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THE CHAIRMAN S REPORT

April 22, 2005

A LETTER FROM ED WHITACRE

New Era, New Company

Fellow Employees,

It s clear to all of us by now that for SBC, 2005 is shaping up to be a year like no other. But here s the really interesting thing: That was the case even before we announced our plans to acquire AT&T.

After years of talking about the day when technologies would converge, it s finally happening. Thanks to superfast broadband and Internet protocol (IP), the worlds of communication and entertainment have merged. Everything we do this year will position us to become the only communications and entertainment provider our customers will want.

We re transforming our network through Project Lightspeed and our company so that we can deliver on the promise of IP. Advances in technology are making this transformation not only possible, but essential. Our customers have high expectations, and we must deliver.

Toward the end of this year or the beginning of next year, we ll have launched IPTV video service over broadband. With IPTV comes the promise of video on demand and many other terrific features.

We ll also expand our use of IP technology to provide advanced voice and data services for business customers of all sizes. And throughout the year, we ll be working with Cingular to continue to integrate the wireless/wire-line experience.

Even as we re transforming, however, some things about our business will never change especially our commitment to providing an outstanding customer experience. No matter what we re selling or what we re installing, excellent service will always be at the heart of our business.

What does all of this mean to you? It means that in 2005, you are a part of the transformation of SBC. Every one of us has the ability to make a real difference. By making referrals, finding ways to drive out costs, reaching out to customers and remaining flexible as we evolve to an IP-based provider, each of us can help SBC complete its transformation into the flagship American communications company of the 21st century.

I feel privileged to be a part of what s happening in our industry today, and I hope you do too. Our future depends on our ability to complete this transformation successfully. Thanks in advance for all you re doing to help us get there.

/s/ Ed Whitacre
Ed Whitacre

SBC 2005

WIRELINE STRATEGY **The Wireline 9**

This year SBC is focused on nine keys to success in the wireline organization a series of imperatives known as the **Wireline 9**. They fall into two general categories *Grow the Core* to keep the momentum going and *Invest in IP*, which will position the company for success for decades to come.

GROW THE CORE

Consumer. Our challenges are wireless and VoIP substitution and cable competition. We are aggressively bundling and targeting our products to the right customers, at the right time, at the right price to drive access line stability and revenue growth.

Small and Medium Business. SBC is uniquely positioned to win in this market. Small and medium businesses are eager to take advantage of emerging IP and wireless technologies.

Wholesale. Opportunities include: UNE-P revenue, switched access compensation from carriers, wholesale IP services compensation and high-capacity services for wireless companies, a revenue stream that can grow at double-digit rates.

Improve the Customer Experience. Simplifying the customer experience and our processes is the theme. Good service means creating online, self-service options; simplifying our product portfolio and our disclosures; and

improving our billing.

Revamp Our Cost Structure. This is critical to compete effectively with companies that have a lower cost structure. We are quickly implementing initiatives such as our call center and network center transformations, which reduce costs and improve service.

INVEST IN IP

Grow the Enterprise Segment. Large business is a key growth driver, and we re becoming a major player in this $100 billion national market. Acquiring AT&T will significantly accelerate our entry into this market and, once the deal closes, we will be the enterprise leader.

Video and Broadband. Our investment in AT&T, coupled with our $4 billion Project Lightspeed fiber expansion plan, will usher in our IP future in the consumer segment. We want to beat the cable companies video offerings and grab a share of this growing $63 billion market.

VoIP. This is a huge opportunity in the business arena where no company matches our selection of solutions. Later, we will offer consumer VoIP service.

Integrate Wireless. We already are tying together our grand slam bundle of wireline, wireless, broadband and video, and soon we ll be introducing a Wi-Fi, dual-mode cellular phone to enterprise customers. It will start there, then we ll work our way to the consumer market.

Consumer and Business Markets

We are taking several steps this year to accelerate our momentum in consumer and business markets.

In **consumer markets**, we ll continue to increase the adoption rates for **bundles** already at 64 percent with simpler offers and new promotions.

We ll accelerate our move into video, where **SBC | DISH Network** is our first step into a $63 billion market nearly all of it untapped potential for SBC.

The next phase comes later this year when we introduce the **HomeZone**, a set-top box that combines SBC Yahoo! DSL and SBC | DISH Network.

Later this year or early next year, we take the biggest step of all with **Project Lightspeed**, our $4 billion, next-generation network initiative. We expect to extend fiber optics into neighborhoods across our 13-state region and initially provide 18 million households with IP-based super high-speed data, video and voice services by the end of 2007. Among **small- to medium-business customers,** we re leading the market with the strongest data growth in years and we re accelerating that trend.

We re doing that by providing business customers with services when, where and how they need them: on the Web, in retail locations and through specialized vendors.

We re offering the coverage and expertise that business customers need including help in making the transition from conventional voice service to the VoIP networks of the future.

And we re working closely with **Cingular** to win customers and provide them with integrated wireline/wireless products. We ll be introducing integrated wireline/wireless devices first with the enterprise market and moving them to consumers after that.

Strengthening **the Core:**

The Wholesale Market

The FCC decision last year to phase out UNE-P has led some to believe that the SBC wholesale business is going away.

In fact, nothing could be farther from the truth.

That s a good thing. In 2004, our $7.6 billion in wholesale revenue represented about 20 percent of our total wireline revenue. And growing strategic portions of our wholesale business is one of the nine wireline imperatives for success in 2005.

The resale of local access lines under the UNE-P mandate represented only about one quarter of the SBC wholesale revenues last year. While some competitors will stop buying local access from SBC when they can no longer get it at government-set rates that often are below SBC cost, others will sign agreements to buy access from SBC at commercial rates.

Even as SBC transitions its local access wholesale customers from regulated to commercial terms, we are seizing opportunities in other segments of our wholesale business where market forces already are in play. High-capacity data already represents more than 40 percent of SBC total wholesale revenues. The sale of big data pipes to other carriers especially cellular companies will be a key growth area this year. Wireless carriers are signing up new subscribers, rolling out new data applications and building towers every day. Increased traffic means more high-speed trunk services purchased from SBC.

To Improve Margins, We Must Reduce Costs

To attract investors in today s marketplace, we must improve our *margins* that s revenues minus costs. We spend a lot of time talking about ways to grow revenue, but reducing costs is equally important. We can t do one without the other.

For the past several years, we ve been engaged in a focused, comprehensive effort to reduce our expenses. We re examining everything we do from how we relate to customers to what kind of toner we use in our printers in order to find ways to do it more efficiently. Just because we ve always done something a certain way doesn t mean we need to continue doing it that way or that we need to continue doing it at all.

Our cost structure still compares unfavorably with that of our peers, such as Verizon and BellSouth, and also with many of our competitors, which puts us at a disadvantage. That s why we must continue to take cost out of the business.

Reducing costs and improving margins results in a stronger, more competitive company and that benefits us all.

We spend a lot of time talking about ways to grow revenue, but reducing costs is equally important.

Service Matters

Service has always been a top priority for SBC, but this year we re sharpening our focus. From the institutional to the individual level, we re recommitting ourselves to providing the outstanding service that not only grows revenue, but also reduces costs.

FIVE REASONS WHY GREAT SERVICE MATTERS

1. Providing outstanding service contributes directly to the bottom line through the revenue we retain (thanks to customer loyalty) and new revenue (very satisfied customers spend more).

2. Only very satisfied customers can be considered loyal; all others are at risk of switching to a competitor. In 2004, 47 percent of SBC customers said they were very satisfied. The remaining 53 percent must be considered at risk and we should consider that an opportunity for growth and improvement.

3. If we can go the extra mile for these customers and increase our very satisfied customers by just 5 percent, it could mean as much as $1 billion in additional revenue.

4. Service problems played a role in about 20 percent of our customer losses in other words, those losses are preventable.

5. It costs five times as much to acquire new customers as it does to retain existing ones.

FIVE OF THE MANY THINGS WE RE DOING TO IMPROVE SERVICE

1. Our Call Center Transformation Program is providing service reps with improved tools so they have quicker access to all the pertinent information about a customer s account.

2. Customers want to do business with us when it s most convenient for them which might be at 2 a.m. We have more than 30 initiatives under way to provide customers with more online, self-service options, allowing them to order products and services, check and pay their bills and even report trouble at **www.sbc.com.**

3. We re implementing skill-based call-routing, and developing Complex Customer Care centers to make it easier to get customers to the right person the first time and keep them there. Minimizing hand-offs is a priority.

4. We re overhauling our billing systems to make bills easier for customers to understand and manage.

5. We re working hard to cut back on time-consuming disclosures. One big success: The SBC | DISH Network disclosure has been reduced from an initial 165 seconds to 25 seconds. Customers are happier and reps are freed up to handle more calls.

ENTERPRISE MARKET

A **Long Time** Coming

Although it sometimes seemed we d never get there, the doors to the lucrative enterprise market (*big, big* companies and government) finally opened to SBC in 2004, and we wasted no time in pushing through. In just 12 months, we completed our network buildout, fielded a winning team, developed hundreds of processes and talked to thousands of potential customers.

And we achieved strong results. In 2004, the industry began to recognize SBC as a national player. We closed a $1 million contract every single day, while achieving CEE scores of 90-plus percent. And we ended the year with momentum.

Still, we remain a small fish in a very big pond and that doesn t sit well with SBC. Bob Ferguson, president and CEO-Enterprise Business Services, said, In anything we do, we want to be the market leader. Being a follower just doesn t cut it for us.

Unfortunately, he said, becoming a big fish is difficult. We have limitations that can t be overcome quickly, cheaply and with certainty. So we faced a choice: Continue growing steadily and organically, or do a transformational deal and speed our entry into the enterprise space.

That was one of the fundamental rationales for seeking to acquire AT&T. Ferguson said we learned a lot last year about why we win and why we don t win in the enterprise market. When we don t win contracts, it s nearly always for one or more of these reasons:

Product limitations.

Shortcomings in our ability to follow customers internationally.

Lack of infrastructure in some out-of-region locations.

AT&T will propel us beyond all of these limitations. Here s a look at how the two companies will complement each another in the enterprise market:

We have a large customer base. AT&T has a national and international brand already familiar to these customers.

SBC carries significant voice and data in the consumer segment. AT&T leads in the enterprise space. As the line between work and home life continues to erode, this becomes very significant.

We re a leader in small and medium business, and we re growing in large business. AT&T is established with the largest multinational corporations and government institutions.

We have extensive local broadband, and we re building that out in a big way with Project Lightspeed. AT&T brings a state-of-the-art national backbone. Combined, the possibilities are limited only by our imaginations.

Our local access network is dense in our 13 states. AT&T has mature national capabilities.

SBC s solid financial position will enable us to leverage the data and IP capabilities that AT&T brings. It takes investment to achieve efficiencies in IP and SBC is able to invest.

And finally, our wireless footprint and customer base as well as our experience in wireless open up tremendous possibilities.

The entire enterprise team is eager for the merger to close, Ferguson said, but for now, their sights are set on 2005. Our plan is to maintain the momentum and focus on the here and now. We will not be distracted. We have plans to deliver strong results for SBC again in 2005, and I m confident we ll succeed.

Project Lightspeed

Opens Up a U-verse of Opportunities

U-verse services will have unique functionalities and can be easily integrated with one another.

SBC is busy working at light speed to deliver the future of communications and home entertainment to our customers. Through Project Lightspeed, SBC expects to deploy fiber to an initial 18 million households by the end of 2007 reaching more than half of our footprint.

The fiber will dramatically expand the bandwidth available to homes in turn expanding our service offerings to include integrated next-generation television, super-high-speed Internet access and Voice over IP services.

The result: SBC will be able to offer customers a cutting-edge experience unmatched in the marketplace.

As our Project Lightspeed-enabled suite of IP-based products and services, the SBC U-verse experience will provide unique functionalities that can be easily integrated with one another.

For example, future versions of our IPTV product will enable customers to program their digital video recorder from their cell phone, get caller ID over their TV and watch multiple channels at the same time through PIP (picture-in-picture) capability. IPTV is also capable of delivering high-definition TV as well as a video store s worth of content.

Separate from our U-verse suite of services, we ll accelerate our move into the video market later this year with the rollout of our HomeZone set-top box, which integrates satellite TV programming, digital video recording, video on demand and Internet content, including Yahoo! Photos and music and ties them all together with the familiar and intuitive SBC Yahoo! user interface.

SBC plans to be the second-largest video provider in our fiber-served footprint within five years. We want to be the company that customers turn to first for innovative, integrated communications and entertainment solutions.

The SBC-AT&T Merger

Together, we are positioned to lead the communications revolution of the 21st century.

Complementary Strengths

Consumer customer base	National and international brand
Consumer voice and data traffic	Enterprise products and services portfolio
Small-, medium- and Large-business customer base	High-end enterprise and government customer base
Local broadband networks	National state-of-the-art network
Dense local access capabilities	Broad local access capabilities
Strong financial position	Data/IP capabilities
National wireless footprint and customer base	International service capabilities

With the AT&T acquisition, we are truly entering a new era as a new company. The combination creates the nation s premier communications company with unmatched global reach.

The $16 billion merger brings together two industry leaders with complementary values and strengths companies that share a 120-year tradition of customer service, innovation and reliability. By uniting, we will have the resources and skill sets to innovate and deliver to customers the next generation of advanced, integrated IP-based wireline and wireless communications services much faster.

As we go through the complex regulatory approval process and consistent with legal requirements, experts at SBC and AT&T are addressing the many issues raised by the proposed acquisition that we expect to be finalized late this year or early next year.

A lot of questions will be asked and decisions will be made in the coming months, but one thing is certain our company will grow stronger and our presence will grow broader, allowing us to maximize opportunities for SBC employees and increase customer and shareholder value.

IMPORTANT NOTE

In connection with the proposed transaction, SBC filed a registration statement, including a proxy statement of AT&T Corp., with the Securities and Exchange Commission (the SEC) on March 11, 2005 (File No. 333-123283). Investors are urged to read the registration and proxy statement (including all amendments and supplements to it) because it contains important information. Investors may obtain free copies of the registration and proxy statement, as well as other filings containing information about SBC and AT&T Corp., without charge, at the SEC s Internet site (www.sec.gov). These documents may also be obtained for free from SBC s Investor Relations web site (www.sbc.com/investor_relations) or by directing a request to SBC Communications Inc., Stockholder Services, 175 E. Houston, San Antonio, Texas 78205. Free copies of AT&T Corp. s filings may be accessed and downloaded for free at the AT&T Investor Relations Web Site (www.att.com/ir/sec) or by directing a request to AT&T Corp., Investor Relations, One AT&T Way, Bedminster, New Jersey 07921.

SBC, AT&T Corp. and their respective directors and executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies from AT&T shareholders in respect of the proposed transaction. Information regarding SBC s directors and executive officers is available in SBC s proxy statement for its 2005 annual meeting of stockholders, dated March 11, 2005, and information regarding AT&T Corp. s directors and executive officers is available in the registration and proxy statement. Additional information regarding the interests of such potential participants is included in the registration and proxy statement and other relevant documents filed with the SEC.

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Cautionary Language Concerning Forward-Looking Statements

Information set forth in this document contains financial estimates and other forward-looking statements that are subject to risks and uncertainties, and actual results might differ materially Such statements include, but are not limited to, statements about the benefits of the business combination transaction involving SBC and AT&T Corporation, including future financial and operating results, the new company s plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of SBC s and AT&T s management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the ability to obtain governmental approvals of the transaction on the proposed terms and schedule; the failure of AT&T shareholders to approve the transaction; the risk that the businesses will not be integrated successfully; the risk that the cost savings and any other synergies from the transaction may not be fully realized or may take longer to realize than expected; disruption from the transaction making it more difficult to maintain relationships with customers, employees or suppliers; competition and its effect on pricing, spending, third-party relationships and revenues. Additional factors that may affect future results are contained in SBC s filings with the Securities and Exchange Commission (SEC), which are available at the SEC s Web site http://www.sec.gov. SBC disclaims any obligation to update and revise statements contained in this presentation based on new information or otherwise.

This document may contain certain non-GAAP financial measures. Reconciliations between the non-GAAP financial measures and the GAAP financial measures are available on SBC s Web site at www.sbc.com/investor_relations.

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vitaMedMD Plus

vitaMedMD Plus is a once-daily, two pill combo pack that contains a complete multivitamin with 16 essential vitamins and minerals and 300 mg of plant based docosohexaenoic acid, or DHA, and is vegan and Kosher certified.

vitaMedMD One Prenatal Multivitamin

vitaMedMD One is a single-dose daily multivitamin that provides 14 vitamins and minerals and 200 mg of plant-based DHA. Each convenient, easy-to-swallow softgel features 975 mcg of folic acid.

vitaMedMD Plus Rx Prenatal Multivitamin

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

vitaMedMD One Rx Prenatal Multivitamin

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

vitaMedMD RediChew® Rx Prenatal Multivitamin

vitaMedMD RediChew® Rx is a prescription, easy-to-chew, small, vanilla-flavored tablet containing Quatrefolic®, vitamin D3, vitamin B2, vitamin B6 and vitamin B12. We believe *vitaMedMD RediChew Rx* is an excellent option for women who have difficulty swallowing tablets or softgels, or are experiencing nausea and morning sickness.

vitaMedMD Iron 21/7

vitaMedMD Iron 21/7 is an iron replacement supplement with a three weeks-on/one 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

vitaMedMD Menopause Relief 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.

BocaGreenMD Prena1 Pearl

BocaGreenMD Prena1 Pearl is our newest prescription product and a complete prenatal vitamin in one tiny pearl. vitaPearl provides 40% more folic acid than the leading prescription prenatal vitamin. vitaPearl delivers 14 key vitamins and minerals plus 200 mg of DHA, providing comprehensive support for a women and her body whether she is planning a pregnancy, pregnant, or nursing.

BocaGreenMD Prena1 Chew

BocaGreenMD Prena1 Chew is a prescription, single daily easy-to-chew, vanilla-flavored 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.

Our Hormone Therapy Drug Candidates

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

TX-001HR

TX-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness, for post-menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman’s body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone bioidentical to the estradiol and progesterone produced by the ovaries, would be approved for use in a single combined product.

On September 5, 2013, we initiated the REPLENISH trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of

TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. We intend to enroll approximately 1,750 patients at approximately 100 sites. We currently anticipate that enrollment in the REPLENISH Trial will be completed in the first-half of 2015 and that results of the trial will be reported in the middle of 2016. Based on such timeline and successful reports of the trial, we would anticipate filing a New Drug Application, or NDA, for TX-001HR during the first-half of 2016 and that such NDA would be approved by the FDA during the first-half of 2017.

We previously conducted a PK study of TX-001HR to demonstrate that our drug candidate is bioequivalent to the reference listed drug based on the criterion that the 90% confidence interval on the test-to-reference ratio is contained entirely within the interval 80% to 125%. The study compared our combined capsule TX-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-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 that the 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-001HR and Prometrium® in 62 female test subjects. When the results were compared over 48 hours of the test that the 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-001HR to Estrace® and Prometrium® based on the criteria for demonstrating bioequivalence established in connection with the study. On September 5, 2013, we began enrollment of the REPLENISH trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. We intend to enroll approximately 1,750 patients at approximately 100 sites. We currently anticipate that enrollment in the REPLENISH Trial will be complete in 2015 and that results of the trial will be reported in 2016.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman’s body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages.

In January 2014, we began recruitment of patients in the SPRY trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY trial encountered enrollment challenges because of Institutional Review Board, or IRB, approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we temporarily suspended enrollment and in October 2014 we stopped the SPRY trial in order to update the phase 3 protocol based on discussions with the FDA. We intend to update the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if approved by the FDA, will allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol that we intend to propose.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate would be chemically identical to the hormones that naturally occur in a woman’s body. We currently do not have plans to further develop this hormone therapy drug candidate.

TX-004HR

TX-004HR is a vaginal suppository estradiol drug candidate for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure, inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments.

We initiated the REJOICE trial, a multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. We are conducting a single 12 week study, evaluating three different doses of estradiol: 4 mcg, 10 mcg and 25 mcg versus placebo. The FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level. The study has been designed to include four primary endpoints: the reduction of vaginal pH levels to less than 5.0, an increase in superficial cells, a decrease in parabasal cells and the improvement of dyspareunia. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The trial is designed to enroll approximately 700 patients across approximately 100 sites. We currently anticipate that enrollment in the REJOICE trial will be complete during the second quarter of 2015 and that results of the trial will be reported during the third quarter of 2015. Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-004HR during the fourth quarter of 2015 and that such NDA would be approved by the FDA during the fourth quarter of 2016.

In August 2013, we initiated a phase 2 clinical trial for VVA, designed to measure the effect of TX-004HR on certain clinical endpoints, including a study candidate’s pH levels, vaginal cytology, and most bothersome symptom of VVA, out of the symptoms identified in FDA guidance. Based upon our phase 2 results, we believe we have a rapidly acting product that differs substantially from the reference listed drug Vagifem® sold by Novo Nordisk.

Preclinical Development

Based upon leveraging our hormone platform technology, we have seven preclinical projects that include development of our proposed progesterone-alone and combination estradiol and progesterone products in a topical cream and transdermal patch form, which we refer to as TX-005HR and TX-006HR, respectively, and transdermal patch form, which we refer to as TX-007HR and TX-008HR, respectively. We recently completed a pilot pharmacokinetic, or PK, study of TX-005HR in eight patients that tested the topical administration on the upper arm of 50 mcg of estradiol and 25 mg of progesterone. The results of the PK study suggest that topical formulations of estradiol and progesterone may be possible using our proprietary solubilized forms of the compounds. We intend to file an IND with respect to TX-005HR and TX-006HR during the second half of 2015 and then commence phase 1 clinical trials. We may in the future engage with a financing partner to advance our topical cream and transdermal patch projects. We are also evaluating various other indications for our hormone technology, including oral contraception, treatment of preterm birth, and premature ovarian failure. According to Symphony Health Solutions, the total FDA-approved menopause-related market for estrogen alone and in combination was approximately $3.7 billion in U.S. sales for the 12 months ended December 31, 2014.

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-up 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 prescription and/or recommendation of our products for the benefit of the 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 in their respective markets. By delivering additional products through the same sales channel, we believe we can leverage our already deployed assets to increase our sales and achieve profitability. We intend to leverage and grow our current marketing and sales organization to commercialize our drug candidates in the United States assuming the successful completion of the FDA regulatory process.

Online Commerce

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

Retail Commerce

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

Competition

Pharmaceutical Industry

The pharmaceutical industry is subject to intense competition and is characterized by extensive research efforts and rapid technological change. Competition in our industry occurs in a variety of areas, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost, and developing new products to provide benefits superior to those of existing products. Most major pharmaceutical companies, as well as numerous specialty pharmaceutical companies, sell products in the women’s health sector of the pharmaceutical industry, which is

comprised of products designed for post-pubescent females and is generally considered very fragmented. There are many companies focused on the women's health sector of the pharmaceutical industry that have significantly greater financial and other resources than we do, including generic manufacturers, drug compounding pharmacies, and large pharmaceutical companies. In addition, academic and other research institutions could be engaged in research and development efforts for the indications targeted by our products.

Hormone Therapy Market

The menopause hormone therapy market includes two major components: an FDA-approved drug market and a non-FDA approved drug market supplied by compounding pharmacies. On November 27, 2013, the Drug Quality and Security Act became law and the FDA was given additional oversight over compounding pharmacies. We believe FDA-approved products are easily measured and monitored, while non-FDA approved hormone therapy drug products, typically referred to as bioidenticals, when produced and sold by compounding pharmacies, are not easily measured or monitored. Our phase 3 clinical trials are intended to establish an indication of the safety and efficacy of our bioidentical drug candidates at specific dosage levels. We intend our hormone therapy drug candidates, if approved by the FDA, to provide hormone therapies with well characterized safety and efficacy profiles that can be consistently manufactured to target specifications. This would provide an alternative to the non-FDA approved compounded bioidentical market. This aim is based on our belief that our drug candidates will offer advantages in terms of demonstrated safety and efficacy consistency in the hormone dose, lower patient cost as a result of insurance coverage and improved access as a result of availability from major retail pharmacy chains rather than custom order or formulation by individual compounders.

TX-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause. The combination of estradiol and progesterone for the treatment of moderate to severe vasomotor symptoms due to menopause for postmenopausal women with an intact uterus is comprised of two components: the FDA-approved drug market and the non-FDA-approved compounded drug market. According to the PHAST Prescription Monthly by Symphony Health Solutions, the U.S. FDA-approved market for menopause-related combination estradiol and progesterone was approximately $659 million for the 12 months ended December 31, 2014. The largest competitors in the FDA-approved market are PREMARIN cream (Pfizer), generic estradiol and progestins (TEVA), FemHRT (Warner Chilcott), Angeliq (Bayer), and Activella (Novo Nordisk), with sales of PREMARIN cream constituting a majority of such sales. None of the current FDA-approved drugs for the treatment of moderate to severe vasomotor symptoms due to menopause is bioidentical to the estradiol and progesterone produced by the ovaries. Based on various reports, included data recently presented at the North American Menopause Society, including Knowledge, Use, and Prescribing of Custom-Compounded Bioidentical Hormones for Menopausal Women: It’s Not What You Think, by JoAnn V. Pinkerton, et al., we estimate that U.S. sales of non-FDA -approved compounded combination estradiol and progesterone products approximate $1.5 billion per year. The market for non-FDA -approved compounded hormone therapy products is generally considered very fragmented because the products are prepared and sold by individual compounding pharmacies. We believe that TX-001HR, if approved by the FDA, would represent the first time a bioidentical combination product of estradiol and progesterone would be approved for use in a single combined product.

TX-002HR, our progesterone only drug candidate, is for the treatment of secondary amenorrhea. According to PHAST Prescription Monthly by Symphony Health Solutions, the U.S. progesterone alone oral market for 2014 was approximately $400 million. The largest competitors in the progestin alone oral market are Aygestin tablets (TEVA), Provera tablets (Pfizer), and Prometrium capsules (AbbVie). We believe that TX-002HR, if approved by the FDA, would provide for treatment of secondary amenorrhea without the potentially allergenic component of peanut oil found in existing products.

TX-004HR, our vaginal suppository estradiol drug candidate, is undergoing clinical trials for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. According to the PHAST Prescription Monthly by Symphony Health Solutions, the U.S. market for vaginal suppository estradiol for the treatment of VVA in post-menopausal women was approximately $1.3 billion for the 12 months ended December 31, 2014. Approximately $1.15 billion of such sales were by three products currently on the market: PREMARIN cream (Pfizer), ESTRACE cream (Warner Chilcott), and Vagifem tablets (Novo Nordisk). We believe that TX-004HR, if approved by the FDA, will be at least as effective as the existing treatments for VVA because of an early onset of action with less systemic exposure inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments.

Prenatal Vitamin Market

The prenatal vitamin market is highly fragmented, with dozens of companies selling hundreds of competitive products. Prenatal vitamin products are marketed as either OTC products or prescription products, with many

companies marketing their products through both channels. According to Symphony Health Solutions' PHAST 2.0 Report, during the 12 months ended December 31, 2014, approximately 8.2 million prescriptions for prenatal vitamins were issued in the United States resulting in total sales of approximately $399 million. 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. We estimate that the U.S. OTC prenatal vitamin market is approximately $800 million a year.

Seasonality

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

Products in Development

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

Raw Materials for Our Products

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

Availability of and Dependence Upon Suppliers

We currently obtain approximately 97% of our vitaMedMD and BocaGreenMD products from Lang Pharma Nutrition, or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars, and functional foods in the dietary supplement category. As a result, we are dependent on Lang and its subcontractors 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 the FDA's current Good Manufacturing Practice, or cGMPs, for dietary supplements. In addition, we employ an outside third party to enforce rigorous quality audits.

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

We use third-party manufacturers to source key raw materials and manufacture and package our products. The FDA must approve the manufacturing facility for compliance with the FDA's cGMP regulations before 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 hormone therapy drug candidates.

Quality Control for our Products

A quality assurance team establishes process controls and documents and tests every stage of the manufacturing process to ensure we meet product specifications and that our finished products 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 prenatal vitamins to patients through their pharmacies. Since the launch of our prescription products, in addition to third-party logistics providers, we use some of the same national and regional distributors as other pharmaceutical companies, including Cardinal, McKesson, AmerisourceBergen, H.D. Smith, and Smith Drug. Wholesaler product inventory is monitored daily and sales out is monitored weekly. National and regional retail chain pharmacies are also an area of focus to make sure our products are purchased and dispensed properly. We sell our OTC products directly to consumers via our website and phone sales and the products are shipped directly from us to the consumer's home or office. In a few instances, we sell OTC product to physicians who then sell the products directly to their patients.

Customer Service

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

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

Our Return Policy

We sell our prescription products through third-party logistics providers, major distributors, and pharmacies, all of whom may return a product within six months prior to or up to 12 months after the expiration date of the product. Once customers buy a product from the pharmacy, the product may not be returned. Customers may return or exchange our non-prescription products for any reason by returning the product within 30 days of receipt. We will refund the entire purchase price, less shipping. The customer is responsible for the cost of returning the products to us, except in cases in which the product is being returned because of a defect or an error made in our order fulfillment. If the purchased product exceeded a 30-day supply, the unused product must be returned to receive the full refund. All unopened OTC products may be exchanged for different products; the customer will be responsible for the difference in price if the replacement product is more expensive or we will refund the difference if the replacement product is less expensive.

Our Quality Guarantee

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

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

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

Research and Development

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

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

Our research and development expenses were $43.2 million in 2014, $13.6 million in 2013, and $4.5 million in 2012.

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 developed hormone products using our SYMBODA® platform, which is our advanced hormone therapy platform to enable delivery of bio-identical hormones through a variety of dosage forms and administrative routes.

In addition to numerous pending patent applications, as of December 31, 2014, we had four issued patents, including:

- one method patent that relates to our OPERA® information technology platform, which is owned by us and is a U.S. jurisdiction patent with an expiration date in 2029; and

- three utility patents that relate to our combination progesterone and estradiol formulations, which is owned by us and is a U.S. jurisdiction patent with expiration date in 2032. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Brazil, Canada, Europe, Japan, Mexico, Russia, South Africa and South Korea.

Subsequent to December 31, 2014, one additional patent was issued related to our combination progesterone and estradiol formulations, which are owned by us and are U.S. jurisdiction patents with an expiration date in 2032.

As of December 31, 2014, we had filed 24 non-provisional and 13 provisional patent applications with the U.S. Patent and Trademark Office, or the USPTO, with respect to our hormone therapy drug candidates, and 55 international patent applications with respect to our hormone therapy drug candidates.

We hold multiple U.S. trademark registrations and have numerous pending trademark applications. Issuance of a federally registered trademark creates a rebuttable presumption of ownership of the mark; however, it is subject to challenge by others claiming first use in the mark in some or all of the areas in which it is used. Federally registered trademarks have a perpetual life as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We believe our patents and trademarks are valuable and provide us certain benefits in marketing our products.

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

OPERA® is our patented information technology platform used in our business. We believe the deployment of OPERA® and the further development and deployment of related technology creates a sustainable competitive advantage in clinical development and product improvement.

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

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

Government Regulation

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

Pharmaceutical Regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

505(b)(2) Applications

We intend to submit NDAs for our hormone therapy drug candidates, assuming that the clinical data justify submission, under section 505(b)(2) of the FDCA, or Section 505(b)(2). Section 505(b)(2) permits the filing of an

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

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

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

Marketing Exclusivity

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

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

Dietary Supplement Regulation

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

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

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

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

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

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

In June 2007, pursuant to the authority granted by the FDCA as amended by DSHEA, the FDA published detailed cGMP regulations that govern the manufacturing, packaging, labeling, and holding operations of dietary supplement manufacturers. The cGMP regulations, among other things, impose significant recordkeeping requirements on manufacturers. The cGMP requirements are in effect for all manufacturers, and the FDA is conducting inspections of dietary supplement manufacturers pursuant to these requirements. There remains considerable uncertainty with respect to the FDA’s interpretation of the regulations and their actual implementation in manufacturing facilities. In addition, the FDA’s interpretation of the regulations will likely change over time as the agency becomes more familiar with the industry and the regulations. The failure of a manufacturing facility to comply with the cGMP regulations renders products manufactured in such facility “adulterated,” and subjects such products and the manufacturer to a variety of potential FDA enforcement actions. In addition, under the Food Safety Modernization Act, or FSMA, which was enacted on January 4, 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.

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

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

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

Other U.S. Health Care Laws and Compliance Requirements

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

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

- The Ethics in Patient Referrals Act of 1989, 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, and authorizes civil actions by the government and also by whistleblowers or qui tam relators, against individuals or entities for knowingly presenting, or causing to be presented, 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, as amended, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

- The federal False Statement Act which prohibits knowingly making a material false statement in connection with a matter within the jurisdiction of the federal government and the Health Care False Statements Act which prohibits false statements in connection with the delivery of or payment for healthcare items or services, even if unconnected to the federal government.

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

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

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

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

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

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

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

Employees

As of December 31, 2014, we had 100 full-time employees, five of whom are executive officers. Additionally, from time to time, we hire temporary contract employees. None of our employees are covered by a collective bargaining agreement, and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike, or dispute. We consider our relationship with our employees to be good.

Our History

On October 3, 2011, we changed our name to TherapeuticsMD, Inc. On October 4, 2011, we closed a reverse merger with VitaMedMD, LLC, pursuant to which (1) all outstanding membership units of VitaMed were exchanged for shares of our common stock, (2) all outstanding VitaMed options and warrants were exchanged and converted into options and warrants to purchase shares of our common stock, and (3) VitaMed became our wholly owned subsidiary. As of December 31, 2011, we determined that VitaMed would become the sole focus of our company and services previously performed relative to the licensing agreement discussed in the following paragraph were discontinued.

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

Available Information

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

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

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

Risk Factors

Item 1A. Risk Factors

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

Risks Related to Our Business

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

We have incurred recurring net losses, including net losses of $54 million, $28 million, and $35 million for the years ended December 31, 2014, 2013, and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of approximately $135 million. We have generated limited revenue and have funded our operations to date primarily from public and private sales of equity and private sales of debt securities. We expect to incur substantial additional losses over the next several years as our research, development, and clinical trial activities increase, especially those related to our hormone therapy drug candidates. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our hormone therapy drug candidates. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our 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.

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

We currently derive all of our revenue from sales of women's health care products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, and natural menopause relief. While sales of our vitamin products grew from 2010 through 2014, 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 prenatal vitamin products;
- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;
- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in health care laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal health care programs;
- the impact or efficacy of any price increases we may implement in the future;
- changes to our label and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

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

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

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

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

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

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

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

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

- license, potentially on unfavorable terms, our rights to our hormone therapy drug candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

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

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

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

Three hormone therapy drug candidates are currently in various stages of clinical testing. We have begun phase 3 clinical trial of our estradiol and progesterone combination drug candidate, our progesterone alone drug candidate and our vaginal suppository estradiol drug candidate. Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. For example, we recently temporarily suspended enrollment in and subsequently stopped the SPRY trial for our progesterone alone drug candidate in order to update the phase 3 protocol based on discussions with the FDA. 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. Prior to approving a new drug, the FDA generally requires that the safety and efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations the FDA approves drugs on the basis of a single well-controlled clinical trial. We believe we may be required to conduct only a single phase 3 clinical trial of each of our estradiol and progesterone combination drug candidate, our progesterone alone drug candidate and our vaginal suppository estradiol drug candidate for the treatment of VVA. However, in connection with our VVA drug candidate, the FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level, and that a trial that is merely statistically significant may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial. If clinical trials for any of our hormone therapy drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

We typically engage one or more CROs on a project-by-project basis for each study or trial. While we have developed and plan to maintain our relationships with CROs that we have previously engaged, we also expect to enter into agreements with other CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to on-going clinical programs and, specifically, the compilation of clinical trial data for submission with an NDA for each of our hormone therapy drug candidates. If any of our relationships with these third parties terminate,

we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. Although we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations, or prospects.

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

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

In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit, or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. For example, in the past the FDA has indicated it would regulate prenatal vitamins containing greater than 0.8 mg of folic acid as a drug under the FDCA. More recently the FDA indicated that there is no specified upper limit on the amount of folic acid permitted in a dietary supplement. If the FDA were to seek to regulate products with higher amounts of folic acid as drugs, it may require us to stop selling certain of our dietary supplement products and otherwise adversely affect our business. If we are slow or unable to adapt to any such changes, our business, prospects, and ability to achieve or sustain profitability would be adversely affected.

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

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

voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our hormone therapy drug candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

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

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

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;

- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or

- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

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

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

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture our existing women's health care products. For example, we depend on Lang, 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, to supply approximately 97% of our vitaMedMD and BocaGreen products. In certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells. We also rely on third-party contract manufacturing organizations, or CMOs to supply our hormone therapy drug candidates for use in the conduct of our clinical trials. We rely on these third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We do not have long-term contracts for the commercial supply of our products or our hormone therapy drug candidates. We intend to pursue long-term manufacturing agreements, but we may not be able to negotiate such agreements on acceptable terms, if at all.

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

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

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

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

- the clinical indications for which our hormone therapy drug candidates are approved, if at all;

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

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

- prevalence and severity of adverse side effects.

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

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

Development and awareness of our brand will depend largely upon our success in increasing our customer base. The dietary supplement and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our products, including any hormone therapy drug candidates that are approved, face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. A new non-hormonal product, Brisdelle, produced by Noven Pharmaceuticals, was approved by the FDA for treatment of vasomotor symptoms in June 2013. 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.

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

Market acceptance and sales of our products, including any hormone therapy drug candidates, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities

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

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

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

On March 4, 2015, the U.S. Supreme Court heard oral arguments in *King v. Burwell* where the Supreme Court has been asked to decide the validity an IRS regulation paying subsidies, in the form of federal tax credits, to individuals who meet certain income guidelines, but who reside in states that have elected to use the federal government's insurance exchange rather than establishing one of their own. Those challenging the IRS regulation have argued that federal subsidies are only available to those residing in states that have established their own insurance exchanges. Should the Supreme Court rule against the government, that could have adverse implications for most health care providers, including companies manufacturing prescription drugs and other products covered by health insurance under the PPACA.

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

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

We face an inherent risk of product liability claims as a result of the marketing of our current products and the clinical testing of our hormone therapy drug candidates despite obtaining appropriate informed consents from our clinical trial participants, and, in light of the history of product liability claims related to other hormone replacement therapy products, we will face an even greater risk if we obtain FDA approval and commercialize our hormone therapy drug candidates in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failures to warn of dangers inherent in the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we

may incur substantial liabilities or be required to limit commercialization of our existing products or hormone therapy drug candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

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

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

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

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

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

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

applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which adversely affect our business, financial condition, results of operations, and prospects.

We are subject to extensive and costly government regulation.

The products we currently market, including the vitamins, and 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, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

commercialize drug candidates will be limited.

Our success is tied to our distribution channels.

We sell our prescription prenatal vitamin 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 75% of our product shipments since inception were to only four customers. 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 ability to utilize net operating loss carryforwards may be limited.

As of December 31, 2014, we had net operating loss carryforwards, or NOLs, of approximately $105.5 million available to offset future taxable income through 2034. These NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce or eliminate our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended, imposes limitations on a corporation's ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percent over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of our common stock in the future. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382, which may result in expiration of a portion of our NOLs before utilization.

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

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

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

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

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

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

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

As of December 31, 2014, we had 100 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our hormone therapy drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

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

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

Risks Related to our Intellectual Property

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

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

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

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

These risks include the possibility of the following:

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

While we apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if

issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our hormone therapy drug candidates. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the USPTO or foreign patent regulatory authorities to determine our rights in the technologies, which may be time-consuming and expensive. Moreover, issued patents may be challenged during in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

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

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

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

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

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

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

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

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

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

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

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

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

We intend to submit NDAs for our hormone therapy drug candidates, assuming that the clinical data justify submission, under Section 505(b)(2), which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. 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. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

If we cannot certify that all of the patents listed in the Orange Book for the approved products referenced in the NDAs for each of our hormone therapy drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA's Orange Book for approved products referenced in the NDAs for each of our hormone therapy drug candidates could have a serious and significant adverse effect on the timing for obtaining approval of our hormone therapy drug candidates. For example, at least one approved product that may be referenced in our 505(b)(2) application as a reference product for our vaginal suppository estradiol product currently lists unexpired patents in the Orange Book.

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- any delay of our phase 3 clinical trials for our hormone therapy drug candidates;
- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our hormone therapy drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our hormone therapy drug candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;

- the inability to obtain adequate clinical supply for our hormone therapy drug candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners' commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;

- sales of our common stock by us or our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;
- increases in our common stock available for sale upon expiration of lock-up agreements;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

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

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

At December 31, 2014, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 61.1% of our common stock on an as converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. In addition, pursuant to a Securities Purchase Agreement dated September 26, 2012, we granted certain of our stockholders the right, expiring in October 2015, if they elect, to purchase on the same terms as in any offering of our common stock, a number of shares of common stock that is sufficient to maintain their respective pro rata ownership percentage of our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. **Properties**

Our corporate headquarters is located in Boca Raton, Florida, where we lease 17,686 square feet of office space pursuant to a 63 month non-cancelable operating lease that commenced on July 1, 2013, was amended on February 18, 2015, and expires on September 30, 2018. The primary functions performed at this location are executive, administrative, accounting, treasury, marketing, and human resources.

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information on Common Stock

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

	High	Low
2014		
Fourth Quarter	$4.95	$3.44
Third Quarter	$6.29	$3.88
Second Quarter	$6.35	$3.42
First Quarter	$9.01	$4.86
2013		
Fourth Quarter	$5.50	$2.86
Third Quarter	$3.18	$2.03
Second Quarter	$3.23	$1.73
First Quarter	$3.70	$1.65

On March 6, 2015, there were approximately 277 shareholders of record and on February 23, 2015, there were approximately 6,965 beneficial owners of our common stock.

Dividends

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

Performance Graph

The following line graph compares cumulative total shareholder return for the five years ended December 31, 2014 for (i) our common stock; (ii) NASDAQ Stock Market (US Companies); (iii) NASDAQ Pharmaceutical Index; and (iv) Peer Group (includes: Acorda Therapeutics, Inc., AMAG Pharmaceuticals, Inc., Arena Pharmaceuticals, Inc., Dendreon Corporation, Dyax Corporation, Exelixis, Inc., Halozyme Therapeutics, Inc., Orexigen Therapeutics, Ind., Spectrium Pharmaceuticals, Inc., and VIVUS Inc.) does not include the following companies that were included in the prior year's performance graph: Amarillo Biosciences Inc., which filed for bankruptcy protection in October 2013, Avanir Pharmaceuticals, Inc., which entered into an agreement and plan of merger to be acquired in December 2014 and was acquired in January 2015, and Cadence Pharmaceuticals Inc., which was acquired in March 2014. The graph assumes $100 invested on December 31, 2009 and includes reinvestment of dividends. Measurement points are at the last trading day of the fiscal years ended December 31, 2009, 2010, 2011, 2012, 2013 and 2014. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

The following line graph compares cumulative total shareholder return for the period beginning when our common stock became listed on the NYSE MKT exchange (April 23, 2013) and ended December 31, 2014 for (i) our common stock; (ii) NASDAQ Stock Market (US Companies); (iii) NASDAQ Pharmaceutical Index; and (iv) our Peer Group (includes: Acorda Therapeutics, Inc., AMAG Pharmaceuticals, Inc., Arena Pharmaceuticals, Inc., Dendreon Corporation, Dyax Corporation, Exelixis, Inc., Halozyme Therapeutics, Inc., Orexigen Therapeutics, Ind., Spectrium Pharmaceuticals, Inc., and VIVUS Inc.) does not include the following companies that were included in the prior year's performance graph: Amarillo Biosciences Inc., which filed for bankruptcy protection in October 2013, Avanir Pharmaceuticals, Inc., which entered into an agreement and plan of merger to be acquired in December 2014 and was acquired in January 2015, and Cadence Pharmaceuticals Inc., which was acquired in March 2014. The graph assumes $100 invested on April 23, 2013 and includes reinvestment of dividends. Measurement points are April 23, 2013 and the last trading day of the fiscal years ended December 31, 2014 and 2013 and each of the following quarters ended therein beginning with the quarter ended June 30, 2013. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial and other data as of and for the periods indicated. You should read the following information together with the more detailed information contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this Annual Report. The consolidated statements of operations for the years ended December 31, 2014, 2013, and 2012, and the consolidated balance sheet data as of December 31, 2014, and 2013 are derived from our audited consolidated financial statements included in this Annual Report. The consolidated statements of operations for the years ended December 31, 2011 and 2010, and the consolidated balance sheet data as of December 31, 2012, 2011, and 2010, are derived from our audited consolidated financial statements not included in this Annual Report, as well as the audited consolidated financial statements of VitaMed, our predecessor, not included in this Annual Report.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

(in thousands, except per share data)

	Year Ended December 31,				
	2014	2013	2012	2011	2010 (Restated)
Consolidated Statements of Operations Data:					
Revenue, net	$15,026	$8,776	$3,818	$2,088	$1,242
Cost of goods sold	3,672	1,960	1,348	947	556
Gross profit	11,354	6,816	2,470	1,141	686
Operating expenses:					
Sales, general, and administration	22,124	19,015	14,070	6,406	3,465
Research and development	43,219	13,551	4,492	107	65
Depreciation and amortization	52	58	56	55	23
Total operating expense	65,395	32,624	18,618	6,568	3,553
Operating loss	(54,041)	(25,808)	(16,148)	(5,427)	(2,867)
Other (expense) income	(176)	(2,611)	(18,972)	(7,486)	
Net loss	$(54,217)	$(28,419)	$(35,120)	$(12,913)	$(2,867)
Net loss per share, basic and diluted	$(0.36)	$(0.22)	$(0.38)	$(0.21)	$(0.07)
Weighted average number of common shares outstanding	149,727	127,570	91,630	62,516	38,289
Consolidated Balance Sheet Data (at end of period)					
Total assets	$59,079	$62,016	$5,926	$1,439	$1,197
Total liabilities	$10,690	$7,318	$7,359	$3,151	$233
Total stockholder' surplus (deficit)	$48,389	$54,698	$(1,433)	$(1,712)	$964
Other Data:					
Capital expenditures	$617	$480	$273	$38	$27
Working Capital (deficit)(end of period)	$45,545	$52,085	$1,015	$(1,914)	$826

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

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

Company Overview

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

Research and Development – Overview

We have obtained FDA acceptance of our IND applications to conduct clinical trials for four of our hormone therapy drug candidates: TX-001HR, our oral combination of progesterone and estradiol; TX-002HR, our oral progesterone alone; TX-003HR, our oral estradiol alone; and TX-004HR, our vaginal suppository estradiol alone.

We are currently conducting phase 3 clinical trials for TX-001HR and TX-004HR. In July 2014, we suspended enrollment in the phase 3 clinical trial for TX-002HR and in October 2014 we temporarily stopped the trial in order to update the phase 3 protocol based on discussions with the FDA. We have no current plans to conduct clinical trials for TX-003HR.

TX-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats, sleep disturbances, and vaginal dryness for post-menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman's body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone (bioidentical to the estradiol and progesterone produced by the ovaries) would be approved for use in a single combined product.

On September 5, 2013, we initiated the REPLENISH trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, six months and 12 months. We intend to enroll approximately 1,750 patients at approximately 100 sites. We currently anticipate that enrollment in the REPLENISH Trial will be completed in the first half of 2015 and that results of the trial will be reported in the first half of 2016.

Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-001HR during the first-half of 2016 and that such NDA would be approved by the FDA during the first-half of 2017.

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman's body. We believe it will be similarly effective to traditional treatments, but may demonstrate efficacy at lower dosages. In January 2014, we began recruitment of patients in the SPRY trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY trial encountered enrollment challenges because of IRB approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we temporarily suspended enrollment, and in October 2014 we stopped the SPRY trial in order to update the phase 3 protocol based on discussions with the FDA. We intend to update the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if approved by the FDA, will allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol that we intend to propose.

TX-004HR is a vaginal suppository estradiol drug candidate for the treatment of VVA in post-menopausal women with vaginal linings that do not receive enough estrogen. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. We initiated the REJOICE trial, a multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. We are conducting a single 12 week study, evaluating three different doses of estradiol: 4 mcg, 10 mcg and 25 mcg versus placebo. The FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level. The study has been designed to include four primary endpoints: the reduction of vaginal pH levels to less than 5.0, an increase in superficial cells, a decrease in parabasal cells and the improvement of dyspareunia. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The trial is designed to enroll approximately 700 patients across approximately 100 sites. We currently anticipate that enrollment in the REJOICE trial will be complete during the second quarter of 2015 and that results of the trial will be reported during the third quarter of 2015. Based on such timeline and successful reports of the trial, we would anticipate filing an NDA for TX-004HR during the fourth quarter of 2015 and that such NDA would be approved by the FDA during the fourth quarter of 2016.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug products. Our business model is dependent upon our company continuing to conduct a significant amount of research and development. Until one of our drug products receives IND approval from the FDA, products costs are listed as “Other Research and Development” costs in the accompanying condensed consolidated financial statements. Our research and development expenses consist primarily of expenses incurred under agreements with CROs, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; employee-related expenses, which include salaries and benefits, and non-cash share-based compensation; the cost of developing our

chemistry, manufacturing and controls capabilities, and acquiring clinical trial materials; and costs associated with other research activities and regulatory approvals.

We make payments to the CROs based on agreed upon terms that 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. Advance payments to be expensed in future research and development activities were $1,175,082 and $2,606,405, at December 31, 2014 and December 31, 2013, respectively.

The following table indicates our research and development expense by project/category for the periods indicated (in thousands):

	Year Ended December 31, (000s)	
	2014	2013
TX-001HR	26,123	4,809
TX-002HR	1,443	1,059
TX-004HR	3,984	—
Other research and development	11,669	7,683
Total research and development	$43,219	$13,551

Research and development expenditures will continue to be significant as we continue development of our drug candidates and advance the development of our proprietary pipeline of novel drug candidates. We expect to incur significant research and development costs as we develop our drug pipeline, complete the ongoing clinical trials of our drug candidates, conduct our planned phase 3 clinical trials, subject to receiving input from regulatory authorities, and prepare regulatory submissions.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include, but are not limited to, the following: per patient trial costs, the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial, the duration of patient follow-up; and the efficacy and safety profile of the drug candidate. We base our expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties.

Results of Operations

Comparison of Years Ended December 31, 2014, 2013, and 2012:

Year ended December 31, 2014 compared with year ended December 31, 2013

	Year Ended December 31,		
	2014	2013	Change
	(000s)		
Revenue	$15,026	$8,776	6,250
Cost of goods sold	3,672	1,960	1,712
Operating expenses	65,395	32,624	32,771
Operating loss	(54,041)	(25,808)	(28,233)
Financing Costs	(260)	(1,504)	1,244
Interest expense	—	(1,166)	1,166
Other income (expense) net	84	59	25
Net loss	$(54,217)	$(28,419)	$(25,798)

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Revenue

Revenue for year ended December 31, 2014 increased by approximately $6,250,000, or 71%, to approximately $15,026,000, compared with approximately $8,776,000 for the year ended December 31, 2013. Of this $6,250,000, approximately $2,003,494, or 32%, was attributable to an increase in the average sales price of our existing products, and approximately $4,247,127, or 68%, was attributable to sales of new products introduced during the year ended December 31, 2014.

Cost of Goods Sold

Cost of goods sold increased by approximately $1,712,000, or 87%, to approximately $3,672,000 for the year ended December 31, 2014, compared with approximately $1,960,000 for the year ended December 31, 2013. Our gross margins decreased to approximately 76% for the year ended December 31, 2014, compared to approximately 78% for the year ended December 31, 2013. The gross margin change was primarily attributable to increases in distribution related costs.

Operating Expenses

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

	Year Ended December 31,	
	2014	2013
Human resource related costs	16%	33%
Sales and marketing costs, excluding human resource costs	9 %	15%
Product research and development costs	66%	41%
Professional fees and consulting costs	4 %	4 %
Other operating expenses	5 %	7 %

Operating expenses increased by approximately $32,771,000, or 100%, to approximately $65,395,000 for the year ended December 31, 2014, compared with approximately $32,624,000 for year ended December 31, 2013, as a result of the following items:

	(000s)
Increase in product research and development costs	$29,668
Increase in human resource related costs	509
Increase in sales and marketing, excluding human resource costs	702
Increase in professional and consulting costs	852
Increase in all other operating expenses	1,040
	$32,771

Research and development costs for the year ended December 31, 2014 increased by approximately $29,668,000, or 219%, to approximately $43,219,000, primarily as a result of the continuing phase 3 clinical trial of TX-001HR, the partial year phase 3 clinical trial for TX-002HR, and phase 1 and partial year phase 3 clinical trial for TX-004HR. Research and developments costs during the year ended December 31, 2014 included the following research and development projects:

During the year ended December 31, 2014 and the period February 2013 (project inception) through December 31, 2014, we have incurred approximately $26,123,000 and $30,932,000, respectively, in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

During the year ended December 31, 2014 and the period April 2013 (project inception) through December 31, 2014, we have incurred approximately $1,443,000 and $2,502,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the year ended December 31, 2014 and since the project’s inception in August 2014, we have incurred approximately $3,984,000 in research and development costs with respect to TX-004HR, our vaginal suppository estradiol drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see “Item 1. Business — Research and Development.” For a discussion of the risks and uncertainties associated with completing development of our products, see “Item 1A. Risk Factors — Risks Related to Our Business.” For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see “— Liquidity and Capital Resources.” For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see “Item 1. Business — Our Hormone Therapy Drug Candidates,” “Item 1. Business — Products in Development” and “Item 1. Business — Pharmaceutical Regulation.” Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Human resource related costs, including salaries and benefits, increased by approximately $509,000, or 5%, to approximately $10,870,000, primarily as a result of an increase in salary and wages and related cost of $1,060,000 associated with additional employees required for our clinical trials, partially offset by a decrease in amortization of non-cash compensation totaling approximately $551,000 related to employee stock options issued during 2014 as compared to 2013.

Sales and marketing costs increased approximately $702,000, or 14%, to approximately $5,717,000, primarily as a result of expanded marketing, advertising, education, and training. Many of these incurred added costs were associated with our new prenatal products introduced in 2014.

Professional and consulting costs increased approximately $852,000, or 67%, to approximately $2,368,000 as a result of additional costs incurred for legal, consulting, and regulatory compliance.

All other costs increased approximately $1,040,000, or 48%, to approximately $3,221,000 as a result of additional costs incurred for rent, travel, corporate communications, insurance, and contract labor.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $28,233,000, or 109%, to approximately $54,041,000 for the year ended December 31, 2014, compared with approximately $25,808,000 for the year ended December 31, 2013, primarily as a result increased research and development costs associated with our continued development of our hormone therapy drug candidates, partially offset by increased revenue from sales of our prenatal vitamin products.

As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Financing Costs

Financing costs decreased approximately $1,244,000, or 83%, to approximately $260,000 for the year ended December 31, 2014, compared with approximately $1,504,000 for the year ended December 31, 2013, primarily as a result of the amortization of the costs associated with warrants granted in 2013 in connection with a $10,000,000 revolving line of credit.

Interest Expense

We did not incur interest expense for the year ended December 31, 2014, compared with approximately $1,166,000 in interest expense incurred for the year ended December 31, 2013, as a result of the retirement of our debt during 2013.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $25,798,000, or 91%, to approximately $54,217,000 for the year ended December 31, 2014, compared with approximately $28,419,000 for the year ended December 31, 2013. Net loss per share of common stock, basic and diluted, was ($0.36) for the year ended December 31, 2014, compared with ($0.22) per share of common stock for the year ended December 31, 2013. Net loss per share of common stock was positively affected by our issuance of shares of common stock in an underwritten public offering in August 2014.

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

	Year Ended December 31,		
	2013	2012	Change
	(000s)		
Revenue	$8,776	$3,818	$4,958
Cost of goods sold	1,960	1,348	612
Operating expenses	32,624	18,618	14,006
Operating loss	(25,808)	(16,148)	(9,660)
Financing Costs	(1,504)	—	(1,504)
Interest expense	(1,166)	(1,905)	739
Other income (expense) net	59	(42)	101
Loss on extinguishment of debt	—	(10,308)	10,308
Beneficial conversion feature	—	(6,717)	6,717
Net loss	$(28,419)	$(35,120)	$(6,701)

Revenue

Revenue for the year ended December 31, 2013 increased by approximately $4,958,000, or 130%, to $8,776,000, compared with the year ended December 31, 2012. Of this $4,958,000, approximately $713,000, or 14%, was attributable to an increase in the average sales price of our existing products, and approximately $4,245,000, or 86%, was attributable to sales of new products introduced in 2012.

Cost of Goods Sold

Cost of goods sold increased by approximately $612,000, or 45%, to $1,960,000 for the year ended December 31, 2013, compared with the year ended December 31, 2012. Our gross margins increased to 78% in 2013 compared to 65% in 2012. The gross margin change was primarily attributable to the increase in average sales price of products sold and product mix of prescription and OTC products.

Operating Expenses

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

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

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

	(000s)
Increase in product research and development costs	$9,059
Increase in human resource related costs	3,333
Increase in sales and marketing costs, excluding human resource costs	582
Increase in professional and consulting costs	79
Increase in all other operating expenses	953
	$14,006

Research and development costs increased by approximately $9,059,000, or 202%, to approximately $13,551,000, primarily as a result of the commencement of phase 3 clinical trials for TX-001HR as well as the preparation of phase 3 clinical trials for TX-002HR, and phase 3 clinical trials for TX-004HR. Research and developments costs during the year ended December 31, 2013 included the following research and development projects:

TX-001HR. Since the project's inception in February 2013, we have incurred approximately $4,809,000 in research and development costs with respect to TX-001HR, our combination estradiol and progesterone drug candidate.

TX-002HR. Since the project's inception in April 2013, we have incurred approximately $1,059,000 in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Research and Development." For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business." For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources." For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drug Candidates," "Item 1. Business — Products in Development" and "Item 1. Business — Pharmaceutical Regulation." Future milestones, including NDA submission dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, including the timing of ongoing patient recruitment efforts to find eligible subjects for the applicable trials.

Human resource related costs, including salaries and benefits, increased by approximately $3,333,000, or 46%, to approximately $10,611,000, primarily as a result of an increase in amortization of non-cash compensation totaling approximately $3,152,000 related to employee stock options issued during 2013 and 2012.

Sales and marketing costs increased by approximately $582,000, or 13%, to approximately $5,015,000, primarily as a result of expanded marketing, advertising, education, and training. In addition, we increased spending in the areas of travel, product samples, and commissions. We also incurred added costs associated with our new product distribution channels introduced in 2013.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $9,660,000, or 60%, to approximately $25,808,000 for the year ended December 31, 2013, compared with approximately $16,148,000 for the year ended December 31, 2012, primarily as a result increased research and development costs associated with our continued development of our hormone therapy drug candidates, partially offset by increased revenue from sales of our prenatal vitamin products.

As a result of the continued development of our hormone therapy drug candidates, we anticipate that we will continue to have operating losses for the near future until our hormone therapy drug candidates are approved by the FDA and brought to market, although there is no assurance that we will attain such approvals or that any marketing of our hormone therapy drug candidates, if approved, will be successful.

Financing Costs

Financing costs increased from $0, to approximately $1,504,000, resulting from the amortization of costs associated with warrants granted in 2013 in connection with a $10,000,000 revolving line of credit.

Interest Expense

Interest expense decreased approximately $739,000, or 39%, to approximately $1,166,000, primarily as a result of the retirement of debt issued during 2012.

Net Loss

As a result of the net effects of the foregoing, including a lack of charges in 2013 for loss on extinguishment of debt and a beneficial conversion feature of debt that were included in our 2012 results, net loss decreased approximately $6,701,000, or 19%, to approximately $28,419,000 for the year ended December 31, 2013, compared with approximately $35,120,000 for the year ended December 31, 2012. Net loss per share of common stock, basic and diluted, was ($0.22) for the year ended December 31, 2013, compared with ($0.38) per share of common stock for the year ended December 31, 2012. Net loss per share of common stock was positively affected by our issuance of shares of common stock in underwritten public offerings in March and September 2013.

Liquidity and Capital Resources

We have funded our operations primarily through the private placement of equity and debt securities, and public offerings of our common stock. For the three year period ending December 31, 2014, we received $9 million in net proceeds from the issuance of debt securities and $130 million in net proceeds from the issuance of shares of our common stock. As of December 31, 2014, we had cash totaling approximately $51.4 million: however, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to

spend more money than currently expected because of circumstances beyond our control.

We believe that our existing cash will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents is insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products. Additionally, we may have to grant licenses on terms that may not be favorable to us.

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

Summary of (Uses) and Sources of Cash

	Year Ended December 31,		
	2014	2013	2012
Net cash flows used in operating activities	$(45,520,996)	$(20,768,069)	$(12,737,326)
Net cash flows used in investing activities	$(606,756)	$(583,561)	$(272,506)
Net cash flows provided by financing activities	$43,298,099	$73,989,416	$14,436,885

Operating Activities

The use of cash in all periods resulted primarily from our net loss adjusted for non-cash charges and changes in components of working capital.

The increase of approximately $25 million in cash used in operating activities for the year ended December 31, 2014 in comparison to the year ended December 31, 2013 was due primarily to research and development, sales, general and administrative costs. These were offset by an approximately $6 million increase in sales.

The increase of approximately $8 million in cash used in operating activities for the year ended December 31, 2013 in comparison to the year ended December 31, 2012 was due primarily to research and development, sales, general and administrative costs. These were offset by an approximately $9 million increase in sales.

Investing Activities

The increase of approximately $23,000 in cash used in investing activities for the year ended December 31, 2014 compared with the prior year was due to patent development costs and purchase of property and equipment.

The increase of approximately $311,000 in cash used in investing activities for the year ended December 31, 2013 compared with the prior year was due to patent development costs and purchase of property and equipment.

Financing Activities

Financing activities represent the principal source of our cash flow.

Our financing activities for the year ended December 31, 2014 provided net cash of approximately $43,298,000.

On July 29, 2014, we entered into an underwriting agreement relating to the issuance and sale by us of 8,565,310 shares of our common stock. Under the terms of the underwriting agreement, we granted the underwriters a 30-day option to purchase up to an additional 1,284,796 shares of our common stock, which was exercised in full on July 30, 2014. The offering closed on August 4, 2014. The net proceeds to us from this offering were approximately $42.8 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Our financing activities for the year ended December 31, 2013 provided net cash of approximately $73,989,000.

On March 14, 2013, we entered into an underwriting agreement relating to the issuance and sale by us of 29,411,765 shares of our common stock. 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 our common stock. On April 12, 2013, the underwriters exercised their option to purchase 1,954,587 shares of our common stock. The net proceeds to us from this offering were approximately $48 million, after deducting underwriting discounts and commissions and other offering expenses.

On September 25, 2013, we entered into an underwriting agreement relating to the issuance and sale by us of 13,750,000 shares of our common stock. The net proceeds to us from this offering were approximately $30 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

In March 2013, we repaid approximately $5 million in notes and credit lines.

Our financing activities for the year ended December 31, 2012 provided net cash of approximately $14,437,000.

In September 2012, we entered into a securities purchase agreement with multiple investors, relating to the issuance and sale of our common stock in a private placement that provided us with approximately $8 million in net proceeds. During 2012, we issued notes in the aggregate principal amount of approximately $9 million to multiple parties, of which approximately $2 million was repaid during 2012.

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, or GAAP, requires us to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. We consider an accounting estimate to be critical if

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

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

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

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques.

Over-the-Counter Products

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

Prescription Products

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

We accept returns of unsalable product from customers within a return period of six months prior to and up to 12 months following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture. Given the limited history of our prescription products, we currently cannot reliably estimate expected returns of the prescription products at the time of shipment. Accordingly, we defer recognition of revenue on prescription products until the right of return no longer exists, which occurs at the earlier of the time the prescription products are dispensed through patient prescriptions or expiration of the right of return.

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

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

Share-Based Compensation. We periodically issue stock options and warrants to employees and non-employees in non-capital raising transactions for services and for financing costs. We account for stock option and warrant grants issued and vesting to employees based on the authoritative guidance provided by the Financial Accounting Standards Board, or FASB, whereas the value of the awards are measured on the date of grant and recognized over the vesting period. We account for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the FASB whereas the value of the stock compensation is based upon the measurement date as determined at either (a) the date at which a performance commitment is reached, or (b) at the date at which the necessary performance to earn the equity instruments is complete. Non-employee stock-based compensation charges generally are amortized over the vesting period on a straight-line basis. In certain circumstances where there are no future performance requirements by the non-employee, option grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date. Determining the fair value of share-based awards at the measurement date requires judgment, including estimating the expected term that stock options and warrants will be outstanding prior to exercise and the associated volatility. We estimate the fair value of options granted using the Black-Scholes-Merton valuation model. The expected life of the options used in this calculation is the period the options are expected to be outstanding and has been determined based on the simplified method in accordance with guidance provided by SEC Staff Accounting Bulletin 07 (ASC 718-10-S00). Expected stock price volatility is based on the historical volatility of the stock of peer entities whose stock prices were publicly available for a period approximating the expected life. We use the historical volatility of peer entities due to the lack of sufficient historical data on our stock prices. The risk-free interest rate is based on the implied yield available on US Treasury zero-coupon issues approximating the expected life. We believe that these assumptions are "critical accounting estimates" because significant changes in the assumptions used to develop the estimates materially affect key financial measures including net income/(loss).

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate income taxes in each of the jurisdictions in which we operate. We determine provision for income taxes using the asset and liability approach to account for income taxes. We record current liability for the estimated taxes payable for

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

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

Segment Reporting. We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single management team that reports to our president. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

New Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-05, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of the ASU 2014-15 to have a material effect on our consolidated financial statements and disclosures.

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. ASU 2014-09 is effective for public business entities, certain not-for-profit entities and certain employee benefit plans, for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted under GAAP. We are currently evaluating the impact of ASU 2014-09 on our consolidated financial statements and disclosures.

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

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

Off-Balance Sheet Arrangements

As of December 31, 2014, 2013, and 2012, we had no off-balance sheet arrangements that have had or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions, which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our drug candidates, use of such drug candidates, or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we have no liabilities recorded for these provisions as of December 31, 2014, 2013, or 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 GAAP, an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements.

Effects of Inflation

For each of the fiscal years ended December 31, 2014, 2013, and 2012, our business and operations have not been materially affected by inflation.

Contractual Obligations

A summary of contractual cash obligations as of December 31, 2014 is as follows:

	Payments Due By Period (in thousands)			
	Total	Less than 1 Year	1-3 Years	4-5 Years
Operating Lease Obligations	$1,450	$371	$1,079	$ 0

Seasonality

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We had cash and cash equivalents totaling $51.4 million as of December 31, 2014. We hold our cash in money market funds and the primary objective of our investment policy is to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain a portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

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

Item 8. ***Financial Statements and Supplementary Data***

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

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

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(f) or 15d-15(f)) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2014, our

disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

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

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on management's assessment, we believe that our internal controls over financial reporting were effective as of December 31, 2014.

Rosenberg Rich Baker Berman & Company, an independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report; and, as part of its audit, has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations on Effectiveness of Controls

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

Item 9B. ***Other Information***

None.

PART III

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

The information required by this Item relating to our directors and corporate governance is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2015 Annual Meeting of Stockholders.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2015 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated by reference to the definitive Proxy Statement to be filed pursuant to Regulations 14A of the Exchange Act for our 2015 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference to the definitive Proxy Statements to be filed pursuant to Regulation 14A of the Exchange Act for our 2015 Annual Meeting of Stockholders.

Item 14. ***Principal Accountant Fees and Services***

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regular 14A of the Exchange Act for our 2015 Annual Meeting of Stockholders.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

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

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

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

(b) **Exhibits**

Exhibit	Date	Description
2.1	July 6, 2009	Agreement and Plan of Reorganization among Croff Enterprises, Inc., AMHN Acquisition Corp., America's Minority Health Network, Inc., and the Major Shareholders[1]
2.2	June 11, 2010	Agreement and Plan of Reorganization among AMHN, Inc., SHN Acquisition Corp., Spectrum Health Network, Inc., and the Sole Shareholder of Spectrum Health Network, Inc.[2]
2.3	October 25, 2007	Croff Enterprises, Inc. Plan of Corporate Division and Reorganization[3]
2.4	July 18, 2011	Agreement and Plan of Merger among VitaMedMD, LLC, AMHN, Inc., and VitaMed Acquisition, LLC[4]
3.1	September 15, 2009	Articles of Amendment to Articles of Incorporation (to change name to AMHN, Inc.)[5]
3.2	July 27, 2009	Certificate of Merger of AMHN Acquisition Corp., with and into America's Minority Health Network, Inc.[6]
3.3	December 27, 2007	Articles of Amendment to Articles of Incorporation of Croff Enterprises, Inc. (to increase authorized common shares from 20,000,000 to 50,000,000)[3]
3.4	July 20, 2010	Articles of Conversion of AMHN, Inc. filed in the State of Nevada[7]
3.5	July 20, 2010	Articles of Incorporation of AMHN, Inc. filed in the State of Nevada[7]
3.6	August 29, 2011	Certificate of Amendment and Restatement of Articles of Incorporation of AMHN, Inc. (to change name and increase authorized shares)[8]
3.7	n/a	Bylaws of AMHN, Inc.[9]
4.1	September 26, 2012	Form of Securities Purchase Agreement [10]

4.2	n/a	Form of Certificate of Common Stock[11]
10.1	November 9, 2010	Demand Promissory Note to Philip M. Cohen for $210,000[12]
10.2	April 18, 2011	Convertible Promissory Note to First Conquest Investment Group, L.L.C. for $105,000[12]
10.3	April 18, 2011	Convertible Promissory Note to Energy Capital, LLC for $105,000[12]
10.4	May 7, 2011	Sales Representative Agreement between AMHN, Inc. and Mann Equity, LLC[12]
10.5	July 9, 2009	Lease Agreement between Liberty Property Limited Partnership and VitaMedMD, LLC[13]
10.6	September 8, 2011	Stock Purchase Agreement between AMHN, Inc. and Pernix Therapeutics, LLC[14]
10.7	September 8, 2011	Lock-Up Agreement between AMHN, Inc. and Pernix Therapeutics, LLC[14]
10.8	n/a	Form of Common Stock Purchase Warrant [13]
10.9*	n/a	Form of Non-Qualified Stock Option Agreement [13]
10.10	September 2011	Form of Convertible Promissory Note[15]
10.11	September 20, 2011	Financing Agreement between Lang Naturals, Inc. and VitaMedMD, LLC[16]
10.12	October 18, 2011	Debt Conversion Agreement between the Company and Energy Capital, LLC[17]
10.13	October 18, 2011	Debt Conversion Agreement between the Company and First Conquest Investment Group, LLC[17]
10.14	October 23, 2011	Consulting Agreement among VitaMedMD, LLC, the Company, and Lang Naturals, Inc.[17]
10.15	October 23, 2011	Common Stock Purchase Warrant to Lang Naturals, Inc.[17]

Exhibit	Date	Description
10.16	October 23, 2011	Lock-Up Agreement between the Company and Lang Naturals, Inc. (17)
10.17	November 3, 2011	Software License Agreement between vitaMedMD, LLC and Pernix Therapeutics, LLC(18)
10.18	November 2011	Form of Promissory Note (19)
10.19	February 24, 2012	Note Purchase Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson(20)
10.20	February 24, 2012	Form of Secured Promissory Note(20)
10.21	February 24, 2012	Security Agreement among the Company, Plato & Associates, Inc., and Steven G. Johnson(20)
10.22	February 24, 2012	Form of Common Stock Purchase Warrant(20)
10.26	April 17, 2012	Master Services Agreement between the Company and Sancilio and Company, Inc.(21)
10.27**	May 17, 2012	Consulting Agreement between the Company and Sancilio and Company, Inc. (21)
10.28*	November 8, 2012	Form of Employment Agreement(22)
10.29	January 31, 2013	Multiple Advance Revolving Credit Note, issued to Plato & Associates, LLC(23)
10.30	January 31, 2013	Common Stock Purchase Warrant, issued to Plato & Associates, LLC(23)
10.31*	May 8, 2013	Agreement to Forfeit Non-Qualified Stock Options between the Company and Robert G. Finizio(24)
10.32	May 7, 2013	Consulting Agreement between the Company and Sancilio and Company, Inc. (24)
10.33	May 16, 2013	Lease between the Company and 6800 Broken Sound LLC(25)
10.34*	n/a	Amended and Restated 2012 Stock Incentive Plan(26)
10.35*	n/a	2009 Long Term Incentive Compensation Plan, as amended(27)
10.36†	February 18, 2015	First Amendment to Lease between the Company and 6800 Broken Sound, LLC
21.1	December 31, 2012	Subsidiaries of the Company(28)
23.1†	March 12, 2015	Consent of Rosenberg Rich Baker Berman & Company
31.1†	March 12, 2015	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
31.2†	March 12, 2015	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1†	March 12, 2015	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	March 12, 2015	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	n/a	XBRL Instance Document
101.SCH†	n/a	XBRL Taxonomy Extension Schema Document

101.CAL†	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB†	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE†	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

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

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

† Filed herewith.

(1) Filed as an exhibit to Form 8-K filed with the Commission on July 10, 2009 and incorporated herein by reference (SEC File No. 000-16731).

(2) Filed as an exhibit to Form 8-K filed with the Commission on June 14, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(3) Filed as an exhibit to Form 10-K for the year ended December 31, 2007 filed with the Commission on May 1, 2008 and incorporated herein by reference (SEC File No. 000-16731).

(4) Filed as an exhibit to Form 8-K filed with the Commission on July 21, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(5) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2009 filed with the Commission on November 16, 2009 and incorporated herein by reference (SEC File No. 000-16731).

(6) Filed as an exhibit to Form 10-K for the year ended December 31, 2009 filed with the Commission on March 17, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(7) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2010 filed with the Commission on August 3, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(8) Filed as an exhibit to Definitive 14C Information Statement filed with the Commission on September 12, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(9) Filed as an exhibit to Definitive 14C Information Statement filed with the Commission on June 29, 2010 and incorporated herein by reference (SEC File No. 000-16731).

(10) Filed as an exhibit to Form 8-K filed with the Commission on October 2, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(11) Filed as an exhibit to Form S-3 filed with the Commission on January 25, 2013 and incorporated hereby by reference (SEC File No. 333-186189).

(12) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2011 filed with the Commission on May 19, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(13) Filed as an exhibit to Form 8-K filed with the Commission on October 11, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(14) Filed as an exhibit to Form 8-K filed with the Commission on September 14, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(15) Filed as an exhibit to Form 8-K/A filed with the Commission on November 22, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(16) Filed as an exhibit to Form 8-K/A filed with the Commission on February 2, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(17) Filed as an exhibit to Form 8-K filed with the Commission on October 24, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(18) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2011 filed with the Commission on November 7, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(19) Filed as an exhibit to Form 8-K filed with the Commission on November 23, 2011 and incorporated herein by reference (SEC File No. 000-16731).

(20) Filed as an exhibit to Form 8-K filed with the Commission on February 24, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(21) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2012 filed with the Commission on August 9, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(22) Filed as an exhibit to Form 10-Q for quarter ended September 30, 2012 filed with the Commission on November 13, 2012 and incorporated herein by reference (SEC File No. 000-16731).

(23) Filed as an exhibit to Form 8-K filed with the Commission on February 6, 2013 and incorporated herein by reference (SEC File No. 000-16731).

(24) Filed as an exhibit to Form 10-Q for quarter ended March 31, 2013 filed with the Commission on May 10, 2013 and incorporated herein by reference (SEC File No. 001-00100).

(25) Filed as an exhibit to Form 10-Q for quarter ended June 30, 2013 filed with the Commission on August 7, 2013 and incorporated herein by reference (SEC File No. 001-00100).

(26) Filed as an exhibit to Form 8-K filed with the Commission on August 22, 2013 and incorporated herein by reference (SEC File No. 001-00100).

(27) Filed as an exhibit to Registration Statement on Form S-8 filed with the Commission on October 15, 2013 and incorporated herein by reference (SEC File No. 333-191730).

(28) Filed as an exhibit to Form 10-K for the year ended December 31, 2012 filed with the Commission on March 12, 2013 and incorporated herein by reference (SEC File No. 000-16731).

SIGNATURES

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

Date: March 12, 2015 THERAPEUTICSMD, INC.

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

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

Signature	**Capacity**	**Date**
/s/ Robert G. Finizio Robert G. Finizio	Chief Executive Officer, Director (Principal Executive Officer)	March 12, 2015
/s/ John C.K. Milligan, IV John C.K. Milligan, IV	President, Secretary, Director	March 12, 2015
/s/ Daniel A. Cartwright Daniel A. Cartwright	Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	March 12, 2015
/s/ Tommy G. Thompson Tommy G. Thompson	Chairman	March 12, 2015
/s/ Brian Bernick Brian Bernick	Director	March 12, 2015
/s/ Cooper C. Collins Cooper C. Collins	Director	March 12, 2015
/s/ Robert V. LaPenta, Jr. Robert V. LaPenta, Jr.	Director	March 12, 2015

/s/ Nicholas Segal

Nicholas Segal Director March 12, 2015

/s/ Jules Musing

Jules Musing Director March 12, 2015

/s/ Randall Stanicky

Randall Stanicky Director March 12, 2015

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of TherapeuticsMD, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended December 31, 2014. We also have audited TherapeuticsMD's internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). TherapeuticsMD's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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, and evaluating the overall financial statement presentation. 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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, the financial statements referred to above present fairly, in all material respects, the financial position of TherapeuticsMD, Inc. as of December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, TherapeuticsMD, Inc. maintained, in all

material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ Rosenberg Rich Baker Berman & Company

Somerset, New Jersey

March 12, 2015

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2014	2013
ASSETS		
Current Assets:		
Cash	$51,361,607	$54,191,260
Accounts receivable, net of allowance for doubtful accounts of $21,119 and $26,555, respectively	2,154,217	1,690,753
Inventory	1,182,113	1,043,618
Other current assets	1,537,407	2,477,715
Total current assets	56,235,344	59,403,346
Fixed assets, net	63,293	61,318
Other Assets:		
Prepaid expense	1,427,263	1,750,455
Intangible assets	1,228,588	665,588
Security deposit	125,000	135,686
Total other assets	2,780,851	2,551,729
Total assets	$59,079,488	$62,016,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$6,327,129	$2,114,217
Deferred revenue	522,613	1,602,580
Other current liabilities	3,840,639	3,601,189
Total current liabilities	10,690,381	7,317,986
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 250,000,000 shares authorized; 156,097,019 and 144,976,757 issued and outstanding, respectively	156,097	144,977
Additional paid in capital	182,982,846	135,086,056
Accumulated deficit	(134,749,836)	(80,532,626)
Total stockholders' equity	48,389,107	54,698,407
Total liabilities and stockholders' equity	$59,079,488	$62,016,393

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THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2014	2013	2012
Revenues, net	$15,026,219	$8,775,598	$3,818,013
Cost of goods sold	3,671,803	1,959,597	1,348,113
Gross profit	11,354,416	6,816,001	2,469,900
Operating expenses:			
Sales, general, and administrative	22,124,072	19,014,837	14,069,701
Research and development	43,218,938	13,551,263	4,492,362
Depreciation and amortization	52,467	58,145	56,260
Total operating expense	65,395,477	32,624,245	18,618,323
Operating loss	(54,041,061)	(25,808,244)	(16,148,423)
Other income and (expense)			
Miscellaneous income	46,569	34,544	3,001
Interest income	37,309	27,234	—
Financing costs	(260,027)	(1,503,922)	—
Interest expense	—	(1,165,981)	(1,905,409)
Loan guaranty costs	—	(2,944)	(45,036)
Loss on extinguishment of debt	—	—	(10,307,864)
Beneficial conversion feature	—	—	(6,716,504)
Total other expense	(176,149)	(2,611,069)	(18,971,812)
Loss before taxes	(54,217,210)	(28,419,313)	(35,120,235)
Provision for income taxes	—	—	—
Net loss	$(54,217,210)	$(28,419,313)	$(35,120,235)
Net loss per share, basic and diluted	$(0.36)	$(0.22)	$(0.38)
Weighted average number of common shares outstanding	149,727,228	127,569,731	91,630,693

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2014, 2013 AND 2012

	Common Stock Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, December 31, 2011	82,978,804	82,979	15,198,241	(16,993,078)	(1,711,858)
Shares issued in private placement, net of cost	3,953,489	3,954	7,891,531	—	7,895,485
Shares issued in exchange for debt	2,775,415	2,775	1,051,882	—	1,054,657
Shares issued for exercise of options	1,931,788	1,932	189,068	—	191,000
Shares issued for exercise of warrants	8,145,486	8,145	3,093,855	—	3,102,000
Employee share based compensation	—	—	1,832,061	—	1,832,061
Warrants issued for financing costs	—	—	13,014,784	—	13,014,784
Warrants issued for services	—	—	1,563,620	—	1,563,620
Warrants issued as compensation-related party	—	—	36,284	—	36,284
Warrants issued for cash	—	—	400	—	400
Cancellation of warrants issued for loan guaranty costs-related parties	—	—	(7,830)	—	(7,830)
Beneficial ownership feature	—	—	6,716,504	—	6,716,504
Net loss	—	—	—	(35,120,235)	(35,120,235)
Balance, December 31, 2012	99,784,982	99,785	50,580,400	(52,113,313)	(1,433,128)
Shares issued in private placements, net of cost	45,116,352	45,117	78,605,236	—	78,650,353
Shares issued for exercise of options	75,423	75	30,835	—	30,910
Employee share based compensation	—	—	3,170,954	—	3,170,954
Non-employee share based compensation	—	—	83,129	—	83,129
Warrants issued for financing costs	—	—	1,711,956	—	1,711,956
Warrants issued for services	—	—	867,262	—	867,262
Warrants issued as compensation-related party	—	—	36,284	—	36,284
Net loss	—	—	—	(28,419,313)	(28,419,313)
Balance, December 31, 2013	144,976,757	144,977	135,086,056	(80,532,626)	54,698,407
Shares issued in private placements, net of cost	9,850,106	9,850	42,761,503	—	42,771,353
Shares issued for exercise of options	854,573	855	344,891	—	345,746
Shares issued for exercise of warrants	365,583	365	180,635	—	181,000
Shares issued for exercise of restricted stock units	50,000	50	(50)	—	—
Employee share based compensation	—	—	4,239,358	—	4,239,358

Non-employee share based compensation	—	—	370,453	—	370,453
Net loss	—	—	—	(54,217,210)	(54,217,210)
Balance, December 31, 2014	156,097,019	$156,097	$182,982,846	$(134,749,836)	$48,389,107

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December, 31,		
	2014	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(54,217,210)	$(28,419,313)	$(35,120,235)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation	28,987	47,883	27,484
Amortization of intangible assets	23,480	10,262	28,776
Provision for doubtful accounts	(5,436)	(15,493)	40,548
Loss on extinguishment of debt	—	—	10,307,864
Beneficial conversion feature	—	—	6,716,504
Amortization of debt discount	—	1,102,680	1,604,240
Stock based compensation	4,239,358	3,207,238	1,868,345
Amortization of deferred financing costs	260,027	1,451,934	—
Stock based expense for services	730,954	636,917	338,457
Loan guaranty costs	—	2,944	45,036
Changes in operating assets and liabilities:			
Accounts receivable	(458,028)	(1,068,619)	(728,253)
Inventory	(138,495)	571,592	(1,027,137)
Other current assets	680,281	(1,386,319)	42,281
Other assets	(37,309)	(565,706)	—
Accounts payable	4,212,912	472,851	1,334,855
Deferred revenue	(1,079,967)	457,828	1,144,752
Accrued expenses and other current liabilities	239,450	2,875,320	639,157
Other liabilities	—	(150,068)	—
Net cash flows used in operating activities	(45,520,996)	(20,768,069)	(12,737,326)
CASH FLOWS FROM INVESTING ACTIVITIES			
Patent costs, net of abandoned costs	(586,480)	(439,034)	(206,101)
Purchase of property and equipment	(30,962)	(40,790)	(66,405)
Refund (payment) of security deposit	10,686	(103,737)	—
Net cash flows used in investing activities	(606,756)	(583,561)	(272,506)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net of costs	42,771,353	78,650,353	7,895,485
Proceeds from exercise of options	345,746	30,910	191,000
Proceeds from exercise of warrants	181,000	—	—
Proceeds from notes and loans payable	—	—	8,700,000
Proceeds bank line of credit	—	500,000	—
Proceeds from sale of warrants	—	—	400

Repayment of bank line of credit	—	(500,000)	(300,000)
Repayment of notes payable-related party	—	—	(200,000)
Repayment of notes payable	—	(4,691,847)	(1,850,000)
Net cash flows provided by financing activities	43,298,099	73,989,416	14,436,885
Increase in cash	(2,829,653)	52,637,786	1,427,053
Cash, beginning of period	54,191,260	1,553,474	126,421
Cash, end of period	$51,361,607	$54,191,260	$1,553,474
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$—	$212,853	$17,253
Cash paid for income taxes	$—	$—	$—
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:			
Warrants issued for financing	$—	$1,711,956	$2,509,537
Warrants issued for services	$—	$462,196	$1,532,228
Warrants exercised in exchange for debt and accrued interest	$—	$—	$3,102,000
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 CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has two wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation, 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 health care product company focused on creating and commercializing products targeted exclusively for women. As of the date of these consolidated financial statements, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of our advanced hormone therapy pharmaceutical products. The drug candidates used in our clinical trials are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling an enhanced side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Cash

We maintain cash at financial institutions that at times may exceed the federally insured limit of $250,000 per financial institution. We have never experienced any losses related to these funds.

Trade Accounts Receivable and Allowance for Doubtful Accounts

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Inventories

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

Pre-Launch Inventory

Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then pre-launch inventory costs associated with such product candidates are expensed as research and development expenses during the period the costs are incurred.

Fixed Assets

Equipment

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

Leasehold Improvements

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

Intangible Assets

Patent and Trademarks

We have adopted the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 350, *Intangible-Goodwill and Other*, or ASC 350. Capitalized patent costs, net of accumulated amortization, include legal costs incurred for patent applications. In accordance with ASC 350, once a patent is granted, we amortize the capitalized patent costs over the remaining life of the patent using the straight-line method. If the patent is not granted, we write-off any capitalized patent costs at that time. We review intangible assets for impairment annually or when events or circumstances indicate that their carrying amount may not be recoverable. As of December 31, 2014, we had 4 issued patents (See Note 7).

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Impairment of Long-Lived Assets

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

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

If impairment indicators are present, we determine whether an impairment loss should be recognized by testing the applicable asset or asset group's carrying value for recoverability. This test requires long-lived assets to be grouped at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and

liabilities, the determination of which requires judgment. We estimate the undiscounted future cash flows expected to be generated from the use and eventual disposal of the assets and compare that estimate to the respective carrying values in order to determine if such carrying values are recoverable. This assessment requires the exercise of judgment in assessing the future use of and projected value to be derived from the eventual disposal of the assets to be held and used. In our assessments, we also consider changes in asset utilization, including the temporary idling of capacity and the expected timing for placing this capacity back into production. If the carrying value of the assets is not recoverable, then we record a loss for the difference between the assets' fair value and respective carrying values. We determine the fair value of the assets using an "income approach" based upon a forecast of all the expected discounted future net cash flows associated with the subject assets. Some of the more significant estimates and assumptions include market size and growth, market share, projected selling prices, manufacturing cost, and discount rate. We base estimates upon historical experience, our commercial relationships, market conditions, and available external information about future trends. We believe our current assumptions and estimates are reasonable and appropriate. Unanticipated events and changes in market conditions, however, could affect such estimates, resulting in the need for an impairment charge in future periods. There was no impairment of intangibles or long-lived assets during the years ended December 31, 2014, 2013 and 2012.

Fair Value of Financial Instruments

Our financial instruments consist primarily of accounts receivable, accounts payable and accrued expenses. The carrying amount of accounts receivable, accounts payable and accrued expenses approximates their fair value because of the short-term maturity of such instruments, which are considered Level 1 assets under the fair value hierarchy.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Fair Value of Financial Instruments (continued)

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.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1 unadjusted quoted prices in active markets for identical assets or liabilities;

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

Level 3 unobservable inputs for the asset or liability.

At December 31, 2014, and 2013, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with our impairment test. There was no impairment of intangible assets during the years ended December 31, 2014, 2013, and 2012.

Income Taxes

Based upon a change in our business model, deferred income taxes are determined by calculating the loss from operations of our company starting October 4, 2011.

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

In accordance with ASC 740, *Income Taxes*, we recognize the effect of uncertain income tax positions only if the positions are more likely than not of being sustained in an audit, based on the technical merits of the position. We measure recognized uncertain income tax positions using the largest amount that has a likelihood of being realized that is greater than 50%. Changes in recognition or measurement are reflected in the period in which those changes in judgment occur. At December 31, 2014, 2013, and 2012 we had no uncertain income tax positions.

We recognize both interest and penalties related to uncertain tax positions as part of the income tax provision. At December 31, 2014 and 2013, we had no tax positions relating to open tax returns that were considered to be uncertain.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes (continued)

Our tax returns are subject to review by the Internal Revenue Service three years after they are filed. Currently, years filed after 2011 are subject to review.

Share-Based Compensation

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

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

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

Debt Discounts

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

Revenue Recognition

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Revenue Recognition (continued)

Our OTC and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. The primary difference between our OTC and prescription prenatal vitamin products is the source of payment. Purchasers of our OTC prenatal vitamin products pay for the product directly while purchasers of our prescription prenatal vitamin products pay for the product via third-party payers. Both OTC and prescription prenatal vitamin products share the same marketing support team utilizing similar marketing techniques. The revenue that is generated by us from major external customers is all generated from sales of our prescription prenatal vitamin products which is disclosed in Note 13. There are no major external customers for our OTC prenatal vitamin or other products.

Over-the-Counter Products

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

Prescription Products

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

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

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Revenue Recognition (continued)

Segment Reporting

We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single management team that reports to the President of our Company. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

Shipping and Handling Costs

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

Advertising Costs

We expense advertising costs when incurred. Advertising costs were $698,871, $11,739 and $65,944 during the years ended December 31, 2014, 2013 and 2012, respectively.

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. Advance payments to be expensed in future R&D activities were $1,175,082 and $2,606,405 for the years ended December 31, 2014 and 2013, respectively. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal counsel. The activities undertaken by our regulatory consultants that were classified as research and development expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as research and development expenses related to designing experiments to generate data for patents and to further the formulation development process for our pipeline technologies. Outside legal counsel also provided professional research regarding the legal landscape of potential patents. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions expense in the period in which the facts that give rise to the revision become known.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, par value $0.001 per share, or Common Stock, outstanding during the period. We compute diluted EPS based on the weighted-average number of shares of our Common Stock outstanding plus all potentially dilutive shares of our Common Stock outstanding during the period. Such potentially dilutive shares of our Common Stock consist of options and warrants and were excluded from the calculation of diluted earnings per share because their effect would have been anti-dilutive due to the net loss reported by us.

The table below presents the potentially dilutive securities that would have been included in our calculation of diluted net loss per share allocable to common stockholders if they were not antidilutive for the periods presented.

	As of December 31,		
	2014	2013	2012
Stock options	16,792,443	15,632,742	13,733,488
Warrants	13,927,916	14,293,499	12,193,499
	30,720,359	29,926,241	25,926,987

Use of Estimates

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

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-05, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of the ASU 2014-15 to have a material effect on our consolidated financial statements and disclosures.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recently Issued Accounting Pronouncements (continued)

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. ASU 2014-09 is effective for public business entities, certain not-for-profit entities and certain employee benefit plans, for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted under GAAP. We are currently evaluating the impact of ASU 2014-09 on our consolidated financial statements and disclosures.

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

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

prepared on the basis of International Financial Reporting Standards. ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those years. ASU 2011-11 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 consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Reclassifications

Certain 2013 and 2012 amounts have been reclassified to conform to current year presentation.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – INVENTORY

Inventory consists of the following:

	December 31,	
	2014	2013
Finished product	$874,294	$621,679
Raw material	155,341	250,943
Deferred costs	152,478	170,996
TOTAL INVENTORY	$1,182,113	$1,043,618

NOTE 4 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	December 31,	
	2014	2013
Prepaid consulting	$411,864	$530,596
Prepaid insurance	394,878	145,722
Prepaid research and development costs	299,498	1,267,588
Other receivables-related party (Note 12)	249,981	249,981
Other prepaid costs	181,186	23,806
Deferred financing costs	—	260,022
TOTAL OTHER CURRENT ASSETS	$1,537,407	$2,477,715

NOTE 5 – FIXED ASSETS

Fixed assets consist of the following:

	December 31,	
	2014	2013
Equipment	$132,150	$108,458
Furniture and fixtures	53,895	46,625
	186,045	155,083
Accumulated depreciation	(122,752)	(93,765)
TOTAL FIXED ASSETS	$63,293	$61,318

Depreciation expense for the years ended December 31, 2014, 2013, and 2012 was $28,987, $47,883, and $27,484, respectively. In December 2013, accumulated depreciation was reduced by $11,980 associated with leasehold improvements of our previously leased office property.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 –PREPAID EXPENSE

Prepaid expense consists of the following:

	December 31,	
	2014	2013
Prepaid manufacturing costs	$899,000	$899,000
Prepaid research and development costs	463,720	824,221
Accreted prepaid costs	64,543	27,234
TOTAL PREPAID EXPENSE	$1,427,263	$1,750,455

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of December 31, 2014 and December 31, 2013:

	December 31, 2014			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$31,951	$ (2,496)	$29,455	14.75
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	439,184	(19,401)	419,783	18
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents (pending)	675,982	—	675,982	n/a
Multiple trademarks for vitamins/supplements	103,368	—	103,368	n/a
Total	$1,342,228	$ (113,640)	$1,228,588	

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THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – INTANGIBLE ASSETS

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

We amortized the intangible asset related to development costs for corporate website over 36 months, which is the prescribed life for software and website development costs. We amortize the intangible asset related to OPERA® using the straight-line method over the estimated useful life of approximately 20 years, which is the life of the intellectual property patents. We amortize the approved hormone therapy drug candidate patents using straight-line method over the estimated useful life of approximately 20 years. During the years ended December 31, 2014 and 2013, there was no impairment recognized.

In addition to numerous pending patent applications, as of December 31, 2014, we had 4 issued patents, including:

- one method patent that relates to our OPERA® information technology platform, which is owned by us and is a U.S. jurisdiction patent with an expiration date in 2029; and
- 3 utility patents that relate to our combination progesterone and estradiol formulations, which are owned by us and are U.S. jurisdiction patents with expiration dates in 2032. We have pending patent applications with respect to certain of these patents in Argentina, Australia, Canada, the European Union, Mexico, Brazil, Japan, Russia, South Africa and South Korea.

Subsequent to December 31, 2014, 1 additional patent was issued related to our combination progesterone and estradiol formulations.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – INTANGIBLE ASSETS

Amortization expense was $23,480, $10,262 and $28,776 for the years ended December 31, 2014, 2013, and 2012, respectively. As of December 31, 2014, the estimated amortization expense for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2015	$ 25,138
2016	$ 25,138
2017	$ 25,138
2018	$ 25,138
2019	$ 25,138

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	December 31,	
	2014	2013
Accrued clinical trial costs	$1,706,542	$665,782
Accrued payroll, bonuses and commission costs	814,205	941,313
Accrued vacation costs	442,430	256,920
Accrued legal and accounting expense	276,470	224,550
Other accrued expenses[(1)]	185,965	177,900
Allowance for wholesale distributor fees	160,503	306,303
Accrued royalties	72,710	52,188
Allowance for coupons and returns	90,446	126,233
Accrued rent	91,368	—
Accrued financing costs	—	850,000

TOTAL OTHER CURRENT LIABILITIES	$3,840,639	$3,601,189

(1) In June 2008, we declared and paid a special dividend of $0.40 per share of our Common Stock to all stockholders of record as of June 10, 2008, of which $41,359 remained unclaimed by certain stockholders at both December 31, 2014 and 2013.

NOTE 9 – NOTES PAYABLE

Issuance and Payment of Multiple Advance Revolving Credit Note

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Borrowing under Business Loan Agreement and Promissory Note

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

Issuance of January and February 2012 Promissory Notes

In January and February 2012, we issued 6% promissory notes in the aggregate principal amount of $900,000, due March 1, 2012, which were subsequently increased to an aggregate principal amount of $1,700,000. 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.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 – NOTES PAYABLE (Continued)

Issuance and Settlement of February 2012 Promissory Notes

On February 24, 2012, we issued promissory notes, the February 2012 Notes, to an individual and an entity, both of which were stockholders of our company, in the principal amount of $1,358,014 and $1,357,110, respectively, and granted warrants to purchase an aggregate of 9,000,000 shares of our Common Stock pursuant to the terms of a Note Purchase Agreement, dated February 24, 2012. We received an aggregate of $1,000,000 of new funding upon issuance of the February 2012 Notes and related warrants and surrender by the holders of certain promissory notes, which we previously issued in the aggregate amount of $1,700,000 plus the aggregate accrued interest of $15,124 (collectively, the "Prior Notes"). Under the February 2012 Notes, as amended, we borrowed an additional $3,000,000 during March, April, and May 2012.

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

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

Issuance and Payment of June 2012 Promissory Notes

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 – NOTES PAYABLE (Continued)

Issuance and Payment of Additional Promissory Notes in 2012

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

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

Issuance and Payment of Additional Promissory Notes in 2011

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

Conversion of July 2011 Secured Notes

In July 2011, VitaMed issued two senior secured promissory notes, or the Secured Notes, each in the amount of $500,000 and also entered into a security agreement under which VitaMed pledged all of its assets to secure the obligation. The Secured Notes were assumed by us upon the merger with VitaMed in October 2011 and bore interest at the rate of 6% per annum, were due on the one year anniversary thereof, and were convertible into shares of our Common Stock at our option. We were permitted to satisfy the obligations underlying the Secured Notes by delivering such number of shares of our Common Stock calculated by dividing the then-outstanding principal balance by the Share Price. For purposes of the Secured Notes, the "Share Price" meant the lower of the most recent price at which we offered and sold shares of our Common Stock (not including any shares of our Common Stock issued upon the

exercise of options and/or warrants or upon the conversion of any convertible securities) or the five-day average closing bid price immediately preceding the date of conversion. On June 19, 2012, we reached an agreement to convert the outstanding amount of the Secured Notes, representing principal and accrued interest through June 19, 2012, of $1,054,647 into an aggregate of 2,775,415 shares of our Common Stock at $0.38 per share. This resulted in a beneficial conversion feature of $6,716,504 as recorded in other income and expense on the accompanying consolidated financial statements. For the year ended December 31, 2012 we recorded an aggregate of $33,204 as interest expense on the accompanying consolidated financial statements.

Issuance, Payment and Conversion of VitaMed Promissory Notes

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 – NOTES PAYABLE (Continued)

Issuance, Payment and Conversion of VitaMed Promissory Notes (continued)

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

For the year ended December 31, 2012, we recorded an aggregate of $6,344 as interest expense on the accompanying consolidated financial statements.

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

At December 31, 2014, we had 10,000,000 shares of Preferred Stock, par value $0.001, authorized for issuance, of which no shares of Preferred Stock were issued or outstanding.

Common Stock

At December 31, 2014, we had 250,000,000 shares of Common Stock, par value $0.001, authorized for issuance, of which 156,097,019 shares of our Common Stock were issued and outstanding.

Issuances During 2014

On July 29, 2014, we entered into an underwriting agreement with Goldman Sachs & Co, as the representative of the underwriters named therein, or the Goldman Sachs Underwriters, relating to an underwritten public offering of 8,565,310 shares of our Common Stock. The price to the public in the offering was $4.67 per share. Under the terms of the underwriting agreement, we granted the Goldman Sachs Underwriters a 30-day option to purchase up to an additional 1,284,796 shares of our Common Stock. On July 30, 2014, the Goldman Sachs Underwriters exercised their option to purchase the additional 1,284,796 shares of our Common Stock. Net proceeds from this offering were approximately $42.8 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering closed on August 4, 2014.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

During the year ended December 31, 2014, certain individuals exercised stock options to purchase 860,800 shares of our Common Stock. Stock options to purchase shares of our Common Stock were exercised as follows: (i) 724,193 options for $345,746 in cash and (ii) 136,607 options, pursuant to the stock options' cashless provision, wherein 130,380 shares of Common Stock were issued. In addition, during 2014, we issued 50,000 shares of Common Stock to an employee upon the vesting of restricted stock units that were granted in December 2013.

During the year ended December 31, 2014, certain individuals exercised warrants to purchase 365,583 shares of our Common Stock for $181,000 in cash.

Issuances During 2013

On March 14, 2013, we entered into an underwriting agreement with Jefferies LLC as the representative of the underwriters named therein, or the Jefferies Underwriters, relating to the issuance and sale of 29,411,765 shares of our Common Stock. The price to the public in the offering was $1.70 per share. In addition, under the terms of the underwriting agreement, we granted the Jefferies Underwriters a 30-day option to purchase up to an additional 4,411,765 shares of our Common Stock. The offering closed on March 20, 2013. On April 12, 2013, the Jefferies Underwriters exercised their option to purchase an additional 1,954,587 shares of our Common Stock, which were issued on April 18, 2013. The net proceeds to us from this offering were approximately $48.5 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

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

During 2013 certain individuals exercised stock options to purchase an aggregate of 75,423 shares of our Common Stock for approximately $31,000.

Issuances During 2012

During June 2012, we settled $3,102,000 in principal and accrued interest of the February 2012 Notes in exchange for the holders' exercise of a portion of the related warrants for an aggregate of 8,145,486 shares of Common Stock. During June 2012, we and the holders also agreed to convert a portion of the February 2012 Notes, and principal and accrued interest through June 19, 2012 totaling $1,054,647, into 2,775,415 shares of Common Stock at $0.38 per share.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Issuances During 2012 (continued)

In September 2012, we entered into a Securities Purchase Agreement with multiple investors, relating to the issuance and sale of Common Stock in a private placement. The private placement closed on October 2, 2012, through which we sold an aggregate of 3,953,489 shares of Common Stock at $2.15 per share, for an aggregate purchase price of $8,500,001. In connection with the private placement, Jefferies LLC served as our exclusive placement agent. Jefferies' compensation for the transaction was a cash fee of $552,500. We also paid legal fees and expenses of the investors in the aggregate of $52,016, resulting in net proceeds to us from the private placement of $7,895,485. Pursuant to the terms of the Securities Purchase Agreement, we agreed to file a registration statement covering the resale of these shares, which was filed on November 27, 2012.

During the year ended December 31, 2012, certain individuals exercised stock options to purchase 1,958,216 shares of Common Stock. Stock options to purchase shares of Common Stock were exercised as follows: (i) 1,691,393 options for $191,000 in cash and (ii) 266,823 options, pursuant to the stock options' cashless provision, wherein 240,395 shares of Common Stock were issued.

Warrants to Purchase Common Stock

As of December 31, 2014, we had warrants outstanding to purchase an aggregate of 13,927,916 shares of our Common Stock with a weighted-average contractual remaining life of 3.0 years, and exercise prices ranging from $0.24 to $3.20 per share, resulting in a weighted average exercise price of $1.82 per share.

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

Warrant Activity During 2014

During the year ended December 31, 2014, we did not issue any warrants. As of December 31, 2014, unamortized costs associated with the Sancilio & Company, Inc., or SCI warrants issued in 2013 and 2012 totaled approximately $875,600.

Warrant Activity During 2013

In January 2013, we issued warrants to purchase 1,250,000 shares of our Common Stock in connection with the issuance of the Revolving Credit Note, or the Plato Warrant, (see NOTE 10 above for more details). The Plato Warrant has an exercise price of $3.20 per share. The Plato Warrant vested on October 31, 2013 and may be exercised prior to its expiration on January 31, 2019. The Plato Warrant, with a fair value of approximately $1,711,956, was valued on the date of the grant using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. During the years ended December 31, 2014 and 2013, $260,027 and $1,451,934, respectively, was recorded as financing costs in connection with the issuance of the Plato Warrant on the accompanying consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Warrant Activity During 2013 (continued)

In May 2013, we entered into a consulting agreement with SCI, to develop drug platforms to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain U.S. Food and Drug Administration, or the FDA, approval for our drug candidates, 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 to purchase 833,000 shares of our Common Stock that were to be granted pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the agreement, we agreed to issue to SCI a warrant to purchase 850,000 shares of our Common Stock at $2.01 per share that has vested or will vest, as applicable, as follows:

1. 283,333 shares were earned on May 11, 2013 upon acceptance of an Investigational New Drug application by the FDA for an estradiol-based drug candidate in a softgel vaginal capsule for the treatment of VVA; however, pursuant to the terms of the consulting agreement, the shares did not vest until June 30, 2013. The fair value of $405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of 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 non-cash compensation as of 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%. As of December 31, 2014, we recorded $154,068 as prepaid expense-short term and $77,026 as prepaid expense-long term in the accompanying consolidated financial statements. During the years ended December 31 2014 and 2013, we recorded $154,068 and $77,034, respectively, as non-cash compensation in the accompanying consolidated financial statements; and

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

Warrant Activity During 2012

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Warrant Activity During 2012

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

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to an unaffiliated entity for services to be rendered over approximately five years beginning in May 2012. Services provided are to include (a) services in support of our drug development efforts, including services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain New Drug Approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. At December 31, 2014, we had $257,796 reported as prepaid expense-short term and $386,694 recorded as prepaid expense-long term. During the years ended December 31, 2014, 2013 and 2012, we recorded $309,165, $360,528 and $218,045, respectively as non-cash compensation with respect to these warrants in the accompanying consolidated financial statements. The contract will expire upon the commercial manufacture of a drug product. 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 warrant to purchase aggregate of 7,000,000 shares of Common Stock in connection with the issuance of the June 2012 Notes, or the June 2012 Warrants, (see NOTE 9). Of the June 2012 Warrants issued, 6,000,000 are exercisable at $2.00 per share and 1,000,000 are exercisable at $3.00 per share. The fair value of the June 2012 Warrants of $9,424,982 was determined on the date of the issuance using a term of five years; a volatility of 44.64%; risk free rate of 0.75%; and a dividend yield of 0%. The relative fair value of the June 2012 Warrants of $1,649,890 was determined by using the relative fair value calculation method on the date of the issuance. $547,210 was amortized to interest expense in 2012 and as a result of the repayment of the associated debt on March 21, 2013, the remaining unamortized debt discount of $1,102,680 was amortized to interest expense.

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Summary of our Warrant activity and related information for 2012-2014

	Number of Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2011	3,057,627	$ 0.36	7.9	$3,483,691
Issued	17,332,500	$ 1.26		
Exercised	(8,145,486)	$ 0.38		
Expired	—			
Cancelled	(51,142)	$ 0.24		
Balance at December 31, 2012	12,193,499	$ 1.63	4.8	$17,971,994
Issued	2,100,000	$ 2.72		
Exercised	—			
Expired	—			
Cancelled	—			
Balance at December 31, 2013	14,293,499	$ 1.79	3.9	$48,932,777
Issued	—			
Exercised	(365,583)	$ 0.50		
Expired	—			
Cancelled	—			
Balance at December 31, 2014	13,927,916	$ 1.82	3.0	$36,623,875
Vested and Exercisable at December 31, 2014	13,562,764	$ 1.83	2.9	$35,599,540

The weighted average fair value per share of warrants issued and the assumptions used in the Black-Scholes Model during the years ended December 31, 2014, 2013 and 2012 are set forth in the table below.

	2014	2013	2012
Weighted average fair value	$—	$2.83	$2.05
Risk-free interest rate	— %	0.88-1.12 %	0.72-1.04 %
Volatility	— %	44.29-45.89 %	44.64-44.81 %

Term (in years)	—		5-6		5	
Dividend yield	0.00	%	0.00	%	0.00	%

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

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our estimated volatility is an average of the historical volatility of the stock prices of 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 peer entities due to the lack of sufficient historical data of our stock price during 2011-2014.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Options to Purchase Common Stock of the Company

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares authorized for issuance thereunder. Prior to the merger with VitaMed, no Awards had been issued under the 2009 Plan. As of December 31, 2014, there were Awards for 18,246,625 shares of our Common Stock issued under the 2009 Plan.

On February 23, 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. There are 10,000,000 shares of our Common Stock authorized for issuance thereunder. As of December 31, 2014, there were awards for 2,600,000 shares issued under the 2012 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The assumptions used in the Black-Scholes Model during the years ended December 31, 2014, 2013 and 2012 are set forth in the table below.

	2014		2013		2012	
Risk-free interest rate	0.07-1.77	%	0.65-1.71	%	0.61-2.23	%
Volatility	68.05-82.29	%	33.35-45.76	%	40.77-46.01	%
Term (in years)	0.5-6.25		5-6.25		5-6.25	
Dividend yield	0.00	%	0.00	%	0.00	%

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – STOCKHOLDERS' EQUITY (Continued)

Options to Purchase Common Stock of the Company (continued)

A summary of activity under the 2009 and 2012 Plans and related information for 2012-2014 follows:

	Number of Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2011	10,590,161	$ 0.16	7.6	$14,067,649
Granted	5,121,250	$ 2.80		
Exercised	(1,931,788)			
Expired	—			
Cancelled	(46,135)			
Balance at December 31, 2012	13,733,488	$ 1.16	7.7	$26,804,117
Granted	2,583,677	$ 3.31		
Exercised	(75,423)			
Expired	(250)			
Cancelled	(608,750)			
Balance at December 31, 2013	15,632,742	$ 1.44	7.2	$58,878,132
Granted	2,442,000	$ 4.71		
Exercised	(854,573)			
Expired	(250)			
Cancelled	(427,476)			
Balance at December 31, 2014	16,792,443	$ 1.88	6.9	$43,996,311
Vested and Exercisable at December 31, 2014	13,276,462	$ 1.39	5.5	$40,720,977

At December 31, 2014, our outstanding options had exercise prices ranging from $0.10 to $5.21 per share.

Share-based compensation expense for options recognized in our results for the years ended December 31, 2014, 2013, and 2012 ($4,393,455, $3,200,655 and $1,832,061, 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, 2014, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $5,160,000, which is expected to be recognized over a weighted-average period of 2.9 years. No tax benefit was realized due to a continued pattern of operating losses. At December 31, 2013 and 2012, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $3,921,000 and $4,391,000, respectively.

In December 2013, we granted a restricted stock unit, or the RSU, under our 2012 Plan to an employee of 50,000 shares of our Common Stock having a fair value of $233,500. During the years ended December 31, 2014 and 2013, we recorded $53,428 and $180,072, respectively, of non-cash compensation related to the RSU on the accompanying consolidated financial statements. The RSU vested and the shares of Common Stock underlying the RSU were issued in June 2014.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 – INCOME TAXES

For the years ended December 31, 2014, 2013 and 2012, there was no provision for income taxes, current or deferred.

At December 31, 2014, we have a federal net operating loss carry forward of approximately $105,529,416 available to offset future taxable income through 2034.

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

	2014	2013	2012
Federal statutory tax rate	34.0 %	35.0 %	35.0 %
State tax rate, net of federal tax benefit	5.8 %	5.8 %	5.5 %
Adjustment in valuation allowances	(50.9)%	(32.4)%	(18.2)%
Permanent and other differences	11.1 %	(8.4)%	(22.3)%
Provision (Benefit) for Income Taxes	— %	— %	— %

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

	2014	2013	2012
Deferred Income Tax Assets:			
Net operating losses	$43,091,437	$14,773,537	$5,920,861
R&D Credit	0	547,511	186,346
Total deferred income tax asset	43,091,437	15,321,048	6,107,207
Valuation allowance	(43,091,437)	(15,321,048)	(6,107,207)
Deferred Income Tax Assets, net	$—	$—	$—

We believe that it is more likely than not that we will not generate sufficient future taxable income to realize the tax benefits related to the deferred tax assets on our balance sheet and as such, a valuation allowance has been established

against the deferred tax assets for the period ended December 31, 2014.

Unrecognized Tax Benefits

As of the period ended December 31, 2014, we had no unrecognized tax benefits.

NOTE 12 – RELATED PARTIES

Loan Guaranty

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – RELATED PARTIES (Continued)

Loans from Affiliates

In June 2011, VitaMed issued the VitaMed Notes in the aggregate principal amount of $500,000, of which $100,000 was sold to affiliates. In June 2012, the affiliate notes were extended to October 15, 2012 (one held by Mr. Milligan for $50,000 and one for $50,000 held by BF Investments, LLC, which is owned by Brian Bernick, a member of the board of directors of our company. On October 4, 2012 these VitaMed 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 promissory note held by Mr. Finizio was paid in full, including $888 in accrued interest. Mr. Milligan's promissory note was extended to October 15, 2012. On October 4, 2012 this promissory note was paid in full including $1,519 in accrued interest.

Purchases by Related Parties

During 2012, we sold our products to Dr. Brian Bernick, a director of our company, in the amount of $2,632, and $1,272 of receivables related thereto remained outstanding at December 31, 2012. No products were sold to Dr. Bernick during 2014 and 2013.

Agreements with Pernix Therapeutics, LLC

On February 29, 2012, Cooper C. Collins, president and largest shareholder of Pernix Therapeutics, LLC, or Pernix, was elected to serve on our board of directors. From time to time, we have entered into agreements with Pernix in the normal course of business. All such agreements are reviewed by independent directors of our company or a committee consisting of independent directors of our company. During the years ended December 31, 2014, 2013, and 2012, we

made purchases of $0, $0 and $404,000, respectively, from Pernix. At December 31, 2014, 2013, and 2012, there were amounts due Pernix of approximately $46,000, $46,000, and $308,000 outstanding, respectively.

Additionally, there were amounts due to us from Pernix for legal fee reimbursement relating to a litigation matter pursuant to a license and supply agreement in the amount of $249,981 for each of the years ended December 31, 2014 and 2013.

Warrants assigned to Related Party

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

NOTE 13 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 82%, 98%, and 76% of our purchases supplied from one vendor for the years ended December 31, 2014, 2013, and 2012, respectively.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 13 - BUSINESS CONCENTRATIONS (Continued)

We sell our vitamins, prenatal dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, other institutions and directly to retail customers. Revenue generated from four customers accounted for approximately 75%, 79%, and 28% of our recognized revenue and 97%, 97%, and 98% of our deferred revenue for the years ended December 31, 2014, 2013, and 2012, respectively.

For the years ended December 31, 2014, 2013 and 2012, we had four customers that generated more than 10% of our sales – these customers are designated as customers “A”, “B”, “C” and “D”. Customers A, B, C and D generated $1,609,950, $1,586,903, $1,804,018 and $4,053,838, respectively, in sales in 2014; $1,221,212, $1,711,417, $2,588,626, and $1,312,192, respectively, in sales in 2013; and $67,599, $490,092, $830,902, and $0, respectively, in sales in 2012.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Operating Lease

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

The straight line rental expense related to our current lease totaled $361,793 for the year ended December 31, 2014, partially offset by the rent income of $41,613 for sublet space. The straight line rental expense related to our current lease totaled $180,894 for the six months ended December 31, 2013, partially offset by rent income of $32,963 for sublet space. The rental expense related to our prior lease which expired June 30, 2013 totaled $60,168 for the six months ended June 30, 2013, and $106,315 for the year ended December 31, 2012.

As of December 31, 2014, future minimum rental payments under our office lease are as follows:

Years Ending December 31,	
2015	$371,240
2016	382,377
2017	393,848
2018	302,748
2019	—
Total minimum lease payments	
Non-cancellable sub-lease income	—
Net minimum lease payments	$1,450,213

Legal Proceedings

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

Off-Balance Sheet Arrangements

As of December 31, 2014, 2013 and 2012, we had no off-balance sheet arrangements that have had or are reasonably likely to have current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 15 – SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal years 2014, 2013, and 2012 is as follows:

	2014 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$2,831	$3,752	$4,186	$4,257
Gross profit	$2,000	$2,859	$3,118	$3,377
Net loss	$(9,183)	$(10,899)	$(17,832)	$(16,303)
Loss per common share, basic and diluted	$(0.06)	$(0.07)	$(0.12)	$(0.10)

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

	2012 Quarters			
(In thousands, except per share)	1st	2nd	3rd	4th
Revenues	$722	$819	$1,036	$1,241
Gross profit	$386	$447	$729	$908
Net loss	$(13,290)	$(11,850)	$(4,253)	$(5,727)
Loss per common share, basic and diluted	$(0.16)	$(0.14)	$(0.04)	$(0.06)

NOTE 16 – SUBSEQUENT EVENTS

On February 10, 2015, we entered into an underwriting agreement, or the Cowen Agreement, with Cowen and Company, LLC, as the representative of the several underwriters, or the Cowen Underwriters, relating to an underwritten public offering of 13,580,246 shares of the our Common Stock, at a public offering price of $4.05 per

share. Under the terms of the Cowen Agreement, we granted the Cowen Underwriters a 30-day option to purchase up to an aggregate of 2,037,036 additional shares of Common Stock, which option was exercised in full. The net proceeds to us from the offering were approximately $59.1 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The offering closed on February 17, 2015.

On February 18, 2015, we entered into an agreement to lease administrative office space in Boca Raton, Florida, pursuant to an addendum to our existing 63 month non-cancelable operating lease commencing on July 1, 2013 and expiring on September 30, 2018. This addendum will be effective beginning April 1, 2015 and will expire with the original lease term on September 30, 2018.