or DSHEA. DSHEA formally defined what may be sold as a dietary supplement, defined statements of nutritional support and the conditions under which they may lawfully be used, and included provisions that permit the FDA to regulate manufacturing practices and labeling claims peculiar to dietary supplements. "Dietary supplements" are defined as vitamins, minerals, herbs, other botanicals, amino acids and other dietary substances that are used to supplement the diet, as well as concentrates, constituents, extracts, metabolites, or combinations of such dietary ingredients. Generally, under DSHEA, dietary ingredients that were on the market before October 15, 1994 may be used in dietary supplements without notifying the FDA. However, a "new" dietary ingredient (i.e., a dietary ingredient that was not marketed in the U.S. before October 15, 1994) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without having been "chemically altered." A new dietary ingredient notification must provide the FDA with evidence of a "history of use or other evidence of safety" which establishes that use of the dietary ingredient "will reasonably be expected to be safe." A new dietary ingredient notification must be submitted to the FDA at least 75 days before the new dietary ingredient can be marketed. There can be no assurance that the FDA will accept evidence purporting to establish the safety of any new dietary ingredients that we may want to market and the FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients.

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

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

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

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

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

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

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

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

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

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

Applicable federal and state healthcare laws and regulations include the following:

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

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

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

- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

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

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

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

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

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

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

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

Legal Proceedings

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

Aceto Corporation

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

Avion Pharmaceuticals, LLC

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

Our Offices

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 951 Broken Sound Parkway NW, Suite 320, Boca Raton, Florida 33487. Our telephone number is (561) 961-1911. We maintain websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and bocagreenmd.com. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

Properties

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

Employees

As of September 30, 2012, we had 62 full-time employees, four of who 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 Exchange Act. As a result of the spin-off, Croff was a "shell company" under the rules of the SEC. In July 2009, Croff (i) closed a transaction to acquire America's Minority Health Network, Inc. as a wholly owned subsidiary, (ii) ceased being a shell company, and (iii) experienced a change in control in which the former shareholders of America's Minority Health Network, Inc. acquired control of our company. On September 14, 2009, we changed our name to AMHN, Inc. On June 11, 2010, we closed a transaction to acquire Spectrum Health Network, Inc. as a wholly owned subsidiary. On July 20, 2010, we filed Articles of Conversion and Articles of Incorporation to redomicile in the state of Nevada. On July 31, 2010, we transferred the assets of America's Minority Health Network, Inc. to a secured noteholder in exchange for the satisfaction of certain debt associated therewith. On February 15, 2011, we transferred the assets of Spectrum Health Network, Inc. to a secured noteholder in exchange for the satisfaction of debt associated therewith and in exchange for a licensing, agreement under which we subsequently sold subscription services and advertising on the Spectrum Health Network for commissions.

On August 3, 2011 (with an effective date of October 3, 2011), in anticipation of closing a merger with VitaMed, we filed Amended and Restated Articles of Incorporation to change our name to TherapeuticsMD, Inc. and to increase the shares of common stock authorized for issuance to 250,000,000. On October 4, 2011, we closed the merger with VitaMed pursuant to which all outstanding membership units of VitaMed were exchanged for shares of the 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.

MANAGEMENT

Executive Officers and Directors

The table below lists all current officers and directors of our company. All officers serve at the discretion of the Board of Directors. The term of office of each of our directors expire at our next Annual Meeting of Shareholders or until their successors are duly elected and qualified.

Name	Age	Position
Robert G. Finizio	40	Chief Executive Officer, Director
John C.K. Milligan IV	50	President, Secretary, Director
Daniel A. Cartwright	54	Chief Financial Officer, Vice President Finance, Treasurer
Mitchell L. Krassan	46	Executive Vice President, Chief Strategy Officer
Brian Bernick, M.D.	44	Chief Medical Officer, Director
Tommy G. Thompson	71	Chairman
Samuel A. Greco	60	Director
Cooper C. Collins	32	Director
Robert V. LaPenta, Jr.	43	Director
Nicholas Segal	30	Director

Robert G. Finizio has served as Chief Executive Officer and a director of our company since October 4, 2011. As co-founder of our VitaMed subsidiary. Mr. Finizio served as its Chief Executive Officer and a director from April 2008 to October 4, 2011. Mr. Finizio has 16 years of successful early stage company development 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., a global leader in healthcare technology and equipment and provider of integrated technology, software, services, and equipment to healthcare institutions worldwide. Mr. Finizio managed CareFusion's growth from inception to over 70 employees and 200 hospital customers prior to its acquisition by Cardinal Health. Mr. Finizio's early business experience was with Omnicell Technologies and Endoscopy Specialists 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 BA from the University of Miami.

John C.K. Milligan, IV was appointed President, Secretary, and a director of our company on October 4, 2011. From December 2008 to October 4, 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. CareFusion, Inc. is a global leader in healthcare technology and equipment and provider of integrated technology, software, services, and equipment to healthcare institutions worldwide. 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 HBOC, both subsequently acquired by McKesson. 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 4, 2011. From July 2011 to October 4, 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, 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, a provider of entertainment video services. Mr. Cartwright currently serves as a member of the Board of Directors of Antenna Technologies Company, Inc., a private engineering firm, and of Primetrica, Inc., a private information research company for the telecommunications industry. 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 4, 2011. From April 2010 to October 4, 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 the lead company in a roll-up and $180 million IPO 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 MBA in Management from New York University.

Dr. Brian Bernick has served as a director of our company since October 4, 2011. In February 2012, he was named as our company's Chief Medical Officer. As co-founder of VitaMed, Dr. Bernick served on VitaMed's Board of Directors since 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 BA 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 been the Chairman of the Board of our company since May 16, 2012. As the former Secretary of the U.S. Department of Health & Human Services Secretary, 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. At the Deloitte Center for Health Solutions and at Akin Gump, Secretary Thompson built on his efforts at HHS to develop 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 in 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]. We believe Secretary Thompson's experience in public service, in 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 29, 2012. Mr. Greco has served as Chief Executive Officer of CareView Communications, Inc. since September 2007 and was elected as a member of the CareView Board of Directors in 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 healthcare provider. At Columbia/HCA, Mr. Greco was responsible for the financial operations of the $28 billion company, which at the time had over 300 hospitals and 125 surgery centers. Over the past 10 years, Mr. Greco has provided consulting services to hospital management companies to greatly improve their financial results from operations. 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 has operated in organizations ranging from 200 beds to multi-facility networks of over 2,000 beds. He was instrumental in the development of the CareView System™. 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 29, 2012. Mr. Collins was appointed President, Chief Executive Officer, and director of Pernix Therapeutics Holdings, Inc. effective with the close of the merger between Pernix and Golf Trust of America, Inc. on March 9, 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, serving in those three capacities until the closing of the GTA merger. 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 NFL franchise, The New Orleans Saints, in their 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 29, 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, Mr. LaPenta served as Vice President of Mergers and Acquisitions and Corporate Strategy for L-1 Identity Solutions, Inc., a 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. While at L-1, he provided assessment for over 100 acquisition opportunities, assisted in the completion of six public and private transactions, and assisted in the sale of L-1 for $1.7 billion in July 2011. 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 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 Senior Associate at Coopers & Lybrand, 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. 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 in the State of New York.

Nicholas Segal has served as a director of our company since February 29, 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 VitaMed prior to its acquisition by our company. Mr. Segal serves on the board of directors of TireVan Corporation, a private company specializing in online tire sales and installation directly to the consumer. He also serves as an observer to the board of directors of Tout, a private company with a new social media platform, and Autonet Mobile, a private company specializing in the first Internet-based service platform for the automotive transportation market. Mr. Segal founded and currently serves as Chief Executive Officer of Polar Generation, LLC, an early-stage consumer products company. Prior to joining Seavest, from September 2004 to April 2007, Mr. Segal served as a senior analyst in the Finance and Business Development group at ESPN. 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 16, 2012. Ms. Amadio has a 25-year background in general management and leading pharmaceutical marketing and product development organizations. From June 2011 to January 2012, Ms. Amadio was President of JMA Consulting, LLC, her own consulting company that she formed in 2008. From June 2009 to May 2011, she served as Global Vice President of Marketing for MeadWestvaco Healthcare Division. Previously, Ms. Amadio was President of a start-up Patients' & Consumers' Pharma in 2007. She was Vice President of Marketing &Marketing Services with Daiichi Pharmaceutical from 2004 to 2006, Vice President of Aventis Pharmaceutical from 1997 to 2004, Senior Director, New Products Women's Health at Wyeth from 1991 to 1997, and started her career at J&J's McNeil Pharmaceutical. Ms. Amadio is an active member and leader in the Healthcare Businesswomen's Association. She was an adjunct lecturer at St. Joseph's University in the pharmaceutical MBA program and authored a chapter on Marketing, Market Research and insights in the book Pharmaceutical Development for Woman (Wiley & Sons). Ms. Amadio earned a B.S. in Accounting from St. Joseph's University and a Masters in Business Administration from Drexel University.

Jason Spitz has served as Vice President - Marketing of our company since December 2011. Mr. Spitz has a 24-year career in marketing, advertising and general management experience in pharmaceutical and biopharmaceutical markets. From June 2008 to December 2010, Mr. Spitz served as Managing Director, Oncology & Hematology at Beacon Healthcare Communications, a company specializing in pharmaceutical and health care advertising. From September 2004 to June 2008, he served as General Manager, Canada and Commercial Strategy and Development at MGI Pharma (later acquired by Eisai, Inc.), a company specializing in oncology and cancer supportive care products. From February 2004 to September 2004 he served as Vice President of Marketing and Sales at Aesgen, Inc., a company specializing in cancer products and drug delivery systems which was acquired by MGI Pharma. Mr. Spitz began his career at Schering Plough as a sales representative, rising within the organization over fifteen years to lead a global pharmaceutical franchise. Mr. Spitz earned his Bachelor of Business Administration in Marketing from The University of Texas at Austin and his Master of Business Administration in Pharmaceutical Studies from Fairleigh Dickinson University.

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

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 shareholders 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 shareholders 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 the 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 the 1934 Act, or subject to the requirements of Section 15(d) of the Securities Act of 1933 or any company registered as an investment company under the Investment Company Act of 1940.

Committees of the Board

On February 29, 2012, our Board of Directors (i) approved charters for each of the Audit Committee, Compensation Committee, and Corporate Governance Committee, (ii) appointed members to each committee, and (iii) named a Chair of each committee. The charters for each of these committees are accessible via our SEC filings on our website at www.therapeuticsmd.com.

Audit Committee

The purpose of the Audit Committee is to assist our Board of Directors with oversight of (i) the quality and integrity of our financial statements and its related internal controls over financial reporting, (ii) our compliance with legal and regulatory compliance, (iii) the independent auditor's qualifications and independence, and (iv) the performance of our independent auditors. The Audit Committee's primary function is to provide advice with respect to our financial matters and to assist our Board of Directors in fulfilling its oversight responsibilities regarding finance, accounting, and legal compliance.

Members of the Audit Committee are Robert V. LaPenta, Jr., Samuel A. Greco and Nicholas Segal. Mr. LaPenta, Jr. serves as Chair.

Compensation Committee

The primary purpose of the our Compensation Committee is to oversee the policies of our company relating to compensation of our executives and make recommendations to the Board, as appropriate, with respect to such policies. The goal of such policies is to ensure that an appropriate relationship exists between executive pay and the creation of shareholder value, while at the same time motivating and retaining key employees.

Members of the Compensation Committee include Cooper C. Collins, Robert G. Finizio and Nicholas Segal. Mr. Collins serves as Chair.

Corporate Governance Committee

The purpose of our Corporate Governance Committee is to (i) identify, review and recommend to the Board qualified candidates for membership on our Board of Directors and the committees of the Board and (ii) develop and recommend to the Board corporate governance principles and other corporate governance policies and otherwise perform a leadership role in shaping our corporate governance.

Members of the Corporate Governance Committee include John Milligan, Brian Bernick and Robert LaPenta, Jr. Mr. Milligan serves as Chair.

Board Policies

Code of Business Conduct and Ethics

On October 4, 2011, our Board of Directors adopted a Code of Business 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. Our Code of Business Conduct and Ethics is accessible via our SEC filings on our website at www.therapeuticsmd.com.

Code of Ethics for Financial Executives

On October 4, 2011, our Board of Directors adopted a Code of Ethics applicable to all of our financial executives and any other senior officer with financial oversight responsibilities. This code governs the professional and ethical conduct of our financial executives, and directs that they (i) act with honesty and integrity; (ii) provide information that is accurate, complete, objective, relevant, and timely; (iii) comply with federal, state, and local rules and regulations; (iv) act in good faith with due care, competence, and diligence; and (v) respect the confidentiality of information acquired in the course of their work and not use the information acquired for personal gain. All of our financial executives are required to sign this code on an annual basis. Our Code of Ethics for Financial Executives is accessible via our SEC filings on our website at www.therapeuticsmd.com.

Insider Trading Policy

On October 4, 2011, our Board of Directors adopted an Insider Trading Policy applicable to all directors and officers. Insider trading generally refers to the buying or selling of a security in breach of a fiduciary duty or other relationship of trust and confidence while in possession of material, non-public information about the security. Insider trading violations may also include ‘tipping’ such information, securities trading by the person ‘tipped,’ and securities trading by those who misappropriate such information. The scope of insider trading violations can be wide reaching. As such, our Board of Directors has adopted an Insider Trading Policy that outlines the definitions of insider trading, the penalties and sanctions determined, and what constitutes material, non-public information. Illegal insider trading is against our policy as such trading can cause significant harm to the reputation for integrity and ethical conduct of our company. Individuals who fail to comply with the requirements of the policy are subject to disciplinary action, at our sole discretion, including dismissal for cause. All members of our Board of Directors and all executive officers are required to ratify the terms of this policy on an annual basis.

Director Independence

Although our securities are not currently traded on a national securities exchange, which would require that the Board of Directors include a majority of directors that are independent, we have four members of its Board of Directors that qualify as independent directors under the rules and listing requirements of such exchanges; namely, Tommy Thompson, Samuel A. Greco, Cooper C. Collins, Robert V. LaPenta, Jr., and Nicholas Segal.

Director Compensation

We do not currently provide any cash compensation to our non-employee directors. From time to time, we have granted stock options to our non-employee directors as compensation for their services, but we do not have a formal policy in place with respect to such awards. We did not grant any stock options or otherwise provide any compensation to our non-employee directors during the fiscal year ended December 31, 2011. The following table lists all outstanding equity awards held by our non-employee directors as of September 30, 2012:

Name	Date of Grant	Number of Shares Underlying Options(1)	Exercise Price	Option Expiration Date
Tommy G. Thompson	6/29/2012	75,000	$ 2.80	6/28/2022
Samuel A. Greco	4/16/2012	50,000	$ 2.55	4/15/2022
Cooper C. Collins	4/16/2012	75,000	$ 2.55	4/15/2022
Robert V. LaPenta, Jr.	4/16/2012	75,000	$ 2.55	4/15/2022
Nicholas Segal	4/16/2012	50,000	$ 2.55	4/15/2022

(1) All options vest 100% on December 31, 2012.

Compensation Committee Interlocks and Insider Participation

For the year ended December 31, 2011, we did not have a Compensation Committee. As of February 29, 2012, our Compensation Committee 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 is an officer and employee of our company. No current 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.

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 performance measures that are expected to position our company for long-term success; and

- 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 and will continue to be to combine the components of our executive compensation program to align compensation with measures that correlate with the creation of long-term shareholder 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 company performance goals because the performance of these officers is more likely to have a direct impact on our achievement of strategic and financial goals that 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 company 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 our board members and our chief executive officer based on their experiences with other companies. We have not engaged third-party consultants to benchmark our compensation packages against our peers. However, going forward, 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 determined and administered the compensation of our chief executive officer and our chief financial 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, will make the ultimate decisions regarding executive officer compensation. We do not anticipate that this shift in our compensation determination processes and procedures will affect our executive officers' 2012 compensation. 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 executive officer 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 without the presence of management prior to its final determination. Decisions regarding the 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 principal executive officers for the years ended December 31, 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.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Robert G. Finizio(2)	2011	$156,000	–	–		–	–	$ 15,986	$171,986
Chief Executive Officer	2010	$140,282	–	–	– –	–	–	$ 2,250	$142,532
John C.K. Milligan(3)	2011	$156,000	–	–		–	–	$ 25,329	$181,329
President and Secretary	2010	$144,787	–	–	– –	–	–	$ 9,554	$154,341
Daniel A. Cartwright(4)	2011	$ 79,615	–	–	$46,216	–	–	$ 730	$126,561
Chief Financial Officer and Treasurer	2010	–	–	–	–	–	–	–	–
Mitchell L. Krassan(5)	2011	$110,000	–	–	–	–	–		$110,000
Chief Strategy Officer	2010	$15,096	–	–	$62,301	–	–	– –	$ 77,397

(1) 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.

(2) 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.

(3) 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.

(4) For 2011, (i) Option Awards include the issuance of a non-qualified option for the purchase of 300,000 shares issued on October 21, 2011; and (ii) All Other Compensation includes health insurance premiums paid on behalf of Mr. Cartwright. This table does not include the issuance of warrant for 600,000 shares issued on October 21, 2011.

(5) For 2010, Option Awards include the issuance of non-qualified options as follows: (A) options for 73,646 and 92,057 shares respectively, as adjusted pursuant to the conversion ratio applied upon our merger with VitaMed which were originally issued on May 1, 2010 and reissued on October 4, 2011 pursuant to this merger and (B) an option for 736,455 shares, as adjusted pursuant to this conversion ratio which was originally issued on September 1, 2010 and reissued on October 4, 2011 pursuant to the merger.

Outstanding Equity Awards at Fiscal Year End

The table below shows equity awards outstanding for our executive officers at fiscal year ended December 31, 2011, which equity awards consists of non-qualified options issued under our 2009 Long Term Incentive Plan. No executive officers have exercised their options. This table does not include the issuance of warrants as described elsewhere herein.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

		Option Awards				
Name (a)	Grant Date(1)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexcercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)
Robert F. Finizio	01/01/2009	1,431,987 (1)	40,914 (1)	–	$ 0.10	01/01/19
John C.K. Milligan, IV	01/01/2009	1,995,248 (1)	57,007 (1)	–	$ 0.10	01/01/19
Daniel A. Cartwright	10/21/2011	–	300,000 (2)	–	$ 0.38	10/21/21
Mitchell L. Krassan	10/04/2011	73,646 (3)	–	–	$ 0.19	05/01/20
		423,015 (4)	69,042 (4)		$ 0.19	05/01/20
		265,943 (5)	470,512 (5)		$ 0.20	09/01/20

(1) The option granted on January 1, 2009 vests monthly on the first of each month over three years.

(2) The option granted on October 21, 2011 vests at the rate of 75,000 shares annually on the anniversary of the date of issuance.

(3) All 73,646 underlying shares vested on May 1, 2011.

(4) The options granted on May 1, 2010 vest annually on the anniversary date over four years.

(5) The options granted on September 1, 2010 vest monthly on the first of each month over three years.

Employment Agreements

On November 8, 2012, our Compensation Committee recommended that the Board of Directors approve employment agreements with our executive officers, namely our Chief Executive Officer (Robert G. Finizio), President (John C.K. Milligan, IV), and Chief Financial Officer (Daniel A. Cartwright), whom we refer to as the Executives. Our Board of Directors approved these 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 of 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 our company is 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 Mr. Finizio as Chief Executive Officer calls for (i) a time-based ten-year stock option to be granted and issued on November 30, 2012 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 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 his 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 ten-year stock option to be granted and issued on November 30, 2012 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 his 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 ten-year stock option to be granted and issued on November 30, 2012 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 his base salary, at the discretion of our Board of Directors.

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 his current base salary 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 salaries over a 12-month period pursuant to their employment agreements:

Name	Salary
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 salaries over a 12-month period pursuant to their employment letter agreements:

Name	Salary
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.

Equity Compensation Plans

2009 Long Term Incentive Compensation Plan

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or 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 Stock Incentive Plan, or 2012 SOP, a non-qualified plan not requiring approval by our shareholders. The 2012 SOP was designed to serve as an incentive for retaining qualified and competent key employees, officers and directors, and certain consultants and advisors of our company. There are 10,000,000 shares authorized for issuance thereunder. No shares have been issued under the 2012 SOP through the date of this prospectus.

Securities Authorized for Issuance under Equity Compensation Plans

As of December 31, 2011, 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 Not Approved by Security Holders	–	–	–
Equity Compensation Plans Approved by Stock Holders	10,536,161	$0.16	14,317,782
Total	10,536,161	$0.16	14,317,782

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.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Except for the transactions described below, none of our directors, officers, or principal shareholders, 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, 2011.

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, which we refer to as 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 September 30, 2012, 460,285 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. This extension accrues interest at the rate of 2.35% and is due on March 1, 2013. At September 30, 2012, the outstanding principle balance of the Bank LOC was $299,220.

Repayment of VitaMed Promissory Notes

In June 2011, VitaMed sold Promissory Notes, which we refer to as 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 of 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 shall 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 five percent 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.

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of November 21, 2012 by the following:

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

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 November 21, 2012. 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.

The Selling Stockholders, if they desire, may dispose of the shares covered by this prospectus from time to time at such prices as it may choose. Before a stockholder not named below may use this prospectus in connection with an offering of shares, this prospectus must be amended or supplemented to include the name and number of shares beneficially owned by the Selling Stockholder and the number of shares to be offered. Any amended or supplemented prospectus also will disclose whether any selling stockholder named in that amended or supplemented prospectus has held any position, office or other material relationship with us or any of our predecessors or affiliates during the three years prior to the date of the amended or supplemented prospectus. None of the Selling Stockholders has held any position or office, or has had any other material relationship with us or any of our affiliates within the past three years. As used in this prospectus, "Selling Stockholders" includes the donees, pledgees, transferees, or other successors-in-interest who may later hold the Selling Stockholders' interests.

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 Owner	Shares Beneficially Owned Prior to this Offering Number	Percent(1)	Number of Shares Being Registered for Sale(2)	Beneficially Owned Upon Completion of this Offering Number	Percent(1)
Executive Officers and Directors:					
Robert G. Finizio, Chief Executive Officer and Director(3)	23,889,066	23.53 %	–	23,889,066	23.53 %
	8,761,215	8.57 %	–	8,761,215	8.57 %

John C.K. Milligan, IV, President, Secretary and Director(4)							
Daniel A. Cartwright, Chief Financial Officer, Vice President, Finance, and Treasurer(5)	279,540	*		–	279,540	*	
Mitchell L. Krassan, Executive Vice President and Chief Strategy Officer(6)	738,499	*		–	738,499	*	
Brian Bernick, M.D., Chief Medical Officer and Director(7)	10,704,049	10.56	%	–	10,704,049	10.56	%
Tommy Thompson, Chairman of the Board(8)	675,000	*		–	675,000	*	
Samuel A. Greco, Director(9)	450,000	*		–	450,000	*	
Cooper C. Collins, Director(10)	2,706,579	2.71	%	–	2,706,579	2.71	%
Robert V. LaPenta, Jr., Director(11)	80,000	*		–	80,000	*	
Nicholas Segal, Director(12)	805,759	*		–	805,759	*	
All executive officers and directors as a group (10 persons)(13)	49,089,707	45.91	%	–	49,089,707	45.91	%

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering Number	Percent(1)	Number of Shares Being Registered for Sale(2)	Beneficially Owned Upon Completion of this Offering Number	Percent(1)
5% Stockholders:					
Steven G. Johnson(14)	9,441,649	9.21 %	1,141,658	8,299,991	8.10 %
Robert J. Smith(15)	9,632,238	9.40 %	1,141,658	8,490,580	8.28 %
Wellington Management Company, LLP(16)	5,000,000	5.01 %	–	5,000,000	5.01 %
Other Selling Stockholders:					
Wellington Management Portfolio (Australia)-Special Strategies Portfolio (nominee: Gerlach and Co.)(17)	133,794	*	26,902	106,892	*
Vanguard Capital Value Fund (nominee: Vanguard Cap Value Fund c/o BBH & Co.)(17)	1,489,571	1.49 %	1,489,571	–	–
Wellington Trust Company, N.A., Multiple Collective Investment Funds Trust II, Global Equities Portfolio (nominee: CASCOFLAG & CO.)(17)	113,016	*	64,751	48,265	*
Wellington Trust Company, N.A., Multiple Collective Investment Funds Trust, All Cap Opportunities Portfolio (nominee: CASCOFISH & CO.)(17)	82,287	*	15,421	66,866	*
Global Multi-Strategy Fund (nominee: Hare & Co.)(17)	59,729	*	15,388	44,341	*
Ralph Daniel Freudenthal	62,540	*	58,140	4,400	*

*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 November 21, 2012, as adjusted for each stockholder.

(2) We have no assurance that the Selling Stockholders will sell any of the shares being registered for sale. See “Plan of Distribution.”

(3) This amount includes (i) 22,161,586 shares directly owned by Finizio, (ii) 1,522,910 shares due to Finizio upon exercise of vested shares under options and (iii) 204,570 shares due to Finizio upon exercise of vested shares under a warrant. The percentage of class for Finizio is based on 101,512,462 shares which would be outstanding if all of Finizio’s vested shares under the options and warrant were exercised.

(4) This amount includes (i) 6,368,018 shares directly owned by Milligan, (ii) 2,127,255 shares due to Milligan upon exercise of vested shares under options, and (iii) 265,942 shares due to Milligan upon exercise of vested shares

under warrants. The percentage of class for Milligan is based on 102,178,179 shares which would be outstanding if all of Milligan's vested shares under the options and warrants were exercised.

(5) This amount includes (i) 75,000 shares due to Cartwright upon exercise of vested shares under options, and (ii) 204,540 shares due to Cartwright upon exercise of vested shares under a warrant. The percentage of class for Cartwright is based on 100,064,522 shares which would be outstanding if all vested shares under the options and warrant were exercised.

(6) This amount includes 738,499 shares due to Krassan upon exercise of vested shares under options. The percentage of class for Krassan is based on 100,523,481 shares which would be outstanding if all of Krassan's vested shares under the options were exercised.

(7) This amount includes (i) 9,119,767 shares beneficially owned by BF Investment Enterprises, Ltd., or BF Investment, a company controlled by Mr. Bernick, (ii) 1,522,910 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 of class for Bernick is based on 101,369,264 shares which would be outstanding if all of BF Investment's vested shares under the options and warrant were exercised.

(8) 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 Thompson, and (ii) 75,000 shares due to Thompson upon exercise of vested shares under options. The percentage of class for Thompson is based on 99,859,982 shares which would be outstanding if all of Thompson's vested shares under the options were exercised.

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

(10) This amount includes (i) 2,631,579 shares beneficially owned by Pernix Therapeutics Holdings, Inc., of which Collins is CEO, director and largest shareholder, 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 Collins upon exercise of vested shares under options. The percentage of class for Collins is based on 99,859,982 shares which would be outstanding if all of Collins' vested shares under the options were exercised.

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

(12) This amount includes (i) 245,485 shares directly owned by Segal, and (ii) 142,057 shares due to Segal upon exercise of vested shares under an option. Segal owns 11.5812% of Fourth Generation Equity Partners, or Fourth Generation, which owns (i) 3,549,805 shares and (ii) 61,372 shares due to Fourth Generation upon exercise of vested shares under a warrant. Segal claims ownership equal to 411,110 shares and 7,107 vested shares under the Fourth Generation warrant. Segal disclaims beneficial ownership to the remaining shares and remaining vested shares under the warrant owned by Fourth Generation. The percentage of class for Segal is based on 99,934,146 shares which would be outstanding if all of Segal's and Fourth Generation's vested shares under options were exercised.

(13) 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. The percentage of class for all officers and directors is based on 106,932,144 shares which would be outstanding if all of the officers' and directors' vested shares under options and warrants were exercised.

(14) This amount includes (i) 6,741,649 shares beneficially owned through SJ Capital, LLC, an entity solely owned by Steven G. Johnson, of which 1,141,658 shares are being registered hereunder and (ii) 2,700,000 shares due to Mr. Johnson upon the exercise of vested warrants. The percentage of class for 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.

(15) This amount includes (i) 5,509,910 shares beneficially owned through Plato and Associates, LLC, an entity solely owned by Robert J. Smith, (ii) 1,422,328 shares beneficially owned through Energy Capital, LLC, an entity solely owned by Mr. Smith, of which 1,141,658 shares are being registered hereunder, and (iii) 2,700,000 shares due to Mr. Smith upon the exercise of vested warrants. The percentage of class for Mr. Smith is based on 102,484,982 shares which 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.

(16) The shares are beneficially owned by Wellington Management, 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 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's address is 280 Congress Street, Boston Massachusetts 02210.

(17) Wellington Management Company, LLP, or Wellington, is an investment adviser registered under the Investment Advisers Act of 1940, as amended. Wellington, in such capacity, may be deemed to share beneficial ownership over these shares held by its client account.

Under Rule 144 promulgated under the Securities Act, our officers, directors and beneficial shareholders may sell up to one percent (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.

PLAN OF DISTRIBUTION

The Selling Stockholders may, from time to time, sell, transfer, or otherwise dispose of any or all of their shares of common stock on any stock exchange, market, or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The Selling Stockholders may use any one or more of the following methods when disposing of shares:

- on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in the transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the listing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

If the Selling Stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions, or commissions from the Selling Stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions, or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The Selling

Stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The Selling Stockholders also may transfer or donate the shares of common stock in other circumstances, in which case the transferees, donees, pledgees, or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealers or agents participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such distributions. In such event, any commissions received, or any discounts or concessions allowed to, such broker-dealers or agents may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Stockholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement of which this prospectus forms a part.

The Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, the anti-manipulation rules of Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the Selling Stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the Selling Stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We are required to pay all expenses of the registration of the shares of common stock, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that the Selling Stockholders will pay all underwriting discounts and selling commissions, if any, and all fees and expenses of their respective legal counsel. We have agreed to indemnify the Selling Stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus. We may be indemnified by the Selling Stockholders against liabilities, including liabilities under the Securities Act, and state security laws, that may arise from any written information furnished to us by the Selling Stockholders specifically for use in this prospectus.

Once effective, our company has agreed to use its commercially reasonable efforts to keep such registration, and any qualification, exemption or compliance under state securities laws which our company determines to obtain, continuously effective, and to keep the registration statement of which this prospectus forms a part free of any material misstatements or omissions, until the earlier of the following: (1) the date on which the Selling Stockholders cease to hold any shares of common stock registered hereunder, or (2) the date all shares of common stock held by the Selling Stockholders may be sold without restriction under Rule 144, including without limitation, any volume and manner of sale restrictions which may be applicable to affiliates under Rule 144.

Once sold under the shelf registration statement of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

We are authorized to issue an aggregate of 250,000,000 shares of capital stock, 250,000,000 shares of common stock, par value $.001 per share, and 10,000,000 shares of preferred stock, par value $.001 per share. As of date of this prospectus, we had 99,784,982 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Description of Our Common Stock

We are authorized to issue up to 250,000,000 shares of common stock, par value $0.001 per share, which shares are non-assessable. All outstanding shares of our common stock are of the same class and have equal rights and attributes. The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders of our company. Our common stock does not have cumulative voting rights. Persons who hold a majority of the outstanding shares of our common stock entitled to vote on the election of directors can elect all of the directors who are eligible for election. Holders of our common stock are entitled to share equally in dividends, if any, as may be declared from time to time by our board of directors. In the event of liquidation, dissolution or winding up of our company, subject to the preferential liquidation rights of any series of preferred stock that we may from time to time designate, the holders of our common stock are entitled to share ratably in all of our assets remaining after payment of all liabilities and preferential liquidation rights. Holders of our common stock have no conversion, exchange, sinking fund, redemption or appraisal rights (other than such as may be determined by the Board of Directors in its sole discretion) and have no preemptive rights to subscribe for any of our securities.

Description of Our Preferred Stock

We are currently authorized to issue up to 10,000,000 shares of preferred stock, par value $0.001 per share. Our Articles of Incorporation authorize the issuance of shares of preferred stock with designations, rights and preferences determined from time to time by our board of directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting, or other rights which could adversely affect the voting power or other rights of the stockholders of the common stock. In the event of issuance, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. As of the date of this prospectus, there are no outstanding shares of preferred stock and no series of preferred stock has been designated by our company.

Registration Rights and Indemnification of Selling Stockholders

On September 26, 2012, we entered into a 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 & Company, Inc. 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 $7,920,501.

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 are obligated to use our best efforts to effect the registration (including a declaration of effectiveness of this registration statement by the SEC) no later than 90 days from October 2, 2012 (120 days if reviewed by SEC). If this registration statement does not become effective on or before the required effectiveness date, we have agreed, among other things, to pay to these investors 1.5% of each investor's aggregate purchase price of the shares for each 30-day period that this registration statement is not effective, up to a maximum of 10% of such aggregate purchase price.

To the extent permitted by law, we will indemnify each Selling Stockholder, with respect to which the registration of the Selling Stockholders' shares pursuant to the Purchase Agreement (subject to the terms thereof), against all claims, losses, damages, and liabilities (or action in respect thereof), including any of the foregoing incurred in settlement of any litigation, commenced or threatened.

Anti-takeover Effects of Nevada Law

Business Combinations

The "business combination" provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statutes, or NRS, generally prohibit a Nevada corporation with at least 200 stockholders from engaging in various "combination" transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the board of directors prior to the date the interested stockholder obtained such status or the combination is approved by the board of directors and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless:

- the combination was approved by the board of directors prior to the person becoming an interested stockholder or the transaction by which the person first became an interested stockholder was approved by the board of directors before the person became an interested stockholder or the combination is later approved by a majority of the voting power held by disinterested stockholders, or

- if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.

A "combination" is generally defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an "interested stockholder" having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, (c) 10% or more of the earning power or net income of the corporation, and (d) certain other transactions with an interested stockholder or an affiliate or associate of an interested stockholder.

In general, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within two years, did own) 10% or more of a corporation's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire our company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Control Share Acquisitions

The "control share" provisions of Sections 78.378 to 78.3793, inclusive, of the NRS apply to "issuing corporations" that are Nevada corporations with at least 200 stockholders, including at least 100 stockholders of record who are Nevada residents, and that conduct business directly or indirectly in Nevada. The control share statute prohibits an acquirer, under certain circumstances, from voting its shares of a target corporation's stock after crossing certain ownership threshold percentages, unless the acquirer obtains approval of the target corporation's disinterested stockholders. The statute specifies three thresholds: one-fifth or more but less than one-third, one-third but less than a majority, and a majority or more, of the outstanding voting power. Generally, once an acquirer crosses one of the above thresholds, those shares in an offer or acquisition and acquired within 90 days thereof become "control shares" and such control shares are deprived of the right to vote until disinterested stockholders restore the right. These provisions also provide that if control shares are accorded full voting rights and the acquiring person has acquired a majority or more of all voting power, all other stockholders who do not vote in favor of authorizing voting rights to the control shares are entitled to demand payment for the fair value of their shares in accordance with statutory procedures established for dissenters' rights.

A corporation may elect to not be governed by, or "opt out" of, the control share provisions by making an election in its articles of incorporation or bylaws, provided that the opt-out election must be in place on the 10th day following the date an acquiring person has acquired a controlling interest, that is, crossing any of the three thresholds described above. We have not opted out of the control share statutes, and will be subject to these statutes if we are an "issuing corporation" as defined in such statutes.

The effect of the Nevada control share statutes is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of our company.

Limitations of Liability and Indemnification of Officers and Directors

Our certificate of incorporation and bylaws limit the liability of directors to the fullest extent permitted by the Nevada Corporation Act. In addition, our certificate of incorporation and bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by law.

Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, officers, or controlling persons pursuant to the provisions described in the preceding paragraph, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transfer Agent

We use Computershare Trust Company, Inc. located at 350 Indiana St., Suite 800, Golden, Colorado 80401 as our transfer agent.

SHARES ELIGIBLE FOR FUTURE SALE

Our common stock is traded on the OTCQB under the symbol "TXMD." We cannot predict the effect, if any, that sales of shares in the market, or the availability of shares for sale, will have on the market price of our common stock from time to time. Sales of our common stock in the public market after the restriction lapses as described below, or the perception that those sales may occur, could cause the prevailing market price to decline or to be lower than it might be in the absence of those sales or perceptions, of which we have no control.

Sale of Restricted Shares

As of the date of this prospectus, we had 99,784,982 shares of our common stock outstanding. Of these shares, the 3,953,489 sold in the September 2012 private placement will be freely tradable without restriction under the Securities Act upon declaration of effectiveness by the SEC of the registration statement of which this prospectus forms a part, except for any shares purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act. In general, affiliates include executive officers, directors, and 10% shareholders. Shares purchased by affiliates will remain subject to the resale limitations of Rule 144. The remaining shares outstanding prior to the offering are restricted securities within the meaning of Rule 144. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 promulgated under the Securities Act, which is summarized below.

Taking into account the lock-up agreements described below, approximately 2,775,415 of our shares are eligible for sale and 10,920,901 shares will be eligible for sale at December 31, 2012 in the public market subject to volume, manner of sale and other limitations under Rule 144.

Lock Up Agreements

As required by of the terms of the merger agreement with VitaMed, we entered into a lock-up agreement with certain security holders covering the 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, the security holders 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.

We closed a stock purchase agreement with Pernix Therapeutics, LLC, or Pernix, on October 4, 2011 pursuant to which Pernix purchased 2,631,579 shares of our common stock. 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 five percent of the shares per quarter for the following 12-month period.

Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned restricted securities of an issuer that has been subject to the reporting requirements of the Exchange Act for at least six months and who is not affiliated with such issuer, would be entitled to sell an unlimited number of shares of common stock so long as the issuer has met its public information disclosure requirements. In addition, an affiliated person who has owned restricted securities for at least six months would be entitled to sell, within any three-month period, a number of shares that does not exceed the greater of the following:

- 1% of the number of shares of common stock then outstanding; or

- The average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice of Form 144 with respect to such sale.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice, and the availability of current public information about us.

Stock Options

We intend to file registration statements under the Securities Act as soon as practicable for shares issued upon the exercise of options and shares to be issued under our employee benefit plans. As a result, any options or shares issued upon any benefit plan after the effectiveness of the registration statements will also be freely tradable in the public market. However, such shares held by affiliates will still be subject to the volume limitation, manner of sale, notice, and public information requirements of Rule 144, in addition to any requirements of the Lock Up Agreements.

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Greenberg Traurig, LLP, Phoenix, Arizona.

EXPERTS

The financial statements as of December 31, 2011 included in this prospectus have been audited by Rosenberg Rich Baker Berman & Company, an independent registered public accounting firm, as stated in their report appearing herein. The financial statements as of December 31, 2010 included in this prospectus have been audited by Parks & Company, LLC. Such financial statements have been so included in reliance upon the report of such firms given upon their authority as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-1 with the SEC relating to the common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in the exhibits and schedules to the registration statement as permitted by the rules and regulations of the SEC. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance we refer you to the copy of the contract or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement, exhibits, and schedules. Anyone may inspect a copy of the registration statement without charge at the public reference facility maintained by the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Copies of all or any part of the registration statement may be obtained from that facility upon payment of the prescribed fees. The public may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website a http://www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC.

We make available free of charge on our website at www.therapeuticsmd.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, and reports on Form 8-K, amendments to such reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, proxy statements, and other information as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or connected to, or that can be accessed via our website is not part of this prospectus.

THERAPEUTICSMD, INC.

INDEX TO FINANCIAL STATEMENTS

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash	$154,247	$126,421
Accounts receivable, net of allowance for doubtful accounts of $34,713 and $1,500, respectively	270,262	26,720
Inventory	955,129	588,073
Other current assets	851,839	496,060
Total current assets	2,231,477	1,237,274
Property and equipment, net	95,066	70,113
Other Assets:		
Prepaid expenses	1,048,952	80,515
Patent costs	107,094	18,870
Security deposit	31,949	31,949
Total other assets	1,187,995	131,334
Total assets	$3,514,538	$1,438,721
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$1,031,053	$306,511
Deferred revenue	701,929	—
Notes payable	2,099,220	2,150,000
Notes payable, related parties	150,000	200,000
Accrued interest	16,986	28,321
Other current liabilities	428,378	465,747
Total current liabilities	4,427,566	3,150,579
Long-Term Liabilities:		
Notes payable, net of debt discount of $1,350,162 and $0, respectively	3,341,686	—
Accrued interest	79,111	—
Total long-term liabilities	3,420,797	—
Total liabilities	7,848,363	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

Additional paid in capital	50,310,369	15,198,241
Subscriptions receivable	(8,358,001)	—
Accumulated deficit	(46,385,978)	(16,993,078)
Total stockholders' deficit	(4,333,825)	(1,711,858)
Total liabilities and stockholders' deficit	$3,514,538	$1,438,721

THERAPEUTICSMD, INC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September30,	
	2012 (Unaudited)	2011 (Unaudited)	2012 (Unaudited)	2011 (Unaudited)
Revenues, net	$1,036,456	$539,572	$2,577,298	$1,533,731
Cost of goods sold	306,843	241,688	1,015,337	684,420
Gross profit	729,613	297,884	1,561,961	849,311
Operating expenses:				
Sales, general, and administration	3,291,357	1,633,180	9,691,892	3,818,710
Research and development	1,334,005	95,223	2,579,308	255,953
Depreciation and amortization	14,839	13,711	43,952	41,133
Total operating expense	4,640,201	1,742,114	12,315,152	4,115,796
Operating loss	(3,910,588)	(1,444,230)	(10,753,191)	(3,266,485)
Other income and (expense)				
Miscellaneous income	932	75	2,486	75
Loss on extinguishment of debt	(197,383)	—	(10,505,247)	—
Beneficial conversion feature	—	—	(6,716,504)	—
Amortization of debt discount	(50,099)	(14,360)	(1,159,375)	(17,950)
Interest expense	(84,376)	(16,505)	(225,834)	(16,737)
Loan guaranty costs	(11,745)	(11,745)	(35,235)	(26,414)
Total other income (expense)	(342,671)	(42,535)	(18,639,709)	(61,026)
Loss before taxes	(4,253,259)	(1,486,765)	(29,392,900)	(3,327,511)