

PROSPECTUS

3,953,489 Shares

# TherapeuticsMD<sup>®</sup>

## Common Stock

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

The Shares 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.

The Shares covered by this prospectus were issued on October 2, 2012 in a private placement, or the October Private Placement, pursuant to a Securities Purchase Agreement, or the Purchase Agreement, dated September 26, 2012, between us and certain investors. As part of the Purchase Agreement, we agreed to file a registration statement, which was filed November 27, 2012. For a more detailed description of the issuance of the Shares pursuant to the Purchase Agreement, see "Summary of the Underlying Transactions" on page 28.

The Selling Stockholders who may sell or otherwise dispose of the Shares are initial investors (or the permitted transferees of such investors) in the October Private Placement described above. The Selling Stockholders may offer the Shares from time to time directly or through underwriters, broker-dealers or agents and in one or more public or private transactions and at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at various prices determined at the time of sale or otherwise at negotiated prices. If the Shares are sold through underwriters, broker-dealers, or agents, the Selling Stockholders (or the purchasers of the Shares as negotiated with the Selling Stockholders) will be responsible for underwriting discounts or commissions or agent commissions, if any. The registration of the Shares does not necessarily mean that any of the Shares will be sold by the Selling Stockholders. The timing and amount of any sale is within the respective Selling Stockholders' sole discretion, subject to certain restrictions. See "Plan of Distribution" beginning on page 92 of this prospectus.

We will not receive any of the proceeds from the sale of the Shares offered by the Selling Stockholders. We received aggregate net proceeds of \$7,896,000 from the initial sale of the Shares to the Selling Stockholders in the October Private Placement on October 2, 2012.

Our common stock is listed on the NYSE MKT under the symbol "TXMD." On October 8, 2013, the reported closing price of our common stock on the NYSE MKT was \$3.74 per share.

**See "Risk Factors" beginning on page 6 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 nor any state securities commission 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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Prospectus dated October 15, 2013.

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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, or 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.

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## 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 women’s healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately \$10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in vulvar and vaginal atrophy, or VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate’s pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman’s body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be approximately \$25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately \$650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately \$490 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman’s body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-002HR to be approximately \$6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately \$340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately \$780 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately \$16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately \$1 billion in U.S. sales.

We intend to leverage and grow our current marketing and sales organization to commercialize our proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved menopause-related estrogen market was approximately \$2.5 billion in U.S. sales.

The hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. We believe the FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies are approximately \$1.5 billion per year. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA approved compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

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

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

Our common stock began trading on the NYSE MKT on April 23, 2013 under the symbol “TXMD” and was previously listed on the OTCQB. We maintain the following websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com) and [www.bocagreenmd.com](http://www.bocagreenmd.com).

## Our Growth Strategy

Our goal is to become the women's healthcare company recommended by healthcare 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 hormone therapy products designed to (1) alleviate the symptoms of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and (2) provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products;
- providing an alternative to the non-FDA approved compound bioequivalent market for estradiol and progesterone products sold by compounding pharmacies;
- maintaining a marketing emphasis on large group OB/GYN practices that provide opportunities to reach large patient bases and that are receptive to the data and savings we provide;
- pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and our website;
- expanding our geographic market and sales team to cover the entire country by increasing our current inside sales force; and
- introducing new products to build upon the introduction of our first three prescription prenatal vitamin products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012, as well as our hormone therapy products consisting of a bioequivalent oral and topical combination drug of estradiol and progesterone, an oral progesterone drug, and a suppository vulvar and vaginal atrophy estradiol drug. Early pharmacokinetic, or PK, studies of our proposed combination estradiol and progesterone drug demonstrated that the product is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250.

## 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 reports related to our financial statements for the two years ended December 31, 2012 and 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 healthcare 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	144,962,706 shares. This number does not include 14,655,793 shares of common stock reserved for issuance upon exercise of stock options, 14,293,499 shares of common stock reserved for issuance upon exercise of warrants, and 18,258,990 shares of common stock reserved for future issuance under our non-qualified stock option plans.
Use of proceeds	We will not receive any of the proceeds from the sale of Shares to be offered by the Selling Stockholders.
NYSE MKT Symbol	TXMD

## Recent Developments

On September 25, 2013, we entered into an underwriting agreement, or the Stifel Underwriting Agreement, with Stifel, Nicolaus and Company, Incorporated, as representative of the underwriters named therein, or the September Underwriters, relating to the issuance and sale of 13,750,000 shares of our common stock. The price to the public in this offering was \$2.40 per share and the September Underwriters agreed to purchase the shares from us pursuant to the Stifel Underwriting Agreement at a price of \$2.232 per share. The net proceeds to us from this offering was approximately \$30.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering was made pursuant to the registration statement on Form S-3 filed with the Commission on January 25, 2013, and deemed effective by the SEC on February 5, 2013, including prospectus supplements filed thereunder.

## Our Offices

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. The Company maintains websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com), and [bocagreenmd.com](http://bocagreenmd.com). The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus, nor is such content incorporated herein by reference.

## 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, 2011 and 2012, and the consolidated balance sheet data as of December 31, 2011 and 2012, are derived from our audited consolidated financial statements included in this prospectus. The consolidated statement of operations for the six months ended June 30, 2012 and 2013 and the balance sheet data as of June 30, 2013 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,		Six Months Ended June 30,	
	2011	2012	2012	2013
	<i>(in thousands, except share data)</i>			
<b>Consolidated Statements of Operations Data:</b>				
Revenue, net	\$ 2,088	\$ 3,818	\$ 1,540	\$ 3,618
Cost of goods sold	947	1,348	708	844
Gross profit	1,141	2,470	832	2,774
Operating expense:				
Sales, general, and administration	6,406	14,070	6,401	10,003
Research and development	107	4,492	1,245	3,312
Depreciation and amortization	55	56	29	19
Total operating expense	6,568	18,618	7,675	13,334
Operating loss	(5,427)	(16,148)	(6,843)	(10,560)
Other income (expense)				
Loss on extinguishment of debt	(7,390)	(10,308)	(10,308)	—
Beneficial conversion feature	—	(6,717)	(6,717)	—
Amortization of debt discount	(29)	(1,604)	—	—
Financing costs	—	—	—	(660)
Interest expense	(36)	(301)	(1,251)	(1,166)
Loan guaranty costs	(38)	(45)	(23)	(3)
Other income	6	3	2	3
Total other income (expense)	(7,486)	(18,972)	(18,297)	(1,825)
Loss before taxes	(12,913)	(35,120)	(25,140)	(12,385)
Provision for income taxes	—	—	—	—
Net loss	\$ (12,913)	\$ (35,120)	\$ (25,140)	\$ (12,385)
Net loss per share, basic and diluted:				
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.38)	\$ (0.29)	\$ (0.11)
Weighted average number of common shares outstanding	62,516,461	91,630,693	85,352,818	116,866,764
<b>Consolidated Balance Sheet Data (at end of period):</b>				
Total assets	\$ 1,439	\$ 5,818	\$ 4,878	\$ 43,066
Total liabilities	\$ 3,151	\$ 7,251	\$ 5,582	\$ 4,599
Total stockholders’ equity (deficit)	\$ (1,712)	\$ (1,433)	\$ (704)	\$ 38,467
<b>Other Data:</b>				
Capital expenditures	\$ 38	\$ 273	\$ 116	\$ 135
Working capital (deficit) (at end of period)	\$ (1,914)	\$ 1,015	\$ 967	\$ 35,908
Net cash provided by (used in)				
Operating activities	\$ (4,967)	\$ (12,737)	\$ (5,249)	\$ (10,685)
Investing activities	\$ (38)	\$ (273)	\$ (516)	\$ (260)
Financing activities	\$ 4,708	\$ 14,437	\$ 6,966	\$ 43,827

## 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 \$12.4 million and \$25.1 million for the six months ended June 30, 2013 and 2012, respectively. As of June 30, 2013, we had an accumulated deficit of approximately \$64.5 million. We have generated limited revenue and have funded our operations to date primarily from private sales of equity and debt securities. We expect to incur substantial additional losses over the next several years as our research, development, and clinical trial activities increase, especially those related to our proposed hormone therapy products. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our proposed hormone therapy products. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

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

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

***We currently derive all of our revenue from sales of our women's healthcare 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 healthcare products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, natural menopause relief, and scar reduction creams. While sales of our vitamin products grew from 2010 through 2012, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic copies of our prescription dietary supplement products;
- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;
- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal healthcare programs;



- the impact or efficacy of any price increases we may implement in the future;
- changes to our label and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

Three proposed hormone therapy products are currently in various stages of clinical testing. We have recently began Phase 3 clinical trial of our estradiol and progesterone combination product and we currently intend to begin Phase 3 clinical trial for our oral progesterone product at the end of 2013. Clinical trials are expensive, can take many years to complete, and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our proposed hormone therapy products fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. The goal of PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. Among other measures, PPACA imposes increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect PPACA will have on federal reimbursement policies in general or on our business specifically, the PPACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

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



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

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

- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to our reputation;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls or withdrawals;
- labeling, marketing, or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or proposed hormone therapy products; and
- a decline in our stock price.

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

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

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

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

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

***We are subject to extensive and costly government regulation.***

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of October 7, 2013, we had 68 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our proposed hormone therapy products, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

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

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

## Risks Related to our Intellectual Property

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

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

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

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

These risks include the possibility of the following:

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

- delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our product candidates under patent protection; and
- we may fail to timely apply for patents on our technologies or products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

### **Risks Related to Ownership of Our Common Stock**

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

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

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

- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;
- increases in our common stock available for sale upon expiration of lock-up agreements;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and the 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 October 7, 2013, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 67% of our common stock on an as-if converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

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

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

- authorizing the issuance of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

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

## 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,” “estimates,” “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;
- the ability of our products to produce the intended effects;
- our ability to develop and commercialize our proposed advanced hormone therapies;
- our estimates regarding our capital requirements and 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;
- our expectations with respect to the potential commercial value of our proposed products;
- the competitive nature of the industries in which we conduct our business;
- the availability of reimbursement from government authorities and health insurance companies for our products;
- the impact of product liability lawsuits;
- unfavorable publicity or lack of customer acceptance;
- our ability to use hazardous or biological materials in compliance with 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, withdrawals, or safety alerts;
- 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;
- our ability to use the proceeds from this offering in an effective manner; 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.

## SUMMARY OF THE UNDERLYING TRANSACTIONS

In September 26, 2012, we entered into the Stock Purchase Agreement with multiple investors, or the Investors, relating to the issuance and sale of our Common Stock in a private placement. The private placement closed on October 2, 2012, or the Closing Date, through which we sold an aggregate of 3,953,489 shares of our Common Stock at \$2.15 per share for an aggregate purchase price of \$8,500,001. In connection with the private placement, Jefferies LLC, or Jefferies, served as our exclusive placement agent. Jefferies' compensation for the transaction was a cash fee of \$552,500, which is included in accounts payable in the consolidated financial statements included in this prospectus. We also paid legal fees and expenses of the Investors in the aggregate of \$52,016, resulting in net proceeds to us of \$7,895,485. The Shares were issued in reliance upon the exemptions from registration under the Securities Act of 1933 provided by Section 4(a)(2) and Rule 506 of Regulation D promulgated thereunder. The Shares were issued directly by us and did not involve a public offering or general solicitation. The Investors in the private placement are "accredited investors" as that term is defined in Rule 501 of Regulation D and acquired the Shares for investment only and not with a view toward, or for resale in connection with, the public sale or distribution thereof. As part of the Stock Purchase Agreement, we agreed to file a registration statement, which was filed November 27, 2012.

### 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

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

					<u>High</u>	<u>Low</u>
<b>2013</b>						
Fourth Quarter (through 2013)		October 8,			\$ 3.80	\$ 2.86
Third Quarter					\$ 3.18	\$ 2.03
Second Quarter					\$ 3.23	\$ 1.73
First Quarter					\$ 3.70	\$ 1.65
<b>2012</b>						
Fourth Quarter					\$ 3.50	\$ 1.25
Third Quarter					\$ 3.60	\$ 2.61
Second Quarter					\$ 2.84	\$ 2.06
First Quarter					\$ 2.50	\$ 1.43
<b>2011</b>						
Fourth Quarter					\$ 1.70	\$ 0.51
Third Quarter					\$ 4.00	\$ 1.00
Second Quarter					\$ 7.00	\$ 1.00
First Quarter					\$ 10.00	\$ 2.00

On October 8, 2013, the closing sale price of our common stock was \$3.74 per share.

**Transfer Agent**

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

 **Holders**

At the close of business on October 7, 2013, we had 327 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.

## 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, 2011 and 2012, and the consolidated balance sheet data as of December 31, 2011 and 2012, are derived from our audited consolidated financial statements included in this prospectus. The consolidated statement of operations for the six months ended June 30, 2012 and 2013 and the balance sheet data as of June 30, 2013 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. The consolidated statements of operations for the year ended December 31, 2010, and the consolidated balance sheet data as of December 31, 2010, are derived from the audited consolidated financial statements of vitaMedMD, LLC, our predecessor, included in this prospectus. The consolidated statements of operations for the year ended December 31, 2009, and the consolidated balance sheet data as of December 31, 2009, are derived from the audited consolidated financial statements of vitaMedMD, LLC, our predecessor, not included in this prospectus. We had no material operations in 2008.



	Fiscal Year Ended December 31,				Six Months Ended	
	2009	2010	2011	2012	June 30,	
	(Restated)	(Restated)			2012	2013
	<i>(in thousands, except share data)</i>					
<b>Consolidated Statements of Operations</b>						
<b>Data:</b>						
Revenue, net	\$ 221	\$ 1,242	\$ 2,088	\$ 3,818	\$ 1,540	\$ 3,618
Gross profit	16	686	1,141	2,470	832	2,774
Total operating expense	1,309	3,553	6,568	18,618	7,675	13,334
Operating loss	(1,293)	(2,867)	(5,427)	(16,148)	(6,843)	(10,560)
Total other income (expense)	5	—	(7,486)	(18,972)	(18,297)	(1,825)
Net loss	\$ (1,288)	\$ (2,867)	\$ (12,913)	\$ (35,120)	\$ (25,140)	\$ (12,385)
<b>Net loss per share, basic and diluted:</b>						
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.07)	\$ (0.21)	\$ (0.38)	\$ (0.29)	\$ (0.11)
Weighted average number of common shares outstanding	27,423,970	38,289,463	62,516,461	91,630,693	85,352,818	116,866,764
<b>Consolidated Balance Sheet Data (at end of period):</b>						
Total assets	\$ 585	\$ 1,197	\$ 1,439	\$ 5,818	\$ 4,878	\$ 43,066
Total liabilities	\$ 102	\$ 233	\$ 3,151	\$ 7,251	\$ 5,582	\$ 4,599
Total stockholders' equity (deficit)	\$ 484	\$ 964	\$ (1,712)	\$ (1,433)	\$ (704)	\$ 38,467
<b>Other Data:</b>						
Capital expenditures	\$ 102	\$ 27	\$ 38	\$ 273	\$ 116	\$ 135
Working capital (deficit) (at end of period)	\$ 361	\$ 826	\$ (1,914)	\$ 1,015	\$ 967	\$ 35,908

**SELECTED QUARTERLY FINANCIAL DATA**

The following selected quarterly consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Registration Statement. The following table sets forth selected financial information for the dates and periods indicated. Our results for any of these periods are not necessarily indicative of the results to be expected for the year ending December 31, 2013 or for any other future period. Dollar amounts are in thousands, except per share amounts.

	<b>Six Months Ended June 30, 2013</b>	
	<b>First Quarter</b>	<b>Second Quarter</b>
	<b>(unaudited)</b>	
Net Revenues	\$ 1,537,195	\$ 2,080,885
Gross Profit	1,156,849	1,617,279
Net Loss	(6,375,653)	(6,009,646)
Net Loss Per Share	\$ (0.06)	\$ (0.05)
Weighted Average Number of Common Shares Outstanding	103,052,956	130,851,978

	<b>Fiscal Year Ended December 31, 2012</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
	<b>(unaudited)</b>			
Net Revenues	\$ 721,692	\$ 819,150	\$ 1,036,456	\$ 1,240,715
Gross Profit	385,568	446,780	729,613	907,939
Net Loss	(13,289,603)	(11,850,038)	(4,253,259)	(5,727,335)
Net Loss Per Share	\$ (0.16)	\$ (0.14)	\$ (0.04)	\$ (0.06)
Weighted Average Number of Common Shares Outstanding	84,556,216	86,149,419	95,895,677	91,630,693

	<b>Fiscal Year Ended December 31, 2011</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
	<b>(unaudited)</b>			
Net Revenues	\$ 485,856	\$ 508,303	\$ 539,572	\$ 554,446
Gross Profit	282,100	269,327	297,884	291,754
Net Loss	(774,365)	(1,066,381)	(1,486,765)	(9,585,854)
Net Loss Per Share	\$ (0.01)	\$ (0.02)	\$ (0.03)	\$ (0.15)
Weighted Average Number of Common Shares Outstanding	55,710,076	57,455,491	58,407,327	62,516,461

## 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 women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately \$10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in vulvar and vaginal atrophy, or VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be approximately \$25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately \$650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately \$490 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-002HR to be approximately \$6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately \$340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately \$780 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately \$16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately \$1 billion in U.S. sales.

We intend to leverage and grow our current marketing and sales organization to commercialize our proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved menopause-related estrogen market was approximately \$2.5 billion in U.S. sales.

The hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. We believe the FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies are approximately \$1.5 billion per year. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA approved compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

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

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

Our common stock began trading on the NYSE MKT on April 23, 2013 under the symbol “TXMD” and was previously listed on the OTCQB. We maintain the following websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com) and [www.bocagreenmd.com](http://www.bocagreenmd.com).

## Recent Developments

### *Repayment of June 2012 Notes*

On March 21, 2013, we repaid \$4,882,019 including accrued interest, related to secured promissory notes issued on June 19, 2012, or the June 2012 Notes, leaving a balance of \$21,595 in accrued interest as of March 31, 2013. On April 25, 2013, the balance of accrued interest was paid in full and the related security agreement was terminated. We issued the June 2012 Notes on June 19, 2012, to an individual and an entity, or, collectively, 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 or the June 2012 Note Purchase Agreement. As consideration for the June 2012 Notes, the Parties surrendered the remaining balance of promissory notes issued in February 2012 in the aggregate amount of \$1,347,128 and \$1,344,719, respectively (which sums included principal and interest through June 19, 2012), and we received an aggregate of \$2,000,000 of new funding from the Parties. The principal base amount of each of the June 2012 Notes, plus any additional advances made to us, together with accrued interest at the annual rate of 6%, was due in one lump sum payment on February 24, 2014. As security for our obligations under the June 2012 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. In connection with the June 2012 Notes, we also granted warrants for the purchase of an aggregate of 7,000,000 shares of our common stock.

### *Bank Line of Credit*

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note with First United Bank, or the Bank for a \$300,000 bank line of credit, or the Bank LOC. On November 13, 2012, we entered into an amendment with the Bank to reduce the Bank LOC to \$100,000 or the Bank LOC. In February 2013, we borrowed \$100,000 under the Amended Bank LOC. The Amended Bank LOC required a personal guarantee and cash collateral limited to \$100,000, which was provided by Reich Family Limited Partnership or Reich Family LP, an entity controlled by Mitchell Krassan, an officer of our company. On April 25, 2013, we paid the principal, fees and interest due under the Amended Bank LOC of \$100,735. On May 1, 2013, the Amended Bank LOC expired and was not renewed. Accordingly, the personal guarantee was canceled and the cash collateral was returned to Reich Family LP.

### *Credit Line for \$10 Million*

On January 31, 2013, we entered into a business loan agreement with Plato and Associates, LLC, a limited liability company, or Plato, for a Multiple Advance Revolving Credit Note or the Plato Note. The Plato Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum. Plato may make advances to us from time to time under the Plato Note at our request, which advances will be of a revolving nature and may be made, repaid, and made from time to time. Interest payments will be due and payable on the tenth day following the end of each calendar quarter in which any interest is accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Plato Note, together with all accrued interest and other amounts payable under the Plato Note, if any, will be due and payable on February 24, 2014. The Plato Note is secured by substantially all of our assets. On each of February 25 and March 13, 2013, \$200,000 was drawn against the Plato Note. On March 21, 2013, we repaid \$401,085, including accrued interest, and as of September 30, 2013, there was no balance outstanding under the Plato Note.

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

### *Public Offerings of Common Stock*

On March 14, 2013, we entered into an underwriting agreement, or the Jefferies Underwriting Agreement, with Jefferies LLC, as representative of the underwriters named therein, or the March Underwriters, relating to the issuance and sale of 29,411,765 shares of our common stock. The price to the public in this offering was \$1.70 per share and the March Underwriters agreed to purchase the shares from us pursuant to the Jefferies Underwriting Agreement at a price of \$1.581 per share. The net proceeds to us from this offering was approximately \$45.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, under the terms of the Jefferies Underwriting Agreement, we granted the March Underwriters a 30-day option, to purchase up to an additional 4,411,765 shares of common stock. The offering closed on March 20, 2013. On April 12, 2013, the March Underwriters exercised their option to purchase an additional 1,954,587 shares of our common stock to cover over-allotments. We issued these shares to the March Underwriters on April 18, 2013 and received net proceeds of approximately \$3.1 million after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering was made pursuant to the registration statement on Form S-3 filed with the Commission on January 25, 2013, and deemed effective by the SEC on February 5, 2013, including prospectus supplements filed thereunder.

On September 25, 2013, we entered into an underwriting agreement, or the Stifel Underwriting Agreement, with Stifel, Nicolaus and Company, Incorporated, as representative of the underwriters named therein, or the September Underwriters, relating to the issuance and sale of 13,750,000 shares of our common stock. The price to the public in this offering was \$2.40 per share and the September Underwriters agreed to purchase the shares from us pursuant to the Stifel Underwriting Agreement at a price of \$2.232 per share. The net proceeds to us from this offering was approximately \$30.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering was made pursuant to the registration statement on Form S-3 filed with the Commission on January 25, 2013, and deemed effective by the SEC on February 5, 2013, including prospectus supplements filed thereunder.

#### *Issuance of Stock Options*

On May 2, 2013, the Compensation Committee of our board of directors recommended the granting of stock options to our directors. The Board approved the recommendation, and we issued 10-year stock options for the purchase of an aggregate of 575,000 shares of our common stock with an exercise price of \$2.80, as follows: (i) stock option for the purchase of 225,000 shares of our common stock to the Chairman of the Board; (ii) stock option for the purchase of 75,000 shares of our common stock to the chair of each committee of the Board; and (iii) stock option for the purchase of 50,000 shares of our common stock to each of the remaining directors. All of these stock options vest in full on December 31, 2013.

On May 6, 2013, we issued 10-year stock options to consultants for the purchase of an aggregate of 96,068 shares with an exercise price of \$2.96, vesting over a 12-month period beginning on June 6, 2013.

On May 10, 2013, we issued 10-year stock options to employees for the purchase of an aggregate of 100,000 shares with an exercise price of \$2.71. An aggregate of 50,000 shares available under the stock options vest over a 4-year period on the anniversary of issuance and an aggregate of 50,000 shares vested immediately.

On June 21, 2013, we issued 10-year stock options to employees and consultants for the purchase of an aggregate of 632,500 shares with an exercise price of \$2.98. An aggregate of 232,500 shares available under the stock options vest over a 3-year period on the anniversary of issuance, an aggregate of 100,000 shares vest monthly over an 18-month period, and an aggregate of 300,000 vest monthly over a 3-year period.

#### *Exercise of Stock Option*

On June 28, 2013, an individual exercised a stock option to purchase an aggregate of 61,372 shares of our common stock for an aggregate purchase price of \$6,251.

#### *Forfeiture of Options by Robert Finizio*

On May 8, 2013, Robert Finizio, our Chief Executive Officer, forfeited his contractual right to receive 600,000 shares upon exercise of a stock option granted in connection with his employment agreement as well as his right to receive any future stock options. Mr. Finizio gave up these rights with the understanding that these stock options would be returned to the pool of options available for issuance to attract future employees.

#### *Issuance of Warrants*

On May 7, 2013, we entered into a consulting agreement, or the Agreement, with Sancilio & Company, Inc., or SCI, to develop drug platforms to be used in hormone replacement drug products, or the Drug Products. These services include support of our efforts to successfully obtain FDA approval for the Drug Products, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the Agreement, SCI agreed to forfeit its rights to receive warrants for the purchase of an aggregate of 833,000 shares of our common stock that were to be issued pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the Agreement, we agreed to issue SCI a warrant to purchase 850,000 shares of our common stock, or the SCI Warrant that vests in three equal installments as follows: (i) 283,333 shares upon SCI's transfer to us of all intellectual property associated with the Drug Products, (ii) 283,333 shares upon successful filing of the IND application with the FDA for the Drug Product for an estradiol-based product in a softgel vaginal capsule for the treatment of VVA, and (iii) 283,333 shares upon the receipt by us of any final FDA approval of a Drug Product that SCI helped us design. It is anticipated that this event will not occur before December 2015. Pursuant to the terms of the Agreement, no portion of the SCI Warrant could have vested prior to June 30, 2013.

Our prior lease for premises located at 951 Broken Sound Parkway in Boca Raton, Florida expired on June 30, 2013. With an effective date of July 1, 2013, we entered into a new lease for administrative office space located at 6800 Broken Sound Parkway in Boca Raton, Florida pursuant to a 63-month non-cancelable operating lease expiring on September 30, 2018. The lease stipulates, among other things, average base monthly rents of \$28,442 (inclusive of estimated operating expenses) and sales tax, for a total future minimum payment over the life of the lease of \$1,791,900.

## Results of Operations

*Six months ended June 30, 2013 compared to six months ended June 30, 2012*

	<b>Six Months Ended June 30,</b>		<b>Change</b>
	<b>2013</b>	<b>2012</b>	
	<i>(in thousands)</i>		
Revenue, net	\$ 3,618	\$ 1,541	\$ 2,077
Cost of goods sold	844	708	136
Operating expenses	<u>13,334</u>	<u>7,675</u>	<u>5,659</u>
Operating loss	(10,560)	(6,842)	(3,718)
Loss on extinguishment of debt	—	(10,308)	10,308
Beneficial conversion feature	—	(6,717)	6,717
Other expense	<u>(1,825)</u>	<u>(1,273)</u>	<u>(552)</u>
Net loss	<u>\$ (12,385)</u>	<u>\$ (25,140)</u>	<u>\$ (12,755)</u>

### Revenue and Cost of Goods Sold

Revenues for the six months ended June 30, 2013 increased approximately \$2,077,000, or approximately 135%, from the six months ended June 30, 2012. 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, April, May and November 2012. Cost of goods sold increased approximately \$136,000, or approximately 19%, for the six months ended June 30, 2013 compared to the six months ended June 30, 2012. Cost of goods sold as a percentage of revenue was 23% and 46% for the six months ended June 30, 2013 and 2012, respectively. Approximately 16% of this increase was due to an increase in the number of units sold and approximately 84% of the increase was related to product mix. Our costs of individual products did not change for the six months ended June 30, 2013 as compared to the same period in 2012.

### Operating Expenses

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

	<b>Six Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
Human resources costs, including salaries, commission, benefits and taxes	45.1%	49.7%
Product and design and development costs	24.8%	14.5%
Sales and marketing, excluding human resources costs	19.0%	29.6%
Professional fees for legal, accounting and consulting	6.2%	7.0%
Other operating expenses	4.9%	(0.8)%

Our operating expenses increased by approximately \$5.7 million (74%) as a result of the following items:

	<i>(in thousands)</i>	
Increase in human resource costs, including salaries, commission, benefits and taxes	\$	2,198
Increase in product design and development costs		2,201
Increase in sales and marketing, excluding human resource costs		260
Increase in legal, accounting and consulting fees		286
Increase in other operating expenses		714
	\$	<u>5,659</u>

Human resource costs, including salaries, commissions, benefits and taxes were higher as a result of increases in personnel between the two periods (approximately \$918,000) and increases in non-cash compensation related to option awards (approximately \$1,280,000).

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

Professional fees increased primarily due to higher costs as a result of SEC reporting and additional requirements related to regulatory compliance.

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

#### *Other Expense*

Other non-operating expense decreased by approximately \$16,472,000 for the six months ended June 30, 2013 in comparison to the same period in 2012. This decrease is primarily a result of loss on extinguishment of debt incurred during 2012 as herein described, partially offset by amortization of financing costs of approximately \$396,000.

#### *Loss on extinguishment of debt*

In February 2012, we issued notes in the aggregate of approximately \$2,700,000 and granted warrants for the purchase of an aggregate of 9,000,000 shares of our common stock. As consideration for these notes and warrants, we received an aggregate of \$1,000,000 of new funding, or the 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 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 warrants issued, valued at approximately \$10,500,000, were expensed as loss on extinguishment of debt. The relative fair value of the New Funding was estimated by calculating the present value of future cash flows discounted at a market rate of return for comparable debt instruments, to be \$1,500,000. 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 New Funding and its fair value.

#### *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.

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

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



## Revenue

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

## Cost of Goods Sold

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

## Operating Expenses

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

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

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

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

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

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

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

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

#### *Loss on Extinguishment of Debt*

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

#### *Beneficial Conversion Feature*

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

#### *Interest Expense*

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

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

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2011</u>	<u>2010</u>	
	<i>(in thousands)</i>		
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	<u>\$ (12,913)</u>	<u>\$ (2,867)</u>	<u>\$ (10,046)</u>

#### *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:

	<i>(in thousands)</i>	
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 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

We have incurred recurring net losses, including net losses of approximately \$12.4 million and \$25.1 million for the six months ended June 30, 2013 and 2012, respectively, and \$35.1 million and \$12.9 million for the years ended December 31, 2012 and 2011, respectively. Net cash outlays from operations and capital expenditures were approximately \$10.9 million and \$5.7 million for the six months ended June 30, 2013 and 2012, respectively, and \$13.0 million and \$5.0 million for the years ended December 31, 2012 and 2011, respectively. As of June 30, 2013, we had an accumulated deficit of approximately \$64.5 million and stockholders' equity of \$38.5 million. As of December 31, 2012, we had an accumulated deficit of approximately \$52.1 million and a stockholders' deficit of \$1.4 million.

We have generated limited revenue and have funded our operations to date primarily from private sales of equity and debt securities. We expect to incur substantial additional losses in the near future as our research, development, and clinical trial activities increase, especially those related to our proposed hormone therapy products. As a result, profitability will elude us unless we successfully commercialize our products, in particular, our proposed hormone therapy products. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices or refinance existing debt obligations on terms unfavorable to us. Such circumstances could compel us to merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

We need substantial amounts of cash to complete the clinical development of our proposed HT products. In March, April, and September 2013, we sold an aggregate of 45,116,352 shares of our common stock in public offerings to raise approximately \$78.9 million, net of commissions and expenses. We believe our existing cash and cash equivalents will be sufficient to fund our operations, including the clinical development of our HT products for the next 12 months; however, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Currently we have a \$10 million line of credit available to us which is our only committed external source of funds. We may need to attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, other necessary means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day to day activities, which may adversely affect our ability to conduct our day to day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
- seek collaborators for our proposed HT 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 HT products that we otherwise would seek to develop or commercialize ourselves.

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

## Cash and Cash Equivalents

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

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

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

The increase (decrease) in cash and cash equivalents consisted of the following components for the years ended December 31, 2012 and December 31, 2011:

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

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

	December 31,		
	2012	2011	Change
	(000s)		
Current assets	\$ 4,527	\$ 1,237	\$ 3,290
Current liabilities	3,512	3,151	361
Working capital (deficit)	<u>\$ 1,015</u>	<u>\$ (1,914)</u>	<u>\$ 2,929</u>

### Primary Sources of Cash

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

In October 2, 2012, we issued 3,953,489 shares of our common stock in a private placement, resulting in aggregate net proceeds of \$7,896,000.

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

## Off Balance Sheet Arrangements

As of December 31, 2012 and June 30, 2013, 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 June 30, 2013 or December 31, 2012.

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

## Contractual Obligations

A summary of contractual cash obligations as of December 31, 2012 is as follows:

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-Term Debt Obligations	4,841,915	—	4,841,915	—	—
Operating Lease Obligations	29,667	29,667	—	—	—
Total	4,871,582	29,667	4,841,915	—	—

## Seasonality

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

## Effects of Inflation

For each of the fiscal years ended December 31, 2012, 2011 and 2010, our business and operations have not been materially affected by inflation.

## Critical Accounting Estimates and New Accounting Pronouncements

### Critical Accounting Estimates

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

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

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

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

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

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

#### *New Accounting Pronouncements*

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

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

In September 2011, the FASB issued ASU No. 2011-08, “*Intangibles – Goodwill & Other,*” or ASU 2011-08, which updates the guidance in ASC Topic 350, “*Intangibles – Goodwill & Other,*” or ASC Topic 350. The amendments in ASU 2011-08 permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than fifty percent. If, after assessing the totality of events or circumstances, an entity determines that it is more likely than now that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. The amendments in ASU 2011-08 include examples of events and circumstances that an entity should consider in evaluating whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. However, the examples are not intended to be all-inclusive and an entity may identify other relevant events and circumstances an entity should consider in determining whether it should test for impairment between annual tests, and also supersede the examples of events and circumstances that an entity having a reporting unit with a zero or negative carrying amount should consider in determining whether to perform the second step of the impairment test. Under the amendments in ASU 2011-08, an entity is no longer permitted to carry forward its detailed calculation of a reporting unit’s fair value from a prior year as previously permitted under ASC Topic 350. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 31, 2011. The adoption of ASU 2011-08 did not have a material impact on our financial position or results of operation.

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

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

### **Quantitative and Qualitative Disclosures About Market Risk**

We had cash and cash equivalents totaling \$1.6 million as of December 31, 2012. We hold our cash in money market funds and the primary objective of our investment policy is to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

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



## Introduction

We are a women's healthcare product company focused on creating and commercializing products targeted exclusively for women. We currently manufacture and distribute branded and generic prescription prenatal vitamins as well as over-the-counter, or OTC, vitamins and cosmetics. We are currently focused on conducting the clinical trials necessary for regulatory approval and commercialization of advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these proposed hormone therapy products, which contain estradiol and progesterone alone or in combination, with the aim of providing equivalent efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products.

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately \$10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in vulvar and vaginal atrophy, or VVA, designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be approximately \$25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately \$650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately \$490 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-002HR to be approximately \$6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately \$340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately \$780 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately \$16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately \$1 billion in U.S. sales.

We intend to leverage and grow our current marketing and sales organization to commercialize our proposed products in the United States assuming the successful completion of the FDA regulatory process. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved menopause-related estrogen market was approximately \$2.5 billion in U.S. sales.

The hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. We believe the FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals when produced by compounding pharmacies, are sold by compounding pharmacies and not monitored or easily measured. We estimate the non-FDA approved compounded bioidentical hormone therapy combination sales of estradiol and progesterone products sold by compounding pharmacies are approximately \$1.5 billion per year. Our Phase 3 trials are intended to establish an indication of the safety and efficacy of our proposed bioidentical products at specific dosage levels. We intend our proposed hormone therapy products, if approved, to provide an alternative to the non-FDA approved compounded bioidentical market based on our belief that our proposed products will offer advantages in terms of proven safety, efficacy, and stability, lower patient cost as a result of insurance coverage, and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

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

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

Our common stock began trading on the NYSE MKT on April 23, 2013 under the symbol “TXMD,” and was previously listed on the OTCQB. We maintain the following websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com) and [www.bocagreenmd.com](http://www.bocagreenmd.com).

## **Industry and Market**

### *Healthcare and Pharmaceutical Market*

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

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

### *Women's Healthcare Market*

The U.S. Census Bureau estimates that there were approximately 157 million women and 152 million men living in the United States in 2010. Women are major consumers of health care services, negotiating not only their own health care but often managing care for their family members as well. Their reproductive health needs and greater health care spending and longer life spans as compared with men make women's relationships with the health care system complex.

### *Hormone Therapy Market*

Menopause is the spontaneous and permanent cessation of menstruation, which naturally occurs in most women between the ages of 40 and 58. It is defined as the final menstrual period and is confirmed when a woman has not had her period for 12 consecutive months. Hormone therapy is the only government-approved treatment in the United States and Canada for relief of menopausal symptoms. These symptoms are caused by the reduced levels of circulating estrogen as the ovarian production shuts down. The symptoms include hot flashes, night sweats, sleep disturbances, and vaginal dryness. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, prescriptions for hormone therapy products for the treatment of menopause symptoms or prevention of osteoporosis generated total sales of over \$3.5 billion on over 37 million prescriptions. Oral hormone therapy accounted for \$1.8 billion on 25 million prescriptions over the same time period.

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

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

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

### *Hormone Therapy Products*

Estrogen (with or without a progestin) is the most effective treatment for menopause-related vasomotor symptoms according to the North American Menopause Society, or NAMS. Sales of total oral and transdermal hormone therapy products were approximately \$2.5 billion for the 12 months ended June 30, 2013. That was up approximately 7% over the same time period from the prior year according to Source Healthcare Analytics. The three primary hormone therapy products are estrogen, progestin, and combination of estrogen and progestin and are produced in a variety of forms, including oral tablets or capsules, skin patches, gels, emulsion, or vaginal suppositories and creams.

### *Estrogen-Only Therapies*

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

Estrogen-only therapy, or ET, is used mainly in women who have had a hysterectomy and are undergoing a surgical menopause, as those women do not require a progestin to protect the uterine endometrium from proliferation. Approximately 600,000 women undergo a hysterectomy each year in the U.S. according to the United States Centers for Disease Control and Prevention. Sales of ET were approximately \$2.5 billion for a 12-month total at June 30, 2013, according to Source Healthcare Analytics.

ET is also used for vulvar and vaginal atrophy, which has a variety of indications, including vaginal dryness, pain, bleeding, urinary symptoms, incontinence, painful intercourse, and other symptoms. Sales of ET for vulvar and vaginal atrophy were approximately \$660 million for a 12-month total at June 30, 2013, according to Source Healthcare Analytics.

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

#### *Progestin-Only Therapies*

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

#### *Estrogen/Progestin Combination Products*

Progestins are used in combination with estrogen in women with uteruses to avoid an increase in the incidence of endometrial hyperplasia. This is a condition caused by chronic use of estrogen alone by a woman with a uterus and is associated with an increased incidence of uterine, or endometrial, cancer. Studies have shown that, after one year, the incidence of endometrial hyperplasia is less than 1% in women taking estrogen/progestin combinations, in contrast to up to 20% in women taking estrogen alone. In accordance with FDA recommendations, doctors typically recommend that a menopausal or postmenopausal woman who has a uterus take estrogen plus a progestin, either as a combination drug or as two separate drugs. Source Healthcare Analytics estimates that sales of estrogen/progestin combinations were approximately \$660 million in the United States for the 12 months ended June 30, 2013, up approximately 12% over the same time period a year prior.

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

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

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

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

There are hundreds of prenatal vitamins available, with both prescription and OTC (non-prescription) choices. According to Source Healthcare Analytics, there were approximately 7.7 million prescriptions for prenatal vitamins sold for a total of approximately \$314 million for the 12 months ended June 30, 2013, with sales between branded and generic products split nearly evenly. According to the 2012 Gallup Target Market Report on Prenatal Vitamins, supplement use has been fairly constant overall between 2008 and 2011. However, shifts have occurred in terms of types used, with the trend toward OTC prenatal vitamins and away from prescription prenatal vitamins. During this same period, the use of OTC products surpassed the use of prescription products, largely driven by increased use among women currently pregnant.

## **Our Business Model**

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

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

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

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

- We believe we will offer physicians a comprehensive product line of women's healthcare products, including our proposed hormone therapy products, if approved.
- Our proposed hormone therapy products are designed to use the lowest effective dose for the shortest duration.
- We believe the attributes of our dietary supplements will result in greater consumer acceptance and satisfaction than competitive products while offering the highest quality products incorporating patented ingredients, such as Quatrefolic®, chelated iron and life's DHA™. All of our prenatal vitamins are gluten, sugar, and lactose free.
- We strive to improve our existing products and develop new products to generate additional revenue through our existing sales channels.
- We believe health care providers are able to offer alternatives to patients that meet the patient's individual nutritional and financial requirements and help patients realize cost savings over competing products.
- Health care provider practices that choose to dispense our OTC products directly to their patients through their offices could earn revenue from the sale of the products.
- Improved patient education, a high level of patient compliance, and reduced cost of products all result in lower cost of care for payors and improved outcomes for patients.

## **Our Growth Strategy**

Our goal is to become the women's healthcare company recommended by healthcare 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 hormone therapy products designed to (1) alleviate the symptoms of and reduce the health effects resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness, and (2) provide equivalent efficiency at lower doses, enabling an enhanced side effect profile compared with competing products;
- providing an alternative to the non-FDA approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies;
- maintaining a marketing emphasis on large group OB/GYN practices that provide opportunities to reach large patient bases and that are receptive to the data and savings we provide;
- pursuing multiple distribution channels, including physicians and pharmacies through our direct sales force and our website;
- expanding our geographic market and sales team to cover the entire country by increasing our current inside sales force; and
- introducing new products to build upon the introduction of our first three prescription prenatal vitamin products in the first and second quarters of 2012 and our generic line of prenatal vitamins in the fourth quarter of 2012, as well as our hormone therapy products consisting of a bioidentical oral and topical combination drug of estradiol and progesterone, an oral progesterone drug, and a suppository vulvar and vaginal atrophy estradiol drug. PK studies of our proposed combination estradiol and progesterone drug demonstrated that the product is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 0.800 to 1.250.

## Our Products

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

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

### *vitaMedMD*<sup>®</sup> Plus (*Prenatal Women's Multivitamin + DHA*)

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

### *vitaMedMD*<sup>®</sup> One Prenatal Multivitamin

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

### *vitaMedMD*<sup>®</sup> Plus Rx Prenatal Multivitamin

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

### *vitaMedMD*<sup>®</sup> One Rx Prenatal Multivitamin

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

### *vitaMedMD*<sup>®</sup> RediChew<sup>™</sup> Rx Prenatal Multivitamin

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

### *vitaMedMD*<sup>®</sup> Iron 21/7

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

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

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

### *vitaMedMD® Vitamin D3 50,000 IU and Vitamin D3 2,000 IU*

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

### *vitaMedMD® Stretch Mark Body Cream*

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

### *vitaMedMD® Scar Reduction Body Cream*

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

### *BocaGreenMD™ Prena1 Plus*

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

### *BocaGreenMD™ Prena1*

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

### *BocaGreenMD™ Prena1 Chew*

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

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

## **Our Proposed Hormone Therapy Products**

We have obtained U.S. Food and Drug Administration, or FDA, acceptance of our IND applications to conduct clinical trials for four of our proposed products: TX 12-001HR, TX 12-002HR, TX 12-003HR, and TX 12-004HR. We are currently conducting a Phase 3 clinical trial for TX 12-001HR; we currently intend to begin Phase 3 clinical trials for TX 12-002HR at the end of 2013; and we currently intend to begin Phase 3 clinical trials for TX 12-004HR in the second quarter of 2014. We have no current plans for clinical trials for TX 12-003HR.

On September 5, 2013, we announced the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001HR in treating the symptoms of menopause and protecting the endometrium. We are also currently conducting formulation development of our proposed combination estradiol and progesterone product in a topical cream form. We currently estimate the cost of this development to be approximately \$10 million. On May 10, 2013, we submitted an IND application to conduct clinical trials for TX 12-004HR, which was accepted by the FDA on June 9, 2013. On August 12, 2013, we announced that we initiated a Phase 1 clinical trial for TX 12-004HR in VVA designed to measure the effect of TX 12-004HR on certain clinical endpoints, including a study candidate's pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance.



#### *TX 12-001HR*

TX 12-001HR is a combination estradiol and progesterone drug candidate under development for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The product will be chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and would be studied as a continuous-combined regimen (where the combination of estrogen and progesterone are taken together in one product daily). If approved by the FDA, we believe this would represent the first time a combination product of these bioidentical hormones would be approved for use in a single combined product. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12-001HR to be approximately \$25 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for menopause-related combination estrogen/progestin was approximately \$650 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for menopause-related combination estrogen/progestin was approximately \$490 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

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

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

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

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

#### *TX 12-002HR*

TX 12-002HR is a natural progesterone formulation without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormones that naturally occur in a woman's body. We believe it would be similarly effective to traditional treatments, but at lower dosages. We currently estimate the cost of our research and development activities through the completion of our Phase 3 trials for TX 12 002HR to be approximately \$6 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for oral progestin was approximately \$340 million in U.S. sales, and according to IMS Health, Inc., for the 12 months ended December 31, 2012, the total market for oral progestin was approximately \$780 million (as converted from the Euro at an exchange rate of €1.0=US\$1.2875) in international sales.

#### *TX 12-003HR*

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

TX 12-004HR is a proposed suppository estradiol product for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe our proposed product will be as effective as the traditional treatments for VVA and we believe it will have an added advantage of simple, easier to use dosage form versus traditional VVA treatments. We currently estimate the cost of our research and development activities through the completion of the anticipated Phase 3 clinical trial for TX 12-004HR to be approximately \$16 million. According to Source Healthcare Analytics, for the 12 months ended June 30, 2013, the total FDA-approved market for VVA treatment was approximately \$1 billion in U.S. sales.

## **Sales and Marketing**

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

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

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

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

### *Online Commerce*

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

### *Retail Commerce*

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

## **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. We compete with existing and new products being developed by our competitors in both branded and generic varieties. Development and awareness of our brand will depend largely upon our success in increasing our customer base. Our potential competitors include major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. We believe that the key competitive factors that will affect the ongoing development and commercial success of the products that we develop are efficacy, safety, convenience in dosing, price and reimbursement.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of products that addresses unmet medical needs and creates value in patient treatment.

### **Seasonality**

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

### **Products in Development**

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

### **Research and Development**

We invested \$65,402, \$107,241 and \$4,492,362 in research and development in the years ended December 31, 2010, 2011 and 2012, respectively. These amounts consisted primarily of activities related to the development of new products and techniques or the ongoing improvement of our existing products and techniques.

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

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

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

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

### **Manufacturing of Our Products**

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

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

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

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

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

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

### **Distribution of our Products**

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

### **Customer Service**

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

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

### **Our Return Policy**

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

## Our Quality Guarantee

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

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

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

## Intellectual Property

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

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

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

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

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

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

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

## **Government Regulation**

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

## **Pharmaceutical Regulation**

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

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

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. We currently have effective INDs for four of our proposed hormone therapy products, *TX 12-001HR*, *TX 12-002HR*, *TX 12-003HR* and *TX 12-004HR*, although we have no current plans to conduct clinical trials for *TX 12-003HR*.

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

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

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

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

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

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

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

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

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

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

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

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

#### *Marketing Exclusivity*

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

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

#### *Dietary Supplement and Cosmetic Regulation*

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

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



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

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

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

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

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

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

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

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

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

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

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

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.
- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.
- The federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

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

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

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

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

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

## **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 currently 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 TherapeuticsMD and BocaGreen in the United States District Court for the Southern District of Florida. The lawsuit alleges, among other things, that we are improperly obtaining and using the Quatrefolic product and related trademarks that we have acquired from Pernix Therapeutics, LLC, a subsidiary of Pernix Therapeutics Holdings, Inc., or Pernix. Cooper C. Collins, a member of our board of directors, is the President, Chief Executive Officer, and a director of Pernix. The lawsuit seeks to enjoin us from using the Quatrefolic product and trademarks, in addition to unspecified actual and punitive damages. We filed a motion to dismiss on January 2, 2013, which was granted by the Court on July 17, 2013 based on Aceto's failure to join the trademark owner, Gnosis, S.p.A. as a party plaintiff. On August 19, 2013, Aceto filed an amended complaint which purported to add Gnosis S.p.A. as an involuntary plaintiff. We have not yet filed a response to that amended complaint. As of September 11, 2013, the parties to this lawsuit reached a tentative settlement agreement, which is subject to and awaiting approval by Gnosis, S.p.A. Based on our initial assessment of currently available information, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

## *Avion Pharmaceuticals, LLC*

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

## **Our Offices**

We are a Nevada corporation. We began our current business in May 2008. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com), and [bocagreenmd.com](http://bocagreenmd.com). The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus.

## **Properties**

Our prior lease for premises located at 951 Broken Sound Parkway in Boca Raton, Florida expired on June 30, 2013. With an effective date of July 1, 2013, we entered into a new lease for administrative office space located at 6800 Broken Sound Parkway in Boca Raton, Florida pursuant to a 63-month non-cancelable operating lease expiring on September 30, 2018. The lease stipulates, among other things, average base monthly rents of \$28,442 (inclusive of estimated operating expenses) and sales tax for a total future minimum payment over the life of the lease of \$1,791,900.

## **Employees**

As of October 7, 2013, we had 68 full-time employees, four of whom are executive officers. Additionally, from time to time, we hire temporary contract employees. None of our employees are covered by a collective bargaining agreement, and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike, or dispute. We consider our relationship with our employees to be good.

## Our History

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

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

## 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	42	Chief Executive Officer, Director
John C.K. Milligan IV	51	President, Secretary, Director
Daniel A. Cartwright	55	Chief Financial Officer, Vice President-Finance, Treasurer
Mitchell L. Krassan	48	Executive Vice President, Chief Strategy Officer
Brian Bernick, M.D.	45	Chief Medical Officer, Director
Tommy G. Thompson	71	Chairman
Samuel A. Greco	62	Director
Cooper C. Collins	34	Director
Robert V. LaPenta, Jr.	44	Director
Jules A. Musing	66	Director
Nicholas Segal	31	Director

*Robert G. Finizio* has served as Chief Executive Officer and a director of our company since October 2011. As co-founder of our VitaMed subsidiary, Mr. Finizio served as its Chief Executive Officer and a director from April 2008 to October 2011. Mr. Finizio has 16 years of successful early stage company development experience in the healthcare industry. Mr. Finizio co-founded and served from August 2001 to February 2008 as President of Care Fusion, LLC and then as Chief Executive Officer of CareFusion, Inc., which was acquired by Cardinal Health, Inc. Mr. Finizio's early business experience was with Omnicell, Inc. (formerly known as Omnicell Technologies, Inc.) and Endoscopy Specialists, Inc. in the healthcare IT and surgical space, respectively. We believe Mr. Finizio's intimate knowledge and experience with all aspects of the business, operations, opportunities, and challenges of our company and experience with early stage company development in the healthcare industry provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. Mr. Finizio earned a B.A. from the University of Miami.

*John C.K. Milligan, IV* has served as President, Secretary, and a director of our company since October 2011. From December 2008 to October 2011, Mr. Milligan served as President and Director of VitaMed. Prior to VitaMed, Mr. Milligan co-founded CareFusion, LLC, serving as President and General Manager from August 2001 to February 2008, and then as President and Chief Operating Officer of CareFusion, Inc. From 1997 to 2001, Mr. Milligan was Vice President, Sales and Operations for Omnicell, Inc., a provider of pharmaceutical supply chain management systems and services. Prior to Omnicell, Mr. Milligan also held executive management positions at Serving Software Inc. and HBO & Co., both subsequently acquired by McKesson Corporation. We believe Mr. Milligan's significant experience in creating, developing and guiding growth-oriented healthcare companies and knowledge of our business provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. Mr. Milligan is a graduate of the U.S. Naval Academy.

*Daniel A. Cartwright* has served as Chief Financial Officer, Vice President of Finance, and Treasurer of our company since October 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 2011. Dr. Bernick also has served as the Chief Medical Officer of our company since February 2012. As co-founder of VitaMed, Dr. Bernick served on VitaMed's board of directors from its inception. Dr. Bernick is a practicing and board certified obstetrician/gynecologist with 20 years of clinical medical experience. Dr. Bernick is the past Chairman of the Department of Obstetrics and Gynecology at Boca Raton Regional Hospital and has served as a member of its Medical Executive Board. He has served on the board of directors of the Palm Beach Medical Society and VitalMD Group Holding, LLC, the largest physician-owned and managed group of obstetricians/gynecologists in Florida covering more than 250 physicians/practices. Dr. Bernick is the recipient of several national and regional awards including the American Medical Association Foundation's Leadership Award and was recognized by both Super Doctors and National Consumers Survey for being in the top 5% of doctors. Dr. Bernick is an Associate Professor of Medicine at Florida Atlantic University and provides medical education in conjunction with Emory University and Florida Atlantic University School of Nursing and Medicine. We believe Dr. Bernick's experience in the OB/GYN field gives him an understanding of sales channels and the needs and requirements of our customers and provides the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. Dr. Bernick earned a B.A. in economics from Northwestern University and a doctorate in medicine from the University of Chicago Medical School. He completed his residency at the University of Pennsylvania.

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

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

*Cooper C. Collins* has served as a director of our company since February 2012. Mr. Collins served as the President, Chief Executive Officer, and a director of Pernix Therapeutics Holdings, Inc. [NASDAQ: PTX] since the close of the merger between Pernix and Golf Trust of America, Inc. in March 2010 until May 2013, when he stepped down as President and Chief Executive Officer and began to serve as Chief Strategic Officer of Pernix. Mr. Collins joined Pernix in 2002. Pernix is a specialty pharmaceutical company focused on the sales, marketing, and development of branded and generic pharmaceutical products primarily for the pediatric market. He was appointed a director of Pernix in January 2007, Pernix's President in December 2007, and Pernix's Chief Executive Officer in June 2008. From December 2005 to December 2007, Mr. Collins served as Vice President of Business and Product Development of Pernix and as Pernix's Territory Manager from December 2003 to December 2005. Mr. Collins was employed for three years by the National Football League franchise, The New Orleans Saints, in its media relations department. We believe Mr. Collins' specialty pharmaceutical company knowledge and executive experience provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. While on a football scholarship, Mr. Collins received a B.A. from Nicholls State University, where he later received an M.B.A.

*Robert V. LaPenta, Jr.* has served as a director of our company since February 2012. Since August 2011, Mr. LaPenta has served as a partner of Aston Capital, a private equity investment firm with a current focus on investments in the aerospace, defense, and intelligence markets. Prior to Aston Capital, Mr. LaPenta served as Vice President of Mergers and Acquisitions and Corporate Strategy for L-1 Identity Solutions, Inc., or L-1, provider of technology, products, systems and solutions, and services that protect and secure personal identities and assets. From April 2007 through July 2011, Mr. LaPenta assisted L-1 senior management in identifying acquisition candidates and investments while assisting in due diligence, structuring, valuation, execution, and related financing. Prior to L-1, Mr. LaPenta spent 13 years as an institutional equity trader focused on healthcare sector trading for both customer and proprietary accounts. From February 2003 to March 2007, Mr. LaPenta served as Managing Director, Co-Head of Equity Trading at Banc of America Securities LLC where he managed capital commitment, proprietary trading, and risk management within cash trading. Prior to Banc of America Securities, he served as Director or Vice President of Equity Trading with Credit Suisse First Boston, PaineWebber, Inc., and Salomon Smith Barney, Inc. Previously, as a Senior Associate at Coopers & Lybrand LLP, Mr. LaPenta assisted with auditing, consulting, due diligence, and SEC reporting. Mr. LaPenta is Co-Investment Manager of a \$250 million family/friends/partners asset portfolio consisting of individual equities, fixed income, equity options, hedge fund strategies, private equity, and alternative investments. He is an active participant and fund raiser for New York City's W. 63rd Street YMCA, Turn the Corner Foundation, and numerous other charities. Mr. LaPenta has recently been added to the board of directors of Revolution Lighting Technologies, Inc. [NASDAQ: RVLTL], a public company engaged in the design, manufacture, marketing and installation of LED lighting systems. We believe Mr. LaPenta's diverse investing background, capital markets knowledge, and his relationships within the financial community provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. Mr. LaPenta graduated in 1991 from Boston College with a B.A. in Accounting and Finance and is a registered CPA (inactive) in the State of New York.

*Jules A. Musing* has served as a director of our company since May 2013. In the course of Mr. Musing's 36-year career in the pharmaceutical and biotechnology industry, specifically at Johnson & Johnson and its affiliates, he has been responsible for the worldwide licensing and acquisition of pharmaceutical and biotechnology products and technologies and the establishment of strategic alliances. This included the establishment of new scientific, technology and product collaborations in various therapeutic areas, the negotiation of licensing and alliance agreements with biotechnology and pharmaceutical companies worldwide, and the partnering, spin-out and out-licensing of company pharmaceutical and biotechnology assets. Prior to moving into those roles, Mr. Musing was Vice President Marketing International for the Janssen Pharmaceutical Group of Companies Worldwide from March 1982 to December 1984; President of Pitman-Moore, Inc., a U.S.-based Johnson & Johnson company from January 1985 to June 1987; Managing Director of Janssen Pharmaceutical in Portugal from July 1987 to March 1990; President of Serono, Inc. in the United States and Executive Vice President with responsibilities for North and South America from April 1990 to January 1993; Member of the Board of Ortho Biotech, Inc. from January 1993 to October 1999; and Managing Director of Ortho Biotech in France (a Johnson & Johnson affiliate) from October 1999 to January 2003. From January 2003 to his retirement in September 2010, Mr. Musing served as Vice President, Licensing and Acquisitions for the Pharmaceutical Group at Johnson & Johnson, where he was responsible for the worldwide licensing and acquisition of pharmaceutical and biotechnology products in all therapeutic areas. He has served as a board member of Delphi Digital, Inc. since March 2012 and Chairman of the Scientific Board of Advisors for Noble Capital Financial Markets since February 2012, and previously served on the board of directors of iBio, Inc. [NYSE MKT: IBIO] from June 2011 to December 2012. We believe Mr. Musing's more than 36-years' experience in the pharmaceutical and biotechnology industry, including the establishment of numerous strategic and global partnerships and various new product collaborations provide the requisite qualifications, skills, perspectives, and experience that make him well qualified to serve on our board of directors. Mr. Musing received his Master's Degree in Biological Sciences from the University of Brussels (Belgium) and his Graduate Degree in Economics and Financial Sciences from the University of Antwerp (Belgium).



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

#### *Non-Executive Officers*

*Julia Amadio* has served as Chief Product Officer of our company since January 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.

*Marlan Walker* has served as Corporate and Intellectual Property Counsel since June 2013. Mr. Walker's experience is focused in the life science industries, including long-term portfolio strategy and management, patent preparation and prosecution, contract negotiation and drafting, life-cycle management, and Hatch-Waxman. From 2005 to 2009, Mr. Walker worked as a patent attorney at Greenberg Traurig LLP and from 2009 to 2011 as a patent attorney at Luce Forward Hamilton & Scripps. From 2011 to 2012, Mr. Walker served as in-house intellectual property counsel at Medicis Pharmaceutical Corp., which was acquired by Valeant Pharmaceutical International, Inc. in December 2012. In 2013, Mr. Walker accepted a position at Kilpatrick Townsend & Stockton, but chose to move in-house again in June 2013. Mr. Walker received his B.S. and his M.S. in Molecular Biology from Brigham Young University. Mr. Walker received his J.D. from Arizona State University in 2004 and his LL.M. in Intellectual Property Law from The George Washington University in 2005. Mr. Walker is registered to practice before the U.S. Patent and Trademark Office.

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), Christian Bloomgren (Vice President Sales), and Marlan Walker (Corporate and Intellectual Property Counsel). An overview of their business experience is included above.

#### **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.

#### **Executive Sessions**

We anticipate that we will regularly schedule executive sessions in which non-employee directors will meet without the presence or participation of management, with at least one of such sessions including only independent directors. Mr. Thompson, as our Chairman of the board of directors, will chair the executive sessions. We did not hold any executive sessions during 2012.

## **Committees of the Board**

Our board of directors has an Audit Committee, a Compensation Committee, and Nominating and Corporate Governance Committee, each consisting entirely of independent directors. The charters for each of these committees are accessible via our SEC filings on our website at [www.therapeuticsmd.com](http://www.therapeuticsmd.com).

### **The Audit Committee**

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

The Audit Committee currently consists of Messrs. LaPenta, Jr., Greco, and Segal, each of whom is an independent director of our company under the NYSE MKT rules as well as under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002. Mr. LaPenta, Jr. serves as the Chairman of the Audit Committee. Our board of directors has determined that Mr. LaPenta, Jr. (whose background is detailed above) qualifies as an "audit committee financial expert" in accordance with applicable rules and regulations of the SEC.

### **The Compensation Committee**

The purpose of the Compensation Committee includes determining, or recommending to our board of directors for determination, the compensation of our Chief Executive Officer and other executive officers and discharging the responsibilities of our board of directors relating to our compensation programs. The Compensation Committee currently consists of Messrs. Collins, Thompson, and Musing, with Mr. Collins serving as Chairman.

### **The Nominating and Corporate Governance Committee**

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

The members of the Nominating and Corporate Governance Committee are Messrs. Thompson and LaPenta, Jr. Mr. Thompson serves as Chair.

### **Committee Charters, Corporate Governance, and Code of Ethics**

Our board of directors has adopted charters for the Audit, Compensation, and Nominating and Corporate Governance Committees describing the authority and responsibilities delegated to each committee by our board of directors. Our board of directors has also adopted Corporate Governance Guidelines, a Code of Conduct and Ethics, and a Code of Ethics for the CEO and Senior Financial Officers. We post on our website, at [www.therapeuticsmd.com](http://www.therapeuticsmd.com), the charters of our Audit, Compensation, and Nominating and Corporate Governance Committees; our Corporate Governance Guidelines, Code of Conduct and Ethics, and Code of Ethics for the CEO and Senior Financial Officers, and any amendments or waivers thereto; and any other corporate governance materials contemplated by SEC or NYSE MKT regulations. These documents are also available in print to any stockholder requesting a copy in writing from our corporate secretary at our executive offices set forth in this proxy statement.

## **Board Policies**

### *Code of Conduct and Ethics*

Our board of directors has adopted a Code of Conduct and Ethics applicable to all of our directors and executive officers. This code is intended to focus the members of our 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 our board of directors and all executive officers are required to sign this code on an annual basis.

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

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

### *Insider Trading Policy*

On June 10, 2013, our board of directors revised our policy regarding insider trading, or the Insider Trading Policy, by extending the trading window period. The Insider Trading Policy provides information regarding insider trading and sets forth the limitations on trading in our securities and the handling of material, non-public information. Specifically, the Insider Trading Policy prohibits our officers, directors, and certain of our employees from purchasing or selling our common stock outside of a period extending from the third business day following the release of our earnings for the immediately preceding fiscal period through 21 days prior to the end of the next fiscal period. The Insider Trading Policy applies to our officers, directors, and certain of our employees and is designed to help ensure compliance with federal securities laws.

## **Director Independence**

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

## **Director Compensation**

Historically, we have not paid cash fees to directors; however, we have reimbursed out-of-state directors for costs associated with travel and lodging to attend board meetings. Beginning in 2013, each director will receive an annual director’s fee of \$28,000, which will be paid in cash. Our directors may also be granted non-qualified options from time to time under our LTIP or 2012 SOP.

The following table and accompanying footnotes details compensation paid to our directors for services rendered for the year ended December 31, 2012. Mr. Musing was not elected to our board of directors until May 2013, and therefore, is not included in the table below.

Name (a)	Fees earned or paid in cash \$(b)	Stock Awards \$(c)	Option Awards \$(d) <sup>(1)(2)</sup>	Non-Equity Incentive Plan Compensation \$(e)	Nonqualified Deferred Compensation Earnings \$(f)	All Other Compensation \$(g)	Total \$(h)
Robert F. Finizio <sup>(3)</sup>	—	—	\$ 53,525	—	—	—	\$ 53,525
John C.K. Milligan, IV <sup>(4)</sup>	—	—	\$ 80,287	—	—	—	\$ 80,287
Brian A. Bernick, MD <sup>(5)(11)</sup>	—	—	\$ 53,525	—	—	\$ 199,036	\$ 252,661
Cooper C. Collins <sup>(6)</sup>	—	—	\$ 80,287	—	—	—	\$ 80,287
Robert V. LaPenta, Jr. <sup>(7)</sup>	—	—	\$ 80,287	—	—	—	\$ 80,287
Tommy G. Thompson <sup>(8)</sup>	—	—	\$ 80,287	—	—	—	\$ 80,287
Samuel A. Greco <sup>(9)</sup>	—	—	\$ 53,525	—	—	—	\$ 53,525
Nicholas Segal <sup>(10)</sup>	—	—	\$ 53,525	—	—	—	\$ 53,525

- (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. For further information, see “Note 10 – Stockholders’ Equity” included in the financial statements included in our Annual Report on Form 10-K.
- (2) Options depicted in the table above were granted to directors for serving on our board of directors and vested on December 31, 2012.
- (3) The amount listed does not include any compensation for services rendered as an executive officer, including (i) options granted to Mr. Finizio in the aggregate of 2,672,910 shares during 2012 or (ii) warrants issued to Mr. Finizio in exchange for a personal bank guarantee in the aggregate of 179,000 shares during 2012. See Summary Compensation Table. On December 31, 2012, Mr. Finizio had an aggregate of 2,722,910 options and 179,000 warrants.
- (4) The amount listed does not include any compensation for services rendered as an executive officer, including (i) options issued to Mr. Milligan in the aggregate of 3,152,255 shares during 2012 or (ii) warrants issued to Mr. Milligan in exchange for a personal bank guarantee and in connection with a promissory note in the aggregate of 240,372 shares during 2012. See Summary Compensation Table. On December 31, 2012, Mr. Milligan had an aggregate of 3,227,255 options and 240,372 warrants.
- (5) The amount listed does not include warrants issued to Dr. Bernick in connection with a promissory note in the aggregate of 61,372 shares during 2012. On December 31, 2012, Dr. Bernick had an aggregate of 1,672,190 options and 61,372 warrants.
- (6) On December 31, 2012, Mr. Collins had an aggregate of 75,000 options.
- (7) On December 31, 2012, Mr. LaPenta, Jr. had an aggregate of 75,000 options.
- (8) On December 31, 2012, Mr. Thompson had an aggregate of 75,000 options.
- (9) On December 31, 2012, Mr. Greco had an aggregate of 50,000 options.
- (10) On December 31, 2012, Mr. Segal had an aggregate of 142,057 options and 61,372 warrants. Mr. Segal owns 11.5812% of Fourth Generation Equity Partners, which has the rights to the 61,372 warrants. Mr. Segal claims ownership equal to 7,107 of these warrants.
- (11) The total amount of compensation includes the options granted to Dr. Bernick for services rendered as a consultant in the aggregate of 150,000 shares during 2012 for a value of \$160,574 and consulting fees of \$38,462.

#### Risk Assessment of Compensation Policies and Practices

We have assessed the compensation policies and practices with respect to our employees, including our executive officers, and have concluded that they do not create risks that are reasonably likely to have a material adverse effect on our company.

## **Board's Role in Risk Oversight**

Risk is inherent in every business. As is the case in virtually all businesses, we face a number of risks, including operational, economic, financial, legal, regulatory, and competitive risks. Our management is responsible for the day-to-day management of the risks we face. Our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management.

In its oversight role, our board of directors' involvement in our business strategy and strategic plans plays a key role in its oversight of risk management, its assessment of management's risk appetite, and its determination of the appropriate level of enterprise risk. Our board of directors receives updates at least quarterly from senior management and periodically from outside advisors regarding the various risks we face, including operational, economic, financial, legal, regulatory, and competitive risks. Our board of directors also reviews the various risks we identify in our filings with the SEC as well as risks relating to various specific developments, such as acquisitions, stock repurchases, debt and equity placements, and product introductions.

Our board committees assist our board of directors in fulfilling its oversight role in certain areas of risks. Pursuant to its charter, the Audit Committee oversees the financial and reporting processes of our company and the audit of the financial statements of our company and provides assistance to our board of directors with respect to the oversight and integrity of the financial statements of our company, our company's compliance with legal and regulatory matters, the independent auditor's qualification and independence, and the performance of our independent auditor. The Compensation Committee considers the risks that our compensation policies and practices may have in attracting, retaining, and motivating valued employees and endeavors to assure that it is not reasonably likely that our compensation plans and policies would have a material adverse effect on our company. Our Nominating and Corporate Governance Committee oversees governance related risks, such as board independence, conflicts of interests, and management succession planning.

## **Board Diversity**

We seek diversity in experience, viewpoint, education, skill, and other individual qualities and attributes to be represented on our board of directors. We believe directors should have various qualifications, including individual character and integrity; business experience and leadership ability; strategic planning skills, ability, and experience; requisite knowledge of our industry and finance, accounting, and legal matters; communications and interpersonal skills; and the ability and willingness to devote time to our company. We also believe the skill sets, backgrounds, and qualifications of our directors, taken as a whole, should provide a significant mix of diversity in personal and professional experience, background, viewpoints, perspectives, knowledge, and abilities. Nominees are not to be discriminated against on the basis of race, religion, national origin, sex, sexual orientation, disability, or any other basis prohibited by law. The assessment of directors is made in the context of the perceived needs of our board of directors from time to time.

All of our directors have held high-level positions in business or professional service firms and have experience in dealing with complex issues. We believe that all of our directors are individuals of high character and integrity, are able to work well with others, and have committed to devote sufficient time to the business and affairs of our company. In addition to these attributes, the description of each director's background sets forth above indicates the specific experience, qualifications, and skills necessary to conclude that each individual should continue to serve as a director of our company.

## **Board Leadership Structure**

We believe that effective board leadership structure can depend on the experience, skills, and personal interaction between persons in leadership roles as well as the needs of our company at any point in time. Our Corporate Governance Guidelines support flexibility in the structure of the board by not requiring the separation of the roles of Chairman of the board of directors and Chief Executive Officer. Mr. Finizio served as our Chairman of the board of directors and Chief Executive Officer until Mr. Thompson's appointment as Chairman of the board of directors in May 2012.

We currently maintain separate roles between the Chief Executive Officer and Chairman of the board of directors. Our Chief Executive Officer is responsible for setting our strategic direction and day-to-day leadership and performance of our company. The Chairman of the board of directors provides input to the Chief Executive Officer, sets the agenda for board meetings, and presides over meetings of the full board of directors as well as executive sessions of the board of directors.

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

For the year ended December 31, 2011, we did not have a Compensation Committee. Upon its formation on February 29, 2012, our Compensation Committee initially consisted of three members of our board of directors, namely, Cooper C. Collins (Chair), Robert G. Finizio, and Nicholas Segal. Of those members, only Mr. Finizio was an officer and employee of our company. On February 11, 2013, Mr. Finizio stepped down from the Compensation Committee. No current executive officer or member of our Compensation Committee serves as a member of a board of directors or compensation committee of any entity that has one or more executive officers serving as members of our board of directors or Compensation Committee. Effective August 22, 2013, Jules Musing was added to the Compensation Committee.

## **Board and Committee Meetings**

Our board of directors held a total of five meetings during the fiscal year ended December 31, 2012. No director attended fewer than 75% of the aggregate of (i) the total number of meetings of the board of directors; and (ii) the total number of meetings held by all committees of the board of directors on which such director was a member.

During the fiscal year ended December 31, 2012, the Audit Committee did not hold any formal meetings; all items subject to committee discussion took place during meetings of the full board of directors, and committee members reviewed our company's financial statements with our independent registered public accounting firm following the end of each fiscal quarter prior to their inclusion in reports filed with the SEC. Our Audit Committee plans to meet on at least a quarterly basis during the fiscal year ending December 31, 2013.

During the year ended December 31, 2012, the Compensation Committee held one meeting. Our Compensation Committee plans to meet at least once during the fiscal year ending December 31, 2013.

During the year ended December 31, 2012, the Nominating and Corporate Governance Committee did not hold any formal meetings; all items subject to committee discussion took place during meetings of the full board of directors. Our Nominating and Corporate Governance Committee plans to meet at least once during the fiscal year ending December 31, 2013.

## **Annual Meeting Attendance**

We encourage our directors to attend each annual meeting of stockholders. To that end, we have scheduled a meeting of our board of directors on the same day as our annual meeting of stockholders. We did not hold an annual meeting of stockholders last year.

## **Communications with Directors**

Interested parties may communicate with our board of directors or specific members of our board of directors, including our independent directors and the members of our various board committees, by submitting a letter addressed to the board of directors at the address listed herein c/o any specified individual director or directors. Any such letters are forwarded to the indicated directors.

## 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 of directors takes into account input from our board members and our chief executive officer based on their experiences with other companies. We have engaged third-party consultants to benchmark our compensation packages against our peers. 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 and Chief Executive Officer

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

## Summary of Cash and Other Compensation

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

**SUMMARY COMPENSATION TABLE**

Name and Principal Position	Year <sup>(1)</sup>	Salary	Bonus	Stock Awards	Option Awards <sup>(2)</sup>	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Robert G. Finizio <sup>(3)</sup> , Chief Executive Officer	2012	\$194,288	\$ —	\$ —	\$ 1,388,859	\$ —	\$ 19,111	\$1,602,258
	2011	\$156,000	\$ —	\$ —	\$ —	\$ —	\$ 15,986	\$ 171,986
	2010	\$140,282	\$ —	\$ —	\$ —	\$ —	\$ 2,250	\$ 142,532
John C.K. Milligan, IV <sup>(4)</sup> President and Secretary	2012	\$181,404	\$ —	\$ —	\$ 1,263,781	\$ —	\$ 18,184	\$1,463,369
	2011	\$156,000	\$ —	\$ —	\$ —	\$ —	\$ 25,329	\$ 181,329
	2010	\$144,787	\$ —	\$ —	\$ —	\$ —	\$ 9,554	\$ 154,341
Daniel A. Cartwright <sup>(5)</sup> Chief Financial Officer, Vice President of Finance, and Treasurer	2012	\$184,715	\$ —	\$ —	\$ 857,547	\$ —	\$ 7,814	\$1,068,076
	2011	\$ 79,615	\$ —	\$ —	\$ 179,261	\$ —	\$ 730	\$ 259,606
	2010	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Mitchell L. Krassan <sup>(6)</sup> Executive Vice President and Chief Strategy Officer	2012	\$120,451	\$ —	\$ —	\$ —	\$ —	\$ 1,336	\$ 121,787
	2011	\$110,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 110,000
	2010	\$ 15,096	\$ —	\$ —	\$ 62,301	\$ —	\$ —	\$ 77,397

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

(2) The valuation methodology used to determine the fair value of the options granted during the year was the Black-Scholes-Merton option-pricing model, an acceptable model in accordance with ASC 718-10. The Black-Scholes-Merton model requires the use of a number of assumptions, including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average expected life of the options. For further information, see "Note 10 – Stockholders' Equity" included in the financial statements included in our Annual Report on Form 10-K.

- (3) This table does not include compensation received by Mr. Finizio in his capacity as a member of our board of directors; see “Director Compensation” above. For 2012, (i) Option Awards included the issuance of a non-qualified option for the purchase of 300,000 shares issued on February 27, 2012 and the issuance of a non-qualified option for the purchase of 900,000 shares issued on November 30, 2012; and (ii) All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf. For 2011, All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf. This table does not include the issuance of warrants for 204,571 shares issued in conjunction with the guarantee of a bank loan. For 2010, All Other Compensation includes health insurance premiums paid on Mr. Finizio’s behalf.
- (4) This table does not include compensation received by Mr. Milligan in his capacity as a member of our board of directors; see “Director Compensation” above. For 2012, (i) Option Awards included the issuance of non-qualified options for the purchase of 300,000 shares issued on February 27, 2012 and the issuance of non-qualified options for the purchase of 800,000 shares issued on November 30, 2012; and (ii) All Other Compensation includes health insurance premiums paid on Mr. Milligan’s behalf and a \$5,100 car allowance. For 2011, All Other Compensation includes \$15,987 for health insurance premiums paid on behalf of Mr. Milligan, \$5,100 paid for car allowance, and \$4,242 paid for housing allowance. This table does not include the issuance of warrants for 61,372 shares issued in conjunction with a promissory note and for 204,571 shares issued in conjunction with the guarantee of a bank loan. For 2010, All Other Compensation includes \$2,250 for insurance premiums paid on Mr. Milligan’s behalf and \$7,304 paid for housing allowance.
- (5) For 2012, (i) Option Awards included the issuance of non-qualified options for the purchase of 700,000 shares issued on November 30, 2012; and (ii) All Other Compensation includes health insurance premiums paid on Mr. Cartwright’s behalf. For 2011, (i) Option Awards include the issuance of non-qualified options for the purchase of 300,000 shares issued on October 21, 2011 and the issuance of a warrant for 600,000 shares issued on October 21, 2011, and (ii) All Other Compensation includes health insurance premiums paid on behalf of Mr. Cartwright.
- (6) For 2012, All Other Compensation includes health insurance premiums paid on Mr. Krassan’s behalf. For 2010, Option Awards include the issuance of non-qualified options as follows: (i) options for 73,646 and 92,057 shares respectively, which were originally issued on May 1, 2010 and reissued on October 4, 2011 pursuant to our merger with VitaMed and (ii) an option for 736,455 shares, which was originally issued on September 1, 2010 and reissued on October 4, 2011 pursuant to our merger with VitaMed.

### Grants of Plan-Based Awards

The following table sets forth certain information with respect to grants of plan-based awards to the named executive officers for the fiscal year ended December 31, 2012.

#### GRANTS OF PLAN-BASED AWARDS

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (1)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (2)
Robert G. Finizio	02/27/2012 <sup>(3)</sup>	300,000	2.20	\$ 263,156
	04/16/2012 <sup>(4)</sup>	50,000	2.40	\$ 53,525
	11/30/2012 <sup>(5)</sup>	900,000	3.00	\$ 1,125,703
John C.K. Milligan, IV	02/27/2012 <sup>(3)</sup>	300,000	2.20	\$ 263,156
	04/16/2012 <sup>(4)</sup>	75,000	2.40	\$ 80,287
	11/30/2012 <sup>(5)</sup>	800,000	3.00	\$ 1,000,625
Daniel A. Cartwright	11/30/2012 <sup>(5)</sup>	700,000	3.00	\$ 875,547
Mitchell L. Krassan	—	—	—	—

- (1) These stock option awards were granted under our LTIP or 2012 SOP.
- (2) The amounts shown in this column represent the grant date fair value for stock option awards granted to our named executive officers during the covered year calculated in accordance with ASC 718, excluding the effects of forfeitures. The assumptions used in determining the grant date fair value of these awards are set forth in the notes to our consolidated financial statements, which are included in our Annual Report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2012. There were no forfeitures during fiscal 2012. We calculated the estimated value of each award based on the closing stock price of our common stock on the date of grant.
- (3) The options granted on February 27, 2012 vested in full on the first anniversary of the date of grant.
- (4) The options granted on April 16, 2012 vested in full on December 31, 2012.
- (5) The options granted on November 30, 2012 vest annually on the anniversary date over three years.

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information with respect to outstanding equity-based awards held by our named executive officers at December 31, 2012.

#### OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name	Grant Date	Option Awards				
		Number of Securities Underlying Unexercised Options (1)(2)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
		Exercisable	Unexercisable			
Robert G. Finizio	01/01/2009	1,472,910 <sup>(1)</sup>	—	—	\$ 0.10	01/01/2019
	02/27/2012	—	300,000 <sup>(2)</sup>	—	\$ 2.20	02/27/2022
	04/16/2012	50,000 <sup>(3)</sup>	—	—	\$ 2.40	04/16/2022
	11/30/2012	—	900,000 <sup>(4)(8)</sup>	—	\$ 3.00	11/30/2022
John C.K. Milligan, IV	01/01/2009	2,052,225 <sup>(1)</sup>	—	—	\$ 0.10	01/01/2019
	02/27/2012	—	300,000 <sup>(2)</sup>	—	\$ 2.20	02/27/2022
	04/16/2012	75,000 <sup>(3)</sup>	—	—	\$ 2.40	04/16/2022
	11/30/2012	—	800,000 <sup>(4)</sup>	—	\$ 3.00	11/30/2022
Daniel A. Cartwright	10/21/2011	75,000 <sup>(5)</sup>	225,000 <sup>(5)</sup>	—	\$ 0.38	10/21/2021
	11/30/2012	—	700,000 <sup>(4)</sup>	—	\$ 3.00	11/30/2022
Mitchell L. Krassan	05/01/2010	73,646 <sup>(6)</sup>	—	—	\$ 0.19	05/01/2020
	05/01/2010	92,057 <sup>(6)</sup>	—	—	\$ 0.19	05/01/2020
	09/01/2010	552,341 <sup>(7)</sup>	184,114 <sup>(7)</sup>	—	\$ 0.20	09/01/2020

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

- (6) All underlying shares vested on May 1, 2011.
- (7) All underlying shares vested on September 1, 2013.
- (8) Mr. Finizio forfeited 600,000 of these options in May 2013.

## **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.

Robert G. Finizio has a three year employment agreement that commenced November 8, 2012, which calls for: (i) a time-based ten-year stock option, or the Time-Based Option, granted and issued on November 30, 2012, the "Date of Grant," to purchase 900,000 shares of our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a performance-based ten-year stock option, or the Performance-Based Option, in an amount to be determined, (iii) a base salary of not less than \$355,100 per year and (iv) an annual short-term incentive compensation bonus of up to 35% of the base salary, at the discretion of our board of directors.

John C.K. Milligan, IV has a three year employment agreement that commenced on November 8, 2012, which calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 800,000 shares of our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$288,100 per year, and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of our board of directors.

Daniel A. Cartwright has a three year employment agreement that commenced November 8, 2012, which calls for: (i) a Time-Based Option granted and issued on the Date of Grant to purchase 700,000 shares of our common stock with the exercise price equal to \$3.00, with the underlying shares vesting annually over three years on the anniversary of the employment date, (ii) the right to receive a Performance-Based Option in an amount to be determined, (iii) a base salary of not less than \$257,100 per year, and (iv) an annual short-term incentive compensation bonus of up to 30% of the base salary, at the discretion of 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*

We have employment agreements with certain of our executive officers as described above. The arrangements reflected in these employment agreements are designed to encourage the officers' full attention and dedication to our company currently and, in the event of any proposed change of control, provide these officers with individual financial security. Pursuant to the employment agreements, if the executive is terminated for any reason other than for "cause," or if he terminates his employment voluntarily for "good reason" (as such terms are defined in the employment agreements), he is entitled to receive severance for a period of 12 months in accordance with our normal payroll practices and will be eligible to receive all benefits under welfare benefit plans, practices, policies, and programs provided by us (including medical and group life plans and programs) for the same period.

Pursuant to the employment agreements with the executive 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.

The tables below reflect the amount of compensation to certain of our executive officers, assuming termination of such executive’s employment without cause or for good reason or following a change in control of our company on December 31, 2012. Other than as set forth below, no amounts will be paid to our named executive officers in the event of termination.

**Robert G. Finizio**

Executive Benefits and Payments Upon Separation	Voluntary Termination on 12/31/12	Involuntary Not for Cause Termination on 12/31/12	For Cause Termination on 12/31/12	Involuntary for Good Reason Termination (Change of Control) on 12/31/12	Death on 12/31/12	Disability on 12/31/12
<b>Compensation:</b>						
Bonus	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Equity awards (1)	\$ —	\$ 4,803,579	\$ —	\$ 4,803,579	\$ —	\$ —
<b>Benefits and Perquisites:</b>						
Cash severance	\$ —	\$ 486,885	\$ —	\$ 516,427	\$ —	\$ —
Health and welfare benefits	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Other	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

**John C.K. Milligan, IV**

Executive Benefits and Payments Upon Separation	Voluntary Termination on 12/31/12	Involuntary Not for Cause Termination on 12/31/12	For Cause Termination on 12/31/12	Involuntary for Good Reason Termination (Change of Control) on 12/31/12	Death on 12/31/12	Disability on 12/31/12
<b>Compensation:</b>						
Bonus	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Equity awards (1)	\$ —	\$ 6,544,321	\$ —	\$ 6,544,321	\$ —	\$ —
<b>Benefits and Perquisites:</b>						
Cash severance	\$ —	\$ 382,030	\$ —	\$ 382,030	\$ —	\$ —
Health and welfare benefits	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Other	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

**Daniel A. Cartwright**

Executive Benefits and Payments Upon Separation	Voluntary Termination on 12/31/12	Involuntary Not for Cause Termination on 12/31/12	For Cause Termination on 12/31/12	Involuntary for Good Reason Termination (Change of Control) on 12/31/12	Death on 12/31/12	Disability on 12/31/12
<b>Compensation:</b>						
Bonus	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Equity awards (1)	\$ —	\$ 886,000	\$ —	\$ 886,000	\$ —	\$ —
<b>Benefits and Perquisites:</b>						
Cash severance	\$ —	\$ 341,730	\$ —	\$ 363,155	\$ —	\$ —
Health and welfare benefits	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Other	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

<b>Executive Benefits and Payments Upon Separation</b>	<b>Voluntary Termination on 12/31/12</b>	<b>Involuntary Not for Cause Termination on 12/31/12</b>	<b>For Cause Termination on 12/31/12</b>	<b>Involuntary for Good Reason Termination (Change of Control) on 12/31/12</b>	<b>Death on 12/31/12</b>	<b>Disability on 12/31/12</b>
<b>Compensation:</b>						
Bonus	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Equity awards (1)	\$ —	\$ 2,615,623	\$ —	\$ 2,615,623	\$ —	\$ —
<b>Benefits and Perquisites:</b>						
Cash severance	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Health and welfare benefits	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Other	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

(1) Amounts represent the dollar amounts that would be recognized for financial statement reporting purposes with respect to the unamortized grant date fair value of stock options

(2) Determined in accordance with ASC 718.

**Nonqualified Deferred Compensation**

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

**Risk Management Considerations**

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

**Limitation of Directors’ Liability; Indemnification of Directors, Officers, Employees, and Agents**

Our amended and restated articles of incorporation and bylaws provide that we may indemnify to the full extent of our power to do so, all directors, officers, employees, and agents. The effect of this provision in the amended and restated articles of incorporation is to eliminate the rights of our company and our stockholders, either directly or through stockholders’ derivative suits brought on behalf of our company, to recover monetary damages from a director for breach of the fiduciary duty of care as a director except in those instances described under Nevada law.

Insofar as indemnification by our company for liabilities arising under the Securities Act may be permitted to officers and directors of our company pursuant to the foregoing provisions or otherwise, we are aware that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

**Option Exercises and Stock Vested**

During fiscal 2012, none of our named executive officers acquired shares upon the exercise of options or the vesting of stock awards.

**Equity Compensation Plan Information**

*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.

*Amended and Restated 2012 Stock Incentive Plan*

On February 23, 2012, our board of directors approved the 2012 Stock Incentive Plan. Our board of directors approved the Amended and Restated 2012 Stock Incentive Plan on June 10, 2013, and our stockholders approved the Amended and Restated 2012 SOP on August 22, 2013. The Amended and Restated 2012 SOP is designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisers of our company. There are 10,000,000 authorized for issuance thereunder. The Amended and Restated 2012 SOP is administered by our Compensation Committee, except to the extent our board of directors elects to administer the Amended and Restated 2012 SOP.

*Securities Authorized for Issuance under Equity Compensation Plans*

As of June 30, 2013, the following table shows the number of securities to be issued upon exercise of outstanding options under equity compensation plans approved by our stockholders, which plans do not provide for the issuance of warrants or other rights.

<b>Plan Category</b>	<b>Number of Securities to Be Issued Upon Exercise of Outstanding Options (a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options (b)</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)</b>
Equity Compensation Plans Approved by Stockholders	14,655,793	\$ 1.26	18,258,990
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	<u>14,655,793</u>	<u>\$ 1.26</u>	<u>18,258,990</u>

**Policy Relating to Certain Transactions**

We have a policy that we will not enter into any material transaction in which a director or officer has a direct or indirect financial interest unless the transaction is determined by our board of directors to be fair to us or is approved by a majority of our disinterested directors or by our stockholders, as provided for under Nevada law. Our board of directors as a whole or, in certain cases when appropriate, a committee of the board of directors consisting solely of independent directors, determines whether a director or officer has a direct or indirect (*i.e.*, any) financial interest in a transaction deemed material based upon the Company's Code of Conduct and Ethics and Nevada law. The policy with respect to such transactions is provided in our company's Code of Conduct and Ethics.

**Related Party Transactions**

Except for the transactions described below, none of our directors, officers, or principal stockholders, nor any associate or affiliate of the foregoing, have any interest, direct or indirect, in any transaction or in any proposed transaction, which materially affected us since January 1, 2012.

*March 2011 Bank Line of Credit*

In March 2011, we entered into a Business Loan Agreement and Promissory Note with First United Bank for a \$300,000 bank line of credit, or the Bank LOC, for which a personal guarantee and cash collateral was required. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of our company, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of our company. In consideration for the personal guarantees and cash collateral, warrants for an aggregate of 613,713 shares of common stock were granted. The ten-year warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter-end and have an exercise price of \$0.2444 per share. In the event that the Bank LOC is repaid prior to such date as the warrants are fully vested, we will only issue warrants for the number of shares vested through such date. As of December 31, 2012, 562,571 shares were vested under the warrants.

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



## *Repayment of VitaMed Promissory Notes*

In June 2011, VitaMed sold Promissory Notes, or the VitaMed Promissory Notes, in the aggregate principal amount of \$500,000, including an aggregate of \$200,000 issued to certain of our directors and officers. Messrs. Milligan and Bernick and entities controlled by Messrs. Krassan and Segal were each issued VitaMed Promissory Notes for \$50,000. In consideration for the VitaMed Promissory Notes, warrants for an aggregate of 613,718 shares of our common stock were granted. The VitaMed Promissory Notes earn interest at the rate of 4% per annum and were due at the earlier of (i) the six month anniversary of the date of issuance and (ii) such time as VitaMed received the proceeds of a promissory note or notes issued in an amount of not less than \$1,000,000. Upon the closing of such funding in July 2011, two of the VitaMed Promissory Notes held by unaffiliated parties in the aggregate of \$200,000 were paid in full. By mutual agreement, the remaining VitaMed Promissory Notes in the aggregate of \$300,000 were extended.

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

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

In December 2011, we sold 4% promissory notes to Mr. Finizio and Mr. Milligan 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 will terminate.

## *Agreements with Pernix Therapeutics, LLC*

We closed a stock purchase agreement with Pernix Therapeutics, LLC, or Pernix, a speciality pharmaceutical company, on October 5, 2011 pursuant to which Pernix purchased 2,631,579 shares of our common stock at a purchase price of \$0.38 per share for a total purchase price of \$1,000,000. The stock purchase agreement included a lock-up agreement pursuant to which, among other things, Pernix agreed that for a period of 12 months from the date of the lock-up agreement, it would not make or cause any sale of the purchased shares. After the completion of this 12-month lock-up period, Pernix agreed not to sell or dispose of more than 5% of the shares per quarter for the following 12-month period. The President and largest shareholder of Pernix, Cooper C. Collins, was elected to serve on our board of directors on February 29, 2012. From time to time, we have and will continue to enter into agreements with Pernix in the normal course of business, which agreements are negotiated in arms-length transactions. On June 14, 2013, we waived the remaining term of the lock-up agreement, and Pernix sold all 2,631,579 shares of our common stock in a private transaction.

## *Warrants Assigned to Related Party*

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

## *Credit Line for \$10 Million*

On January 31, 2013, we issued a Multiple Advance Revolving Credit Note, or the Note, Plato, an entity solely owned by Robert J. Smith, one of our principal stockholders as of December 31, 2012. The Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum. Plato may make advances to us from time to time under the Note at our request, which advances will be of a revolving nature. Interest payments will be due and payable on a quarterly basis, commencing on April 10, 2013, and the principal balance outstanding under the Note, together with all accrued interest and other amounts payable under the Note, if any, will be due and payable on February 24, 2014. As additional consideration for the Note, we issued to Plato a warrant to purchase 1,250,000 shares of our common stock at an exercise price \$3.20 per share. This warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to its January 31, 2019 expiration date. As of September 30, 2013, there was no balance outstanding under the Note.

## PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of October 7, 2013 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 October 7, 2013. Shares issuable pursuant to stock options, warrants, and convertible securities are deemed outstanding for computing the percentage of the person holding such options, warrants, or convertible securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose.

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., 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487.

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Number of Shares Being Registered for Sale <sup>(2)</sup>	Beneficially Owned Upon Completion of this Offering	
	Number	Percent <sup>(1)</sup>		Number	Percent <sup>(1)</sup>
<b>Executive Officers and Directors:</b>					
Robert G. Finizio, Chief Executive Officer and Director <sup>(3)</sup>	24,463,496	16.61%	—	24,463,496	16.61%
John C.K. Milligan, IV, President, Secretary and Director <sup>(4)</sup>	9,302,311	6.29%	—	9,302,311	6.29%
Daniel A. Cartwright, Chief Financial Officer, Vice President-Finance, and Treasurer <sup>(5)</sup>	724,233	*	—	724,233	*
Mitchell L. Krassan, Executive Vice President and Chief Strategy Officer <sup>(6)</sup>	902,155	*	—	902,155	*
Brian Bernick, M.D., Chief Medical Officer and Director <sup>(7)</sup>	9,254,049	6.31%	—	9,254,049	6.31%
Tommy Thompson, Chairman of the Board <sup>(8)</sup>	675,000	*	—	675,000	*
Samuel A. Greco, Director <sup>(9)</sup>	450,000	*	—	450,000	*
Cooper C. Collins, Director <sup>(10)</sup>	75,000	*	—	75,000	*
Robert V. LaPenta, Jr., Director <sup>(11)</sup>	80,000	*	—	80,000	*
Jules A. Musing, Director	22,400	*	—	22,400	*
Nicholas Segal, Director <sup>(12)</sup>	879,887	*	—	879,887	*
All executive officers and directors as a group (11 persons) <sup>(13)</sup>	46,828,531	31.83%	—	46,828,531	31.83%
<b>5% Stockholders:</b>					
Steven G. Johnson <sup>(14)</sup>	9,453,149	6.40%	1,141,658	8,311,491	5.63%
Robert J. Smith <sup>(15)</sup>	13,054,426	8.77%	1,141,658	11,912,768	8.00%
Wellington Management Company, LLP <sup>(16)</sup>	18,087,342	12.48%	—	18,087,342	12.48%
RA Capital Management, LLC <sup>(17)</sup>	11,262,608	7.77%	—	11,262,608	7.77%
FMR LLC <sup>(18)</sup>	10,121,621	6.98%	—	10,121,621	6.98%
<b>Other Selling Stockholders:</b>					
Wellington Management Portfolio (Australia)-Special Strategies Portfolio (nominee: Gerlach and Co.) <sup>(19) (20)</sup>	133,794	*	26,902	106,892	*
Vanguard Capital Value Fund (nominee: Vanguard Cap Value Fund c/o BBH & Co.) <sup>(19) (20)</sup>	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.) <sup>(19) (20)</sup>	113,016	*	64,751	48,265	*
Wellington Trust Company, N.A., Multiple Collective Investment Funds Trust, All Cap Opportunities Portfolio (nominee: CASCOFISH & CO.) <sup>(19) (20)</sup>	82,287	*	15,421	66,866	*
Global Multi-Strategy Fund (nominee: Hare & Co.) <sup>(19) (20)</sup>	59,729	*	15,388	44,341	*
Ralph Daniel Freudenthal <sup>(20)</sup>	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 144,962,706 shares of Common Stock outstanding as of October 7, 2013, 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) 2,122,910 shares due to Finizio upon exercise of vested shares under options and (iii) 179,000 shares due to Finizio upon exercise of vested shares under a warrant. The percentage of class for Finizio is based on 147,264,616 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) 2,693,921 shares due to Milligan upon exercise of vested shares under options, and (iii) 240,372 shares due to Milligan upon exercise of vested shares under warrants. The percentage of class for Milligan is based on 147,896,999 shares which would be outstanding if all of Milligan’s vested shares under the options and warrants were exercised.

- (5) This amount includes (i) 383,333 shares due to Cartwright upon exercise of vested shares under options, and (ii) 340,900 shares due to Cartwright upon exercise of vested shares under a warrant. The percentage of class for Cartwright is based on 145,686,939 shares which would be outstanding if all vested shares under the options and warrant were exercised.
- (6) This amount includes 902,155 shares due to Krassan upon exercise of vested shares under options. The percentage of class for Krassan is based on 145,864,861 shares which would be outstanding if all of Krassan's vested shares under the options were exercised.
- (7) This amount includes (i) 7,519,767 shares beneficially owned by BF Investment Enterprises, Ltd., or BF Investment, a company controlled by Bernick, (ii) 1,672,910 shares due to BF Investment upon exercise of vested shares under options and (iii) 61,372 shares due to BF Investment upon exercise of vested shares under a warrant. The percentage of class for Bernick is based on 146,696,988 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 145,037,706 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 145,012,706 shares which would be outstanding if all of Greco's vested shares under the options were exercised.
- (10) This amount includes 75,000 shares due to Collins upon exercise of vested shares under options. The percentage of class for Collins is based on 145,037,706 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 145,037,706 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, out of which Segal claims ownership equal to 411,110 shares and 7,107 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. Segal owns 4.633% of Seavest Capital Ventures, LLC, or Seavest, which owns 1,600,000 shares, out of which Segal claims ownership equal to 74,128 shares. Segal disclaims beneficial ownership to the remaining shares beneficially owned by Seavest. The percentage of class for Segal is based on 145,111,870 shares which would be outstanding if all of Segal'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 153,983,743 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) 6,753,149 shares beneficially owned through SJ Capital, LLC, an entity solely owned by Johnson, of which 1,141,658 shares are being registered hereunder and (ii) 2,700,000 shares due to Johnson upon the exercise of vested warrants. The percentage of class for Johnson is based on 147,662,706 shares which would be outstanding if all of Johnson's shares under the vested warrants were exercised. Johnson exercises voting and dispositive power over all such shares. The information is as reported on Schedule 13D as filed on February 4, 2013. Johnson's address is 804 Tree Haven Court, Highland Village, Texas 75077.
- (15) This amount includes (i) 5,690,468 shares beneficially owned through Plato and Associates, LLC, or Plato, an entity solely owned by Smith, (ii) 1,432,228 shares beneficially owned through Energy Capital, LLC, an entity solely owned by Smith, of which 1,141,658 shares are being registered hereunder, (iii) 1,981,730 shares beneficially owned through Jo Cee, LLC, an entity solely owned by Smith, and (iii) 3,950,000 shares due to Plato upon the exercise of vested warrants. The percentage of class for Smith is based on 148,912,706 shares which would be outstanding if all of Smith's shares under the vested warrants were exercised. Smith exercises voting and dispositive power over all such shares. The information is as reported on Schedule 13D as filed on May 2, 2013. Smith's address is 13650 Fiddlesticks Boulevard, #202-324, Ft. Myers, Florida 33912.

- (16) The shares are beneficially owned by Wellington Management Company, LLP, or Wellington, 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 has (i) sole investment power over 17,237,879 shares and shared investment power over 849,463 shares, and (ii) sole voting power over 12,943,608 shares and shared voting power over 849,463 shares. The information is as reported on Form 13F for the quarter ended June 30, 2013. Wellington Management's address is 280 Congress Street, Boston, Massachusetts 02210.
- (17) The shares are beneficially owned by RA Capital Management, LLC, or RA Capital, in its capacity as investment adviser, for its clients. RA Capital exercises sole voting and sole investment power over all such shares. The information is as reported on Form 13F for the quarter ended June 30, 2013. RA Capital's address is 20 Park Plaza, Suite 1200, Boston, Massachusetts 02116.
- (18) The shares are beneficially owned by FMR LLC, or FMR, in its capacity as investment adviser, for its clients. FMR has shared investment power over such shares. The information is as reported on Form 13F, as amended and restated, for the quarter ended June 30, 2013. FMR's address is 245 Summer Street, Boston, MA 02210.
- (19) 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.
- (20) Information regarding beneficial ownership, as reported in the beneficial ownership table, reflects the stock ownership information of the investors as disclosed by the investors in connection with the October 2012 Private Placement. Updated information regarding beneficial ownership is not publicly available for these investors.

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 reallocated 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 260,000,000 shares of capital stock, 250,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. As of date of this prospectus, we had 144,962,706 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 our 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 stock 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 used 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 served as our exclusive placement agent. We also incurred legal fees and expenses of 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(a)(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 stock purchase agreement, we agreed to file a registration statement, which was filed November 27, 2012. We also agreed to indemnify each selling stockholder, to the extent permitted by law, 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**

We are a Nevada corporation and generally governed by the Nevada Private Corporations Code, Title 78 of the Nevada Revised Statutes, or NRS.

Section 78.138 of the NRS provides that, unless the corporation’s articles of incorporation provide otherwise, a director or officer will not be individually liable unless it is proven that (i) the director’s or officer’s acts or omissions constituted a breach of his or her fiduciary duties, and (ii) such breach involved intentional misconduct, fraud, or a knowing violation of the law.

Section 78.7502 of the NRS permits a company to indemnify its directors and officers against expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with a threatened, pending, or completed action, suit, or proceeding, if the officer or director (i) is not liable pursuant to NRS 78.138, or (ii) acted in good faith and in a manner the officer or director reasonably believed to be in or not opposed to the best interests of the corporation and, if a criminal action or proceeding, had no reasonable cause to believe the conduct of the officer or director was unlawful. Section 78.7502 of the NRS also precludes indemnification by the corporation if the officer or director has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court determines that in view of all the circumstances, the person is fairly and reasonably entitled to indemnity for such expenses and requires a corporation to indemnify its officers and directors if they have been successful on the merits or otherwise in defense of any claim, issue, or matter resulting from their service as a director or officer.

Section 78.751 of the NRS permits a Nevada company to indemnify its officers and directors against expenses incurred by them in defending a civil or criminal action, suit, or proceeding as they are incurred and in advance of final disposition thereof, upon determination by the stockholders, the disinterested board members, or by independent legal counsel. Section 78.751 of NRS requires a corporation to advance expenses as incurred upon receipt of an undertaking by or on behalf of the officer or director to repay the amount if it is ultimately determined by a court of competent jurisdiction that such officer or director is not entitled to be indemnified by the company if so provided in the corporations articles of incorporation, bylaws, or other agreement. Section 78.751 of the NRS further permits the company to grant its directors and officers additional rights of indemnification under its articles of incorporation, bylaws, or other agreement.

Section 78.752 of the NRS provides that a Nevada company may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee, or agent of the company, or is or was serving at the request of the company as a director, officer, employee, or agent of another company, partnership, joint venture, trust, or other enterprise, for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee, or agent, or arising out of his status as such, whether or not the company has the authority to indemnify him against such liability and expenses.

The foregoing discussion of indemnification merely summarizes certain aspects of indemnification provisions and is limited by reference to the above discussed sections of the Nevada Corporation Law.

Our Articles of Incorporation and Bylaws provide that we may indemnify to the full extent of its power to do so, all directors, officers, employees, and/or agents. Insofar as indemnification by our company for liabilities arising under the Securities Act may be permitted to officers and directors of the Company pursuant to the foregoing provisions or otherwise, we are aware that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

### **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 750, Golden, Colorado 80401, as our transfer agent.

### **SHARES ELIGIBLE FOR FUTURE SALE**

Our common stock began trading on the NYSE MKT on April 23, 2013 under the symbol “TXMD” and was previously listed on the OTCQB. 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 144,962,706 shares of our common stock outstanding. Of these shares, the 3,953,489 that we issued in the October 2012 Private Placement became freely tradable without restriction under the Securities Act on December 12, 2012 when the SEC declared effective the registration statement of which this prospectus forms a part, with the exception of 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 our affiliates 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 74,962,706 of our shares are eligible for sale in the public market subject to volume, manner of sale, and other limitations under Rule 144. As a result of the dribble out period described below, 80,569,672 shares will be eligible for sale at December 31, 2013 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 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.

## **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 has been passed upon for us by Greenberg Traurig, LLP, Phoenix, Arizona.

## **EXPERTS**

The financial statements as of December 31, 2012 and 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 firm given upon its authority as an expert 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 or any other materials we have filed with the SEC without charge at the public reference facility maintained by the SEC at 100 F Street, N.E., 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 at <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](http://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 reports 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 and is not incorporated herein by reference.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

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**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>June 30,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(Unaudited)	
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash	\$ 34,435,468	\$ 1,553,474
Accounts receivable, net of allowance for doubtful accounts of \$100,385 and \$42,048, respectively	957,779	606,641
Inventory	1,506,059	1,615,210
Other current assets	3,607,283	751,938
<b>Total current assets</b>	<u>40,506,589</u>	<u>4,527,263</u>
Fixed assets, net	<u>76,494</u>	<u>65,673</u>
<b>Other Assets:</b>		
Prepaid expenses	1,980,519	953,655
Intangible assets	345,238	239,555
Security deposit	156,949	31,949
<b>Total other assets</b>	<u>2,482,706</u>	<u>1,225,159</u>
<b>Total assets</b>	<u>\$ 43,065,789</u>	<u>\$ 5,818,095</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 2,045,116	\$ 1,641,366
Deferred revenue	1,219,072	1,144,752
Other current liabilities	1,334,730	725,870
<b>Total current liabilities</b>	<u>4,598,918</u>	<u>3,511,988</u>
<b>Long-Term Liabilities:</b>		
Notes payable, net of debt discount of \$0 and \$1,102,680, respectively	—	3,589,167
Accrued interest	—	150,068
<b>Total long-term liabilities</b>	<u>—</u>	<u>3,739,235</u>
<b>Total liabilities</b>	<u>4,598,918</u>	<u>7,251,223</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity (Deficit):</b>		
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; 131,212,706 and 99,784,982 issued and outstanding, respectively	131,213	99,785
Additional paid in capital	102,834,270	50,580,400
Accumulated deficit	(64,498,612)	(52,113,313)
<b>Total stockholder' equity (deficit)</b>	<u>38,466,871</u>	<u>(1,433,128)</u>
<b>Total liabilities and stockholders' equity (deficit)</b>	<u>\$ 43,065,789</u>	<u>\$ 5,818,095</u>

**THERAPEUTICSMD, INC AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues, net	\$ 2,080,885	\$ 819,150	\$ 3,618,080	\$ 1,540,842
Cost of goods sold	463,606	372,370	843,952	708,494
Gross profit	1,617,279	446,780	2,774,128	832,348
Operating expenses:				
Sales, general, and administration	5,476,553	3,573,485	10,003,135	6,400,535
Research and development	1,747,084	833,342	3,312,285	1,245,303
Depreciation and amortization	10,636	14,535	18,593	29,113
Total operating expense	7,234,273	4,421,362	13,334,013	7,674,951
Operating loss	(5,616,994)	(3,974,582)	(10,559,885)	(6,842,603)
Other income (expense):				
Miscellaneous income	3,479	1,554	3,479	1,554
Interest expense	(150)	(1,148,761)	(1,165,981)	(1,250,734)
Financing costs	(395,981)	—	(659,968)	—
Loan guaranty costs	—	(11,745)	(2,944)	(23,490)
Beneficial conversion feature	—	(6,716,504)	—	(6,716,504)
Loss on extinguishment of debt	—	—	—	(10,307,864)
Total other income (expense)	(392,652)	(7,875,456)	(1,825,414)	(18,297,038)
Loss before taxes	(6,009,646)	(11,850,038)	(12,385,299)	(25,139,641)
Provision for income taxes	—	—	—	—
Net loss	\$ (6,009,646)	\$ (11,850,038)	\$ (12,385,299)	\$ (25,139,641)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.14)	\$ (0.11)	\$ (0.29)
Weighted average number of common shares outstanding	130,851,978	86,149,419	116,866,764	85,352,818



**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Six Months Ended	
	June 30,	
	2013	2012
	(Unaudited)	(Unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (12,385,299)	\$ (25,139,641)
Adjustments to reconcile net loss to net cash flows used in operating activities		
Depreciation	12,084	15,141
Amortization of intangible assets	6,509	13,972
Provision for doubtful accounts	58,337	15,023
Amortization of debt discount	1,102,680	1,109,276
Stock based compensation	1,179,912	529,129
Amortization of deferred financing costs	659,938	—
Stock based expense for services	637,155	120,120
Loan guaranty costs	2,944	23,490
Loss on debt extinguishment	—	10,307,864
Beneficial conversion feature	—	6,716,504
Changes in operating assets and liabilities:		
Accounts receivable	(409,475)	(396,232)
Inventory	109,151	(232,168)
Other current assets	(1,696,551)	(118,566)
Other assets	(899,000)	—
Accounts payable	403,750	385,620
Accrued interest	(150,068)	133,702
Other current liabilities	608,860	248,450
Deferred revenue	74,320	618,877
Net cash flows used in operating activities	<u>(10,684,753)</u>	<u>(5,649,439)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Payment of security deposit	(125,000)	—
Patent costs, net of abandoned costs	(112,192)	(49,184)
Purchase of property and equipment	(22,905)	(66,404)
Net cash flows used in investing activities	<u>(260,097)</u>	<u>(115,588)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from sale of common stock, net	48,512,460	—
Proceeds from notes and loans payable	—	6,900,000
Repayment of notes payable	(4,691,847)	(50,780)
Repayment of notes payable-related party	—	(50,000)
Proceeds from exercise of options	6,231	165,999
Proceeds from line of credit	500,000	—
Repayment of line of credit	(500,000)	—
Proceeds from sale of warrants	—	400
Net cash flows provided by financing activities	<u>43,826,844</u>	<u>6,965,619</u>
Increase in cash	32,881,994	1,200,592
Cash, beginning of period	1,553,474	126,421
Cash, end of period	<u>\$ 34,435,468</u>	<u>\$ 1,327,013</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 212,853	\$ 7,756
Cash paid for income taxes	\$ —	\$ —
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:</b>		
Warrants issued for financing	\$ 1,711,956	\$ 2,509,537
Warrants exercised in exchange for debt and accrued interest	\$ —	\$ 3,102,000
Warrants issued for services	\$ 462,196	\$ 1,532,228
Shares issued in exchange for debt and accrued interest	\$ —	\$ 1,054,658
Notes payable issued for accrued interest	\$ —	\$ 15,123

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

**NOTE 1 – THE COMPANY**

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

Nature of Business

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

**NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS**

Interim Financial Statements

Our accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles, or GAAP, for complete financial statements. In our opinion, such financial statements include all adjustments (consisting solely of normal recurring adjustments) necessary for the fair statement of the financial information included herein in accordance with GAAP and the rules and regulations of the Securities and Exchange Commission, or SEC. The balance sheet at December 31, 2012 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. Actual results could differ from those estimates. Results of operations for interim periods are not necessarily indicative of results for the full year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes included in our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2012.

Fair Value of Financial Instruments

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

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by Accounting Standards Codification, or ASC 820 *Fair Value Measurements and Disclosures*. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

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

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

At June 30, 2013 and December 31, 2012, we had no assets or liabilities that were valued at fair value on a recurring basis.

Research and Development

Research and development, or R&D, expenses include internal R&D activities, external contract research organization, or CRO, services and their clinical research sites, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Earnings Per Share

We calculate earnings per share, or EPS, in accordance with ASC 260, *Earnings Per Share*, which requires the computation and disclosure of two EPS amounts, basic and diluted. We compute basic EPS based on the weighted average number of shares of common stock outstanding during the period. We compute diluted EPS based on the weighted average number of shares of common stock outstanding plus all potentially dilutive common shares outstanding during the period. Such potentially dilutive common shares consist of stock options and warrants. Potentially dilutive common shares totaling 21,773,002 and 18,884,154 at June 30, 2013 and 2012, respectively, have been excluded from the diluted earnings per share calculation as they are anti-dilutive due to the net loss reported by us.

Recently Issued and Newly Adopted Accounting Pronouncements

On July 18, 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in ASU No. 2013-11 are not expected to have an impact on our condensed consolidated financial statements.

Reclassifications

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

**NOTE 3 – INVENTORY**

Inventory consists of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Finished product	\$ 1,100,486	\$ 1,124,739
Raw material	291,035	\$ 380,000
Deferred costs	114,538	110,471
TOTAL INVENTORY	<u>\$ 1,506,059</u>	<u>\$ 1,615,210</u>

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

**NOTE 4 – OTHER CURRENT ASSETS**

Other current assets consist of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Prepaid research and development costs	\$ 1,686,254	\$ 189,375
Deferred financing costs	1,051,988	-0-
Prepaid consulting	541,936	432,216
Other receivables-related party (Note 12)	171,261	-0-
Prepaid insurance	125,266	127,403
Other prepaid costs	30,578	-0-
Prepaid guaranty costs	-0-	2,944
<b>TOTAL OTHER CURRENT ASSETS</b>	<u><u>\$ 3,607,283</u></u>	<u><u>\$ 751,938</u></u>

**NOTE 5 – FIXED ASSETS**

Fixed assets consist of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Equipment	\$ 90,573	\$ 67,668
Furniture and fixtures	46,625	46,625
Leasehold improvements	11,980	11,980
	149,178	126,273
Accumulated depreciation	(72,684)	(60,600)
<b>TOTAL FIXED ASSETS</b>	<u><u>\$ 76,494</u></u>	<u><u>\$ 65,673</u></u>

Depreciation expense for the six months ended June 30, 2013 and 2012 was \$12,084 and \$15,141, respectively.

**NOTE 6 – OTHER ASSETS**

Prepaid expenses consist of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Prepaid manufacturing costs	\$ 899,000	\$ -0-
Prepaid consulting expense	1,081,519	953,655
<b>TOTAL PREPAID EXPENSE</b>	<u><u>\$ 1,980,519</u></u>	<u><u>\$ 953,655</u></u>

Intangible assets consist of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Patent costs	\$ 337,163	\$ 224,971
Website costs, net of amortization of \$83,668 and \$77,159, respectively	8,075	14,584
<b>TOTAL INTANGIBLE ASSETS</b>	<u><u>\$ 345,238</u></u>	<u><u>\$ 239,555</u></u>

Amortization expense for the six months ended June 30, 2013 and 2012 was \$6,509 and \$13,972, respectively.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

**NOTE 7 – OTHER CURRENT LIABILITIES**

Other current liabilities consist of the following:

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
Accrued offering costs	\$ 500,000	\$ -0-
Accrued payroll and commission costs	228,877	397,210
Accrued vacation costs	263,851	114,899
Accrued professional fees	120,250	90,000
Allowance for coupons and returns	86,540	53,002
Other accrued expenses	93,853	29,400
Dividends payable <sup>(1)</sup>	41,359	41,359
<b>TOTAL OTHER CURRENT LIABILITIES</b>	<b>\$ 1,334,730</b>	<b>\$ 725,870</b>

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

**NOTE 8 – NOTES PAYABLE**

Issuance and Payment of Multiple Advance Revolving Credit Note

On January 31, 2013, we entered into a business loan agreement with Plato and Associates, LLC, a Florida limited liability company, or Plato, for a Multiple Advance Revolving Credit Note, or the Plato Note. The Plato Note allows us to draw down funding up to the \$10 million maximum principal amount, at a stated interest rate of 6% per annum. Plato may make advances to us from time to time under the Plato Note at our request, which advances will be of a revolving nature and may be made, repaid, and made from time to time. Interest payments shall be due and payable on the tenth day following the end of each calendar quarter in which any interest is accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Plato Note, together with all accrued interest and other amounts payable under the Plato Note, if any, will be due and payable on February 24, 2014. The Plato Note is secured by substantially all of our assets. On each of February 25 and March 13, 2013, \$200,000 was drawn against the Plato Note. On March 21, 2013, we repaid \$401,085, including accrued interest, and as of June 30, 2013, there was no balance outstanding under the Plato Note.

As additional consideration for the Plato Note, we issued Plato a warrant to purchase 1,250,000 shares of our common stock at an exercise price \$3.20 per share (see NOTE 9 – STOCKHOLDERS' EQUITY for more details).

Borrowing Under Amended Bank LOC

In February 2013, we borrowed \$100,000 from First United Bank under the Amended Bank LOC. The Amended Bank LOC required a personal guarantee and cash collateral limited to \$100,000 which was provided by Reich Family Limited Partnership, or Reich Family LP, an entity controlled by Mitchell Krassan, an officer of the Company. On April 25, 2013, we paid the principal and interest due under the Amended Bank LOC of \$100,735. On May 1, 2013, the Amended Bank LOC expired and was not renewed. Accordingly, the personal guarantee was canceled and the cash collateral was refunded to Reich Family LP.

Issuance of Promissory Notes

In January and February 2012, we sold 6% promissory notes for an aggregate of \$900,000 with due dates of March 1, 2012. As discussed below in Issuance and Settlement of February 2012 Notes, these promissory notes were modified on February 24, 2012 through the issuance of secured promissory notes, or the February 2012 Notes.

Issuance and Settlement of February 2012 Notes

On February 24, 2012, we issued the February 2012 Notes to an individual and an entity, or the Parties, both of which are our stockholders, in the principal base amount of \$1,358,014 and \$1,357,110, respectively, and granted warrants for the purchase in the aggregate of 9,000,000 shares of our common stock, or the February 2012 Warrants, pursuant to the terms of a Note Purchase Agreement, also dated February 24, 2012. As consideration for the February 2012 Notes and the February 2012 Warrants, we received an aggregate of \$1,000,000 of new funding from the Parties and the Parties surrendered certain promissory notes previously issued by us in the aggregate amount of \$1,700,000 plus accrued interest of \$15,124. Under the February 2012 Notes, the Parties loaned us an additional \$3,000,000 during March, April, and May 2012.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

On June 19, 2012, we settled \$3,102,000 in principle and interest of the February 2012 Notes in exchange for the exercise of 8,145,486 warrants. As discussed below in Issuance and Payment of June 2012 Notes, the remaining balance of \$2,691,847 of the February 2012 Notes was modified on June 19, 2012 through the issuance of secured promissory notes, or the June 2012 Notes, (see NOTE 9 – STOCKHOLDERS' EQUITY, Warrants Issued in Connection with Debt, for more details).

Issuance and Payment of June 2012 Notes

On June 19, 2012, we 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, or the June 2012 Note Purchase Agreement. As consideration for the June 2012 Notes, the Parties surrendered the remaining balance of the February 2012 Notes in the aggregate amount of \$1,347,128 and \$1,344,719, respectively (which sums included principle and interest through June 19, 2012), and we received an aggregate of \$2,000,000 of new funding from the Parties (the "June Funding"). The principal base amount of each of the June 2012 Notes, plus any additional advance made to us thereafter, together with accrued interest at the annual rate of 6%, was due in one lump sum payment on February 24, 2014. As security for our obligations under the June 2012 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 also granted warrants to purchase an aggregate of 7,000,000 shares of our common stock in connection with the June Funding. On March 21, 2013, we repaid \$4,882,019 including accrued interest, leaving a balance of \$21,595 in accrued interest as of March 31, 2013 related to the June 2012 Notes. On April 25, 2013, the balance of accrued interest was paid in full.

**NOTE 9 – STOCKHOLDERS' EQUITY**

Common Stock

At June 30, 2013, we had 250,000,000 shares of common stock, \$0.001 par value per share, authorized with 131,212,706 shares issued and outstanding.

Public Offering

On March 14, 2013, we entered into an underwriting agreement, or the Underwriting Agreement, with Jefferies LLC, as representative of the underwriters named therein, or the Underwriters, relating to the issuance and sale of 29,411,765 shares of our common stock. The price to the public in the offering was \$1.70 per share and the Underwriters agreed to purchase the shares from us pursuant to the Underwriting Agreement at a price of \$1.581 per share. The net proceeds to us from this offering was approximately \$45.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, under the terms of the Underwriting Agreement, we granted the Underwriters a 30-day option to purchase up to an additional 4,411,765 shares of common stock. The offering closed on March 20, 2013.

Additional Shares Purchased under Offering

As part of the public offering of our common stock described in Public Offering above, on April 12, 2013, the Underwriters exercised their option to purchase an additional 1,954,587 shares of our common stock to cover over-allotments. We issued these shares to the Underwriters on April 18, 2013 and received proceeds of approximately \$3.1 million, net of expenses.

Warrants to Purchase Common Stock of the Company

As of June 30, 2013, we had common stock purchase warrants outstanding for an aggregate of 14,293,499 shares of our common stock with a weighted average contractual remaining life of 4.8 years and exercise prices ranging from \$0.24 to \$3.20 per share, resulting in a weighted average exercise price of \$1.86 per share.

The valuation methodology used to determine the fair value of our Warrants is the Black-Scholes-Merton option-pricing model, or Black-Scholes Model, an acceptable model in accordance with ASC 718-10, Compensation – Stock Compensation. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the Warrant.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

Warrants Issued in Connection with Debt

On January 31, 2013, we granted a warrant for the purchase of 1,250,000 shares of our common stock in connection with the issuance of the Plato Note, or the Plato Warrant, (see *NOTE 8 – NOTES PAYABLE, Issuance of Multiple Advance Revolving Credit Note*). The Plato Warrant has an exercise price of \$3.20 per share. The Plato Warrant will vest and become exercisable on October 31, 2013 and may be exercised any time after that date prior to the January 31, 2019 expiration date of the Plato Warrant. This Warrant, with a fair value of approximately \$1,711,956, was valued on the date of the grant using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. At June 30, 2013, \$1,051,988 was reported as deferred financing costs included in other current assets in the accompanying condensed consolidated balance sheet and is being amortized over the life of the Plato Note. For the six months ended June 30, 2013, \$659,938 was recorded as financing costs on the accompanying condensed consolidated financial statements.

On June 19, 2012, we granted warrants for the purchase of an aggregate of 7,000,000 shares of our common stock in connection with the issuance of the June 2012 Notes, or the June 2012 Warrants, (see *NOTE 8 – NOTES PAYABLE, Issuance of June 2012 Notes*). Of the June 2012 Warrants issued, 6,000,000 are exercisable at \$2.00 per share and 1,000,000 are exercisable at \$3.00 per share. The fair value of the June 2012 Warrants of \$9,424,982 was determined by using the Black-Scholes Model on the date of the grant using a term of 5 years; a volatility of 44.64%; risk free rate of 0.75%; and a dividend yield of 0%. The relative fair value of the June 2012 Warrants of \$1,649,890 was determined by using the relative fair value calculation method on the date of the grant. As a result of the repayment of the associated debt on March 21, 2013, we expensed the remaining unamortized debt discount of \$885,709 at the time of the repayment.

On February 24, 2012, we issued warrants for the purchase of an aggregate of 5,685,300 shares of our common stock in connection with the modification of certain existing promissory notes, or the Modification Warrants, and warrants for the purchase of an aggregate of 3,314,700 shares of our common stock in connection with the issuance of the February 2012 Notes (the “February 2012 Warrants”) (see *NOTE 8 – NOTES PAYABLE, Issuance of February 2012 Notes*). Both the Modification Warrants and the February 2012 Warrants are exercisable at \$0.38 per share. The Modification Warrants’ fair value of \$10,505,247 and the February 2012 Warrants’ fair value of \$6,124,873 was determined by using the Black-Scholes Model on the date of the grant using a term of 5 years; a volatility of 44.5%; risk free rate of 0.89%; and a dividend yield of 0%. We recorded the fair value of the Modification Warrants as part of the loss on extinguishment of debt in the accompanying condensed consolidated financial statements. The relative fair value of the February 2012 Warrants of \$859,647 was recorded as debt discount. As a result of the surrender of the February 2012 Notes on June 19, 2012, we expensed the remaining unamortized debt discount.

Warrants Issued for Services

On May 7, 2013, we entered into a consulting agreement, or the Agreement, with Sancilio & Company, Inc., or SCI, to develop drug platforms to be used in hormone replacement drug products, or the Drug Products. These services include support of our efforts to successfully obtain U.S. Federal Drug Administration, or FDA, approval for the Drug Products, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the Agreement, SCI agreed to forfeit its rights to receive warrants for the purchase of an aggregate of 833,000 shares of our common stock that were to be issued pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the Agreement, we agreed to issue SCI a warrant to purchase 850,000 shares of our common stock that vest as follows:

1. 283,333 shares were earned on May 11, 2013 upon successful filing of the IND application with the FDA for the Drug Product for an estradiol-based product in a softgel vaginal capsule for the treatment of VVA. The fair value of \$405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of the vesting using a term of 5 years; a volatility of 45.89%; risk free rate of 1.12%; and a dividend yield of 0%. We recorded the entire \$405,066 as consulting expense in the accompanying condensed consolidated financial statements,

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

2. 283,333 shares vested on June 30, 2013. The fair value of \$462,196 for these shares was determined by using the Black-Scholes Model on the date of the vesting using a term of 5 years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. We recorded \$154,068 as prepaid expense-short term and \$308,128 as prepaid expense-long term in the accompanying condensed consolidated financial statements. We will begin amortizing this expense monthly over 3 years beginning in July 2013, and
3. 283,334 shares will vest upon the receipt by us of any final FDA approval of a Drug Product that SCI helped us design. It is anticipated that this event will not occur before December 2015.

In March 2012, we issued a warrant for the purchase of an aggregate of 31,000 shares of our common stock to five unaffiliated individuals for services rendered. These warrants were valued on the date of the grant using a term of 5 years; a volatility of 44.81%; risk free rate of 1.04%; and a dividend yield of 0%; \$29,736 was recorded as consulting expense in the accompanying condensed consolidated financial statements.

A summary of our warrant activity and related information for 2013 follows:

	<b>Number of Shares Under Company Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life in Years</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2012	12,193,499	\$ 1.63	4.8	\$ 17,971,994
Granted	2,100,000	\$ 2.72	7.3	\$ 867,000
Exercised	-0-			
Expired	-0-			
Cancelled	-0-			
Balance at June 30, 2013	<u>14,293,499</u>	\$ 1.79	4.8	\$ 17,985,449
Vested and Exercisable at June 30, 2013	<u>12,149,559</u>	\$ 1.67	4.3	\$ 16,540,175

As of June 30, 2013, we had warrants outstanding with exercise prices ranging from \$0.24 to \$3.20 per share. As of June 30, 2013, unamortized costs associated with warrants totaled approximately \$3,995,000.

#### Stock Options

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or LTIP, to provide financial incentives to our employees, members of our Board, and our advisers and consultants 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, or the Awards. 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 under the LTIP. Under this LTIP, non-qualified stock options for the purchase of an aggregate of 12,934,725 shares of our common stock were outstanding at June 30, 2013.

On February 23, 2012, the Board adopted the 2012 Stock Incentive Plan, a non-qualified plan not requiring approval by our stockholders, or the 2012 SOP. 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. There are 10,000,000 shares authorized for issuance under the 2012 SOP and non-qualified stock options for the purchase of an aggregate of 1,625,000 shares of our common stock were outstanding at June 30, 2013.

The valuation methodology used to determine the fair value of the stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The assumptions used in the Black-Scholes Model during the six months ended June 30, 2013 are set forth in the table below.



**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
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	<b>Six Months Ended June 30, 2013</b>	<b>Year Ended December 31, 2012</b>
Risk-free interest rate	0.65-1.42%	0.61-2.23%
Volatility	33.35-45.76%	40.77-46.01
Term (in years)	5-6.25	5-6.25
Dividend yield	0.00%	0.00%

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

On June 28, 2013, an individual exercised his stock option to purchase an aggregate of 61,372 shares of our common stock for an aggregate purchase price of \$6,251.

On June 21, 2013, we issued 10-year stock options to employees and consultants for the purchase of an aggregate of 632,500 shares with an exercise price of \$2.98. An aggregate of 232,500 shares available under the stock options vest over a 3-year period on the anniversary of issuance, an aggregate of 100,000 shares vest monthly over an 18 month period, and an aggregate of 300,000 shares vest monthly over a 3-year period.

On May 10, 2013, we issued 10-year stock options to employees for the purchase of an aggregate of 100,000 shares with an exercise price of \$2.71. An aggregate of 50,000 shares available under the stock options vest over a 4-year period on the anniversary of issuance and an aggregate of 50,000 shares vested immediately.

On May 6, 2013, we issued a 10-year stock option to a consultant for the purchase of an aggregate of 96,068 shares with an exercise price of \$2.96. The shares available under the stock options vest monthly over a 12-month period.

On May 2, 2013, the Compensation Committee of the Board recommended the granting of stock options to our directors. The Board approved the recommendation and we issued 10-year stock options for the purchase of an aggregate of 575,000 shares of our common stock with an exercise price of \$2.80, as follows: (i) a stock option for the purchase of 225,000 shares of our common stock to the Chairman of the Board; (ii) a stock option for the purchase of 75,000 shares of our common stock to the chair of each committee of the board; and (iii) an Option for the purchase of 50,000 shares of our common stock to each of the remaining directors. All of these stock options vest on December 31, 2013.

On May 8, 2013, Robert Finizio, our Chief Executive Officer, forfeited his contractual right to receive 600,000 shares upon exercise of a stock option granted in connection with his employment agreement as well as his right to receive any future stock options. Mr. Finizio gave up these rights with the understanding that these stock options would be returned to the pool of stock options available for issuance to attract future employees.

On March 29, 2013, we issued 10-year stock options to employees and consultants for the purchase of an aggregate of 180,109 shares with exercise prices ranging from \$1.70 to \$2.70. An aggregate of 500 shares available under the stock options vest over a 4-year period on the anniversary of issuance, an aggregate of 12,500 shares vest monthly over a 1-year period, 92,109 shares vest monthly over a 13-month period from the date of issuance, and an aggregate of 75,000 shares vest as follows: an aggregate of 31,250 vest immediately and an aggregate of 43,750 vest monthly over the subsequent seven months.

On June 29, 2012, we issued 10-year stock options to employees, consultants, and a director for the purchase of an aggregate of 250,000 shares with an exercise price of \$2.80. An aggregate of 7,500 shares available under the stock options vest over a 4-year period on the anniversary of issuance, an aggregate of 115,000 shares vest over a 2-year period on the anniversary of issuance, 2,500 shares vest over a 1-year period on the anniversary of issuance, 75,000 shares vest monthly from December 31, 2012, and 50,000 vest immediately.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
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On April 16, 2012, the Board approved the issuance of 10-year stock options for our directors for the purchase of: (i) an aggregate of 350,000 shares (50,000 shares each) to our directors for services to be rendered during calendar year 2012 and (ii) an aggregate of 75,000 shares (25,000 shares each) to the chairs of the Audit, Compensation and Nominating and Corporate Governance Committees for services to be rendered during calendar year 2012. The stock options have an exercise price of \$2.55 per share vested in full on December 31, 2012. In addition, Dr. Brian Bernick, a director and employee, was issued a stock option for 150,000 shares for services rendered as an employee, having an exercise price of \$2.55, which vested in full on April 16, 2013.

On March 30, 2012, we issued 10-year stock options to employees and consultants for the purchase of an aggregate of 480,000 shares with an exercise price of \$2.40. An aggregate of 405,000 shares available under the stock options vest over a 4-year period on the anniversary of issuance, an aggregate of 60,000 shares vest over a 2-year period on the anniversary of issuance, and 15,000 shares vest monthly over a 12-month period from the date of issuance.

On March 30, 2012, the Board approved a cashless exercise provision for use by holders of stock options. Also on March 30, 2012, an individual exercised his option to purchase 245,485 shares of our common stock. The aggregate purchase price of approximately \$60,000 was paid pursuant to a cashless exercise provision wherein the individual surrendered his right to receive 25,000 shares thereunder.

On February 27, 2012, we issued stock options to our officers and directors for the purchase of an aggregate of 600,000 shares with an exercise price of \$2.20 per share. The stock options vested in full on February 27, 2013.

In January 2012, certain individuals exercised their stock options to purchase an aggregate of 1,630,022 shares of our common stock for an aggregate purchase price of \$166,000.

A summary of activity under the LTIP and 2012 SOP and related information follows:

	<b>Number of Shares Under Company Option</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life in Years</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2012	13,733,488	\$ 1.16	7.7	\$ 26,804,117
Granted	1,583,677	\$ 2.79	9.9	\$ 365,845
Exercised	(61,372)			
Expired	-0-			
Cancelled	(600,000)			
Balance at June 30, 2013	<u>14,655,793</u>	\$ 1.08	7.8	\$ 26,038,328
Vested and Exercisable at June 30, 2013	<u>9,623,443</u>	\$ 0.60	6.5	\$ 23,208,051

The weighted-average issue date fair value of stock options issued during the six months ended June 30, 2013 was \$1.01.

At June 30, 2013, we had stock options outstanding with exercise prices ranging from \$0.10 to \$3.40 per share.

Share-based compensation expense for stock options recognized in our results for the six months ended June 30, 2013 and 2012 (\$1,161,770 and \$510,987, respectively) is based on awards vested and was estimated without forfeitures. ASC 718-10, requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates.

At June 30, 2013, total unrecognized estimated compensation expense related to non-vested stock options issued prior to that date was approximately \$3,695,420 which is expected to be recognized over a weighted-average period of 1.49 years. No tax benefit was realized due to a continued pattern of operating losses.

**NOTE 10 – INCOME TAXES**

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We do not expect to pay any significant federal or state income tax for 2013 as a result of (i) the losses recorded during the six months ended June 30, 2013, (ii) additional losses expected for the remainder of 2013, and/or (iii) net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is “more likely than not” that some component or all of the benefits of deferred tax assets will not be realized. As of June 30, 2013, we maintain a full valuation allowance for all deferred tax assets. Based on these requirements, no provision or benefit for income taxes has been recorded. There were no recorded unrecognized tax benefits at the end of the reporting period.

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

**NOTE 11 – RELATED PARTIES**

Loan Guaranty

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit, or the Bank LOC, for which the bank required personal guarantees and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family LP, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.02% per annum based on a year of 360 days and was due on March 1, 2012. On March 19, 2012, the bank and VitaMed negotiated a one year extension to the Bank LOC and a subsequent 2-month extension until May 1, 2013.

In consideration for the personal guarantees and cash collateral, we issued warrants for an aggregate of 613,713 shares. On November 13, 2012, we entered into an amendment with the bank to reduce the Bank LOC to \$100,000, or the Amended Bank LOC. As part of the Amended Bank LOC, the personal guarantees and cash collateral for Mr. Finizio and Mr. Milligan were released. In accordance with the terms of the warrants, the warrants previously granted to Mr. Finizio and Mr. Milligan were amended to reflect the amount vested prior to the date of the Amended Bank LOC (179,000 each). At June 30, 2013, an aggregate of 562,571 warrants related to this loan guaranty were vested.

In February 2013, we borrowed \$100,000 under the Amended Bank LOC. The Amended Bank LOC required a personal guarantee and cash collateral limited to \$100,000 which was provided by Reich Family LP. On April 25, 2013, we paid the principal and interest due under the Amended Bank LOC of \$100,735. On May 1, 2013, the Amended Bank LOC expired and was not renewed. Accordingly, the personal guarantee was canceled and the cash collateral was returned to Reich Family LP.

Lock-Up Agreements

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

Purchases by Related Parties

During the six months ended June 30, 2013 and 2012, we sold our products to Dr. Brian Bernick, our Chief Medical Officer and director, in the amounts of \$0 and \$1,440, respectively, while \$0 and \$1,272 in receivables related thereto remained outstanding at both June 30, 2013 and December 31, 2012, respectively.

Agreements with Pernix Therapeutics, LLC

On February 29, 2012, Cooper C. Collins, President and largest stockholder of Pernix Therapeutics, LLC, or Pernix, was elected to serve on the Board. The Company entered into a Stock Purchase Agreement with Pernix on October 4, 2011. From time to time, we have entered into agreements with Pernix in the normal course of business primarily for the purchase of inventory. During the six months ended June 30, 2013 and 2012, we made purchases of approximately \$0 and \$96,250, respectively, from Pernix. At June 30, 2013 and December 31, 2012, there were outstanding amounts due to Pernix of approximately \$0 and \$308,000, respectively.

Additionally, there were amounts due to us from Pernix for legal fee reimbursement in regards to the Aceto litigation described below in the amounts of \$171,261 and \$0 for the periods ending June 30, 2013 and December 31, 2012, respectively.

**THERAPEUTICSM D, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2013**

**NOTE 12 - BUSINESS CONCENTRATIONS**

We purchase our products from several suppliers with approximately 98% and 87% of our purchases were supplied from one vendor for the six months ended June 30, 2013 and 2012, respectively.

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. Revenue generated from sales to two customers, Cardinal Health, Inc. and McKesson Corporation accounted for 62% and 36% of our recognized revenue for the six months ended June 30, 2013 and 2012, respectively.

**NOTE 13 – COMMITMENTS AND CONTINGENCIES**

**Office Lease**

We lease administrative office space in Boca Raton, Florida pursuant to a 63 month non-cancelable operating lease commencing on July 1, 2013 and expiring on September 30, 2018. The lease stipulates, among other things, average base monthly rents of \$28,442 (inclusive of estimated operating expenses) and sales tax, for a total future minimum payments over the life of the lease of \$1,791,900.

The rental expense related to our prior lease which expired June 30, 2013 totaled \$60,168 and \$56,918 for the six months ended June 30, 2013 and 2012, respectively.

**Litigation**

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

*Aceto Corporation*

On November 13, 2012, Aceto Corporation filed a lawsuit against TherapeuticsMD and Boca-Green in the United States District Court for the Southern District of Florida seeking to enjoin us from using the Quatrefolic product and trademarks, among other things. On July, 17, 2013, the Court dismissed Aceto Corporation's Complaint with leave to file an Amended Complaint on or before August 5, 2013. Based on our assessment of the case which is in the discovery stage, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

*Avion Pharmaceuticals, LLC*

On November 30, 2012, Avion Pharmaceuticals, LLC, filed a lawsuit against TherapeuticsMD and Boca- Green in the United States District Court for the Northern District of Georgia seeking to enjoin us from using the Prenal name, among other things. Based on our assessment of the case which is in the discovery stage, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

For additional information on these litigation matters, see our Annual Report on Form 10-K for the year ended December 31, 2012.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of TherapeuticsMD, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2012. TherapeuticsMD, Inc.'s management is responsible for the consolidated financial statements. Our responsibility is to express an opinion on the consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of TherapeuticsMD, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), TherapeuticsMD, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 11, 2013, expressed an unqualified opinion.

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

/s/ Rosenberg Rich Baker Berman & Company

Somerset, New Jersey  
March 11, 2013

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited TherapeuticsMD, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). TherapeuticsMD, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Controls and Procedure*. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, TherapeuticsMD, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of operations, stockholders' equity (deficit), and cash flows of TherapeuticsMD, Inc., and our report dated March 11, 2013 expressed an unqualified opinion.

/s/ Rosenberg Rich Baker Berman & Company

Somerset, New Jersey  
March 11, 2013

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2012	2011
ASSETS		
Current Assets:		
Cash	\$ 1,553,474	\$ 126,421
Accounts receivable, net of allowance for doubtful accounts of \$42,048 and \$1,500, respectively	606,641	26,720
Inventory	1,615,210	588,073
Other current assets	751,938	496,060
Total current assets	<u>4,527,263</u>	<u>1,237,274</u>
Fixed assets, net	<u>65,673</u>	<u>26,752</u>
Other Assets:		
Prepaid consulting	953,655	80,515
Intangible assets	239,555	62,231
Security deposit	31,949	31,949
Total other assets	<u>1,225,159</u>	<u>174,695</u>
Total assets	<u>\$ 5,818,095</u>	<u>\$ 1,438,721</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 1,641,366	306,511
Deferred revenue	1,144,752	—
Other current liabilities	725,870	465,747
Notes payable	—	2,150,000
Notes payable, related parties	—	200,000
Accrued interest	—	28,321
Total current liabilities	<u>3,511,988</u>	<u>3,150,579</u>
Long-Term Liabilities:		
Notes payable, net of debt discount of \$1,102,680 and \$0, respectively	3,589,167	—
Accrued interest	150,068	—
Total long-term liabilities	<u>3,739,235</u>	<u>—</u>
Total liabilities	<u>7,251,223</u>	<u>3,150,579</u>
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	50,580,400	15,198,241
Accumulated deficit	(52,113,313)	(16,993,078)
Total stockholder' deficit	<u>(1,433,128)</u>	<u>(1,711,858)</u>
Total liabilities and stockholders' deficit	<u>\$ 5,818,095</u>	<u>\$ 1,438,721</u>

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

**THERAPEUTICSMD, INC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

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



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

	<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Balance, December 31, 2010</b>	55,487,321	55,487	4,988,637	(4,079,713)	964,411
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	165,879	166	(255,919)	—	(255,753)
Shares issued in private placement	5,551,589	5,552	1,701,448	—	1,707,000
Shares issued in exchange for debt	21,681,958	21,682	8,217,455	—	8,239,137
Shares issued in exercise of warrants	92,057	92	17,158	—	17,250
Options issued as compensation	—	—	183,355	—	183,355
Warrants issued for services	—	—	190,280	—	190,280
Warrants issued for loan guaranty costs-related parties	—	—	93,969	—	93,969
Warrants issued for financing costs	—	—	45,362	—	45,362
Warrants issued as financing costs-related parties	—	—	9,338	—	9,338
Warrants issued as compensation-related party	—	—	7,158	—	7,158
Net loss	—	—	—	(12,913,365)	(12,913,365)
<b>Balance, December 31, 2011</b>	82,978,804	\$ 82,979	\$ 15,198,241	\$ (16,993,078)	\$ (1,711,858)
Shares issued in private placement, net of cost	3,953,489	3,954	7,891,531	—	7,895,485
Shares issued in exchange for debt	2,775,415	2,775	1,051,882	—	1,054,657
Shares issued for exercise of options	1,931,788	1,932	189,068	—	191,000
Shares issued in exercise of warrants	8,145,486	8,145	3,093,855	—	3,102,000
Options issued as compensation	—	—	1,832,061	—	1,832,061
Warrants issued for financing costs	—	—	13,014,784	—	13,014,784
Warrants issued for services	—	—	1,563,620	—	1,563,620
Warrants issued as compensation-related party	—	—	36,284	—	36,284
Warrants issued for cash	—	—	400	—	400
Cancellation of warrants issued for loan guaranty costs-related parties	—	—	(7,830)	—	(7,830)
Beneficial conversion feature	—	—	6,716,504	—	6,716,504
Net loss	—	—	—	(35,120,235)	(35,120,235)
<b>Balance, December 31, 2012</b>	<u>99,784,982</u>	<u>\$ 99,785</u>	<u>\$ 50,580,400</u>	<u>\$ (52,113,313)</u>	<u>\$ (1,433,128)</u>

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

**THERAPEUTICSMD, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December, 31,	
	2012	2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (35,120,235)	\$ (12,913,365)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	—	(255,753)
Depreciation	27,484	25,686
Amortization of intangible assets	28,776	29,159
Provision for doubtful accounts	40,548	1,500
Loss on extinguishment of debt	10,307,864	7,390,000
Beneficial conversion feature	6,716,504	—
Amortization of debt discount	1,604,240	28,719
Stock based compensation	1,868,345	190,513
Stock based expense for services	338,457	22,630
Loan guaranty costs	45,036	38,159
Non-cash financing costs	—	25,980
Changes in operating assets and liabilities:		
Accounts receivable	(620,469)	(16,409)
Inventory	(1,027,137)	29,996
Other current assets	42,281	(346,822)
Accounts payable	1,334,855	188,876
Accrued interest	270,252	33,994
Deferred revenue	1,144,752	—
Accrued expenses and other current liabilities	261,121	560,541
Net cash flows used in operating activities	<u>(12,737,326)</u>	<u>(4,966,596)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(66,405)	(28,766)
Patent costs, net of abandoned costs	(206,101)	(8,870)
Net cash flows used in investing activities	<u>(272,506)</u>	<u>(37,636)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from sale of common stock, net of costs	7,895,485	1,000,000
Proceeds from notes and loans payable	8,700,000	2,684,160
Proceeds from exercise of options	191,000	17,250
Proceeds from sale of warrants	400	—
Proceeds from notes and loans payable-related parties	—	300,000
Proceeds from sale of membership units, net of expenses	—	707,000
Proceeds bank line of credit	—	300,000
Repayment of bank line of credit	(300,000)	—
Repayment of notes payable-related party	(200,000)	(100,696)
Repayment of notes payable	(1,850,000)	(200,000)
Net cash flows provided by financing activities	<u>14,436,885</u>	<u>4,707,714</u>
Increase (decrease) in cash	1,427,053	(296,518)
Cash, beginning of period	126,421	422,939
Cash, end of period	<u>\$ 1,553,474</u>	<u>\$ 126,421</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	<u>\$ 17,253</u>	<u>\$ 696</u>
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
<b>SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:</b>		
Warrants exercised in exchange for debt and accrued interest	<u>\$ 3,102,000</u>	<u>\$ —</u>
Warrants issued for financing	<u>\$ 2,509,537</u>	<u>\$ 148,668</u>
Warrants issued for services	<u>\$ 1,532,228</u>	<u>\$ 190,280</u>
Shares issued in exchange for debt and accrued interest	<u>\$ 1,054,658</u>	<u>\$ 849,137</u>
Notes payable issued for accrued interest	<u>\$ 15,123</u>	<u>\$ —</u>

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

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

**NOTE 1 – THE COMPANY**

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

Agreement and Plan of Merger with VitaMed

On July 18, 2011, Therapeutics entered into an Agreement and Plan of Merger (“Merger Agreement”) by and among VitaMed and VitaMed Acquisition, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company (the “Merger Sub”), pursuant to which the Company would acquire 100% of VitaMed. The proposed acquisition was to be accomplished by the merger of Merger Sub with and into VitaMed with VitaMed being the surviving limited liability company (the “Merger”) in accordance with the Limited Liability Company Act of the State of Delaware. The Merger became effective upon the filing of the Certificate of Merger with the Secretary of State of the State of Delaware on October 4, 2011 (the “Effective Date”). In preparation of and prior to the closing of the Merger Agreement, the Company completed the following required corporate actions:

- a reverse split of the Company’s 16,575,209 issued and outstanding shares of Common Stock on a ratio of 1 for 100 (the “Reverse Split”). As a result of the Reverse Split, each share of Common Stock outstanding on July 28, 2011 (the “Record Date”), without any action on the part of the holder thereof, became one one-hundredth of a share of Common Stock. The Reverse Split decreased the number of outstanding shares of the Company’s Common Stock by approximately 99% resulting in 165,856 shares outstanding after the Reverse Split. The effectuation of the Reverse Split did not result in a change in the relative equity position or voting power of the shareholders of the Company;
- an increase of our authorized shares of Common Stock to 250,000,000;
- a change in the name of the Company to TherapeuticsMD, Inc.; and
- an amendment to the Company’s Long Term Incentive Compensation Plan to increase the authorized shares for issuance thereunder to 25,000,000.

On the Effective Date, we acquired 100% of VitaMed in exchange for the issuance of shares of the Company’s Common Stock, as more fully described below (the “Merger”). In accordance with the provisions of this triangulated merger, the Merger Sub was merged with and into VitaMed as of the Effective Date. Upon consummation of the Merger Agreement and all transactions contemplated therein, the separate existence of the Merger Sub ceased and VitaMed became a wholly owned subsidiary of the Company.

Exchange of Securities

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

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

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

Nature of Business

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

New Products

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

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Principles of Consolidation

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

Cash

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

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

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card charge-backs and provide an allowance for doubtful accounts which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due more than 90 days to be delinquent. We write-off delinquent receivables to bad debt expense based on individual credit evaluations, results of collection efforts, and specific circumstances of the customer. Recoveries of accounts previously written off are recorded as reductions of bad debt expense when received. Historically, our bad debt expense has been limited because the majority of our trade receivables are paid via credit card. To the extent data we use to calculate these estimates does not accurately reflect bad debts; adjustments to these reserves may be required. At December 31, 2012 and 2011, we recorded an allowance for doubtful accounts of \$42,048 and \$1,500, respectively.

Inventories

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

Fixed Assets

*Equipment*-We state equipment at cost, net of accumulated depreciation. Maintenance costs, which do not significantly extend the useful lives of the respective assets, and repair costs are charged to operating expense as incurred. We compute depreciation using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years. Depreciation expense totaled \$19,904 and \$23,962 for the years ended December 31, 2012 and 2011, respectively.

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

*Leasehold Improvements*-We state improvements at cost, net of accumulated depreciation. We compute depreciation using the straight-line method over the remaining term of the lease. Depreciation expense totaled \$7,580 and 1,724 for the years ended December 31, 2012 and 2011, respectively.

Intangible Assets

*Patent and Trademarks*-We have adopted the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 350 *Intangible-Goodwill and Other* ("ASC 350"). Capitalized patent costs, net of accumulated amortization, include legal costs incurred for a patent application. In accordance with ASC 350, once the patent is granted, we amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, we write-off any capitalized patent costs at that time. Intangible assets are reviewed annually for impairment or when events or circumstances indicate that their carrying amount may not be recoverable.

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

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

Impairment of Long-Lived Assets

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

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

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

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

Fair Value of Financial Instruments

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

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

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

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

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

Income Taxes

We account for income taxes under the asset and liability method. We recognize deferred tax assets and liabilities for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the related temporary differences are expected to be recovered or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates when the rate change is enacted. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized. In accordance with ASC 740, *Income Taxes*, we recognize the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. We measure recognized uncertain income tax positions using the largest amount that has a likelihood of being realized that is greater than 50%. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur. We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. As of December 31, 2012 and 2011, we had no tax positions relating to open tax returns that were considered to be uncertain.

Stock Based Compensation

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

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

We recognize compensation expense for all share-based payments granted based on the grant date fair value estimated in accordance with ASC 718-10, “*Share Based Payments.*” Compensation expense is generally recognized on a straight-line basis over the employee’s requisite service period.

Debt Discounts

Costs incurred with parties that are providing long-term financing, which include warrants issued with the underlying debt, are reflected as a debt discount based on the relative fair value of the debt and warrants to the total proceeds. These discounts are generally amortized over the life of the related debt using the effective interest rate method. In connection with debt issued during the years ended December 31, 2012 and 2011, we recorded debt discounts totaling \$2,706,920 and \$28,719, respectively. The aggregate balance of unamortized debt discount at December 31, 2012 and 2011 was \$1,102,680 and \$0, respectively. Amortization expense related to debt discounts totaled \$1,604,240 and \$28,719 for the years ended December 31, 2012 and 2011, respectively, and is included in amortization of debt discount on the accompanying consolidated financial statements.

Revenue Recognition

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

Over The Counter Products

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

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

Prescription Products

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

We accept returns of unsalable product from customers within a return period of six months prior to and following product expiration. Our prescription products currently have a shelf-life of 24 months from date of manufacture. Given the limited history of prescriptions products, we currently cannot reliably estimate expected returns of the prescription products at the time of shipment. Accordingly, we defer recognition of revenue on prescription products until the right of return no longer exists, which occurs at the earlier of the time the prescription products are dispensed through patient prescriptions or expiration of the right of return. As a result of this policy, we had a deferred revenue balance of \$1,144,752 and \$0 at December 31, 2012 and 2011, respectively.

We maintain various rebate programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The rebate program is designed to enable the end-user to return a coupon to us. If the coupon qualifies, we send a rebate check to the end-user. We estimate the allowance for rebates based on industry averages, which is reviewed, and adjusted if necessary, on a quarterly basis. For the years ended December 31, 2012 and 2011, we recorded reduction to income for rebates of \$34,255 and \$0, respectively.

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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Shipping and Handling Costs

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

Advertising Costs

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

Research and Development Expenses

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

Earnings Per Share

We calculate earnings per share ("EPS") in accordance with ASC 260, "Earnings Per Share," which requires the computation and disclosure of two EPS amounts, basic and diluted. We compute basic EPS based on the weighted average number of shares of Common Stock outstanding during the period. We compute diluted EPS based on the weighted average number of shares of Common Stock outstanding plus all potentially dilutive common shares outstanding during the period. Such potential dilutive common shares consist of stock options and warrants. Potential common shares totaling 25,926,987 and 13,639,845 at December 31, 2012 and 2011, respectively, have been excluded from the diluted earnings per share calculation as they are anti-dilutive due to the net loss reported by us.

Use of Estimates

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

Recently Issued Accounting Pronouncements

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

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



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

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

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

Reclassifications

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

**NOTE 3 – GOING CONCERN**

The accompanying financial statements have been prepared assuming that our company will continue as a going concern. For the year ended December 31, 2012, we incurred a loss from operations of approximately \$16 million and had negative cash flow from operations of approximately \$13 million. Accumulated deficit as of December 31, 2012 was approximately \$52 million. These matters raise substantial doubt about our ability to continue as a going concern. Our plans include raising additional proceeds from debt and equity transactions and to continue to increase our sales and marketing activities; however, there are no assurances that we will be successful in these efforts. On March 7, 2013 we filed a Prospectus Supplement for an underwritten public offering of our common stock with anticipated gross proceeds of \$50 million. The securities being offered by us are pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (the “SEC”) on January 25, 2013, which the SEC declared effective on February 5, 2013. The financial statements do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation.

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**NOTE 4 – INVENTORY**

Inventory consists of the following:

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

**NOTE 5 – OTHER CURRENT ASSETS**

Other current assets consist of the following:

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

**NOTE 6 – FIXED ASSETS**

Fixed assets consist of the following:

	December 31,	
	2012	2011
Equipment	\$ 67,668	\$ 33,650
Furniture and fixtures	46,625	22,169
Leasehold improvements	11,980	4,049
	126,273	59,868
Accumulated depreciation	(60,600)	(33,116)
TOTAL FIXED ASSETS	\$ 65,673	\$ 26,752

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

**NOTE 7 – INTANGIBLE ASSETS**

Other assets consist of the following:

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

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

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**NOTE 8 – OTHER CURRENT LIABILITIES**

Other current liabilities consist of the following:

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

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

**NOTE 9 – NOTES PAYABLE**

Issuance of Promissory Notes

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

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

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

Issuance of February 2012 Notes

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

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

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

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

On June 19, 2012, we settled \$3,102,000 in principal and interest of the February 2012 Notes in exchange for the exercise of 8,145,486 Common Stock purchase warrants. As discussed below, the remaining balance of \$2,691,847 of the February 2012 Notes was modified on June 19, 2012 through the issuance of secured promissory notes (the "June 2012 Notes").

Issuance of June 2012 Notes

On June 19, 2012, we issued and sold secured promissory notes (the "June 2012 Notes") to the Parties in the principal base amounts of \$2,347,128 and \$2,344,719, respectively pursuant to the terms of a note purchase agreement (the "June 2012 Note Purchase Agreement"). As consideration for the June 2012 Notes, the Parties surrendered the remaining balance of the February 2012 Notes in the aggregate amount of \$1,347,128 and \$1,344,719, respectively (which sums included principal and interest through June 19, 2012), and we received an aggregate of \$2,000,000 of new funding from the Parties (the "June Funding"). The principal amount of each of the June 2012 Notes, plus any additional advance made to us thereafter, together with accrued interest at the annual rate of 6%, is due in one lump sum payment on February 24, 2014. As security for our obligations under the June 2012 Note Purchase Agreement and the June 2012 Notes, we entered into a Security Agreement and pledged all of our assets, tangible and intangible, as further described therein. We granted 7,000,000 Common Stock purchase warrants in connection with the June Funding.

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

Issuance of Other Promissory Notes During 2011

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

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

Conversion of July 2011 Secured Notes

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

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March 2011 Bank Line of Credit

In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note with First United Bank (“1<sup>st</sup> United”) for a \$300,000 bank line of credit (the “Bank LOC”) for which personal guarantees and cash collateral were required. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. In consideration for the personal guarantees and cash collateral, Common Stock purchase warrants for an aggregate of 613,713 shares were granted (see NOTE 10 for more details). The Bank LOC accrued interest at the rate of 3.02% per annum based on a year of 360 days and was due on March 1, 2012. We and 1<sup>st</sup> United negotiated a one-year extension to the Bank LOC which was executed on March 19, 2012 (the “Bank LOC Extension”). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and 1<sup>st</sup> United amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit (the “Amended Bank LOC”). In accordance with the Amended Bank LOC, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. During the years ended December 31, 2012 and 2011, interest expense of \$7,366 and \$5,650, respectively, was paid and is included in interest expense on the accompanying consolidated financial statements. We have made no withdrawals against the Amended Bank LOC as of December 31, 2012.

Issuance of VitaMed Promissory Notes

In June 2011, VitaMed sold Promissory Notes (the “VitaMed Promissory Notes”) in the aggregate principal amount of \$500,000. In consideration for the VitaMed Promissory Notes, Warrants for an aggregate of 613,718 shares were granted. The VitaMed Promissory Notes earn interest at the rate of 4% per annum and were due at the earlier of (i) the six month anniversary of the date of issuance and (ii) such time as VitaMed received the proceeds of a promissory note(s) issued in an amount of not less than \$1,000,000 (the “Funding”). Upon the closing of the Funding in July 2011, as more fully described above in Conversion of July 2011 Secured Notes, two of the VitaMed Promissory Notes in the aggregate of \$200,000 were paid in full. By mutual agreement, the remaining VitaMed Promissory Notes in the aggregate of \$300,000 were extended. In October 2011, one of the VitaMed Promissory Notes for \$50,000 was paid in full. Also in October 2011, by mutual agreement, VitaMed Promissory Notes in the aggregate of \$100,000 were converted into 266,822 shares of our Common Stock at \$0.38 per share, which represents the fair value of the shares on the date of conversion. In June 2012, a VitaMed Promissory Note held by an unaffiliated individual was paid in full including \$2,160 in accrued interest. The remaining VitaMed Promissory Notes in the aggregate of \$100,000 were extended to October 15, 2012 (one held by Mr. Milligan for \$50,000 and one for \$50,000 held by BF Investments, LLC (owned by Brian Bernick, a member of the board of directors of the Company)). On October 4, 2012 these VitaMed Promissory Notes were paid in full including \$5,341 in accrued interest.

In September and October 2011, VitaMed sold Convertible Promissory Notes (the “VitaMed Convertible Notes”) in the aggregate of \$534,160. The VitaMed Convertible Notes earned interest at the rate of 4% per annum and were due December 1, 2011. On November 18, 2011, we and the VitaMed Convertible Noteholders entered into Debt Conversion Agreements and converted the principal and accrued interest of the VitaMed Convertible Notes into 1,415,136 shares of our Common Stock at \$0.38 per share which represents the fair value of the shares on the date of conversion.

In December 2011, we issued 4% promissory notes to Mr. Finizio and Mr. Milligan and for an aggregate of \$100,000 (\$50,000 each) with original due dates of March 1, 2012. These promissory notes were extended by mutual agreement to June 1, 2012. In June 2012, the VitaMed Promissory Note held by Mr. Finizio was paid in full, including \$888 in accrued interest. Mr. Milligan’s VitaMed Promissory Note was extended to October 15, 2012. On October 4, 2012 this VitaMed Promissory Notes was paid in full including \$1,519 in accrued interest.

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

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Conversion of 2010 Demand Promissory Note

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

**NOTE 10 – STOCKHOLDERS' EQUITY**

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

Preferred Stock

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

Common Stock

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

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

- Options to purchase an aggregate of 1,691,393 shares of our Common Stock were exercised for \$191,000.
- Using the cashless exercise feature an aggregate of 240,395 Options were exercised, with 26,428 Options surrendered, resulting in the issuance of 240,395 shares of the Company's Common Stock.

During June 2012, we settled \$3,102,000 in principal and interest of the February 2012 Notes in exchange for the Parties' exercise of a portion of the February 2012 Warrants for an aggregate of 8,145,486 shares of our Common Stock. The shares were issued in reliance upon an exemption from the registration provisions of the Securities Act of 1933 provided by Section 4(1) of the Securities Act of 1933 and Rule 144. During June 2012, we and the Parties also agreed to convert a portion of the February 2012 Notes, and according to the terms thereof, principal and interest through June 19, 2012 of totaling \$1,054,647 was converted at \$0.38 per share into 2,775,415 shares of our Common Stock. The shares were issued in reliance upon an exemption from the registration provisions of the Securities Act of 1933 provide by Section 4(1) of the Act and Rule 144.

In September 2012, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with multiple investors (collectively, the "Investors") relating to the issuance and sale of our Common Stock in a private placement. The Purchase Agreement was closed on October 2, 2012 (the "Closing Date") through which we sold an aggregate of 3,953,489 shares of our Common Stock (the "Shares") at \$2.15 per share for an aggregate purchase price of \$8,500,001. In connection with the private placement, Jefferies LLC ("Jefferies") served as our exclusive placement agent. Jefferies compensation for the transaction was a cash fee of \$552,500, which is included in accounts payable in the accompanying consolidated financial statements. We also paid legal fees and expenses for the Investors in the aggregate of \$52,016, resulting in net proceeds to us of \$7,895,485. The Shares were issued in reliance upon the exemptions from registration under the Securities Act of 1933 provided by Section 4(2) and Rule 506 of Regulation D promulgated thereunder. The Shares were issued directly by us and did not involve a public offering or general solicitation. The Investors in the private placement are "Accredited Investors" as that term is defined in Rule 501 of Regulation D and acquired the Shares for investment only and not with a present view toward, or for resale in connection with, the public sale or distribution thereof. As part of the Purchase Agreement, we agreed to file a registration statement, which was filed November 27, 2012.

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

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

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

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

Warrants

The valuation methodology used to determine the fair value of Common Stock purchase warrants is the Black-Scholes-Merton option-pricing model (“Black-Scholes Model”), an acceptable model in accordance with ASC 718-10. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate and the term of the Common Stock purchase warrant.

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

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

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

Warrants Issued in Conjunction with Debt

On February 24, 2012, we issued an aggregate of 5,685,300 Warrants in connection with the modification of certain existing promissory notes (the “Modification Warrants”), and 3,314,700 Warrants with the issuance of secured promissory notes (the “February 2012 Warrants”) (see NOTE 9). Both the Modification Warrants and the February 2012 Warrants are exercisable at \$0.38. The Modification Warrants’ fair value of \$10,505,247 and the February 2012 Warrants’ fair value of \$6,124,873 were determined by using the Black-Scholes Model on the date of the grant. Both valuations used a term of five years; a volatility of 44.5%; risk free rate of 0.89%; and a dividend yield of 0%. We recorded the fair value of the Modification Warrants as part of the loss on extinguishment of debt in the accompanying consolidated financial statements. The relative fair value of the February 2012 Warrants of \$859,647 was recorded as debt discount. As a result of the surrender of the February 2012 Notes on June 19, 2012, we expensed the remaining unamortized debt discount. As of December 31, 2012, we recorded amortization of debt discount totaling \$859,647 related to the February 2012 Notes.

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On June 19, 2012, we issued an aggregate of 7,000,000 Warrants in connection with the issuance of secured promissory notes (the "June 2012 Warrants") (see [NOTE 9](#)). Of the 7,000,000 June 2012 Warrants, 6,000,000 are exercisable at \$2.00 and 1,000,000 are exercisable at \$3.00. The fair value of the June 2012 Warrants of \$9,424,982 was determined by using the Black-Scholes Model on the date of the grant. The Warrants were valued on the date of the grant using a term of five years; a volatility of 44.64%; risk free rate of 0.75%; and a dividend yield of 0%. The relative fair value of the June 2012 Warrants of \$1,649,890 was determined by using the relative fair value calculation method on the date of the grant. At December 31, 2012, \$1,102,680 was reported as debt discount and \$547,210 was recorded as amortization of debt discount on the accompanying consolidated financial statements.

Warrants Issued for Services

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

In May 2012, we issued an aggregate of 1,300,000 Warrants to an unaffiliated entity for services to be rendered over approximately five years beginning in May 2012. Services provided are to include (a) services in support of our drug development efforts including, but not limited to, services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain New Drug Approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The Warrants were valued at \$1,532,228 on the date of the grant using a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. At December 31, 2012 we reported \$360,528 as prepaid expense-short term, \$953,655 as prepaid expense-long term, and recorded \$218,045 as consulting expense in the accompanying consolidated financial statements. The contract will expire upon the commercial manufacture of a drug product. Based on the review, we have determined that the process will take approximately five years. As a result, we are amortizing the \$1,532,228 over five years.

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

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

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



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In March 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the "Bank LOC") for which the bank required personal guarantees and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one-year extension to the Bank LOC, which was executed on March 19, 2012 (the "Bank LOC Extension"). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The ten-year Company Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the bank loan is repaid prior to being fully vested, the Company Warrants will be reissued only for the number of shares vested through the date of repayment. On November 13, 2012, the then outstanding balance of \$299,220 was repaid in full and we and the bank amended the Business Loan Agreement and Promissory Note to reflect a \$100,000 bank line of credit (the "Amended Bank LOC"). As part of the Amended Bank LOC, the personal guarantees and cash collateral were removed for Mr. Finizio and Mr. Milligan. In accordance with the terms of the Company Warrants, the Company Warrants previously granted to Mr. Finizio and Mr. Milligan have been amended to reflect the amount vested prior to the date of the Amended Bank LOC (179,000 each). At December 31, 2012, an aggregate of 562,571 Company Warrants were vested.

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

In June 2011, VitaMed issued Promissory Notes (the "VitaMed Promissory Notes") in the aggregate of \$500,000 with accompanying VitaMed Warrants for an aggregate of 500,000 shares (or Company Warrants for an aggregate of 613,718 shares pursuant to the Conversion Ratio). The VitaMed Warrants were valued on the date of the grant using a term of five years; a range of volatility from 39.13% to 39.15%; risk free rate ranging from 1.38-1.65%; and a dividend yield of 0%. The Company Warrants vested immediately. Although the fair value was \$30,993, using the appropriate accounting treatment, \$28,719 was recorded as debt discount and fully amortized during 2011 with the amortized amount recorded as interest expense on the accompanying consolidated financial statements.

In July 2011, VitaMed entered into a one-year consulting agreement with Lang Naturals, Inc. ("Lang"), providing for Lang to assist in the design, development, and distribution efforts of VitaMed's initial product offering. As compensation, Lang received a VitaMed Warrant for 200,000 shares (or a Company Warrant for 245,485 shares pursuant to the Conversion Ratio). The VitaMed Warrant was valued on the date of the grant at \$12,548 using a term of five years; a volatility of 39.44%; risk free rate of 1.56%; and a dividend yield of 0%. The Company Warrant vested immediately. As of December 31, 2012 and 2011, \$6,936 and \$5,612, respectively was recorded as non-cash compensation on the accompanying consolidated financial statements.

In October 2011, we (i) issued a Company Warrant for 600,000 shares with a fair value of \$133,045 to an officer of the Company for services performed. The Company Warrant was valued on the date of the grant using a term of 10 years; volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Company Warrant vests over a 44-month period beginning on November 21, 2011 (or 13,636 shares for months 1-43 and 13,652 shares for month 44). As of December 31, 2012 and 2011, of the \$133,045 fair value, \$36,284 and \$7,158, respectively, was recorded as non-cash compensation on the accompanying consolidated financial statements. The remaining \$89,603 will be expensed to non-cash compensation equitably over the remaining 30 months; (ii) issued a Company Warrant for 184,211 shares with a fair value of \$25,980 to an unrelated entity for consulting services covered under a two month agreement. The Company Warrant was valued on the date of the grant using a term of five years; volatility of 41.04%; risk free rate of 1.08%; and a dividend yield of 0%. As of December 31, 2011, the \$25,980 fair value was recorded as financing expense on the accompanying consolidated financial statements; and (iii), VitaMed entered into a two-year consulting agreement with Lang providing for a Lang representative to help evaluate improvements to existing products and new products as well as services, including but not limited to, research, design, compliance, scientific and regulatory affairs and commercialization of products.

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

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

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

	2012	2011
Weighted average fair value	\$ 2.05	\$ 0.16
Risk-free interest rate	0.72-1.04%	0.91-3.48%
Volatility	44.64-44.81%	39.13-51.83%
Term (in years)	5	5-10
Dividend yield	0.00%	0.00%

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

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our estimated volatility is an average of the historical volatility of the stock prices of its peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the historical volatility of peer entities due to the lack of sufficient historical data of its stock price during 2001-2012.

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

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

Stock Options

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan (the "2009 Plan") to provide financial incentives to employees, members of the Board, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives (the "Awards"). The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares authorized for issuance thereunder. Prior to the Merger, no awards had been issued under the 2009 Plan. As of December 31, 2012 there were 11,508,488 shares issued under the 2009 Plan.

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On February 23, 2012, our Board of Directors adopted the 2012 Stock Incentive Plan, a non-qualified plan not requiring approval by our stockholders (the "2012 Plan"). The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. There are 10,000,000 shares of our Common Stock authorized for issuance thereunder. As of December 31, 2012 there were 2,225,000 shares issued under the 2012 Plan.

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

	<b>Number of Shares Under Company Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life in Years</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2010	-0-			
Granted <sup>(1)</sup>	10,682,218	\$ 0.16	7.6	\$ 14,188,484
Exercised	(92,057)	\$ 0.19		
Expired	-0-			
Cancelled	-0-			
Balance at December 31, 2011	10,590,161	\$ 0.16	7.6	\$ 14,067,649
Granted	5,121,250	\$ 2.80	9.7	\$ 1,737,530
Exercised	(1,931,788)	\$ 0.13		
Expired	-0-			
Cancelled	(46,135)			
Balance at December 31, 2012	<u>13,733,488</u>	\$ 1.16	7.7	\$ 26,804,117
Vested and Exercisable at December 31, 2012	<u>8,370,408</u>	\$ 0.38	6.7	\$ 22,811,422

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

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

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

The valuation methodology used to determine the fair value of Company Options is the Black-Scholes-Merton option-pricing model ("Black-Scholes Model"), an acceptable model in accordance with ASC 718-10. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life.

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

	<b>2012</b>	<b>2011</b>
Risk-free interest rate	0.61-2.23%	0.91-2.54%
Volatility	40.77-46.01%	37.92-40.48%
Expected life (in years)	5-6.25	5.5-6.25
Dividend yield	0.00%	0.00%

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

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our estimated volatility is an average of the historical volatility of the stock prices of its peer entities whose stock prices were publicly available. Our calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the historical volatility of peer entities due to the lack of sufficient historical data of its stock price during 2001-2011. The average expected life is based on the contractual term of the option using the simplified method.

Share-based compensation expense for Company Options recognized in our results for the years ended December 31, 2012 and 2011 (\$1,832,062 and \$183,355 respectively) is based on awards vested and we estimated no forfeitures. ASC 718-10 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates.

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

**NOTE 11- INCOME TAXES**

With the advent of the Merger, we determined that VitaMed would become the sole focus of our company and previous business performed by our predecessor was discontinued. Because of these events, deferred income taxes are determined by calculating the loss from operations of our company starting October 4, 2011. Deferred income taxes are determined using the liability method for the temporary differences between the financial reporting basis and income tax basis of our assets and liabilities. Deferred income taxes are measured based on the tax rates expected to be in effect when the temporary differences are included in our tax return. Deferred tax assets and liabilities are recognized based on anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. For the years December 31, 2012 and 2011, there was no provision for income taxes, current or deferred.

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

At December 31, 2012 and 2011, we had state net operating loss carryforwards of approximately \$12,800,000 and \$25,000, respectively, available to offset future losses through 2032. We established valuation allowances equal to the full amount of the deferred tax assets because of the uncertainty of the utilization of the operating losses in future periods. We periodically assess the likelihood that we will be able to recover the deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income.

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

	<u>2012</u>	<u>2011</u>
Deferred Income Tax Assets:		
Net operating losses	\$ 5,920,861	\$ 748,404
Valuation allowance	(5,920,861)	(748,404)
Deferred Income Tax Assets, net	<u>-0-</u>	<u>-0-</u>

Our provision for income taxes differs from applying the statutory U.S. federal income tax rate to the income before income taxes. The primary differences result from deducting certain expenses for financial statement purposes but for federal income tax purposes.

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

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

**NOTE 12 – RELATED PARTIES**

Loan Guaranty

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

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

Loans from Affiliates

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

In December 2011, we issued 4% promissory notes to Mr. Finizio and Mr. Milligan and for an aggregate of \$100,000 (\$50,000 each) with original due dates of March 1, 2012. These promissory notes were extended by mutual agreement to June 1, 2012. In June 2012, the VitaMed Promissory Note held by Mr. Finizio was paid in full, including \$888 in accrued interest. Mr. Milligan’s VitaMed Promissory Note was extended to October 15, 2012. On October 4, 2012 this VitaMed Promissory Notes was paid in full including \$1,519 in accrued interest.

Lock Up Agreements

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

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Purchases by Related Parties

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

Agreements with Pernix Therapeutics, LLC

On February 29, 2012, Cooper C. Collins, President and largest shareholder of Pernix Therapeutics, LLC ("Pernix"), was elected to serve on our Board of Directors. We closed a Stock Purchase Agreement with Pernix on October 5, 2011. From time to time, we have entered and will continue to enter into agreements with Pernix in the normal course of business. All such agreements are reviewed by independent directors or a committee consisting of independent directors. During the years ended December 31, 2012 and 2011, we made purchases of approximately \$404,000 and \$19,000, respectively, from Pernix. At December 31, 2012 and 2011, there were amounts due Pernix of approximately \$308,000 and 19,000 outstanding, respectively.

Warrants assigned to Related Party

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

**NOTE 13 - BUSINESS CONCENTRATIONS**

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

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. For the year ended December 31, 2012, 28% of our recognized revenue and 98% of our deferred revenue was generated from sales to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. We did not sell to these customers in prior years.

**NOTE 14- COMMITMENTS AND CONTINGENCIES**

Operating Lease

We lease administrative and distribution facilities in Boca Raton, Florida pursuant to a 45 month non-cancelable operating lease expiring in 2013. The lease stipulates, among other things, base monthly rents ranging from \$5,443 to \$5,933 over the term of the lease plus our share of monthly estimated operating expenses of \$3,500 and sales tax. The lease expires May 31, 2013 and we believe we will be able to extend the lease in a manner adequate to meet our current needs.

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

Employment Agreements

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

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

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

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

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

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

#### Litigation

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

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*Aceto Corporation*

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

*Avion Pharmaceuticals, LLC*

On November 30, 2012, Avion Pharmaceuticals, LLC ("Avion"), filed a lawsuit against our company in the United States District Court for the Northern District of Georgia. The lawsuit alleges, among other things, unfair competition and trademark infringement against Avion's "Prenate" trademarks based on the use of our Prena1 branded products which we launched in November 2012. The lawsuit seeks to enjoin us from using the Prena1 name, in addition to unspecified actual and punitive damages. We filed an answer and counterclaim on January 17, 2013, as amended on February 27, 2013. Based on our initial assessment of the case which is in the early discovery stage, we believe that the case is without merit and, as a result, should not have a material adverse effect on our consolidated financial condition, results of operations, or cash flows.

**NOTE 15 – SUBSEQUENT EVENTS**

Revolving Credit Note

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

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

March 2013 Prospectus Supplement

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



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and

Stockholders of TherapeuticsMD, Inc.

We have audited the accompanying balance sheet of TherapeuticsMD, Inc. as of December 31, 2011, and the related statements of operations, stockholders' equity and cash flows for the year then ended. TherapeuticsMD, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of TherapeuticsMD, Inc. as of December 31, 2011, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note C to the financial statements, the Company has suffered a loss from operations of approximately \$5.4 million and had negative cash flow from operations of approximately \$5.0 million. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note C. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Rosenberg Rich Baker Berman & Company

Somerset, NJ  
March 27, 2012

**Parks & Company, LLC**  
**Certified Public Accountants & Consultants**  
**1761 W. Hillsboro Boulevard, Suite 326**  
**Deerfield Beach, FL 33442 Phone (954) 719-7569**  
**www.parkscpas.com Fax (954) 719-3704**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and

Members' of VitamedMD, LLC

We have audited the accompanying balance sheet of VitamedMD, LLC as of December 31, 2010, and the related statements of operations, changes in members' equity and cash flows for the year ended December 31, 2010. VitamedMD, LLC's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of VitamedMD, LLC as of December 31, 2010, and the results of its operations and its cash flows for the year ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note C to the financial statements, the Company has not yet established profitable operations and has incurred significant losses since inception. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note C. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note N, the Company restated its 2010 financial statements to correct errors related to the valuation of compensation and consultant expense using the Black-Scholes option-pricing model.

**Parks & Company, LLC**

Deerfield Beach, Florida  
February 28, 2012

**THERAPEUTICSMD, INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS**

	December 31,	
ASSETS	2011	2010
<b>Current Assets:</b>		
Cash	\$ 126,421	\$ 422,939
Accounts receivable, net of allowance for doubtful accounts of \$1,500 and \$0, respectively	26,720	11,812
Inventory	588,073	618,069
Other current assets	496,060	6,292
Total current assets	1,237,274	1,059,112
<b>Fixed Assets:</b>		
Property and equipment, net of accumulated depreciation of \$81,500 and \$26,655, respectively	70,113	96,192
<b>Other Assets:</b>		
Security deposit	31,949	31,949
Patent costs	18,870	10,000
Other assets	80,515	—
Total assets	\$ 1,438,721	\$ 1,197,253
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Notes payable	\$ 2,150,000	\$ —
Accounts payable	306,511	117,636
Notes payable, related parties	200,000	—
Accrued interest	28,321	—
Other current liabilities	465,747	115,206
Total current liabilities	3,150,579	232,842
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity:</b>		
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; 82,978,804 and 55,487,321 issued and outstanding, respectively	82,979	55,487
Additional paid in capital	15,198,241	4,988,637
Accumulated deficit	(16,993,078)	(4,079,713)
Total stockholder' equity	(1,711,858)	964,411
Total liabilities and stockholders' equity	\$ 1,438,721	\$ 1,197,253

**THERAPEUTICSMD, INC AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Revenues, net	\$ 2,088,177	\$ 1,241,921
Cost of goods sold	947,112	556,390
Gross profit	1,141,065	685,531
Operating expenses:		
Sales, general, and administration	6,406,197	3,464,810
Research and development	107,241	65,402
Depreciation and amortization	54,845	22,783
Total operating expense	6,568,283	3,552,995
Operating loss	(5,427,218)	(2,867,464)
Other income and (expense)		
Settlement of debt	(7,390,000)	—
Interest expense	(64,380)	—
Loan guaranty costs	(38,159)	—
Other income	6,392	—
Total other income (expense)	(7,486,147)	—
Loss before taxes	(12,913,365)	(2,867,464)
Provision for income taxes	—	—
Net loss	\$ (12,913,365)	\$ (2,867,464)
Loss per share, basic and diluted:		
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.07)
Weighted average number of common share outstanding	62,516,461	38,289,463

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2011 AND 2010**

	<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Balance, December 31, 2009</b>	39,516,450	\$ 39,516	\$ 1,656,364	\$ (1,212,249)	\$ 483,631
Shares issued in private placement	15,970,871	\$ 15,971	—	—	3,170,643
Options issued as compensation	—	—	177,601	—	177,601
Net loss	—	—	—	(2,867,464)	(2,867,464)
<b>Balance, December 31, 2010</b>	55,487,321	55,487	4,988,637	(4,079,713)	964,411
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	165,879	166	(255,919)	—	(255,753)
Shares issued in private placement	5,551,589	5,552	1,701,448	—	1,707,000
Shares issued in exchange for debt	21,681,958	21,682	8,217,455	—	8,239,137
Shares issued in exercise of warrants	92,057	92	17,158	—	17,250
Options issued as compensation	—	—	183,355	—	183,355
Warrants issued for services	—	—	190,280	—	190,280
Warrants issued for loan guaranty costs-related parties	—	—	93,969	—	93,969
Warrants issued for financing costs	—	—	45,362	—	45,362
Warrants issued as financing costs-related parties	—	—	9,338	—	9,338
Warrants issued as compensation-related party	—	—	7,158	—	7,158
Net loss	—	—	—	(12,913,365)	(12,913,365)
<b>Balance, December 31, 2011</b>	<u>82,978,804</u>	<u>\$ 82,979</u>	<u>\$ 15,198,241</u>	<u>\$ (16,993,078)</u>	<u>\$ (1,711,858)</u>

**THERAPEUTICSMD, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December, 31,	
	2011	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (12,913,365)	\$ (2,867,464)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Effect of merger and recapitalization pursuant to execution of Security Exchange Agreement	(255,753)	—
Depreciation	54,845	22,783
Allowance for doubtful accounts	1,500	—
Amortization of debt discount	28,719	—
Stock based debt settlement	7,600,000	—
Stock based compensation	190,513	177,601
Warrants issued for services	22,630	—
Non-cash financing costs	25,980	—
Loan guaranty costs	38,159	—
Changes in operating assets and liabilities:		
Accounts receivable	(16,409)	(6,008)
Inventory	29,996	(454,683)
Other current assets	(346,822)	152,916
Accounts payable	188,876	95,034
Accrued interest	33,994	—
Accrued expenses and other current liabilities	350,541	36,033
Net cash flows used in operating activities	<u>(4,966,596)</u>	<u>(2,843,788)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(28,766)	(27,348)
Patent costs, net of abandoned costs	(8,870)	—
Net cash flows used in investing activities	<u>(37,636)</u>	<u>(27,348)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from notes and loans payable	2,684,160	—
Proceeds from sale of common stock	1,000,000	—
Proceeds from sale of membership units, net of expenses	707,000	3,170,645
Proceeds bank line of credit	300,000	—
Proceeds from notes and loans payable-related parties	300,000	—
Proceeds from exercise of options	17,250	—
Repayment of notes payable	(200,000)	—
Repayment of notes payable-related party	(100,696)	—
Net cash flows provided by financing activities	<u>4,707,714</u>	<u>3,170,645</u>
Increase in cash	(296,518)	299,509
Cash, beginning of period	422,939	123,429
Cash, end of period	<u>\$ 126,421</u>	<u>\$ 422,938</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	<u>\$ 696</u>	<u>\$ —</u>
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
<b>SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:</b>		
Warrants issued for financing	<u>\$ 148,668</u>	<u>\$ —</u>
Warrants issued for services	<u>\$ 190,280</u>	<u>\$ —</u>
Conversion of notes payable and accrued interest into common stock	<u>\$ 849,137</u>	<u>\$ —</u>

## NOTE A – THE COMPANY

### Corporate Overview and History of Therapeutics

TherapeuticsMD, Inc., a Nevada corporation (“Therapeutics” or the “Company”) was incorporated in Utah in 1907 under the name Croff Mining Company. The Company changed its name to Croff Oil Company in 1952 and in 1996 changed its name to Croff Enterprises, Inc. In the twenty (20) years 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 Commission. In July 2009, the Company (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 the Company. On September 14, 2009, the Company changed its name to AMHN, Inc. On June 11, 2010, the Company closed a transaction to acquire Spectrum Health Network, Inc. as a wholly owned subsidiary. On July 20, 2010, the Company filed Articles of Conversion and Articles of Incorporation to redomicile in the State of Nevada and changed the par value of its shares of capital stock to \$0.001 per share. On July 31, 2010, the Company transferred the assets of America’s Minority Health Network, Inc. to a secured noteholder in exchange for the satisfaction of debt associated therewith. On February 15, 2011, the Company 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 an Exclusive Licensing, Distribution and Advertising Sales Agreement (“Licensing Agreement”) under which the Company could sell 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 the Merger (as defined and described below), the Company filed Amended and Restated Articles of Incorporation to change its name to TherapeuticsMD, Inc. and to increase the shares of Common Stock authorized for issuance to 250,000,000. On October 4, 2011, the Company closed the Merger with vitaMedMD, LLC, a Delaware limited liability company (“VitaMed”). As of December 31, 2011, Company management determined that VitaMed would become the sole focus of the Company and services performed relative to the Licensing Agreement were discontinued. Unless otherwise stated or unless the context otherwise requires, the description of our business set forth below is provided on a combined basis, taking into account our newly-acquired wholly owned subsidiary, VitaMed.

The Company maintains a website at [www.therapeuticsmd.com](http://www.therapeuticsmd.com).

### Agreement and Plan of Merger with VitaMed

On July 18, 2011, Therapeutics entered into an Agreement and Plan of Merger (“Merger Agreement”) by and among VitaMed and VitaMed Acquisition, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company (the “Merger Sub”), pursuant to which the Company would acquire 100% of VitaMed. The proposed acquisition was to be accomplished by the merger of Merger Sub with and into VitaMed with VitaMed being the surviving limited liability company (the “Merger”) in accordance with the Limited Liability Company Act of the State of Delaware. The Merger became effective upon the filing of the Certificate of Merger with the Secretary of State of the State of Delaware on October 4, 2011 (the “Effective Time”). In preparation of and prior to the closing of the Merger Agreement, the Company completed the following required corporate actions with an effective date of October 3, 2011:

- a reverse split of the Company’s 16,575,209 issued and outstanding shares of Common Stock on a ratio of 1 for 100 (the “Reverse Split”). As a result of the Reverse Split, each share of Common Stock outstanding on July 28, 2011 (the “Record Date”), without any action on the part of the holder thereof, became one one-hundredth of a share of Common Stock. The Reverse Split decreased the number of outstanding shares of the Company’s Common Stock by approximately 99% resulting in 165,856 shares outstanding after the Reverse Split. The effectuation of the Reverse Split did not result in a change in the relative equity position or voting power of the shareholders of the Company,
- an increase of its authorized shares of Common Stock to 250,000,000,

## NOTE A – THE COMPANY (continued)

### Agreement and Plan of Merger with VitaMed (continued)

- a change in the name of the Company to TherapeuticsMD, Inc., and
- an amendment to the Company’s Long Term Incentive Compensation Plan (“LTIP”) to increase the authorized shares for issuance thereunder to 25,000,000.

On October 4, 2011, the Closing Date of the Merger Agreement, the Company acquired 100% of VitaMed in exchange for the issuance of shares of the Company’s Common Stock, as more fully described below (the “Merger”). In accordance with the provisions of this triangulated merger, the Merger Sub was merged with and into VitaMed as of the Effective Date. Upon consummation of the Merger Agreement and all transactions contemplated therein, the separate existence of the Merger Sub ceased and VitaMed became a wholly owned subsidiary of the Company.

### Exchange of Securities

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

### Corporate Overview and History of VitaMed

VitaMed is a specialty pharmaceutical company organized as a limited liability company in the State of Delaware on May 13, 2008. VitaMed is focused on providing the highest quality products to the women’s health market. Our national sales force that calls on physicians and pharmacies is enhanced by our patent-pending technology and business methodology. This combination allows us to market both over-the-counter (“OTC”) and prescription nutritional supplements, drugs, medical foods and other medical products through pharmacies and our web-site with the recommendation of physicians by creating unique value propositions for patients, physician/providers and insurance payors.

In the early part of 2009, we completed formulation of our first products, a prenatal multivitamin and a vegan docosahexaenoic acid (“DHA”) supplement and introduced the product to the market in June 2009 with sales primarily in South Florida. In September 2010, we achieved a milestone of \$1 million in total sales and had begun to expand our sales force nationally and currently have product sales into 46 states. Our product line has been expanded to ten core products and our new product development continues to focus on the women’s health market. As we continue our product development efforts for both new products and refinements to existing products, we are also seeking proprietary ingredients and formulations that can be exclusively licensed or patented for use in women’s healthcare that will further differentiate our products from the competition.



## **NOTE A – THE COMPANY (continued)**

### **Corporate Overview and History of VitaMed (continued)**

VitaMed maintains websites at [www.vitamedmd.com](http://www.vitamedmd.com) and [www.vitamedmdrx.com](http://www.vitamedmdrx.com).

Throughout these Notes to Consolidated Financial Statements, the terms “we,” “us,” “our,” “Therapeutics,” or the “Company” refers to TherapeuticsMD, Inc., and unless otherwise specified, includes our wholly owned subsidiary, VitaMed.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **Principles of Consolidation**

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

### **Cash and Cash Equivalents**

Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. All of our non-interest bearing cash balances were fully insured at December 31, 2011 and 2010 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit to the amount of insurance for eligible accounts. Beginning 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and our non-interest bearing cash balances may again exceed federally insured limits. The Company had no interest-bearing amounts on deposit in excess of federally insured limits at December 31, 2011 and 2010.

### **Trade Accounts Receivable and Allowance for Doubtful Accounts**

Trade accounts receivable are customer obligations due under normal trade terms. The Company reviews the accounts receivable for uncollectible accounts and credit card charge-backs and provides an allowance for doubtful accounts which is based upon a review of outstanding receivables, historical collection information and existing economic conditions. Trade accounts receivable past due more than 90 days are considered delinquent. Delinquent receivables are written off to bad debt expense based on individual credit evaluations, results of collection efforts, and specific circumstances of the customer. Recoveries of accounts previously written off are recorded as reductions of bad debt expense when received. Historically, our bad debt expense has been limited because the majority of our trade receivables are paid via credit card. Data we use to calculate these estimates does not accurately reflect bad debts; adjustments to these reserves may be required. At December 31, 2011 and 2010, the Company recorded an allowance for doubtful accounts of \$1,500 and \$0, respectively.

### **Inventories**

Inventories represent packaged nutritional products and supplements which are valued at the lower of cost or market using the average cost method.

### **Fixed Assets**

*Property and Equipment*-Property and equipment is stated at cost, net of accumulated depreciation. Maintenance costs, which do not significantly extend the useful lives of the respective assets, and repair costs are charged to operating expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from 3 to 7 years. Depreciation expense totaled \$25,686 and \$5,105 for the years ended December 31, 2011 and 2010, respectively.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

### Fixed Assets (continued)

*Website*-Costs incurred in the planning stage of a website are expensed, while costs incurred in the development stage are capitalized and amortized over the estimated three-year life of the asset. Amortization of website development costs totaled \$29,159 and \$17,678 for the years ended December 31, 2011 and 2010, respectively.

### Intangible Assets

The Company has adopted the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification 350 *Intangible-Goodwill and Other* (“ASC 350”).

Capitalized patent costs, net of accumulated amortization, include legal costs incurred for a patent application. In accordance with ASC 350, once the patent is granted, the Company will amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, the Company will write-off any capitalized patent costs at that time. Intangible assets are reviewed annually for impairment or when events or circumstances indicate that their carrying amount may not be recoverable. There was no amortization expense related to patent costs for the years ended December 31, 2011 and 2010 as patents have not yet been granted.

### Impairment of Long-Lived Assets

Carrying values of property and equipment and finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. Such events or circumstances include, but are not limited to:

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

If impairment indicators are present, the Company determines whether an impairment loss should be recognized by testing the applicable asset or asset group’s carrying value for recoverability. This test requires long-lived assets to be grouped at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities, the determination of which requires judgment. The Company estimates the undiscounted future cash flows expected to be generated from the use and eventual disposal of the assets and compares that estimate to the respective carrying values in order to determine if such carrying values are recoverable. This assessment requires the exercise of judgment in assessing the future use of and projected value to be derived from the eventual disposal of the assets to be held and used. Assessments also consider changes in asset utilization, including the temporary idling of capacity and the expected timing for placing this capacity back into production. If the carrying value of the assets is not recoverable, then a loss is recorded for the difference between the assets’ fair value and respective carrying value. The fair value of the assets is determined using an “income approach” based upon a forecast of all the expected discounted future net cash flows associated with the subject assets.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

### **Impairment of Long-Lived Assets (continued)**

Some of the more significant estimates and assumptions include: market size and growth, market share, projected selling prices, manufacturing cost and discount rate. The Company's estimates are based upon its historical experience, its commercial relationships, market conditions and available external information about future trends. The Company believes its current assumptions and estimates are reasonable and appropriate; however, unanticipated events and changes in market conditions could affect such estimates, resulting in the need for an impairment charge in future periods.

### **Fair Value of Financial Instruments**

The Company's financial instruments consist primarily of receivables, accounts payable, accrued expenses and short-term debt. The carrying amount of receivables, accounts payable and accrued expenses approximates its fair value because of the short-term maturity of such instruments. Interest rates that are currently available to the Company for issuance of short-term debt with similar terms and remaining maturities are used to estimate the fair value of the Company's short-term debt.

### **Fair Value of Financial Instruments (continued)**

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

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

- |                |  |
|----------------|--|
| <b>Level 1</b> | Unadjusted quoted prices in active markets for identical assets or liabilities;  |
| <b>Level 2</b> | Quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and |
| <b>Level 3</b> | Unobservable inputs for the asset or liability.  |

At December 31, 2011 and 2010, the Company had no assets or liabilities that are valued at fair value on a recurring basis.

### **Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the related temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized when the rate change is enacted. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized. In accordance with ASC 740, *Income Taxes*, the Company recognizes the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. Recognized uncertain income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur. The Company recognizes both interest and penalties related to uncertain tax positions as part of the income tax provision. As of December 31, 2011 and 2010, the Company has no tax positions relating to open tax returns that were considered to be uncertain.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

### **Stock Based Compensation**

In December 2004, the FASB issued ASC 718, *Compensation – Stock Compensation* (“ASC 718”). ASC 718 companies are required to measure the compensation costs of unit-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Unit-based compensation arrangements include unit options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant. The Company uses the Black-Scholes option pricing model which requires the input of highly complex and subjective variables including the expected life of options granted and the Company’s expected stock price volatility over a period equal to or greater than the expected life of the options.

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

The Company recognizes compensation expense for all share-based payments granted based on the grant date fair value estimated in accordance with ASC 718-10, “*Share Based Payments.*” Compensation expense is generally recognized on a straight-line basis over the employee’s requisite service period.

### **Debt Discounts**

Costs incurred with parties who are providing long-term financing, which include warrants issued with the underlying debt, are reflected as a debt discount based on the relative fair value of the debt and warrants to the total proceeds. These discounts are generally amortized over the life of the related debt using the effective interest rate method. In connection with debt issued during the years ended December 31, 2011 and 2010, the Company recorded debt discounts totaling \$28,719 and \$0, respectively. Amortization expense related to debt discounts totaled \$28,719 and \$0 for the years ended December 31, 2011 and 2010, respectively, and is included in interest expense on the accompanying consolidated financial statements. Debt discount was fully amortized at December 31, 2011.

### **Revenue Recognition**

The Company recognizes revenue on arrangements in accordance with ASC 605, “*Revenue Recognition*” (“ASC 605”). Revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, the service is performed and collectability is reasonably assured. The Company generates revenue by sales of products primarily to retail consumers. The Company’s policy is to recognize revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. Outbound shipping and handling fees are included in sales and are billed upon shipment. Shipping expenses are included in cost of sales. The majority of the Company’s sales are paid with credit cards and the Company usually receives the cash settlement in two to three banking days. Credit card sales minimize accounts receivable balances relative to sales. We provide an unconditional thirty-day money-back return policy whereby we accept product returns from our retail, wholesale and eCommerce customers. Historically we have experienced returns (monitored on a daily basis) equal to approximately one percent of sales. Total returns were \$20,726 and \$13,734 for the years ended December 31, 2011 and 2010, respectively. We consider the potential returns to be de minimis and have not established an allowance for product returns at this time.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

### **Shipping and Handling Costs**

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

### **Advertising Costs**

The Company expenses advertising costs when incurred. Advertising expenses totaled \$19,408 and \$25,698 during the years ended December 31, 2011 and 2010, respectively.

### **Research and Development Expenses**

Research and development expenditures, which are expensed as incurred, totaled \$107,241 and \$65,402 during the years ended December 31, 2011 and 2010, respectively.

### **Earnings Per Share**

The Company calculates earnings per share (“EPS”) in accordance with ASC 260, “*Earnings Per Share*,” which requires the computation and disclosure of two EPS amounts, basic and diluted. Basic EPS is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted EPS is computed based on the weighted average number of common shares outstanding plus all potentially dilutive common shares outstanding during the period. Such potential dilutive common shares consist of stock options and warrants. Potential common shares totaling 96,618,626 and 165,752 (Reverse Split shares) at December 31, 2011 and 2010, respectively, have been excluded from the diluted earnings per share calculation as they are anti-dilutive due to the net loss reported by the Company.

### **Use of Estimates**

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

### **Recently Issued Accounting Pronouncements**

In December 2011, FASB issued Accounting Standards Update (“ASU”) 2011-11, *Balance Sheet - Offsetting*. This guidance requires disclosures about offsetting and related arrangements for recognized financial instruments and derivative instruments. The standard is effective for us as of January 1, 2013 and will not materially impact our financial statement disclosures.

In September 2011, the FASB issued ASU 2011-08, “Testing Goodwill for Impairment.” This guidance provides the option to evaluate prescribed qualitative factors to determine whether a calculated goodwill impairment test is necessary. The standard is effective for us as of January 1, 2012 and will not materially impact on our financial condition, results of operations, or financial statement disclosures.

## **NOTE B – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

### **Recently Issued Accounting Pronouncements (continued)**

In May 2011, FASB issued ASU 2011-05, *Comprehensive Income: Presentation of Comprehensive Income*, to allow an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments do not change the guidance regarding the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments should be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. Early adoption is permitted. The adoption is not expected to have a material impact on the Company's results of operations, financial position or cash flows.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement: Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. This ASU represents the converged guidance of the FASB and the IASB (the "Boards") on fair value measurement, and results in common requirements for measuring fair value and for disclosing information about fair value measurements, including a consistent meaning of the term "fair value." These amendments change some of the terminology used to describe many of the existing requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. The amendments should be applied prospectively, and they are effective during interim and annual periods beginning after December 15, 2011. Early application by public entities is not permitted. The adoption is not expected to have a material impact on the Company's results of operations, financial position or cash flows.

Management does not believe there would be a material effect on the accompanying financial statements had any other recently issued but not yet effective accounting standards been adopted in the current period.

### **NOTE C – GOING CONCERN**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company incurred a loss from operations of approximately \$5,400,000, had negative cash flow from operations of approximately \$5,000,000 and had an accumulated deficit of approximately \$17,000,000 at December 31, 2011. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans include raising additional proceeds from debt and equity transactions and to continue to increase its sales and marketing activities; however, there are no assurances that management will be successful in their efforts. The financial statements do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should the Company be unable to continue in operation.

### **NOTE D – STOCKHOLDERS' EQUITY**

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

## **NOTE D – STOCKHOLDERS' EQUITY (continued)**

### **Preferred Stock**

At December 31, 2011, the Company had 10,000,000 shares of Preferred Stock, par value \$0.001 authorized and none outstanding, which shares can be designated by the Company's Board of Directors.

### **Common Stock**

At December 31, 2011, the Company had 250,000,000 shares of Common Stock, \$0.001 par value authorized, with 82,978,781 shares of Common Stock issued and outstanding.

Between February and May 2011, VitaMed sold 2,892,630 Units for an aggregate purchase price of \$707,000.

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

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

In October and November 2011, the Company converted principle and accrued interest in the aggregate of \$849,137 into shares of Common Stock of the Company totaling 20,000,000 and 1,681,958, respectively, as more fully described in NOTE I – NOTES PAYABLE.

In December 2011, a former director of VitaMed exercised Company Options to purchase 92,057 shares of the Company's Common Stock at an aggregate exercise price of \$17,250.

### **Warrants**

The valuation methodology used to determine the fair value of Common Stock purchase warrants is the Black-Scholes-Merton option-pricing model ("Black-Scholes Model"), an acceptable model in accordance with ASC 718-10. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate and the term of the Common Stock purchase warrant.

As of December 31, 2011, the Company had Company Warrants outstanding for an aggregate of 3,057,627 shares of the Company's Common Stock (including the conversion of VitaMed Warrants as described above) with a weighted average contractual life of 8.0 years and exercise prices ranging from \$0.24 to \$1.50 per share resulting in a weighted average exercise price of \$0.39 per share.

As of December 31, 2011, unamortized costs associated with Company Warrants totaled approximately \$349,000.

**NOTE D – STOCKHOLDERS' EQUITY (continued)**Warrants (continued)

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

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

On March 7, 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the "Bank LOC") for which the bank required a personal guarantee and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one-year extension to the Bank LOC which was executed on March 19, 2012 (the "Bank LOC Extension"). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The ten-year Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the bank loan is repaid prior to being fully vested, the Company Warrants will be reissued only for the number of shares vested through the date of repayment. At March 31, 2012, an aggregate of 306,867 shares will be vested thereunder. The VitaMed Warrants were valued on the date of the grant using a term of 10 years; a volatility of 47.89%; risk free rate of 3.48%; and a dividend yield of 0%. Of the \$93,969 fair value, \$38,159 was recorded as loan guaranty costs in other income and expense and \$55,810 was recorded as prepaid expense on the accompanying consolidated financial statements.

In June 2011, VitaMed sold Promissory Notes (the "VitaMed Promissory Notes") in the aggregate of \$500,000 with accompanying VitaMed Warrants for an aggregate of 500,000 shares (or Company Warrants for an aggregate of 613,718 shares pursuant to the Conversion Ratio). The VitaMed Warrants were valued on the date of the grant using a term of five (5) years; a range of volatility from 39.13% to 39.15%; risk free rate ranging from 1.38-1.65%; and a dividend yield of 0%. The Company Warrants vested immediately. Although the fair value was \$30,993, using the appropriate accounting treatment, \$28,719 was recorded as debt discount and fully amortized during 2011 with the amortized amount recorded as interest expense on the accompanying consolidated financial statements.

On July 21, 2011, VitaMed entered into a one-year consulting agreement with Lang Naturals, Inc. ("Lang"), wherein Lang would assist in the design, development and distribution efforts of VitaMed's initial product offering. As compensation, Lang received a VitaMed Warrant for 200,000 shares (or a Company Warrant for 245,485 shares pursuant to the Conversion Ratio). The VitaMed Warrant was valued on the date of the grant using a term of five (5) years; a volatility of 39.44%; risk free rate of 1.56%; and a dividend yield of 0%. The Company Warrant vested immediately. Of the \$12,548 fair value, \$5,612 was recorded as non-cash compensation and \$6,936 was recorded as prepaid expense on the accompanying consolidated financial statements.



**NOTE D – STOCKHOLDERS' EQUITY (continued)**Warrants (continued)

On October 21, 2011, the Company granted a Company Warrant to Daniel A. Cartwright, the Company's Chief Financial Officer, for 600,000 shares with a fair value of \$133,045 for services performed. The Company Warrant was valued on the date of the grant using a term of 10 years; volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Company Warrant vests over a 44-month period beginning on November 21, 2011 (or 13,636 shares for months 1-43 and 13,652 shares for month 44). Of the \$133,045 fair value, \$7,158 was recorded as non-cash compensation on the accompanying consolidated financial statements. The remaining \$125,887 will be expense to non-cash compensation equitably over the remaining 42 months.

Also on October 21, 2011, the Company granted a Company Warrant for 184,211 shares with a fair value of \$25,980 to an unrelated entity for consulting services covered under a two (2) month agreement. The Company Warrant was valued on the date of the grant using a term of five (5) years; volatility of 41.04%; risk free rate of 1.08%; and a dividend yield of 0%. The \$25,980 fair value was recorded as financing expense on the accompanying consolidated financial statements.

On October 23, 2011, VitaMed entered into a two-year consulting agreement with Lang wherein a Lang representative will help evaluate improvements to existing products and new products as well as services including but not limited to research, design, compliance, scientific and regulatory affairs and commercialization of products. As compensation, Lang received a Company Warrant for 800,000 shares. The Company Warrant was valued on the date of the grant using a term of 10 years; a volatility of 45.94%; risk free rate of 2.23%; and a dividend yield of 0%. The Company Warrant vested immediately. Of the \$177,394 fair value, \$17,010 was recorded as non-cash compensation and \$160,384 was recorded as prepaid expense on the accompanying consolidated financial statements.

On December 28, 2011, the Company granted a Company Warrant for 500 shares with a fair value of \$338 to an unrelated individual for consulting services covered under a three (3) month agreement. The Company Warrant was valued on the date of the grant using a term of 10 years; volatility of 51.83%; risk free rate of 0.91%; and a dividend yield of 0%. The Company Warrant vested immediately. Of the \$338 fair value, \$15 was recorded as non-cash compensation and \$323 was recorded as prepaid expense on the accompanying consolidated financial statements.

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

	<b>2011</b>	
Weighted average fair value	\$	0.36
Risk-free interest rate		0.91-3.48%
Volatility		39.13-51.83%
Term (in years)		5-10
Dividend yield		0.00%

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term. Estimated volatility is a measure of the amount by which the Company's stock price is expected to fluctuate each year during the term of the award. The Company's estimated volatility is an average of the historical volatility of the stock prices of its peer entities whose stock prices were publicly available. The Company's calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. The Company used the historical volatility of peer entities due to the lack of sufficient historical data of its stock price during 2001-2011.

**NOTE D – STOCKHOLDERS' EQUITY (Continued)**Warrants (continued)

The Company issued no Common Stock purchase warrants during the year ended December 31, 2010. A summary of the Company's Common Stock purchase warrant activity and related information for 2011 follows:

	<b>Number of Shares Under Company Warrant</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2010	-0-			
Granted	3,057,627	\$ 0.36	8.7	\$ 3,483,691
Exercised	-0-			
Expired	-0-			
Cancelled	-0-			
Balance at December 31, 2011	<u>3,057,627</u>	\$ 0.36	8.7	\$ 3,483,691
Vested and Exercisable at December 31, 2011	<u>2,254,758</u>	\$ 0.37	5.6	\$ 2,361,339

Stock Options

In 2009, the Company adopted the 2009 Long Term Incentive Compensation Plan (the "LTIP") to provide financial incentives to employees, members of the Board, and advisers and consultants of the Company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives (the "Awards"). The Awards available under the 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. Prior to the Merger, no awards had been issued under the LTIP.

A summary of activity under the LTIP and related information follows:

	<b>Number of Shares Under Company Option</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2010	-0-			
Granted <sup>(1)</sup>	10,682,218	\$ 0.16	7.6	\$ 14,188,484
Exercised	(92,057)	\$ 0.19		
Expired	-0-			
Cancelled	-0-			
Balance at December 31, 2011	<u>10,590,161</u>	\$ 0.16	7.6	\$ 14,067,649
Vested and Exercisable at December 31, 2011	<u>6,581,049</u>	\$ 0.13	7.5	\$ 9,038,719

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

## **NOTE D – STOCKHOLDERS’ EQUITY (Continued)**

### **Stock Options (continued)**

The weighted-average grant date fair value of Company Options granted during the years ended December 31, 2011 and 2010 was \$0.19 and \$0.09, respectively.

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

The valuation methodology used to determine the fair value of Company Options is the Black-Scholes-Merton option-pricing model (“Black-Scholes Model”), an acceptable model in accordance with ASC 718-10. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life.

The assumptions used in the Black-Scholes Model during the years ended December 31, 2011 and 2010 and are set forth in the table below.

	<b>2011</b>	<b>2010</b>
Risk-free interest rate	0.91-2.54%	1.27-3.12%
Volatility	37.92-40.48%	36.34-42.46%
Expected life (in years)	5.5-6.25	5-6.25
Dividend yield	0.00%	0.00%

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the expected life. Estimated volatility is a measure of the amount by which the Company’s stock price is expected to fluctuate each year during the term of the award. The Company’s estimated volatility is an average of the historical volatility of the stock prices of its peer entities whose stock prices were publicly available. The Company’s calculation of estimated volatility is based on historical stock prices over a period equal to the term of the awards. The Company used the historical volatility of peer entities due to the lack of sufficient historical data of its stock price during 2001-2011. The average expected life is based on the contractual term of the option using the simplified method.

Share-based compensation expense for Company Options recognized in our results for the years ended December 31, 2011 and 2010 (\$180,087 and \$177,601 respectively) is based on awards vested and we estimated no forfeitures. ASC 718-10 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates.

At December 31, 2011 and 2010, total unrecognized estimated compensation expense related to non-vested Company Options granted prior to that date was approximately \$244,000 and \$206,000, respectively, which is expected to be recognized over a weighted-average period of 3.3 years. No tax benefit was realized due to a continued pattern of operating losses.

## **NOTE E – INCOME TAXES**

With the advent of the Merger, Company management determined that VitaMed would become the sole focus of the Company and previous business performed by Therapeutics was discontinued. Because of these events, deferred income taxes are determined by calculating the loss from operations of the Company from October 4, 2011 to December 31, 2011. Deferred income taxes are determined using the liability method for the temporary differences between the financial reporting basis and income tax basis of the Company’s assets and liabilities. Deferred income taxes are measured based on the tax rates expected to be in effect when the temporary differences are included in the Company’s tax return. Deferred tax assets and liabilities are recognized based on anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. As of December 31, 2011, there is no provision for income taxes, current or deferred.

**NOTE E- INCOME TAXES (Continued)**

At December 31, 2011, the Company had a net operating loss carry forward of approximately \$2.1 million, available to offset future taxable income through 2031. The Company established valuation allowances equal to the full amount of the deferred tax assets due to the uncertainty of the utilization of the operating losses in future periods. The Company periodically assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income.

At December 31, 2011, the differences between the actual income tax benefit and the amount computed by applying the statutory federal tax rate (35%) to the loss before taxes are as follows:

Expected income tax benefit at statutory rate	\$ (4,519,678)
Non-deductible expenses:	
Debt settlement	2,586,500
VitaMed pre-merger loss	1,164,629
Other non-deductible expenses	22,912
Change in valuation account	745,637
Income tax expense (benefit)	<u>\$ -0-</u>

**NOTE F – OTHER CURRENT ASSETS**

Other current assets consist of the following:

	December 31,	
	2011	2010
Deposits with vendors	\$ 300,503	\$ -0-
Prepaid consulting	95,962	-0-
Prepaid insurance	52,611	6,292
Prepaid guaranty costs	46,984	-0-
TOTAL OTHER CURRENT ASSETS	<u>\$ 496,060</u>	<u>\$ 6,292</u>

**NOTE G – FIXED ASSETS**

Fixed assets consist of the following:

	December 31,	
	2011	2010
Website	\$ 91,743	\$ 65,791
Equipment	33,651	30,837
Furniture and fixtures	26,219	26,219
	151,613	122,847
Accumulated depreciation	(81,500)	(26,655)
TOTAL FIXED ASSETS	<u>\$ 70,113</u>	<u>\$ 96,192</u>

Depreciation expense for the years ended December 31, 2011 and 2010 was \$54,845 and \$22,783, respectively.

**NOTE H – OTHER ASSETS**

Other assets consist of the following:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Prepaid consulting	\$ 71,689	\$ -0-
Prepaid guaranty costs	8,826	-0-
<b>TOTAL OTHER ASSETS</b>	<b>\$ 80,515</b>	<b>\$ -0-</b>

**NOTE I – NOTES PAYABLE**

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

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

On March 7, 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the “Bank LOC”) for which the bank required a personal guarantee and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one-year extension to the Bank LOC which was executed on March 19, 2012 (the “Bank LOC Extension”). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. At December 31, 2011, the outstanding principle balance of the Bank LOC was \$300,000. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The ten-year Company Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the Bank LOC is repaid prior to being fully vested, the Company Warrants will be reissued only for the number of shares vested through the date of repayment. At March 31, 2012, an aggregate of 306,867 shares will be vested thereunder.

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

On June 1, 2011, VitaMed sold Promissory Notes (the “VitaMed Promissory Notes”) in the aggregate of \$500,000 with accompanying VitaMed Warrants to purchase an aggregate of 500,000 Units (or Company Warrants to purchase an aggregate of 613,718 shares pursuant to the Conversion Ratio). The VitaMed Promissory Notes earn interest at the rate of four percent (4%) per annum and were due at the earlier of (i) the six (6) month anniversary of the date of issuance and (ii) such time as VitaMed received the proceeds of a promissory note(s) issued in an amount of not less than \$1,000,000 (the “Funding”). Upon the closing of the Funding on July 18, 2011, as more fully described in the following paragraph, 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 until the Closing of the Merger. On October 6, 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 the Company’s Common Stock at \$0.38 per share, which represents fair value of the shares on the date of conversion. Other VitaMed Promissory Notes in the aggregate of \$150,000 were extended to March 1, 2012. At December 31, 2011, the outstanding principle balance of the VitaMed Promissory Notes was an aggregate of \$150,000. As mentioned hereinafter in FOOTNOTE O – SUBSEQUENT EVENTS, two VitaMed Promissory Notes in the aggregate of \$100,000 were further extended to April 14, 2012 and one for \$50,000 was further extended to June 1, 2012. The ten-year Company Warrants have an exercise price of \$0.4074 per share and none have been exercised.

On July 18, 2011, VitaMed sold two Senior Secured Promissory Notes (the “Secured Notes”) in the amount of \$500,000 each and also entered into a Security Agreement under which VitaMed pledged all of its assets to secure the obligation. The Secured Notes bear interest at the rate of six percent (6%) per annum and are due on the one (1) year anniversary thereof. The Senior Secured Notes bear interest at the rate of six percent (6%) per annum and are due on the one (1) year anniversary of the date thereof. The Company may pay the Senior Secured Notes by delivering such number of shares of the Company’s Common Stock as shall be determined by dividing the outstanding principal then due and owing by the Company’s Share Price. For purposes of the Senior Secured Notes, the “Share Price” shall mean the lower of the most recent price at which the Company offered and sold shares of its Common Stock (not including any shares issued upon the exercise of options and/or warrants or upon the conversion of any convertible securities) or the five-day average closing bid price immediately preceding the date of conversion. At December 31, 2011, the outstanding principle balance of the Secured Notes was \$500,000 each.

In September and October 2011, VitaMed sold Convertible Promissory Notes (the “VitaMed Convertible Notes”) in the aggregate of \$534,160. The VitaMed Convertible Notes earned interest at the rate of four percent (4%) per annum and were due December 1, 2011. On November 18, 2011, the Company and the VitaMed Convertible Noteholders entered into Debt Conversion Agreements and converted the principal and accrued interest of the VitaMed Convertible Notes into 1,415,136 shares of the Company’s Common Stock at \$0.38 per share which represents the fair value of the shares on the date of conversion.

In November and December, 2011, the Company sold six-percent Promissory Notes for an aggregate of \$800,000 with due dates of March 1, 2012. At December 31, 2011, the outstanding principle balance of the Promissory Notes was \$800,000. As mentioned hereinafter in FOOTNOTE O – SUBSEQUENT EVENTS, these Notes were paid in full on February 24, 2012 through the issuance of Secured Promissory Notes.

In December 2011, the Company sold four-percent Promissory Notes for an aggregate of \$100,000 with due dates of March 1, 2012. At December 31, 2011, the outstanding principle balance of the Promissory Notes was \$100,000. As mentioned hereinafter in FOOTNOTE O – SUBSEQUENT EVENTS, these Notes were further extended by mutual agreement to April 14, 2012.

## **NOTE J – OTHER CURRENT LIABILITIES**

Other current liabilities consist of the following:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Accrued payroll	\$ 227,477	\$ -0-
Accrued vacation	68,438	24,208
Other accrued expenses	128,473	90,998
Dividends payable <sup>(1)</sup>	41,359	-0-
<b>TOTAL OTHER CURRENT LIABILITIES</b>	<b>\$ 465,747</b>	<b>\$ 115,206</b>

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

## **NOTE K – RELATED PARTIES**

### Loan Guaranty

On March 7, 2011, VitaMed entered into a Business Loan Agreement and Promissory Note for a \$300,000 bank line of credit (the “Bank LOC”) for which the bank required a personal guaranty and cash collateral. Personal guarantees and cash collateral limited to \$100,000 each were provided by Robert Finizio and John Milligan, officers of VitaMed, and by Reich Family Limited Partnership, an entity controlled by Mitchell Krassan, also an officer of VitaMed. The Bank LOC accrued interest at the rate of 3.020% per annum based on a year of 360 days and was due on March 1, 2012. The bank and VitaMed negotiated a one-year extension to the Bank LOC which was executed on March 19, 2012 (the “Bank LOC Extension”). The Bank LOC Extension accrues interest at the rate of 2.35% and is due on March 1, 2013. In consideration for the personal guarantees and cash collateral, VitaMed issued VitaMed Warrants for an aggregate of 499,998 Units (or Company Warrants for an aggregate of 613,713 shares pursuant to the Conversion Ratio). The ten-year Warrants vest at the rate of an aggregate of 76,714 shares per calendar quarter end and have an exercise price of \$0.2444 per share. In the event that the bank loan is repaid prior to being fully vested, the Company Warrants will be reissued only for the number of shares vested through the date of repayment. At March 31, 2012, an aggregate of 306,867 shares will be vested thereunder.

### Loans from Affiliates

The VitaMed Promissory Notes for an aggregate of \$500,000 (see NOTE I -- NOTES PAYABLE) included an aggregate of \$200,000 being issued to certain officers and directors of the Company. John Milligan, President and Director, and Dr. Brian Bernick, Director, were issued VitaMed Promissory Notes for \$50,000 each. Reich Family LP, an entity controlled by Mitchell Krassan, Executive Vice President, and Fourth Generation Equity Partners, LLC (“Fourth Generation”), an entity controlled by Nick Segal, a director of VitaMed at the time of the issuance, were issued VitaMed Promissory Notes for \$50,000 each. The VitaMed Promissory Notes bear interest at the rate of four percent (4%) per annum. On October 6, 2011, (i) principal and interest of approximately \$50,696 under the Note to Reich Family LP was repaid, (ii) principal and interest of approximately \$50,696 under the Note to Fourth Generation was converted into 133,411 shares of the Company’s Common Stock at \$0.38 per share, and (iii) the due date for the VitaMed Promissory Notes to Mr. Milligan and Dr. Bernick was extended to March 1, 2012. As mentioned hereinafter in FOOTNOTE O – SUBSEQUENT EVENTS, the VitaMed Promissory Notes to Mr. Milligan and Dr. Bernick were further extended by mutual agreement to April 14, 2012.

The 4% Promissory Notes issued in the aggregate of \$100,000 (see NOTE I -- NOTES PAYABLE) included one issued to Robert Finizio, Chief Executive Officer and Director, and one issued to John Milligan, President and Director, in the amount of \$50,000 each.

**NOTE K – RELATED PARTIES (continued)****Lock Up Agreements**

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

**Sales to Related Parties**

During 2011 and 2010, the Company sold its products to Dr. Brian Bernick, a director of the Company, in the amounts of \$20,669 and \$25,269, respectively. At December 31, 2011 and 2010, \$0 and \$79, respectively, remained outstanding.

**Agreements with Pernix Therapeutics, LLC**

As previously mentioned the Company closed a Stock Purchase Agreement with Pernix on October 4, 2011. From time to time, the Company has, and will continue to, enter into agreements with Pernix in the normal course of business, which agreements are, and will be negotiated in, arms-length transactions. The President and largest shareholder of Pernix, Cooper C. Collins, was recently elected to serve on the Company’s Board of Directors.

**NOTE L - BUSINESS CONCENTRATIONS**

The Company purchases its products from several suppliers with approximately 95% and 93% coming from one supplier for the years ended December 31, 2011 and 2010, respectively.

**NOTE M – COMMITMENTS AND CONTINGENCIES**

The Company leases administrative and distribution facilities in Boca Raton, Florida pursuant to a forty-five month non-cancelable operating lease expiring in 2013. The lease stipulates, among other things, base monthly rents of \$5,443 plus the Company’s share of monthly estimated operating expenses of \$3,500 and sales tax. The lease contains one renewal option for an additional two-year period.

The rental expense related to this lease totaled \$106,315 and \$116,175 for the years ended December 31, 2011 and 2010.

As of December 31, 2011, future minimum rental payments are as follows:

<b>Years Ending December 31,</b>		
2012	\$	111,725
2013		56,601
2014		-0-
2015		-0-
Thereafter		-0-
Total	\$	<u>168,326</u>



**NOTE M – COMMITMENTS AND CONTINGENCIES (continued)**

In December 2011, the Company paid approximately \$245,000 to a non-affiliated third party for fees related to research and development of new products. The Company believes that it could incur additional related fees up to \$950,000 in 2012.

**NOTE N – RESTATEMENT OF 2010 AUDITED FINANCIALS**

Subsequent to the filing of the Company's Current Report on Form 8-K, Amendment 3 filed on December 9, 2011, the Company determined that an error was made in certain assumptions used in the Black-Scholes calculation to determine the fair value of options issued from inception through December 31, 2010.

For the year ended December 31, 2010, \$363,750 was recorded as non-cash compensation on the audited financial statements of VitaMed. The Company determined that the fair value should have been \$177,601, an overstatement of \$186,149. The Company is restating sales, general and administration for the year ended December 31, 2010 to include the \$186,149 reduction in non-cash compensation expense.

For the period from inception through December 31, 2010, \$559,917 was recorded as non-cash compensation on the audited financial statements of VitaMed, of which \$196,167 pertains to the period from May 13, 2008 ("Inception") through December 31, 2009. The Company determined that the fair value should have been \$283,530, of which \$105,929 pertains to the period from Inception through December 31, 2009, an overstatement of \$276,387, of which \$90,238 pertains to the period from Inception through December 31, 2009. The Company is restating accumulated deficit for the year ended December 31, 2010 to include the \$276,387 reduction for the year ended December 31, 2010 and the \$90,238 reduction for the period from Inception through December 31, 2009.

The tables below summarize the impact of the restatements.

	As of December 31, 2010	
	As Reported	As Restated
Additional paid in capital	\$ 537,561	\$ 261,174
Accumulated deficit	\$ (4,356,100)	\$ (4,079,713)

  

	For the Year Ended December 31, 2010	
	As Reported	As Restated
Sales, general and administration	\$ 3,650,959	\$ 3,464,810
<b>Total operating expense</b>	\$ 3,739,144	\$ 3,552,994
<b>Operating loss</b>	\$ (3,053,613)	\$ (2,867,464)
<b>Net loss</b>	\$ (3,053,613)	\$ (2,867,464)

**NOTE O – SUBSEQUENT EVENTS**Formation of New Subsidiary

On January 10, 2012, the Company formed a new wholly owned subsidiary, BocagreenMD, Inc., a Nevada corporation, for the purpose of selling certain of its products to select markets.

## **NOTE O – SUBSEQUENT EVENTS (continued)**

### **Issuance of Promissory Notes**

Between January 2012 and February 10, 2012, the Company issued Promissory Notes for an aggregate of \$700,000 (the “Notes”). The Notes bore interest at a rate of six (6%) per annum and were due on March 1, 2012. The Notes were repaid on February 24, 2012 through the issuance of Secured Promissory Notes as outlined below.

### **Issuance of Secured Promissory Notes**

On February 24, 2012, TherapeuticsMD, Inc. (the “Company”) sold and issued Secured Promissory Notes (the “Notes”) to Steven G. Johnson (“Johnson”) and Plato & Associates, LLC (“Plato”) in the principal base amount of \$1,358,014 and \$1,357,110 respectively (the “Principal Base Amount(s)”) pursuant to the terms of that certain Note Purchase Agreement (the “Note Purchase Agreement”) of even date therewith. As consideration for the Notes, Johnson and Plato surrendered certain promissory notes previously issued by the Company in the aggregate amount of \$858,014 and \$857,110 respectively (which sums include principle and interest through February 24, 2011) (collectively known as the “Prior Notes”). As a result of the foregoing the Company received an aggregate of \$1,000,000 of new funding from Johnson and Plato. On March 23, 2012, each of Johnson and Plato loaned the Company an additional \$500,000 under the Notes for an aggregate of \$1,000,000.

The Principal Base Amount of each Note, plus any and all additional advances made to the Company thereafter (the “Aggregated Principal Amount”), together with accrued interest at the annual rate of six percent (6%), is due in one lump sum payment twenty-four (24) months from the date of issuance of the Notes (the “Maturity Date”). As security for the Company’s obligations under the Note Purchase Agreement and the Notes, the Company entered into a Security Agreement of even date therewith and pledged all of its assets, tangible and intangible, as further described therein.

As an inducement for the Purchasers to lend additional funds to the Company as outlined therein on Schedule I to the Note Purchase Agreement, and for the Purchaser’s leniency to, in essence, extend the maturity date of the Prior Notes for an additional twenty-four month period, the Purchasers, and/or assigns, received Company Warrant(s) to purchase an aggregate of 9,000,000 Shares. The Company Warrant(s) shall terminate on the date that is five (5) years from the date of the issuance of the Notes and shall have an exercise price of \$0.38 per share. The Company is currently evaluating and quantifying the affect of the issuance of the Company Warrants on its financial statements.

### **Extension and/or Payment of Promissory Notes**

As previously mentioned herein, on June 1, 2011, VitaMed Promissory Notes in the aggregate of \$500,000. The due date for three of the VitaMed Promissory Notes in the aggregate of \$150,000 had previously been extended to March 1, 2012. Two of the VitaMed Promissory Notes were further extended to April 14, 2012 and the other was further extended to June 1, 2012.

In November and December, 2011, the Company sold six-percent Promissory Notes for an aggregate of \$800,000 with due dates of March 1, 2012. As mentioned hereinabove, these Notes were paid in full on February 24, 2011 through the issuance of Secured Promissory Notes to Johnson and Plato.

In December 2011, the Company sold four-percent Promissory Notes for an aggregate of \$100,000 with due dates of March 1, 2012. These Notes were further extended by mutual agreement to April 14, 2012.

As previously mentioned herein, the Bank LOC in the principle amount of \$300,000 was extended until March 1, 2013.

## **NOTE O – SUBSEQUENT EVENTS (Continued)**

### **Approval of 2012 Stock Incentive Plan**

On February 23, 2012, the Company's Board of Directors adopted the 2012 Stock Incentive Plan, a non-qualified plan not requiring approval by the Company's shareholders ("2012 SOP"). There are 10,000,000 shares authorized for issuance thereunder. No shares have been issued under the 2012 SOP.

### **Election of Additional Directors**

On February 29, 2012, the Company's Board of Directors elected four additional individuals to serve as members of its Board of Directors, including: Samuel A. Greco, Cooper Collins, Robert V. LaPenta, Jr. and Nicholas Segal.

### **Issuance of Company Options**

On February 27, 2012, the Company issued Company Options to Robert G. Finizio and John Milligan, officers and directors of the Company. The ten-year Company Options are for 300,000 shares each and have an exercise price of \$2.20 per share. The Company Options vest in full on February 27, 2013.

### **Approval of Committee Charters and Committee Appointments**

On February 29, 2012, the Company's 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.

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

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

Members of the Corporate Governance Committee include John C.K. Milligan, IV, Brian Bernick and Robert LaPenta, Jr. Mr. Milligan will serve as Chair.

### **Release of First Prescription Product**

On March 1, 2012, the Company launched its first prescription prenatal vitamin, *vitaMedMD™ Plus Rx*, a single-dose product containing one prenatal vitamin tablet and one life's DHA™ capsule.

### **Cancellation of Options**

Between January 1, 2012 and March 24, 2011, Company Options for an aggregate of 5,000 shares were canceled due to expiration of the Company Option or termination of the employee.

**3,953,489 Shares**  
**TherapeuticsMD**  
**Common Stock**

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PROSPECTUS

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October 15, 2013

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