PERNIX THERAPEUTICS HOLDINGS, INC.
Form 10-K
March 02, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

þ Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2014

o Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number: 001-14494

Pernix Therapeutics Holdings, Inc.
(Exact name of registrant as specified in its charter)

Maryland	33-0724736
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification Number)
10 North Park Place, Suite 201 Morristown, NJ 07960 (Address of principal executive offices) (Zip Code)	(800) 793-2145 (Telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.01 per share	NASDAQ Global Market

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þNo o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

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

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2014 (the last business day of the registrant's most recently completed second quarter) was approximately $327,475,000, based upon the $8.98 closing sales price of the registrant's common stock as reported on the NASDAQ Stock Market on such date. Shares of common stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

On February 25, 2015, the registrant had 38,386,381 shares of its common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2015 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2014.

PERNIX THERAPEUTICS HOLDINGS, INC.
Annual Report on Form 10-K for the Year Ended December 31, 2014
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Cautionary Statement Regarding Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of current or historical fact, including statements regarding our current expectations of our future growth, results of operations, financial condition, cash flows, performance and business prospects, and opportunities and any other statements about management's future expectations, beliefs, goals, plans or prospects, constitute forward-looking statements. We have tried to identify forward-looking statements by using words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "target," "will," "would," other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the rate and degree of market acceptance of, and our ability and our distribution and marketing partners' ability to obtain reimbursement for, any approved products; our ability to successfully execute our sales and marketing strategy, including to continue to successfully recruit and retain sales and marketing personnel in the U.S.; our ability to obtain additional financing; our ability to maintain regulatory approvals for our products; the accuracy of our estimates regarding expenses, future revenues and capital requirements; our ability to manage our anticipated future growth; the ability of our products to compete with generic products as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products; the performance of our manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to operate our business without infringing the intellectual property rights of others; the success and timing of our clinical development efforts; the loss of key scientific or management personnel; regulatory developments in the U.S. and foreign countries; our ability to either acquire or develop and commercialize other product candidates in addition to our current products and other risks detailed below in Part I—Item 1A "Risk Factors."

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. In addition, any forward-looking statements in this Annual Report on Form 10-K represent our views only as of the date of this Annual Report on Form 10-K and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so unless required by law, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make in the future.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

Growing sales of the existing products in our portfolio in various ways, including identifying new growth opportunities;

Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure; and

Pursuing targeted development of a pipeline of post-discovery specialty product candidates.

We target underserved segments, such as central nervous system (CNS) indications, including neurology and psychiatry, as well as other specialty therapeutic areas. We promote our core branded products to physicians through our sales force. We promote our non-core branded products, such as our cough and cold products, through contract sales organizations, and we distribute our generic products through our wholly owned subsidiaries, Macoven Pharmaceuticals, LLC ("Macoven") and Cypress Pharmaceuticals, Inc. ("Cypress").

We experienced significant revenue and earnings growth in 2014, as a result of the following:

We relocated our corporate headquarters to Morristown, New Jersey and replaced our entire senior management team as well as reconfigured our board of directors to replace insiders with independent directors that each have over fifteen years of experience in the pharmaceutical industry;

The acquisition of a new market-proven branded product, Treximet;

Realigning our sales force from a regionally-focused 87-person sales force to a sales force with approximately 100 sales territories and a nationwide footprint;

Prioritization of our selling and marketing activities around our CNS franchise;

Divesting under-performing assets, such as our manufacturing facility in Houston, Texas; and

Closing our distribution facilities in Madison, Mississippi and Magnolia, Texas and transitioning to an industry-known third party logistics provider;

As a result, in 2014, Pernix reported its highest net revenues since becoming a pharmaceutical company through a reverse merger in March 2010. Going into 2015, we have a portfolio of approved products that address medical needs in several therapeutic areas, including:

Pain/Neurology: Treximet (sumatriptan/naproxen), the only second-line analgesic indicated for acute migraine;

Insomnia: Silenor (doxepin), the only nonnarcotic, nonscheduled prescription sleep aid for the treatment of insomnia characterized by difficulty with sleep maintenance; and

Psychiatry: Khedezla (desvenlafaxine extended-release tablets), for major depressive disorder.

In addition, we made significant progress and investment in expanding our product development pipeline. We submitted a supplemental New Drug Application for a pediatric indication for Treximet that has the potential to provide an additional six months of market exclusivity at the end of the patent life. We also executed third-party agreements with contract research organizations to initiate the development of new formulations for Treximet and to initiate efficacy studies for an over-the-counter ("OTC") formulation of Silenor – each designed to add years to the life span of these brands.

Our Products and Product Candidates

Pernix-Promoted Products

Treximet (sumatriptan/naproxen)

Treximet is the only combination sumatriptan and naproxen sodium product approved by the US Food and Drug Administration ("FDA"). Sumatriptan, one of the two active ingredients in Treximet, is a synthetic drug belonging to the triptan class used for the treatment of migraine headaches. Naproxen sodium, the other active ingredient in Treximet, is a non-steroidal anti-inflammatory drug ("NSAID") used to relieve pain from various conditions such as headaches, muscle aches, tendonitis, dental pain, and menstrual cramps, as well as pain, swelling, and joint stiffness caused by arthritis, bursitis, and gout attacks. Treximet was approved in April 2008 for acute migraine attacks, with or without aura, in adults. The product is a unique formulation of sumatriptan and naproxen sodium that employs POZEN Inc.'s ("POZEN") patented formulation technology and GlaxoSmithKline's ("GSK") RT Technology™. This unique combination provides a synergistic therapeutic effect. The triptan component shrinks the swollen blood vessels in the

head, which has been demonstrated to provide relief of migraine pain. The NSAID component inhibits the enzyme responsible for the production of prostaglandins, which are the mediators of pain and inflammation. This dual mechanism of action, Treximet, has been shown to provide superior sustained pain relief compared to placebo and to both of the single mechanism of action in components. In clinical trials, Treximet demonstrated significantly greater pain relief at two hours compared to sumatriptan 85mg or naproxen sodium 500 mg alone. In addition, Treximet provided more patients with sustained migraine pain relief from two to 24 hours compared to the individual components.

Migraines are a common and disabling neurologic condition that affect an 17% of females and 6% of males in the United States. Based on current US census data, there are over 28 million individuals in the US who suffer from migraines. A variety of medications have been specifically designed to treat migraines. Medications used to combat migraines fall into two broad categories: acute or abortive medications; and preventative or prophylactic medications. Triptans, which are the most commonly prescribed class of drugs for acute migraine, are available as oral pills, nasal sprays, injections and tablets that dissolve under the tongue. NSAIDs, such as ibuprofen and naproxen, are also used to treat acute migraine. Treximet is a higher potency acute medication that combines the benefits of both of these commonly used classes of drugs.

Migraines have an estimated prevalence of 8% to 23% in children 11 years of age and older. Acute and prophylactic treatments are similar to those used for adults. Sumatriptan is the most widely studied triptan in adolescents. In clinical trials to date, sumatriptan has failed to demonstrate efficacy versus placebo, primarily as a result of a high placebo response. Currently there is no sumatriptan or combination prescription medication for the treatment of acute migraine attacks with or without aura approved for use in this population. We believe Treximet has the potential to meet this void. On November 14, 2014 we submitted a supplemental New Drug Application (sNDA) seeking approval for Treximet for use in adolescent patients, aged 12 – 17, for the acute treatment of migraine with or without aura. Included in the filing are safety and efficacy data sets from three trials conducted to evaluate the pharmacokinetic, efficacy, and long-term safety of Treximet for the acute treatment of adolescent migraine. On January 15, 2015, we announced that our sNDA was accepted by the FDA.

In 2014, net product sales of Treximet were $54.8 million for the months of September (our launch) through December, which represents 46% of our total net product sales for the full year of 2014.

We promote Treximet in the United States through our nationwide specialty sales force, which covers approximately 100 territories. Treximet is manufactured by GSK under a license from POZEN. In June 2003, POZEN licensed the US rights for Treximet to GSK. Prior to our acquisition of Treximet, GSK was responsible for all commercialization activities in the US. GSK paid milestones and royalties on sales to POZEN during this time. In November 2011, POZEN sold most of these future royalty and milestone payments to CPPIB Credit Investments Inc. (“CPPIB”). Near the end of 2012, GSK stopped promoting Treximet. Treximet is exclusively licensed to us for US marketing, sales and distribution. GSK is our sole supplier. We are currently qualifying an additional manufacturing source to support future supply. Treximet is covered by four patents in the U.S., which are currently held by our subsidiary, Pernix Ireland Limited (“PIL”). Three of the patents expire August 14, 2017, and one expires in October 2, 2025. In addition, we are seeking pediatric exclusivity, which may provide an additional six months of exclusivity. Four companies have filed abbreviated new drug applications (ANDAs) with the FDA seeking approval to market a generic version of Treximet. Settlement agreements have been executed with all of these generic filers, which will result in generic entrants at the conclusion of our exclusivity period.

Silenor (doxepin)

Silenor is the only nonnarcotic, nonscheduled prescription sleep aid for the treatment of insomnia characterized by difficulty with sleep maintenance. Silenor is marketed as an oral tablet formulation, and is available in 3 mg and 6 mg dosage forms. Doxepin, the active ingredient in Silenor, binds to H1 receptors in the brain and blocks histamine, which is believed to play an important role in the regulation of sleep. Doxepin has been marketed and used for over 35 years at dosages ranging from 75 mg to 300 mg for the treatment of anxiety and depression, but has historically not been used to treat insomnia due to undesirable next-day residual effects. We believe that Silenor, which uses doxepin at much lower dosages, does not exhibit the same pharmacological effects as high-dose doxepin.

In four separate Phase III clinical trials, Silenor demonstrated a favorable safety and tolerability profile, including a low dropout rate and an adverse event profile comparable to placebo. Silenor demonstrated no clinically meaningful

next-day residual effects and no evidence of amnesia, complex sleep behaviors, hallucinations, tolerance or withdrawal effects. Silenor was approved by the FDA in March 2010 for the treatment of insomnia characterized by difficulty with sleep maintenance, and was launched commercially in the United States in September 2010 by Pernix Sleep, Inc. (f/k/a Somaxon Pharmaceuticals, Inc.), or "Pernix Sleep.". We acquired the Silenor product line as a result of our merger with Somaxon on March 6, 2013, and we launched Silenor in the second quarter of 2013.

The current market-leading prescription products for the treatment of insomnia include: GABA-receptor agonists, which are classified by the FDA as Schedule IV controlled substances; melatonin agonists; hypnotic benzodiazepines; and sedating antidepressants. Currently, the most widely-prescribed products for the treatment of insomnia include GABA-receptor agonists such as: zolpidem (Ambien); zolpidem tartrate extended-release tablets (Ambien CR), a controlled-release formulation of Ambien; eszopiclone (Lunesta); and zalepon (Sonata). In addition, melatonin agonists such as ramelteon (Rozerem), hypnotic benzodiazepines, such as temazapam (Restoril) and flurazepam (Dalmane), and sedating antidepressants such as trazodone (Desyrel) are used to treat insomnia. Our market research indicated that the market is underserved due in large part to characteristics associated with many of these products, such as next-day grogginess, memory impairment, amnesia, hallucinations, physical and psychological dependence, complex sleep behaviors such as sleep driving, hormonal changes and gastrointestinal effects.

We believe that Silenor offers many benefits, including improved safety, tolerability and efficacy in the treatment of sleep maintenance. Unlike many of the other insomnia treatments currently available, Silenor is not designated as a controlled substance, and according to its FDA-approved labeling, Silenor does not appear to have any potential for dependency, addiction or abuse. Because Silenor is not a Schedule IV controlled substance, it can be made available to physicians, facilitating initial physician and patient trials without the additional sampling regulation that applies to controlled substances.

As a result of the numerous benefits presented by Silenor, the limitations of other current therapies, and because it is the first and only nonscheduled prescription sleep medication approved by the FDA for the treatment of insomnia characterized by difficulty with sleep maintenance, we believe that Silenor has the potential for increased growth in the market. We plan to strategically invest in sales and marketing activities to maximize revenue and market share of this product, and we intend to engage in life-cycle management activities relating to Silenor, including potential OTC opportunities.

In 2014, net product sales of Silenor were $15.3 million, which represents 13% of our total net product sales.

We promote Silenor in the United States through our nationwide specialty sales force, which covers approximately 100 territories. This sales force is also responsible for selling Treximet. We market and sell Silenor through Paladin Labs (a division of Endo Pharmaceuticals plc) in Canada and are currently working with CJ Cheiljedang to launch in South Korea in 2015. Silenor is covered by three US patents, currently held by ProCom One, Inc. (“ProCom”), related to the development and commercialization of low dosages of doxepin and other antidepressants for the treatment of insomnia. We are the exclusive licensee of these patents, the last of which expires in 2030. We have an exclusive supply agreement with JRS Pharma L.P. for the exclusive use of ProSolv®HD90, an ingredient used in our formulation for Silenor, in combination with doxepin. See further discussion under the heading “Intellectual Property” later in this Item 1 for a more detailed description of the rights associated with the Silenor.

Khedezla (desvenlafaxine extended-release tablets)

Khedezla is a prescription formulation of desvenlafaxine, which is a selective norepinephrine reuptake inhibitor used to treat major depressive disorder. Khedezla is available in oral tablet formulations of 50 mg and 100 mg and are bioequivalent to Pristiq®, which is marketed by Pfizer, Inc. Khedezla was approved by the FDA in July 2013 under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. We launched Khedezla in the second quarter of 2014.

Khedezla competes directly with Pristiq. In 2013, Pristiq had US sales of approximately $700 million. Khedezla also competes with other treatments for depression such as Effexor XR® (venlafaxine) (Pfizer), Cymbalta® (duloxetine) (Eli Lilly) and Lexapro® (escitalopram) (Forest). We believe that Khedezla is an economically attractive alternative to Pristiq that we can promote cost effectively, with simple market positioning.

We received the rights to Khedezla through our exclusive license agreement with Osmotica Pharmaceuticals Corp. (“Osmotica”). Please see further discussion under the heading “Osmotica License Agreement” later in this Item 1 for a more detailed description of our rights associated with Khedezla.

Externally-Promoted and Non-Promoted Products

We market and sell our non-core products through contract sales arrangements with organizations such as PDI, Inc. We market our non-promoted products through distributors and trade partners.

Cedax®. Cedax is a third generation oral cephalosporin indicated for the treatment of mild to moderate acute bacterial exacerbations of chronic bronchitis and middle ear infection due to haemophilus influenza or streptococcus pyogenes. We acquired the Cedax product line from Shionogi Pharma, Inc., (“Shionogi"), in March 2010, and launched our Cedax product line in the second quarter of 2010. We sell a variety of dosages utilizing both capsule and oral suspension drug delivery methodologies. Other branded and similar prescription treatments marketed in the US that compete with our Cedax line include Suprax, Amoxicillin, Omnicef, Cefzil, Ceclor and Ceftin. We have a non-exclusive license to the patent used in our Cedax product line. This patent expired on February 4, 2014; however, we believe that the manufacturing barrier related to CEDAX and the fact that we market an authorized generic version of Cedax reduces the possibility of generic entrants to the market. We also own a trademark on the name

Cedax in the US. Please see further discussion under the heading “Intellectual Property” later in this Item 1 for a more detailed description of the rights associated with the Cedax line of products.

Cough & cold products. We market and sell a family of cough and cold products including: Zutripro®, Rezira® and Vituz® which we acquired in our acquisition of Cypress and its subsidiary Hawthorn Pharmaceuticals on December 31, 2012. Zutripro is a proprietary oral formulation of hydrocodone bitartrate, chlorpheniramine maleate and pseudoephedrine HCl indicated for the relief of cough and nasal congestion associated with the common cold, and relief of upper respiratory allergy symptoms including nasal congestion, in adults 18 years of age or older. Rezira is a proprietary oral formulation of hydrocodone bitartrate and pseudoephedrine HCl indicated for the relief of cough and nasal congestion associated with the common cold in adults 18 years of age or older. Zutripro and Rezira were launched late June 2011. We began selling these products in January 2013 through our acquisition of Hawthorn. We also sell an authorized generic of Zutripro through Cypress which was launched in February 2014. Vituz is a proprietary hydrocodone bitartrate and chlorpheniramine maleate combination oral solution indicated for the treatment of patients with cough and allergies associated with the common cold. This product was in-process research and development when we closed on the acquisition of Cypress and Hawthorn. We launched Vituz in April 2013. The FDA issued a final rule effective October 6, 2014 that reschedules hydrocodone combination products from schedule III to schedule II. This action imposes regulatory controls and administrative , civil, and criminal sanction applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research conduct instructional activities with, conduct chemical analysis with, or posess) or propose to handle hydrocodone combination products. This reclassification may limit access or reduce demand for these products.

Research and Development

Our development pipeline projects currently include clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products. These projects are concentrated in our migraine, insomnia and pain therapeutic areas, where we believe we will be able to leverage our existing specialty commercial expertise and infrastructure, as well as our strong clinical, medical and commercial teams. We intend to be opportunistic in exploiting our in-house expertise and intellectual property to initiate additional low risk development projects. In addition, we will look for external opportunities through in-licensing, collaborations or partnerships to build the Pernix pipeline.

In the migraine area, we are investigating opportunities to expand use and extend the lifecycle of Treximet. We are currently exploring the following development programs:

Adolescent Supplemental New Drug Application (sNDA). We have evaluated the use of Treximet in adolescents aged 12 to 17. On January 15, 2015, we announced that the FDA accepted our sNDA for Treximet with Priority Review status. Priority Review generally implies a 6-month review, and we anticipate an FDA decision before June 30, 2015.

Alternate dose formulations for Treximet. We are currently evaluating new formulations of Treximet, which if approved by FDA, could provide life cycle extension opportunities.

In the insomnia area we have the following programs under development:

Silenor Phase IV arousability study. We are evaluating Silenor in a post-marketing study to determine a patient's arousability from sleep while taking Silenor. We intend to compare these findings with arousability while taking other sleep medications, such as GABA-receptor agonists.

Silenor OTC. We are evaluating an OTC formulation of Silenor. We expect to submit an Investigational New Drug Application ("IND") for Silenor OTC in 2015.

For the years ended December 31, 2014, 2013 and 2012, we recorded $3.9 million, $4.8 million and $0.7 million, respectively, in research and development expenses. For 2014 and beyond, we expect that our research and development expenses will increase substantially from these historical levels, particularly as we initiate our various planned clinical trials and development initiatives, aimed at extended the life span and prolonging sales of our promoted brands

Sales and Marketing

Our commercial activities in the United States are dedicated to our marketed products Treximet, Silenor and Khedezla. Our commercial team also provides support for sales of certain of our other products from time to time. We currently sell our products through our sales force, which covers approximately 100 territories nationwide. Our team of experienced sales professionals details our products to physicians in specialties appropriate for each marketed product.

Our commercial activities include marketing and related services and commercial support services. We also employ third-party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services, to assist with our commercial activities.

We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. We believe that the size of our sales force is appropriate to effectively reach our target audience for our marketed products in the specialty markets in which we currently operate. Continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization in the United States and internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization.

Business Development and Restructuring

Acquisition of Treximet

On August 20, 2014, we, through our wholly owned subsidiary PIL, formerly known as Worrigan Limited, completed the acquisition of the US intellectual property rights to the pharmaceutical product, Treximet, from GSK.

The total purchase price originally consisted of an upfront cash payment of $250.0 million to GSK upon closing of the transaction, and up to $17.0 million payable to GSK upon receipt of an updated written request for pediatric exclusivity from the FDA. As a result of supply constraints, the contingent payment amount was subsequently reduced from $17.0 million to $1.95 million. We funded this acquisition with $220.0 million in debt and approximately $32.0 million from available cash.

In connection with the transaction, GSK assigned to PIL the Product Development and Commercialization Agreement, (the "PDC Agreement") between GSK and POZEN. In connection with the assignment of the PDC Agreement, PIL paid $3.0 million to CPPIB (which owns the rights to the royalty payments under the PDC Agreement), and the Company has also granted POZEN a warrant (the "Warrant") to purchase 500,000 shares of our common stock at an exercise price of $4.28 per share (the closing price of the our common stock on May 13, 2014 as reported on NASDAQ). The Warrant is exercisable from the closing date (August 20, 2014) of the Agreement until February 28, 2018. We will continue to pay a royalty to POZEN under the PDC Agreement, equal to 18% of net sales with quarterly minimum royalty amounts of $4.0 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018.

Pursuant to the agreement between GSK and PIL, GSK will manufacture Treximet for sale to the Company for a period of three years, unless terminated earlier due to GSK's failure to supply resulting from a force majeure event, the Company's failure to pay the holdback amount, or a material contract breach, insolvency, or bankruptcy by wither party as defined in the supply agreement. We are required to purchase 100% of our requirements of Treximet product from GSK during the first year of the term and to purchase at least 75% of our requirements of Treximet product from GSK during the second and third years of the term, based on a rolling forecast of non-binding estimates of future Treximet product requirements. Additionally, the price of Treximet shall be firm for the first year of the term. Thereafter, the price of Treximet is subject to increase based the Pharmaceutical Preparation – Manufacturing Index for the twelve month immediately preceding the beginning of the second, or this year of the term. We are currently qualifying an additional manufacturing source to support future supply.

Osmotica License Agreement

On February 27, 2014, we entered into an exclusive license agreement with Osmotica to promote Khedezla. Pursuant to the agreement, we agreed to make an upfront payment for the license and Osmotica's existing inventory of Khedezla in the amount of $4.0 million in the aggregate, certain milestone payments payable upon the achievement of certain cumulative sales milestones and royalty payments of 60% of net profits realized for promoting the product. The royalty payments reduce to 55% in the second contract year and 50% for each year thereafter. Subject to certain earlier termination rights, the initial term of the agreement expires in February 2024. Thereafter, this agreement may be renewed for two additional, consecutive five year terms.

Acquisition and Disposition of Pernix Manufacturing, LLC ("PML") (formerly Great Southern Laboratories ("GSL"))

On July 2, 2012, we acquired the business assets of PML, a pharmaceutical contract manufacturing company located in Houston, Texas. We closed on the related real estate on August 30, 2012. We paid an aggregate of approximately $4.6 million and assumed certain liabilities totaling approximately $5.9 million, for substantially all of

PML's assets, including the land and buildings in which PML operated. On April 21, 2014, we completed the disposition of the business assets of PML. We received approximately $1.2 million in proceeds net of the assumed mortgage and working capital liabilities at closing and expect to realize approximately $5.0 million in annualized costs savings from the divestiture. As part of the agreement, the purchaser will continue to manufacture the existing Pernix products under a long-term supply agreement with terms similar to those provided to us by other third-party manufacturers.

Acquisition of Somaxon Pharmaceuticals, Inc. ("Somaxon")

On March 6, 2013, we acquired all of the outstanding common stock of Somaxon pursuant to an agreement and plan of merger. As a result of the merger, we issued an aggregate of approximately 3,665,689 shares of our common stock to the former stockholders of Somaxon. We subsequently changed the name of Somaxon to Pernix Sleep, Inc. We acquired the Silenor product in this acquisition.

Acquisition of Cypress

On December 31, 2012, we completed the acquisition of Cypress Pharmaceuticals, Inc., a privately-owned, generic pharmaceutical company, and its branded pharmaceutical subsidiary, Hawthorn Pharmaceuticals, Inc., or Hawthorn, collectively referred to as Cypress herein. We paid an aggregate purchase price of up to $102.3 million. This purchase price included (i) $52 million in cash, (ii) the issuance of 4,427,084 shares of our common stock having an aggregate market value equal to approximately $34.3 million (based on the closing price of $7.75 per share of our common stock as reported on the NYSE MKT LLC on December 31, 2012), (iii) up to $6.5 million in holdback and contingent payments, (iv) $4.5 million that was to be deposited in escrow on December 15, 2013, and (v) the issuance of $5.0 million in shares of our common stock contingent upon the occurrence of a milestone event. The matter of the contingent consideration has been settled and is reflected at the estimated fair value at December 31, 2013.

As part of the funding for this acquisition, we entered into a $42 million credit facility on December 31, 2012 with Midcap Funding V, LLC. For additional information regarding our credit facility, see Note 16, Debt and Lines of Credit, to our audited consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Sale of Certain Cypress Assets

On September 11, 2013, we completed the sale of certain generic assets and Abbreviated New Drug Applications, or ANDAs, owned by our Cypress subsidiary to Breckenridge Pharmaceutical, Inc., or Breckenridge, pursuant to an Asset Purchase Agreement between Cypress and Breckenridge. The assets included seven previously marketed products, eight ANDAs filed at the FDA, and certain other ANDAs in various stages of development. Breckenridge paid us an aggregate of $29.55 million consisting of cash and two promissory notes, each in an amount of $4.85 million, which are due on the first and second anniversary date of the closing, respectively. We received payment for the first note in the amount of $4.85 million in September of 2014.

Gastroenterology Product License and Supply Agreement

In January 2012, we entered into a license and supply agreement with a private company for Omeclamox-Pak, an FDA-approved prescription product designed to treat gastroenterology disease. Under the terms of the agreement, we obtained exclusive marketing rights to this product in the United States. We paid an up-front license fee of $2.0 million and an additional fee of $2.0 million upon commercial launch of the product in July 2012. In addition to these license fees, we are required to pay minimum quarterly royalty payments of $750,000 and milestones based on certain net sales levels. On October 28, 2013, the Company entered into an agreement with Cumberland Pharmaceuticals Inc. (“Cumberland”) to promote Omeclamox-Pak. Cumberland paid an upfront payment of $4.0 million to the Company on October 29, 2013. There are also additional milestones at the first and second anniversary dates of the execution of the agreement totaling $4.0 million in the aggregate. The first milestone of $1.0 million was not earned. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits are paid by Cumberland to the Company monthly.

Financing Activities

8% Convertible Notes Offering, February 2014 (“February 2014 Convertible Notes”)

On February 21, 2014, we issued $65.0 million aggregate principal amount of the Company’s 8.00% Convertible Senior Notes due 2019 in accordance with each of the Securities Purchase Agreements dated February 4, 2014 by and between the Company and the investors party thereto and the related Indenture dated February 21, 2014, by and between the Company and the trustee. See further discussion under the heading “Liquidity and Capital Resources” in Part II, Item 7 of this Annual Report on Form 10-K.

12% Senior Secured Notes Offering, August 2014 (“Treximet Notes”)

On August 19, 2014, we issued $220.0 million aggregate principal amount of our 12% Senior Secured Notes due 2020 (the “Treximet Notes”) pursuant to an Indenture (the “Treximet Notes Indenture”) dated as of August 19, 2014 among us, certain of our subsidiaries (the “Guarantors”) and US Bank National Association (the “Treximet Notes Trustee”), as trustee and collateral agent.

The Treximet Notes mature on August 1, 2020 and bear interest at a rate of 12% per annum, payable in arrears on February 1 and August 1 of each year (each, a “Payment Date”), beginning on February 1, 2015. On each Payment Date, commencing August 1, 2015, we will pay an installment of principal of the Treximet Notes in an amount equal to 50% of net sales of Treximet for the two consecutive fiscal quarters immediately preceding such Payment Date (less the amount of interest paid on the Treximet Notes on such Payment Date).

MidCap Revolver Amendment

On February 21, 2014, we, together with our subsidiaries, entered into Amendment No. 1 to the Amended and Restated Credit Agreement with MidCap Funding IV, LLC, as Agent and as a lender, and the other lenders from time to time parties thereto. This Amendment No. 1 amends the Amended and Restated Credit Agreement that the Company and its subsidiaries entered into, effective May 8, 2013, with MidCap Financial, LLC, as Administrative Agent and as a lender, and the additional lenders from time to time parties thereto. On April 23, 2014 we entered into Amendment No. 2 to the Amended and Restated Credit Agreement with MidCap to increase the letter of credit sublimit from $0 to $750,000. On August 19, 2014, we entered into Amendment No. 3 to the Amended and Restated Credit Agreement with MidCap to permit us to consummate the purchase of the Treximet asset from GSK.

See further discussion in Note 16, Debt and Lines of Credit, to our audited consolidated financial statements in Part II, Item 8 and also under the heading “Liquidity and Capital Resources” in Part II, Item 7 of this Annual Report on Form 10-K.

Business Strategy

Our strategy is to maximize the commercial strengths and the infrastructure that we have put in place to create a fully-integrated specialty pharmaceutical company. We have re-launched Treximet, Silenor and Khedezla in the US market, and we intend to expand upon and leverage our early commercial success. We are focused on developing, acquiring and in-licensing additional products, and on partnering with and acquiring companies with which we can execute a targeted commercial approach. We are focused primarily on central nervous system (CNS) indications, including neurology and psychiatry, as well as other specialty therapeutic areas that lend themselves to focused promotional activities

Manufacturing

We currently outsource all of our manufacturing to third-parties. We maintain internal quality standards, regulatory compliance and a committed level of resources to administer the operations of these third-party relationships. We currently depend on third-party relationships for the supply of the active ingredients in our pharmaceutical products and product candidates, the manufacture of the finished product and the related packaging. To date, we have established relationships with several manufacturers to manufacture our products. This may increase the risk that we will not have sufficient quantities of our products or product candidates or that such quantities if available can be acquired at an acceptable cost, which could result in development and commercialization of our product candidates being delayed, prevented or impaired. Where possible and commercially reasonable, we qualify more than one source for manufacturing and packaging of our products to mitigate the risk of supply disruptions. In such circumstances, if one of our manufacturers or packagers were unable to supply our needs, we would have an alternative source available for those products.

Our products and product candidates are manufactured using established processes in a reduced number of steps. There are no complex chemistry designs or unusual manufacturing equipment used in the processes. We plan to continue to develop product candidates that can be manufactured in a cost effective manner at third-party manufacturing facilities.

We and all of our other manufacturers and suppliers are subject to the FDA’s current Good Manufacturing Practices, or cGMP, requirements. Certain of our manufacturers are also subject to the United States Drug Enforcement Administration, or DEA, regulations and other rules and regulations stipulated by other regulatory bodies.

Intellectual Property

Our performance relies partly on our capacity to achieve and maintain proprietary protection for our products and product candidates, technology and know-how to function without infringing on the ownership rights of others and to defend against others from infringing on our ownership rights. Most of our products face competition from generics. Our key intellectual property is described below.

Patents

The following table shows the United States ("U.S.") patents relating to our products. We own or license the rights to the intellectual property in these patents described in more detail below.

Product(s) / Product Candidate(s)	Patent Owners	Patent Description	Expiration
Treximet	POZEN Inc. (1)	Use of a combination dosage form containing naproxen and sumatriptan or methods of treating migraine headaches by administering the combination dosage form	August 14, 2017 or February 14, 2018 if pediatric exclusivity is granted
		Use of a multilayer pharmaceutical tablet comprising naproxen and sumatriptan, and a method for rapid release of sumatriptan and naproxen.	October 2, 2025
Silenor	ProCom One, Inc.(2)	Use of doxepin and other antidepressants in low dosages for treatment of insomnia(1)	February 17, 2020; June 5, 2020; April 14, 2030
	Pernix Sleep, Inc.(3)	Methods of application to improve the pharmacokinetics of doxepin use for treatment of insomnia(6)	August 24, 2027

(1) In connection with the certain Asset Purchase and Sale Agreement dated as of May 23, 2014 by and among GSK and certain of its affiliates and us, GSK assigned to our wholly-owned subsidiary, PIL, all of its right, title and interest in and to that certain Product Development and Commercialization Agreement dated as of June 11, 2003, as amended, by and between GSK and POZEN, Inc. Pursuant to such assignment, we acquired the right and license make, use, offer to sell, sell products in the United States and Puerto Rico using certain POZEN patents and other technology. The primary patents expire on August 17, 2017 and exclusivity will be extended until February 14, 2018 if a pediatric formulation of Treximet is approved by FDA. The term of the Product Development and Commercialization Agreement extends until the later of the date the last licensed patent expires and fifteen years from the first commercial sale of a product developed using the licensed patents. The agreement is terminable at any time by us with 90 days' notice for any reason. Either party may terminate the agreement with 60 days' notice if the other party commits a material breach of its obligations (or 15 days in the case of a failure to pay amounts due) and fails to remedy the breach within such notice period. Under the terms of the agreement, we pay a royalty of eighteen percent (18.0%) of net sales (as defined in the agreement). Our predecessor-in-interest made upfront and milestone payments upon certain development milestones and regulatory approvals, all of which were satisfied prior to our acquisition of Treximet assets by us.

(2) In a license agreement dated August 2003 and amended and restated in September 2010, Pernix Sleep acquired the exclusive, worldwide license from ProCom to certain patents to develop and commercialize low dosages of doxepin for the treatment of insomnia. Although patent protection for the current dosage form is limited to the United States, our license to these low-dose doxepin patents is a worldwide license. The term of the license

extends until the last licensed patent expires, which is expected to occur no earlier than 2030. The license agreement is terminable at any time by us with 30 days' notice if we believe that the use of the product poses an unacceptable safety risk or if it fails to achieve a satisfactory level of efficacy. Either party may terminate the agreement with 30 days' notice if the other party commits a material breach of its obligations and fails to remedy the breach within 90 days, or upon the filing of bankruptcy, reorganization, liquidation, or receivership proceedings relating to the other party. Under the terms of the agreement, we pay a royalty of five percent (5%) of net sales (as defined in the license agreement) to ProCom. Our predecessor-in-interest made upfront and milestone payments upon certain development milestones and regulatory approvals, all of which were satisfied prior to our acquisition of Somaxon.

(3) In March 2011, Pernix Sleep, Inc. received a patent, which expires on August 24, 2027 entitled "Methods of Improving the Pharmacokinetics of Doxepin." This patent generally relates to the varied effects that occur when dosing Silenor 3 mg and 6 mg formulation tablets at least three hours after a meal, as compared to such dosing within three hours of a meal. These effects have important implications relating to the efficacy and safety of Silenor and are reflected and described in Silenor's prescribing information.

Companies in our industry tend to own or license patent portfolios that are generally uncertain and involve complicated legal and factual issues. To maintain and solidify our rights to our technology, we must obtain effective claims and enforce those claims once granted. Any patents we have obtained or will obtain in the future might be found invalidated and/or unenforceable, or may be circumvented by third parties. If any challenges are successful, competitors might be able to market products substantially similar to ours. Additionally, the competition may separately develop similar technologies to ours and the rights granted under issued patents may not provide us with a meaningful competitive advantage against these competitors. Furthermore, because of the extensive amount of time required to bring products to market, it is possible that any related patents may expire or be close to expiring before our products can be commercialized, thus reducing any advantage of the patents. One way that we mitigate the impact of generics that enter the market on our products when we no longer have patent protection is to have Macoven or Cypress launch an authorized generic of our brand product in the market potentially ahead of others.

Trademarks

We own trademark interests in most of our current products and believe that having distinguishing marks is an important factor in marketing these products. We currently own approximately 34 trademarks registered on the principal register of the United States Patent and Trademark Office. These registered marks include ALDEX, ALLRES, ARBINOXA, BROVEX (WORD MARK), BROVEX (STYLIZED), CARDEC, Cedax, COCO-COF, CYPRESS PHARMACEUTICALS, INC. (DESIGN), DYTAN (STYLIZED), ELIPHOS (STYLIZED), GRANISOL (STYLIZED), HYLIRA (STYLIZED), ICAR (STYLIZED), NODOLOR, PEDIATEX, PERNIX, PERNIX THERAPEUTICS (DESIGN), QUINZYME, Rezira, REZYST, Silenor, SOMAXON PHARMACEUTICALS, TCT (STYLIZED) , TCT (WORD MARK), TCT TANNATE CONVERSION TECHNOLOGY, TREXIMET, TUSSINAC, Vituz, Z-COF (STYLIZED), ZEMA-PAK and Zutripro. In addition to the 34 registered marks listed above, we own seven intent-to-use trademark applications filed with the United States Patent and Trademark Office that can be registered as use-in-commerce trademarks as soon as we can file a statement of use illustrating use of the marks in commerce. The 7 unregistered trademark applications are, ALLANHIST PDX, INFAPRED, PAINERGY, and PEDIAHIST. We expect that having distinctive marks for any additional products that we develop will also be an important marketing characteristic. U.S. trademark registrations generally are for fixed, but renewable, terms.

Trade Secrets

In some circumstances, we may depend on trade secrets to protect our technology. We try to protect our own technology by entering into confidentiality agreements with our employees, independent contractors, consultants, and advisors. We also aim to protect the confidentiality and integrity of our technology by maintaining physical security of our facilities and physical and electronic security of our data systems. While we have confidence in these security measures, they may be breached and we may not have appropriate responses to manage those breaches.

Customers, Distribution, and Reimbursement

Customers and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the U.S. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Our top three customers which represented 91%, 79% and 75% of gross product sales in 2014, 2013 and 2012, respectively, are all drug wholesalers, each customer and its respective percentage of our gross product sales are listed by year below:

Customer	2014	2013	2012
Cardinal Health	23%	24%	39%
McKesson Corporation	37%	35%	26%
AmerisourceBergen Drug Corporation	31%	20%	10%

Consistent with industry practice, we maintain a returns policy that allows our customers to return products within a specified period prior and subsequent to the expiration date. Occasionally, we may also provide additional discounts to some customers to ensure adequate distribution of our products.

We actively market our products to authorized distributors through regular sales calls. We have many years of experience working with various industry distribution channels. We believe that this significantly enhances our performance in the following ways:

ensuring product stocking in major channels in the geographic areas where we do business;

continually following up with accounts and monitoring product performance;

developing successful product launch strategies; and

partnering with customers on other value-added programs.

Our active marketing effort is designed to ensure appropriate distribution of our products so that patients' prescriptions can be filled with our products.

In an effort to consolidate all distribution operations, we entered into an agreement with Cardinal to be our exclusive third-party logistics provider during 2014. We rely on Cardinal for the distribution of our products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. Cardinal ships our products from its warehouse in Tennessee to our customers throughout the US.

Reimbursement

In the US market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care organizations, or MCOs, and private insurance plans. Most of our products are generally covered by managed care and private insurance plans. The status or tier within each plan varies, but coverage for our products is similar to other products within the same class of drugs. We also participate in the Medicaid Drug Rebate Program with the Centers for Medicare & Medicaid Services and submit substantially all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for our products and ultimately the net proceeds realized from the sales of our products.

Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies as well as specialty pharmaceutical companies that market neurology, psychology, primary care and other products. Many of these companies, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our ability to continue to grow requires that we compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Actavis, Endo Pharmaceuticals, Teva and Valeant. These established companies may have a competitive advantage over us due to their size and financial resources.

We also face competition from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

Our products and product candidates may also compete in the future with new products currently under development by others. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive.

With respect to all of our products and product candidates, we believe that our ability to successfully compete will depend on, among other things:

- the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products;
- the efficacy, safety and reliability of our products and product candidates compared to competing or alternative products;
- product acceptance by physicians, other health care providers and patients;
- protection of our proprietary rights;
- obtaining reimbursement for our products in approved indications;
- our ability to complete clinical development and obtain regulatory approvals for our product candidates, and the timing and scope of regulatory approvals;
- our ability to supply commercial quantities of a product to the market; and
- our ability to recruit, retain and develop skilled employees.

Government Regulation

In the US and other countries, federal, state, and local government authorities comprehensively regulate the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, importing and exporting of pharmaceutical products that we market, sell and develop.

FDA Regulation of Drug Products

The FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and regulations in the US Obtaining regulatory approvals and the additional compliance with appropriate federal, state and local statutes and regulations requires the use of significant time and financial resources. Noncompliance with applicable FDA requirements during the development, approval or post approval process may subject an applicant to a range of judicial or administrative penalties, such as the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, suspension of production or distribution, fines, refusals of contracts, restitution, disgorgement or civil or criminal sanctions.

Before a drug may be marketed in the US, the FDA requires a process that generally involves the following:

performance of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

an investigational new drug application, or IND, submitted to the FDA, which must become effective before human clinical trials may commence;

an independent institutional review board (IRB) approval at each clinical site before each trial may begin;

completion of approved, well-controlled human clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;

submission of a new drug application, or NDA, to the FDA;

adequate completion of an FDA advisory committee review, if applicable;

satisfactory completion of an FDA inspection of clinical trial sites to ensure clinical trials were conducted in accordance with GCPs;

satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is produced to evaluate compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are satisfactory to preserve the drug's identity, strength, quality and purity; and

FDA review and approval of the NDA.

Preclinical Studies. Product candidates that undergo preclinical studies are subject to extensive laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. The preclinical test results must be submitted by an IND sponsor, along with a clinical trial protocol, manufacturing information, analytical data and any available clinical data and literature to the FDA as part of the IND. Even after the IND is submitted, some preclinical testing may continue. Unless the FDA raises concerns or questions related to proposed clinical trials and places the clinical trials on a clinical hold, an IND automatically becomes effective 30 days after receipt by the FDA. If the FDA issues a clinical hold, the IND sponsor and the FDA must settle any pending concerns before the clinical trial can begin. Thus, submission of an IND may result in the FDA not allowing the commencement of clinical trials. In addition, the FDA can impose clinical holds at any time before or during trials due to safety concerns or non-compliance.

Clinical Trials. In accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators.

Clinical trials are performed in accordance with protocols detailing, among other things, the objectives of the study, dosing procedures and the parameters to be used to monitor subject safety and the effectiveness criteria to be evaluated. Additionally, each institution participating in the clinical trial must have an IRB review and approve the plan for any clinical trial before it commences at that institution. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted for FDA review and to the IRBs for approval.

Clinical trials performed on humans are generally conducted in three consecutive phases, which may coincide or be combined:

Phase I: The product is initially introduced into healthy human subjects or, in certain circumstances, patients with the target disease or condition, and is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

Phase II: A limited patient population is administered the drug to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

Phase III: An expanded patient population is administered the drug, generally at geographically unique clinical trial sites, to further evaluate dosage, clinical efficacy and safety, to establish the overall risk-benefit ratio of the drug, and to provide an adequate basis for regulatory approval and product labeling.

The FDA must receive progress reports annually, detailing the results of the clinical trials, and IND sponsors must submit reports of serious and unexpected adverse events. Phase I, II, and III trials might not be successfully completed within a specified period of time, or at all. Moreover, clinical trials may be suspended or terminated by the FDA or sponsor at any time on a variety of grounds, including findings that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the drug has been connected to unanticipated serious harm to patients.

Special Protocol Assessment. The SPA process was created to facilitate the FDA’s review and approval of drug products by permitting the FDA to assess the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product’s efficacy. If a clinical trial sponsor specifically requests, the FDA will evaluate the protocol and respond to a sponsor’s questions regarding primary efficacy endpoints, trial conduct and data analysis within 45 days of receipt of the request. The FDA ultimately decides whether the protocol design and planned analysis of the trial adequately address objectives in support of a regulatory submission. An SPA letter or the minutes of a meeting between the sponsor and the FDA must clearly document all agreements and disagreements between the sponsor and FDA regarding the SPA.

The FDA may revoke or alter its agreement, even if it agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA, under the following circumstances:

a substantial scientific issue essential to determining the safety or efficacy of the drug has been identified after testing has begun;

the protocol that was agreed upon with the FDA has not been followed by a sponsor;

the relevant data, assumptions, or information provided by a sponsor in a request for SPA change are found to be false or misleading, or are found to exclude important facts; or

the FDA and sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

Marketing Approval. If the required clinical testing is completed successfully, the results of the preclinical and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information are submitted as part of an NDA to the FDA, requesting approval to market the product for one or more indications. The submission of an NDA is subject to a substantial application fee in most cases.

Additionally, an NDA or supplement to an NDA must contain data that is acceptable to properly assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective, according to the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized by the Food and Drug Administration Amendment Act of 2007, or FDAAA. The Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, requires manufacturers of drugs that include a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to submit a pediatric study plan to the IND. The plan must be submitted not later than 60 days after the end-of-phase 2 meeting with FDA; if there is no such meeting, before the initiation of any phase 3 studies or a combined phase 2 and phase 3 study; or if a phase 3 study or a combined phase 2 and phase 3 study will not be conducted, no later than 210 days before a marketing application or supplement is submitted. The FDA is also authorized, under the FDAAA, to require sponsors of currently marketed drugs to perform pediatric studies if the drug is used for a substantial number of pediatric patients for the labeled indication and adequate pediatric labeling could benefit such patients, there is reason to believe the drug would provide a “meaningful therapeutic benefit” for pediatric patients, or the absence of pediatric labeling could pose a risk to pediatric patients. At the request of an applicant or by its own initiative, the FDA may grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or, may grant full or partial waivers from the pediatric data requirements. The pediatric data requirements do not apply to products with orphan designation, unless otherwise required by regulation.

Sixty days after its receipt of an NDA, the FDA has to determine whether the application will be accepted for filing based on the agency’s threshold determination that it is adequately complete to permit substantive review. Rather than accept an NDA for filing, the FDA may request additional information. In such an event, the NDA must be resubmitted with the additional information and is subject to additional fees. Before the FDA accepts the resubmitted application for filing, it is also subject to review. Once the submission is accepted for filing, the FDA commences a detailed substantive review. The FDA may refer the NDA to an advisory committee for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA considers such recommendations when making decisions but is not bound by the recommendations of the advisory committee.

The FDA will also examine the facility or facilities where the product is manufactured before approving an NDA. The FDA will not approve an application if it determines that the manufacturing processes and facilities do not comply with cGMP requirements and are unsatisfactory to assure consistent production within required specifications. In addition, the FDA will typically inspect one or more clinical sites to assure compliance with GCP before approving an NDA.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. As a condition of approval, FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Once adopted, REMS are subject to periodic assessment and modification. In addition, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. Based on the results of post-market studies or surveillance programs, the FDA may prevent or limit further marketing of a product. Some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further FDA review and approval even after initial approval has been granted.

FDA Expedited Development and Review Programs. To expedite or simplify the process for the development and FDA review of drug products that are intended for the treatment of life threatening or other serious conditions and demonstrate the potential to address unmet medical needs, the FDA has a variety of programs, including fast track designations, accelerated approval and priority review. The purpose of these expedited review and approval programs is to provide important new drugs to patients faster than the standard FDA review procedures.

New drug products are eligible for fast track designation if they are intended to treat a life threatening or serious condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. The FDA may later decide that the drug no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened even if a drug product qualifies for one or more of these programs.

In addition, FDASIA amended the FDCA to require FDA to expedite the development and review of a breakthrough technology. A drug can be designated as a breakthrough technology if it is intended to treat a serious or

life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug be designated as a breakthrough therapy at any time during the clinical development of the product. If so designated, FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Post-approval Requirements. Drugs that receive FDA approval remain subject to continuing regulation by the FDA, including reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, advertising and promotion, product sampling and distribution, complying with certain electronic records and signature requirements, periodic reporting and requirements relating to recordkeeping. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. An organization that is found to have improperly promoted off label uses may be subject to significant liability imposed by the FDA and other agencies that actively enforce laws and regulations prohibiting the promotion of off label uses. The Federal Trade Commission regulates advertising for OTC drug products. Advertising for these products must be truthful, not misleading and adequately substantiated.

Additionally, drug manufacturers and other organizations involved in the distribution and manufacture of approved drugs are required to register their organizations with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process generally require prior FDA approval before implementation. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. Future FDA and state inspections may identify compliance issues at our manufacturing facilities or the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct. Accordingly, we and our contract manufacturers must continue to spend time, money, and effort in the area of quality control and production to maintain cGMP compliance.

The FDA may withdraw an approval, once granted, if compliance with regulatory requirements and standards is not maintained or if problems arise after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as product recalls, complete withdrawal of the product from the market or restrictions on the marketing or manufacturing of the product; warning letters, fines or holds on post-approval clinical trials; suspension or revocation of product approvals, or refusal of the FDA to approve pending applications or supplements to approved applications; refusal to permit the import, or export of products or product seizure or detention; or civil or criminal penalties or injunctions.

The Prescription Drug Marketing Act, or PDMA, regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the licensing and regulation of drug distributors by the states. The distribution of prescription drug products is also regulated by the PDMA. Both the PDMA and state laws limit the distribution of prescription pharmaceutical samples and enforce requirements to ensure accountability in distribution.

In November 2013, the Drug Quality and Security Act became law, and establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain. Specifically, the law requires FDA to establish standards for the exchange of transaction documentation and to establish processes to provide waivers and exceptions to requirements. By January 1, 2015, manufacturers, wholesalers, dispensers, and repackagers must ensure that all prior transaction information is provided at each transfer of ownership. Additionally, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, manufacturers, wholesalers, dispensers, and repackagers must provide within a reasonable time the applicable transaction documentation upon request to FDA or other appropriate federal or state officials. This law includes a number of new requirements that will be implemented over time and will require us to devote additional resources to satisfy these requirements.

From time to time, legislation is drafted, introduced and enacted by Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or reinterpreted by the agency or the courts in ways that may considerably affect our business and our products. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Prescription Drug Wrap-Up

The FDCA, enacted in 1938, was the first statute requiring premarket approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the FDCA to require that

sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. These amendments also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted with the National Academy of Science/National Research Council, or the NAS/NRC, to make an initial evaluation of the effectiveness of many drug products. The FDA's administrative implementation of the NAS/NRC reports was the Drug Efficacy Study Implementation, or DESI.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, however, spurred by serious adverse reactions to one of these products, Congress urged the FDA to expand the new drug requirements to include all marketed unapproved prescription drugs. The FDA created a program, known as the Prescription Drug Wrap-Up, to address these remaining unapproved drugs. Many of these drugs claimed to have been on the market prior to 1938 or to be identical, related, or similar to such a drug. A drug subject to the Prescription Drug Wrap-Up is marketed illegally, unless the manufacturer can establish that the drug is grandfathered or otherwise not a "new drug." Under the 1938 grandfather clause, a drug product that was on the market prior to the passage of the 1938 Act and which contained in its labeling the same representations concerning the conditions of use as it did prior to passage of that Act was not considered a "new drug" and was therefore exempt from the requirement of having an approved NDA. Under the 1962 grandfather clause, a drug is exempt from the effectiveness requirements if its composition and labeling have not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the US, (b) not a new drug as defined by the FDCA at the time, and (c) not covered by an effective application. The two grandfather clauses have been construed very narrowly by the courts and the FDA believes that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions. If a firm claims that its product is grandfathered, it is the firm's burden to prove that assertion. Pernix believes that several of its marketed pharmaceutical products are identical, related or similar to products that have existed on the market without an NDA or ANDA. Beginning in 2008, we began converting these cough and cold products to OTC monograph from DESI drugs. For additional information, see "Risks Related to Regulatory Matters- Some of our specialty pharmaceutical products are now being marketed without FDA approvals."

Over The Counter Drugs

As for over the counter, or OTC, drugs, in 1972, the FDA implemented a process of reviewing OTC drugs through rulemaking by therapeutic classes (e.g., antacids, antiperspirants, cold remedies). Advisory panels are convened for each therapeutic class and their reports are published in the Federal Register. After FDA review, tentative final monographs for the classes of drugs are published. The final step is the publication of a final monograph for each class, which sets forth the allowable claims, labeling, and active ingredients for the OTC drugs in each class. Monographs are a kind of "Recipe Book" for acceptable ingredients, doses, formulations and labeling. Drugs must meet all of the general conditions for OTC drugs and all of the conditions contained in an applicable final monograph to be considered generally recognized as safe and effective (GRAS/GRAE) and to be marketed without FDA approval of a marketing application. The general conditions include, among other things, compliance with cGMP, establishment registration and labeling requirements. Any product that fails to conform to each of the general conditions and a monograph is subject to regulatory action. We believe our promoted branded cough and cold OTC products conform to an FDA OTC monograph.

Pursuant to the Dietary Supplement and Nonprescription Drug Consumer Protection Act, enacted in 2006, manufacturers, packers, or distributors of OTC drugs marketed in the United States without an approved application must also submit to the FDA reports of serious adverse events associated with such drugs when used in the United States, accompanied by a copy of the label on or within the retail package of such drug. In addition, the manufacturer, packer, or distributor must submit follow-up reports received within one year of the initial report.

The Hatch-Waxman Act

Abbreviated New Drug Applications. Through the NDA approval process, applicants are obligated to list with the FDA each patent with claims that cover the applicant's product or an approved use of the product. When the drug has been approved, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in pursuit of approval of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical ingredients in the same strengths, route of administration, conditions of use and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or efficacy of their drug product, other than the requirement for bioequivalence testing. ANDA approved drugs are commonly referred to as "generic equivalents" to the listed drug, and can be replaced by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning each patent listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent will expire on a particular date, but has not expired and approval is sought after patent expiration; or
- the listed patent is unenforceable, invalid or will not be infringed by the manufacture, sale or use of the new product, also known as a Paragraph IV certification.

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A Paragraph IV certification demonstrates that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable. Provided the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. ANDA approval will not be delayed if there are no listed patents or all patents have expired.

If a Paragraph IV certification has been provided to the FDA by the ANDA applicant, the NDA and patent holders must also receive notice from the applicant of the Paragraph IV certification with a comprehensive account of the factual and legal basis for the applicant's belief that the patents are invalid, unenforceable or not infringed once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV notice automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the receipt of notice by the patent holder, or until a court deems the patent unenforceable, invalid or not infringed. Hatch-Waxman provides for a 180 day period of generic product exclusivity for the first generic applicant to challenge a listed patent for an NDA-approved drug. Thus, many if not most successful new drug products are subject to generic applications and patent challenges prior to the expiration of all listed patents.

Section 505(b)(2) New Drug Applications. As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for some or all 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.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is subject to existing exclusivity for the reference product and is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Therefore, authorization of a Section 505(b)(2) NDA can be delayed until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months from when the patent holder receives notice or a decision or settlement in the infringement case finding the patents to be unenforceable, invalid or not infringed.

Some pharmaceutical companies and others have opposed the FDA's interpretation of Section 505(b)(2), despite the approval of numerous products by the FDA pursuant to Section 505(b)(2) over the last several years. A change in interpretation by the FDA of Section 505(b)(2) could prevent or delay the approval of any Section 505(b)(2) NDAs that we submit.

Marketing Exclusivity and Patent Term Restoration. Newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity under the Hatch-Waxman Act. The Hatch-Waxman Act grants five-year marketing exclusivity to the first applicant to achieve approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active pharmaceutical ingredient. The Hatch-Waxman Act prohibits the submission of a Section 505(b)(2) NDA or an ANDA for another version of such drug during the exclusivity period. But, submission of a Section 505(b)(2) NDA or an ANDA

containing a Paragraph IV certification is allowed after four years, which may activate a 30-month stay of approval of the Section 505(b)(2) NDA or ANDA if the patent holder sues. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five year and three-year exclusivity will not block the submission or approval of another “full” NDA. The applicant submitting a full NDA would be required to conduct its own preclinical studies and clinical trials or obtain a right of reference to such studies or trials.

Pediatric Exclusivity. Pediatric exclusivity is another type of non-patent marketing exclusivity in the US If granted, it provides an additional six months of marketing security to the term of any existing regulatory exclusivity or listed patent term. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study. We plan to work with the FDA to establish the need for pediatric studies for our product candidates, and may consider attempting to obtain pediatric exclusivity for some of our product candidates.

Medical Devices

Medical devices are also subject to extensive regulation by the FDA under the FDCA. FDA regulations govern, among other things, product development, testing, clinical trials, manufacture, packaging, labeling, storage, marketing clearance or approval, advertising and promotion, sales and distribution, and import and export.

Typically medical devices must receive either premarket notification (510(k)) clearance, unless they are exempt, or premarket application approval, or PMA approval, from the FDA prior to commercial distribution. The appropriate type of marketing application is determined by the device classification. Generally, lower risk devices are placed in either class I or II. Most class II devices require 510(k) clearance while most class I devices are exempt from premarket notification and may be commercially distributed without 510(k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a legally marketed device, or preamendment class III devices, i.e., devices in commercial distribution before May 28, 1976, for which a regulation requiring a PMA application has been promulgated, are required to have approved PMAs before marketing. The 510(k) clearance and PMA approval processes can be expensive, uncertain and lengthy and a device may never be cleared or approved for marketing.

After a device is approved or cleared and placed into commercial distribution, numerous regulatory requirements apply. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the Quality System Regulation, cGMP requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation and distribution of all finished medical devices intended for human use.

If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as: (i) fines, injunctions, and civil penalties; (ii) recall or seizure of products; (iii) operating restrictions, partial suspension or total shutdown of production; (iv) refusing requests for 510(k) clearance or approval of new products; (v) imposing a clinical hold on or terminating a study; (vi) withdrawing 510(k) clearance or approvals already granted; and (vii) criminal prosecution. The FDA also has the authority to require repair, replacement or refund of the cost of any medical device.

The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA approval are subject to FDA export requirements. Additionally, exported medical devices must also comply with applicable regulatory requirements in the importing countries. In the European Union, a single regulatory approval process has been created, and approval is represented by the CE Mark.

Medical Foods

The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are prescription foods specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet alone. They were defined in the FDA's 1988 Orphan Drug Act Amendments and are subject to the general food safety and labeling requirements of the FDCA but are exempt from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990. Medical foods are distinct from the broader category of foods for special dietary use and from traditional foods that bear a health claim. In order to be considered a medical food the product must, at a minimum:

be a specially formulated and processed product (as opposed to a naturally occurring food in its natural state) for oral ingestion or tube feeding (nasogastric tube);

be labeled for the dietary management of a specific medical disorder, disease or condition for which there are distinctive nutritional requirements; and

be intended to be used under medical supervision.

In addition, medical foods must comply with all applicable requirements for the manufacture of foods, including food cGMPs, registration of food facility requirements and, if applicable, FDA regulations for low acid canned food and emergency permit controls. The FDA advises that it considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. The FDA inspects medical food manufacturers annually to assure the safety and integrity of the products. Failure of our contract manufacturers to comply with applicable requirements could lead to sanctions that could adversely affect our business.

Regulation of Controlled Substances

We, our third party manufacturers and certain of our products including Zutripro, Rezira, Vituz, Zutripro's generic equivalent, and certain other generic products are subject to the Controlled Substances Act, which institutes registration, recordkeeping, reporting, labeling, packaging, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. Accordingly, we must adhere to a number of requirements with respect to our controlled substance products including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use in treatment in the U.S. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest relative risk of abuse and Schedule V substances the lowest relative risk of abuse. In January 2013, an FDA advisory panel voted to impose tighter restrictions on all products containing hydrocodone that, if approved by the FDA, would result in Zutripro, Rezira, Vituz and being classified as Schedule II substances.

Any facility that manufactures, distributes, dispenses, imports or exports any controlled substance is required to register annually with the DEA. The registration is specific to the particular location, activity and controlled substance schedule. A separate registration is needed for import and manufacturing, and each registration will indicate which schedules of controlled substances are authorized.

Prior to issuing a registration, the DEA may inspect a facility to evaluate whether an applicant meets registration requirements, including applicable security measures. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. To evaluate security measures the DEA takes into consideration, among other things, the type of building construction, the type of vault, safe, and secure enclosures or storage systems, the adequacy of key control systems and electronic detection and alarm systems. The DEA also requires employers to conduct comprehensive employee screening programs. Records must be maintained for the handling of all controlled substances and periodic reports issued to the DEA, including distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and any person registered by the DEA who desires to dispose of a controlled substance may request authority to dispose of the controlled substance from the Office of Controlled Substances. Additionally, particular authorization and notification requirements apply to imports and exports.

Registered establishments that handle controlled substances must go through periodic inspections by the DEA. Failure to comply with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a significant negative effect on our business, results of operations and financial performance. Depending on the violation, the DEA may suspend or revoke registrations, pursue civil penalties, or pursue criminal penalties.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation concerning the manufacture and distribution of these products.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products and product candidates to the extent we choose to

clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain permission to commence clinical trials and approval by the comparable regulatory authorities of foreign countries before we can commence marketing of the product in those countries. The approval procedure differs among countries and can involve requirements for additional testing. The time necessary for approval may vary from that required for the FDA. Thus, there can be significant delays in obtaining mandatory approvals from foreign regulatory authorities after the appropriate applications are filed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

In the European Union, medicinal products must be authorized either through the decentralized procedure by the competent authorities of the EU Member States, or through the centralized procedure by the European Commission following an opinion by the EMA. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products, and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized approval procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state objects to approval of the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states. In many EU countries, pricing and reimbursement negotiations must also take place before the product is sold in their national market between the company marketing the product and the competent national authorities.

Hazardous Materials

Prior to the disposition of PML, as a by-product of its daily operations as a manufacturer of pharmaceutical finished products, PML consistently generated small quantities of hazardous waste, both as a result of its manufacturing processes and its analytical testing processes. PML contracted with certified third-party service providers to legally dispose of its hazardous waste in a manner required by local, state, and federal laws. The expense of responsibly disposing of its hazardous waste was factored into the cost of goods and was not of significance.

We also depend on third parties to support us in manufacturing and developing certain products and do not directly handle, store or transport hazardous materials or waste products. We depend on these parties to abide by all applicable federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not anticipate the cost of complying with the laws and regulations to be material.

Pharmaceutical Pricing and Reimbursement

Our ability to commercialize our products effectively depends substantially on the availability of sufficient coverage and reimbursement from third-party payors, including governmental bodies such as the Medicare and Medicaid programs, managed care organizations and private insurers. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of governmental payors in rendering coverage and reimbursement determinations. Third-party payors are more frequently contesting the prices charged for treatments and examining their cost effectiveness, in addition to their efficacy and safety. We may need to conduct expensive pharmacoeconomic studies in order to illustrate the cost effectiveness of our products, in addition to the costs required to obtain FDA approvals. Even with these studies, our products may be considered less effective, less safe or less cost-effective than existing products, and third-party payors may decide not to provide coverage and reimbursement for our products, in whole or in part. The resulting payment rates may not be sufficient for us to sell our products at a profit even if third-party payors approve coverage and reimbursement.

The cost of pharmaceuticals continues to generate substantial governmental and third-party interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Current and future healthcare reforms could substantially affect our business.

We expect that federal and state governments and the private sector will continue to evaluate and may adopt health care policies intended to limit rising health care costs. These cost containment measures could include:

- regulations on government backed reimbursement for drugs;
- regulations on payments to health care providers that affect demand for drug products;
- objections to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- waning of restrictions on imports of drugs; and
- increase of managed care systems in which health care providers commit to provide comprehensive health care for a fixed cost per person.

Within the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare participants can obtain prescription drug coverage from private plans that are allowed to limit the number of prescription drugs that are covered on their formularies. In this program, certain of our products may be disqualified from formularies and may be subject to substantial price pressures that reduce the prices we are able to charge.

Outpatient pharmaceuticals sold to state managed Medicaid programs are subject to the national Medicaid Drug Rebate Program. To have their drugs included under state Medicaid programs, pharmaceutical companies must enter into an agreement with the Secretary of Health and Human Services in which they agree to pay a rebate to the state and federal governments that is decided on the basis of a calculation specified by the Centers for Medicare & Medicaid Services (CMS). Pharmaceutical companies are also required to take part in a similar agreement with the US Department of Veterans Affairs, which requires additional discounts. We participate in these types of pricing agreements with respect to certain of our currently marketed products.

In general, the amount of the Medicaid prescription drug rebate is calculated based in part on the average manufacturer's price (AMP) for the drug. There has been historical and current legislation surrounding this calculation. The Health Care Reform legislation, discussed in more detail below, changed the definition of AMP to the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. The term expressly excludes certain payments and discounts, including customary prompt payment discounts to wholesalers; service fees paid by manufacturers to wholesalers or retailers; and payments from managed care organizations, mail order pharmacies, long-term care providers, and any other entity that does not conduct business as a wholesaler or retail community pharmacy. On February 2, 2012, CMS published in the Federal Register a proposed rule providing details regarding the calculation and reporting requirements for such rebates. We cannot predict whether and in what form the regulations will be made final and what effect these regulations may have on our pricing and reimbursement.

Foreign countries that have price controls in place on pharmaceutical products may generate lower-priced product competition. Proposed federal legislation may increase consumers' ability to import lower-priced versions of competing products from Canada and elsewhere. If such proposals become law, our products may be susceptible to an increase in price competition from lower priced imported drugs. Additionally, several local and state governments have launched importation schemes for their citizens, and, absent any federal action to restrict such activities, we anticipate other states and local governments will launch importation programs. The importation of foreign products that compete with ours could adversely impact our business.

Effects of Legislation on the Pharmaceutical Industry

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act, or Affordable Care Act. On March 30, 2010, the President signed H.R. 4872, the Health Care and Education Reconciliation Act of 2010, or Reconciliation Act, which included a package of corrective changes to the Affordable Care Act as well as additional elements to reform healthcare in the United States. We refer to the Affordable Care Act and the Reconciliation Act as Health Care Reform.

The passage of Health Care Reform is expected to result in a transformation of the delivery and payment for healthcare services in the US The combination of these measures will expand health insurance coverage to an estimated 32 million Americans by 2019. In addition, there are significant health insurance reforms that will improve patients' ability to obtain and maintain health insurance. Such measures include, for example, the elimination of lifetime caps, no rescission of policies, no denial of coverage due to preexisting conditions, a prohibition on varying premiums by more than 3:1 for age and 1.5:1 for tobacco use, a prohibition on imposing excessive waiting periods for coverage, and enhanced support for the Children's Health Insurance Program. The legislation provides for implementation of this expansion in a variety of ways, including the creation of exchanges for finding health insurance policies, tax penalties on individuals without health insurance and on certain employers who do not provide it, and tax credits to make health insurance more affordable. The expansion of healthcare insurance and these additional market reforms should result in greater access to our products.

However, a number of provisions contained in Health Care Reform may adversely affect reimbursement for and access to our products. The Health Care Reform requires states to expand Medicaid coverage to all non-elderly individuals whose income is less than 133% of the federal poverty line by 2014. The legislation also extends Medicaid prescription drug rebates to drugs dispensed to enrollees of certain Medicaid managed care organizations. Additionally, the new laws increase the minimum basic Medicaid rebate for brand name and generic prescription drugs, create an alternate Medicaid rebate calculation for “line extensions” of oral solid dosage forms of innovator products and expand the entities eligible for 340B pricing to include children’s hospitals. As discussed above under “Pricing and Reimbursement,” Health Care Reform changed the calculation and reporting requirements for the Medicaid prescription drug rebate calculation. Finally, the new laws also limit distributions from flexible spending accounts for medicines to prescribed drugs and insulin only.

Beginning in 2011, Health Care Reform also required drug manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap, also known as the “donut hole.” The legislation then expands on the manufacturers’ 50% discount on brand-name prescriptions and gradually closes the coverage gap, with 75% discounts on brand-name and generic drugs by 2020. The elimination of the coverage gap may result in greater access to our products for Part D beneficiaries. Moreover, Health Care Reform makes a number of other revisions to the Medicare Part D program, including, for example, a reduction in Part D premium subsidies for higher-income beneficiaries, improvement in determining the Medicare Part D low-income benchmark, improved information for subsidy-eligible individuals under prescription drug plans, and funding outreach and assistance for low-income programs.

Finally, Health Care Reform created an Independent Payment Advisory Board (IPAB), which is tasked with reducing the per capita growth rate in Medicare spending in the event that that growth rate exceeds a certain target. The IPAB is prohibited by statute from making payment reductions to certain sectors, such as hospitals and health agencies. This limitation increases the risk that the IPAB would propose to limit access to certain pharmaceutical products and/or to mandate price controls for pharmaceuticals.

On June 28, 2012, the United States Supreme Court upheld certain provisions of the Affordable Care Act, including the constitutionality of its individual mandate that requires most Americans to buy health insurance starting in 2014. However, certain members of Congress have proposed a number of legislative initiatives, including repeal of all or part of all of the Affordable Care Act.

The Budget Control Act, passed in 2011, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction was unable to reach required goals, triggering, among other things, automatic reductions to the budgets of federal health agencies and an automatic two-percent reduction to Medicare payments to healthcare providers. These spending reductions went into effect on April 1, 2013. The Bipartisan Budget Act of 2013 extended the two-percent reduction to Medicare payments to healthcare providers for two years through fiscal year 2023.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including rules and regulations that will be issued to implement provisions of Health Care Reform or the outcome of any legal challenges to such legislation or regulations. Health Care Reform and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Other Regulations

A number of federal and state laws and regulations, including those loosely referred to as fraud and abuse laws, contain certain requirements and penalties, and are used to prosecute health care providers, suppliers, physicians and others related to health care products or services in connection with government programs, such as Medicare and Medicaid. These laws are extremely complicated, apply broadly and may constrain our business and the financial arrangements through which we market, sell and distribute our products. Examples of these laws and regulations include:

Anti-kickback Statute. The federal anti-kickback statute is a criminal statute that, among other things, makes it a felony for individuals or entities to knowingly and willfully offer, pay, solicit or receive, any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) to induce or in return for (i) the referral of an individual to a person for arranging for or furnishing any item or service for which payment may be made in whole or in part under a federal health care program, or (ii) the purchase, lease, or order of, or arranging for or recommending the purchase, lease or order of any good, facility, service or item for which payment may be made in whole or in part under a federal health care program. The term “remuneration” has been interpreted broadly and includes both direct and indirect compensation and other items and services of value. Both the party offering or paying remuneration and the recipient may be found to have violated the statute. Some courts, as well as certain governmental guidance, have interpreted the scope of the anti-kickback statute to cover any situation where one purpose of the remuneration is to obtain money for the referral of services or to induce future referrals, even if there are other legitimate reasons for the remuneration. There are narrow exemptions and regulatory safe harbors, but to qualify for a safe harbor an arrangement must precisely meet each of the requirements. Further, many legitimate arrangements fall outside of the scope of any exemption or safe harbor, although that does not necessarily mean such arrangements will be subject to penalties under the anti-kickback statute.

The Health Care Reform added a new section to the anti-kickback statute, which provides that neither actual knowledge of the anti-kickback statute nor specific intent is required to show a violation of the anti-kickback statute. Violations of the anti-kickback statute may now also be treated as a false or fraudulent claim for purposes of the False Claim Act or constitute a federal health care offense.

Federal False Claims Act. The Federal False Claims Act imposes civil liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government. Penalties include three times the government's damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the Federal False Claims Act permits a person who meets certain requirements, referred to as a qui tam plaintiff or "whistleblower," to file a lawsuit on behalf of the government against the person or entity that allegedly violated the law. If the government determines to intervene in the lawsuit and the government prevails, the qui tam plaintiff is rewarded with a percentage of the recovery.

Health Care Reform as well as other legislation, such as Fraud Enforcement and Recovery Act of 2009, makes it easier for the government and qui tam realtor to bring a Federal False Claims Act case.

Foreign Corrupt Practices Act. The Foreign Corrupt Practices Act prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment. Similar anti-bribery laws exist in other countries where we intend to commercialize our products. For example, the U.K. Bribery Act imposes significant potential fines and other penalties for, among other things, giving, offering, or promising bribes in the public and private sectors, and bribing a foreign public official or private person.

Federal Health Insurance Portability and Accountability Act of 1996. The HIPAA statute imposes criminal liability in connection with the delivery of or payment for health care benefits, items or services, for, among other things, knowingly and willfully (i) executing a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money of the health care benefit program, or (ii) falsifying, concealing or covering up by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statements or representations, or making or using any materially false writing or document knowing it contains any materially false, fictitious or fraudulent statement or entry. Further, the HIPAA statute and implementing regulations established certain standards and requirements for the privacy and security of individuals' health information, which standards and requirements were expanded by the Health Information Technology for Economic and Clinical Health Act.

Other Federal Criminal and Civil Health Care Laws. The Social Security Act contains numerous penalties for fraud and abuse in the health care industry, such as imposition of a civil monetary penalty, a monetary assessment, exclusion from participation in federal health care programs or a combination of these penalties. Additionally, Health Care Reform provided that a violation of certain provisions of the FDCA constitutes a federal health care offense.

In addition, there is a trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Health Care Reform includes examples of this trend. Applicable manufacturers, including drug and biological manufacturers, must report information to the US Department of Health and Human Services related to payments and other transfers of value to physicians during the preceding calendar year, which information will later be made publicly available. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not appropriately reported.

Various states have disclosure laws as well.

There are certain federal and state laws that require compliance programs for certain sectors of the health care industry. For instance, one state requires that pharmaceutical companies must adopt a comprehensive compliance program that among other items, is in accordance with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, and includes certain policies for compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or PhRMA Code.

The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals and entertainment, among other things. In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in 2012 issued a Code of

Practice relating to interactions with the heath care community, which replaces and expands upon its 2006 Code of Pharmaceutical Marketing Practices. Further, certain states have also imposed restrictions on relationships between health care professionals and the pharmaceutical industry.

Various states have enacted laws and regulations comparable to the federal laws and regulations, including those related to fraud and abuse. These state laws and regulations may apply to items or services reimbursed by any third-party payor, including private, commercial insurers and other payors. Moreover, these laws and regulations vary significantly from state to state and, in some cases, are broader than the federal laws and regulations. These differences increase the costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

The pharmaceutical industry is experiencing greater scrutiny and regulation by government authorities and has been the subject of numerous investigations, often involving marketing and other business practices. More particularly, these investigations relate primarily to financial arrangements with health care providers, regulatory compliance, and product promotional practices.

Employees

As of December 31, 2014, we had 155 full-time employees, including a field sales force that covers 100 territories nationwide. We have 49 employees engaged in management, finance, marketing, research, development, regulatory affairs, supply chain and administration. None of our employees are subject to a collective bargaining agreement. We consider our employee relations to be good.

About Pernix Therapeutics Holdings, Inc.

Pernix Therapeutics Holdings, Inc. is a US public company. We were incorporated in Maryland as Golf Trust of America, Inc., or GTA, in November 1996. Pernix is the surviving corporation of the March 2010 merger between GTA and Pernix Therapeutics, Inc. In connection with the merger, we changed our name to Pernix Therapeutics Holdings, Inc.

Our principal executive offices are located at 10 North Park Place, Suite 201, Morristown, New Jersey 07960 and our telephone number is (800) 793-2145. Our website address is www.pernixtx.com. The information contained in or that can be accessed through our website is not part of this Annual Report on Form 10-K.

Unless the context indicates otherwise, as used in this Annual Report on Form 10-K, the terms “Pernix,” “Company,” “we,” “us” and “our” refer to Pernix Therapeutics Holdings, Inc., a Maryland corporation, and its subsidiaries taken as a whole.

We have identified in this Annual Report on Form 10-K our registered trademarks and service marks. In addition, this Annual Report on Form 10-K includes references to trademarks and service marks of other entities and those trademarks and service marks are the property of their respective owners.

Available Information

We make available free of charge on or through our internet website 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 such material is electronically filed with or furnished to the Securities and Exchange Commission. Our internet address is www.pernixtx.com. Information is also available through the Securities and Exchange Commission’s website at www.sec.gov or is available at the Securities and Exchange Commission’s Public Reference Room located at 100 F Street, NE, Washington DC, 20549. Information on the operation of the Public Reference Room is available by calling the Securities and Exchange Commission at 800-SEC-0330.

ITEM 1A. RISK FACTORS

If any of the following risks actually occur, our business, financial condition, results of operations and cash flows could be materially adversely affected and the value of our securities could be negatively impacted. Although we believe that we have identified and discussed below the key risk factors affecting our business, there may be additional risks and uncertainties that are not presently known that may materially adversely affect our business.

Risks Related to our Acquisition Strategy and Managing Growth

We may not be able to continue to grow through acquisitions of businesses and assets.

We have sought growth largely through acquisitions, including the acquisitions of Cypress in 2012, Pernix Sleep in 2013 and the rights to Treximet intellectual property in 2014. As part of our ongoing expansion strategy, we

plan to make additional strategic acquisitions of assets and businesses. However, our credit agreement with MidCap and the indentures governing our outstanding notes include restrictive covenants, which include, among other things, restrictions on the incurrence of indebtedness, as well as certain consolidations, acquisitions, mergers, purchases or sales of assets and capital expenditures, subject to certain exceptions and permissions limited in scope and dollar value. In addition to these restrictive covenants our credit agreement with MidCap contains certain financial covenants. For additional information see the notes to our audited consolidated financial statements for the years ended December 31, 2014, 2013 and 2012 contained in Part II, Item 8 of this Annual Report on Form 10-K. In the future, we may pursue growth opportunities through acquisitions that are not directly similar to those currently operated by us. We cannot assure you that acquisitions will be available on terms attractive to us. Moreover, we cannot assure you that such acquisitions will be permissible under our existing credit agreement with MidCap or the indentures governing our outstanding notes or that we will be able to arrange financing on terms acceptable to us or to obtain timely federal and state governmental approvals on terms acceptable to us, or at all.

We may be unable to successfully integrate newly acquired businesses or assets and realize the anticipated benefits of these acquisitions.

Management has in the past devoted, and will in the future devote, significant attention and resources to integrating newly acquired businesses and assets. Potential difficulties we have or may in the future encounter in the integration process include the following:

- the inability to successfully combine our businesses with any newly acquired business, to integrate any newly acquired assets into our existing product portfolio, and to meet our capital requirements following such acquisition, in a manner that permits us to achieve the cost savings or revenue enhancements anticipated to result from these acquisitions, which would result in the anticipated benefits of the acquisitions not being realized in the time frame currently anticipated or at all;

- lost sales and customers as a result of certain customers of Pernix or the newly acquired business or asset deciding not to do business with us following such acquisition;

- the additional complexities of integrating newly acquired businesses and assets with different core products and markets;

- potential unknown liabilities and unforeseen increased expenses associated with an acquisition of a business or asset; and

- performance shortfalls as a result of the diversion of management's attention caused by integrating the operations of a newly acquired business with those of Pernix or a newly acquired asset into the existing product portfolio.

For all these reasons, you should be aware that it is possible that integrating a newly acquired business or asset could result in the distraction of our management, the disruption of our ongoing business or inconsistencies in our products, standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits of the acquisitions, or could otherwise adversely affect our business and financial results.

Our future results will suffer if we do not effectively manage our expanded operations.

Our acquisitions of Cypress, Somaxon and the rights to Treximet intellectual property significantly changed the composition of our operations, markets and product mix. Our future success depends, in part, on our ability to address these changes, and, where necessary, to attract and retain new personnel that possess the requisite skills called for by these changes.

We may continue to expand our operations through additional acquisitions, license arrangements, other strategic transactions and new product offerings. Our future success depends, in part, upon our ability to manage our expansion opportunities. Integrating new operations into our existing business in an efficient and timely manner, successfully monitoring our operations, costs, regulatory compliance and customer relationships, and maintaining other necessary internal controls pose substantial challenges for us. As a result, we cannot assure you that our expansion or acquisition opportunities will be successful, or that we will realize our expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits.

Our business operations and financial position could be adversely affected as a result of our substantial indebtedness.

As of December 31, 2014, after giving effect to our issuance of an aggregate of $65.0 million of February 2014 Convertible Notes and an aggregate of $220.0 million of Treximet Notes in August 2014, we had approximately $292.3 million of debt outstanding and the ability to borrow approximately $32.7 million under our credit agreement with MidCap, utilizing the revolver accordion feature and subject to borrowing base capacity. This significant indebtedness could have important consequences. For example, it may:

- make it difficult for us to satisfy our obligations under our outstanding notes, the credit agreement with MidCap and our other indebtedness and contractual and commercial commitments;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- restrict us from making strategic acquisitions, entering new markets or exploiting business opportunities;
- place us at a competitive disadvantage compared to our competitors that have proportionally less debt;
- limit our ability to borrow additional funds and/or leverage our cost of borrowing; and
- decrease our ability to compete effectively or operate successfully under adverse economic and industry conditions.

In the event our capital resources are otherwise insufficient to meet future capital requirements and operating expenses, we may seek to finance our cash needs through public or private equity or debt financings, strategic relationships, including the divestiture of non-core assets, assigning receivables, milestone payments or royalty rights, or other arrangements. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of its attention away from our day-to-day activities, which may adversely affect our management’s 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:

- significantly delay, scale back or discontinue the development or commercialization of our products and product candidates;
- seek collaborators for one or more of our current or future products or product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be permissible under the indentures governing our outstanding notes or the credit agreement with MidCap or otherwise available on acceptable terms, if at all. Additional equity financing will be dilutive to stockholders, and debt financing, if available,

may involve additional restrictive covenants. Any exploration of strategic alternatives may not result in an agreement or transaction and, if completed, any agreement or transaction may not be successful or on attractive terms. The inability to enter into a strategic transaction, or a strategic transaction that is not successful or on attractive terms, could accelerate our need for cash and make securing funding on reasonable terms more difficult. In addition, if we raise additional funds through collaborations or other strategic transactions, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Despite our significant level of indebtedness, we and our subsidiaries may still be able to incur substantially more debt, which could exacerbate the risks associated with our substantial leverage.

We may be able to incur substantial additional indebtedness in the future. Although certain of our agreements, including the credit agreement with MidCap and the indentures governing our outstanding notes limit our ability and the ability of our subsidiaries to incur additional indebtedness, these restrictions are subject to a number of qualifications and exceptions and, under certain circumstances, debt incurred in compliance with these restrictions could be substantial. To the extent that we incur additional indebtedness, the risks associated with our substantial leverage described herein, including our possible inability to service our debt, would increase.

Our debt service obligations may adversely affect our cash flow.

A higher level of indebtedness increases the risk that we may default on our debt obligations. We may not be able to generate sufficient cash flow to pay the interest on our debt, and future working capital, borrowings or equity financing may not be available to pay or refinance such debt. If we are unable to generate sufficient cash flow to pay the interest on our debt, we may have to delay or curtail our operations.

Our ability to generate cash flows from operations and to make scheduled payments on our indebtedness will depend on our future financial performance. Our future financial performance will be affected by a range of economic, competitive and business factors that we cannot control, such as those risks described in this section. A significant reduction in operating cash flows resulting from changes in economic conditions, increased competition or other events beyond our control could increase the need for additional or alternative sources of liquidity and could have a material adverse effect on our business, financial condition, results of operations, prospects and our ability to service our debt and other obligations. If we are unable to service our indebtedness we will be forced to adopt an alternative strategy that may include actions such as reducing capital expenditures, selling assets, restructuring or refinancing our indebtedness or seeking additional equity capital. These alternative strategies may not be effected on satisfactory terms, if at all, and they may not yield sufficient funds to make required payments on our indebtedness.

If for any reason we are unable to meet our debt service and repayment obligations, we would be in default under the terms of the agreements governing our debt, which may allow our creditors at that time to declare outstanding indebtedness to be due and payable, which would in turn trigger cross-acceleration or cross-default rights between the relevant agreements.

In addition, the borrowings under our credit agreement with MidCap bear interest at variable rates and other debt we incur could likewise be variable-rate debt. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed thereunder remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, would correspondingly decrease.

The indentures governing our outstanding notes and the credit agreement with MidCap impose significant operating and/or financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

The indentures governing our outstanding notes and the credit agreement with MidCap contain covenants that restrict our and our subsidiaries' ability to take various actions, such as:

- incur additional debt;
- pay dividends and make distributions on, or redeem or repurchase, their capital stock;
- make certain investments, purchase certain assets or other restricted payments;
- sell assets, including in connection with sale-leaseback transactions;
- create liens;
- enter into transactions with affiliates;
- make lease payments in exceeding a specified amount; and
- merge, consolidate or transfer all or substantially all of their assets.

In addition, the terms of these agreements require us to maintain a minimum liquidity of $8.0 million at all times.

Upon the occurrence of a change of control, as described in the indenture governing the February 2014 Convertible Notes, holders of the February 2014 Convertible Notes may require us to repurchase for cash all or part of their February 2014 Convertible Notes at a repurchase price equal to 100% plus a specified percentage (that is initially 40% and declines over the life of the February 2014 Convertible Notes) of the principal amount of the February 2014 Convertible Notes to be repurchased, plus accrued and unpaid interest. If, upon the occurrence of a change of control, as described in the indenture, a holder elects to convert its February 2014 Convertible Notes in connection with such change of control, such holder may be entitled to an increase in the conversion rate as described in the indenture. To the extent such increase in the conversion rate would result in the conversion price of the February 2014 Convertible Notes to be less than $2.3278 per share (subject to adjustment) and equal to or greater than $2.09 per share (subject to adjustment), we will be obligated to deliver cash in lieu of any share that was not delivered on account of such limitation. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the February 2014 Convertible Notes surrendered therefor or payments of cash on February 2014 Convertible Notes converted in connection with certain change of control transactions. In addition, our ability to repurchase the February 2014 Convertible Notes or to pay cash upon conversions of the February 2014

Convertible Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the February 2014 Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the February 2014 Convertible Notes in connection with certain change of control transaction as required by the indenture would constitute a default under the indenture. A default under the indenture or the change of control itself could also lead to a default under agreements governing our indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the February 2014 Convertible Notes or make cash payments upon conversions in connection with certain change of control transactions. These and other provisions could prevent or deter a third party from acquiring us, even where the acquisition could be beneficial to you.

In addition, the credit agreement with MidCap requires that we maintain a minimum amount of EBITDA and net invoiced revenues unless we demonstrate minimum liquidity of at least $30 million.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our debt-related obligations could result in an event of default under the particular debt instrument, which could permit acceleration of the indebtedness under that instrument and, in some cases, the acceleration of our other indebtedness, in whole or in part.

These restrictions will also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

Our ability to borrow under the credit agreement with MidCap is limited by the amount of our borrowing base. Any negative impact on the elements of our borrowing base, such as accounts receivable and inventory could reduce our borrowing capacity under the credit agreement with MidCap.

If we fail to attract and retain key personnel, we may be unable to successfully develop or commercialize our products.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified managerial personnel. We are highly dependent upon our executive management team, particularly Douglas Drysdale, our Chairman, President and Chief Executive Officer. The loss of the services of Mr. Drysdale or any one or more other members of our executive management team or other key personnel could delay or prevent the successful completion of some of our development and commercialization objectives.

Recruiting and retaining qualified sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our management devotes substantial time to comply with public company regulations.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, impose various requirements on public companies, including with respect to corporate governance practices. Moreover, these rules and regulations increase legal and financial compliance costs and make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that our management maintain adequate disclosure controls and procedures and internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and, as applicable, our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require us to incur substantial accounting and related expenses and expend significant management efforts. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our financial reporting could be unreliable and misinformation could be disseminated to the public.

Any failure to develop or maintain effective internal control over financial reporting or difficulties encountered in implementing or improving our internal control over financial reporting could harm our operating results and prevent

us from meeting our reporting obligations. Ineffective internal controls also could cause our stockholders and potential investors to lose confidence in our reported financial information, which would likely have a negative effect on the trading price of our common stock. In addition, investors relying upon this misinformation could make an uninformed investment decision and we could be subject to sanctions or investigations by the SEC, NASDAQ Global Market or other regulatory authorities, or to stockholder class action securities litigation.

Our August 2014 acquisition of the rights to Treximet intellectual property and our strategy of obtaining, through asset acquisitions and in-licenses, rights to other products and product candidates for our development pipeline and to proprietary drug delivery and formulation technologies for our life cycle management of current products may not be successful.

We acquired the rights to Treximet intellectual property in August 2014 and from time to time we may seek to engage in additional strategic transactions with third parties to acquire rights to other pharmaceutical products, pharmaceutical product candidates in the late stages of development and proprietary drug delivery and formulation technologies. Because we do not have discovery and research capabilities, the growth of our business will depend in significant part on our ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that we believe have significant commercial potential and are consistent with our commercial objectives. However, we may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products, product candidates and drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities for us as well as higher acquisition prices. Many of our competitors have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Other factors that may prevent us from licensing or otherwise acquiring suitable products, product candidates or technologies include:

- we may be unable to license or acquire the relevant products, product candidates or technologies on terms that would allow us to make an appropriate return on investment;
- companies that perceive us as a competitor may be unwilling to license or sell their product rights or technologies to us;
- we may be unable to identify suitable products, product candidates or technologies within our areas of expertise; and
- we may have inadequate cash resources or may be unable to obtain financing to acquire rights to suitable products, product candidates or technologies from third parties.

If we are unable to successfully identify and acquire rights to products, product candidates and proprietary drug delivery and formulation technologies and successfully integrate them into our operations, we may not be able to increase our revenues in future periods, which could result in significant harm to our financial condition, results of operations and development prospects.

If we fail to successfully manage any acquisitions, our ability to develop our product candidates and expand our product pipeline may be harmed.

Our failure to adequately address the financial, operational or legal risks of any acquisitions or in-license arrangements could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or stock price include:

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

challenges associated with managing an increasingly diversified business;

disruption of our ongoing business;

difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company;

diversion of management's time and attention from other business concerns;

entry into a geographic or business market in which we have little or no prior experience;

inability to maintain uniform standards, controls, procedures and policies;

the assumption of known and unknown liabilities of the acquired business or asset, including intellectual property claims; and

subsequent loss of key personnel.

If we are unable to successfully manage our acquisitions, our ability to develop and commercialize new products and continue to expand our product pipeline may be limited.

If we are unable to effectively train and equip our sales force to sell newly acquired products, our ability to successfully commercialize our products will be harmed.

We have in the past made, and may in the future continue to make, acquisitions of pharmaceutical products. The members of our sales force may have no prior experience promoting the pharmaceutical products that we may acquire in the future. As a result, we may have to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense these pharmaceutical products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials relating to the pharmaceutical products that we may acquire in the future` , including medical and sales literature to help them inform and educate potential customers about the benefits of such products and their proper administration and label indication, our efforts to successfully market these pharmaceutical products could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

Risks Related to Commercialization

The commercial success of our currently marketed products and any additional products that we successfully commercialize will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be profitable. The degree of market acceptance of our products depends on a number of factors, including:

- the prevalence and severity of any side effect;
- the efficacy and potential advantages over the alternative treatments;
- the ability to offer our branded products for sale at competitive prices, including in relation to any generic products;
- substitution of our branded products with generic equivalents at the pharmacy level;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

We face competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The development and commercialization of drugs is highly competitive. We face competition with respect to our currently marketed products and any products that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. We face significant competition for our currently marketed products. Some of our currently marketed branded products, including Zutripro, Rezira and Vituz, do not have patent protection and in most cases face generic competition. All of our products face significant price competition from a range of branded and generic products for the same therapeutic indications.

Some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. For example, our product candidates may not demonstrate sufficient additional clinical benefits to physicians to justify a higher price compared to other lower cost products within the same therapeutic class. Notwithstanding the fact that we may devote substantial amounts of our resources to bringing product candidates to market, our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop and/or commercialize.

Our patent rights may not protect our patent protected products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights. For example, our patent rights in Silenor are limited in ways that affect our ability to exclude third parties from competing against us. In particular, we do not hold composition of matter patents covering the active pharmaceutical ingredient, or API, of Silenor. Composition of matter patents on APIs are a particularly effective form of intellectual property protection for pharmaceutical products, as they apply without regard to any method of use or other type of limitation. As a result, competitors who obtain the requisite regulatory approval can offer products with the same API as Silenor so long as the competitors do not infringe any method of use or formulations patents that we may hold.

The Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations and policies provide certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications ("ANDAs") for generic substitutes. These same types of exclusivity incentives encourage manufacturers to submit new drug applications ("NDAs") that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as our product and that the generic product is absorbed in the body at the same rate and to the same extent as our product, a comparison known as bioequivalence. Such products would be significantly less costly than certain of our products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit our ability to obtain a return on the investments we have made in those products. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates.

Products in our portfolio that do not have patent protection are potentially at risk for generic competition. We utilize our generic business to attempt to retain market share from other generic competitors for our branded products. For example, we have attempted to maintain market share in the prescription cough and cold market by offering an authorized generic of Cedax and Zutripro. Additionally, products we sell through our collaborative or co-promotion arrangements may also face competition in the marketplace.

Some of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in marketing and sales, research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products and thus may be better equipped than us to discover, develop, manufacture and commercialize products. These competitors also compete with us in recruiting and retaining qualified management personnel and acquiring technologies. Many of our competitors have collaborative arrangements in our target markets with leading companies and research institutions. In many cases, products that compete with our products have already received regulatory approval or are in late-stage development, have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, our revenue and profit from existing products and anticipated revenue and profit from product candidates. If our products or product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those products or product candidates.

If our competitors introduce their own generic equivalents of our products, our net revenues from such products are expected to decline.

Product sales of generic pharmaceutical products often follow a particular pattern over time based on regulatory and competitive factors. The first company to introduce a generic equivalent of a branded product is often able to capture a substantial share of the market. However, as other companies introduce competing generic products, the first entrant’s market share, and the price of its generic product, will typically decline. The extent of the decline generally depends on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors.

For example, in the generic drug industry, when a company is the first to introduce a generic drug, the pricing of the generic drug is typically set based on a discount from the published price of the equivalent branded product. Other generic manufacturers may enter the market and, as a result, the price of the drug may decline significantly. In such event, we may in our discretion provide our customers a credit with respect to the customers' remaining inventory for the difference between our new price and the price at which we originally sold the product to our customers. There are circumstances under which we may, as a matter of business strategy, not provide price adjustments to certain customers and, consequently, we may lose future sales to competitors.

Negative publicity regarding any of our products or product candidates could delay or impair our ability to market any such product, delay or prevent approval of any such product candidate and may require us to spend time and money to address these issues.

If any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers and/or subject to FDA enforcement action, our ability to successfully market and sell our products could be impaired. Because of our dependence on patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could limit the commercial potential of our products and expose us to potential liabilities.

If we are unable to attract, hire and retain qualified sales and management personnel and successfully manage our sales and marketing programs and resources, or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

As of December 31, 2014, our sales force consisted of approximately 100 sales territories. In October 2013 we entered into a co-promotion agreement with Cumberland, under which Cumberland will promote Omeclamox-Pak to gastroenterologists across the United States through its field sales force. In September 2014, we entered into an agreement with Sallus Laboratories LLC under which Sallus will promote Zutripro, Rezira and Vituz through its field sales force until March 31, 2015. In August 2014, the Company entered into an agreement with PDI, Inc. for services related to the promotion of Cedax and its authorized generic.

We, Cumberland and any other commercialization partner we engage may not be able to attract, hire, train and retain qualified sales and sales management personnel in the future. If we or they are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. Even if we are able to effectively maintain such sales personnel, their efforts may not be successful in commercializing our products.

In addition, a significant portion of revenues we receive from sales of products that are the subject to commercial partnerships will largely depend upon the efforts our partners, including Cumberland. The efforts of our partners in many instances are likely to be outside our control. If we are unable to maintain our commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected. In addition, despite our arrangements with Cumberland and our other partners, we still may not be able to cover all of the prescribing physicians for our products at the same level of reach and frequency as our competitors, and we ultimately may need to further expand our selling efforts in order to effectively compete.

The efforts of our sales force and partners are complemented by on-line and other non-personal promotional initiatives that target both physicians and patients. We are also focused on ensuring broad patient access to our products by negotiating agreements with leading commercial managed care organizations and with government payors. Although our goal is to achieve sales through the efficient execution of our sales and marketing plans and programs, we may not be able to effectively generate prescriptions and achieve broad market acceptance for our

products on a timely basis, or at all.

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

Some of our products, including Zutripro, its generic equivalent, Rezira, Vituz and certain other generic products contain controlled substances, which are regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer can manufacture and the amount of API it can use to manufacture those products. We may experience difficulties obtaining raw materials needed to manufacture our products as a result of DEA regulations and because of the limited number of suppliers of pseudoephedrine, an active ingredient in several of our products. If we are unsuccessful in obtaining quotas, unable to manufacture and release inventory on a timely and consistent basis, fail to maintain an adequate level of product inventory, or if inventory is destroyed or damaged or reaches its expiration date, patients might not have access to our products, our reputation and our brands could be harmed and physicians may be less likely to prescribe 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.

We and our contract manufacturers may not be able to obtain the regulatory approvals or clearances that are necessary to manufacture pharmaceutical products.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, which we refer to herein as cGMP, requirements which include requirements relating to quality control and quality assurance, as well as the maintenance of records and documentation and utilization of qualified raw materials. To be successful, our products must be manufactured for development and, following approval, in commercial quantities, in compliance with regulatory requirements and at acceptable costs.

We and our contract manufacturers must comply with these cGMP requirements. While we believe that we and our contract manufacturers currently meet these requirements, we cannot assure that our manufacturing facilities or those of our contract manufacturers will continue to meet cGMP requirements or will be sufficient to manufacture all of our needs and/or the needs of our customers for commercial materials.

We and our contract manufacturers may also encounter problems with the following:

production yields;

possible facility contamination;

quality control and quality assurance programs;

shortages of qualified personnel;

compliance with FDA or other regulatory authorities' regulations, including the demonstration of purity and potency;

changes in FDA or other regulatory authorities' requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

In addition, we and our contract manufacturers are required to register our manufacturing facilities with the FDA and other regulatory authorities and to subject them to inspections confirming compliance with cGMP or other regulations. If we or our contract manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to permit us or our contract manufacturers to continue manufacturing approved products. As a result, our business, financial condition and results of operations may be materially harmed.

If we or our third party manufacturers fail to comply with regulatory requirements for our controlled substance products, the DEA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our third party manufacturers and certain of our products including Zutripro, its generic equivalent, Rezira, Vituz and certain other generic products are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we must adhere to a number of requirements with respect to our controlled substance products including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls,

procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our currently marketed products and any other products that we successfully develop or commercialize. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products or any products that we may develop;

injury to reputation;

withdrawal of client trial participants;

withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to trial participants or patients;

diversion of management time and attention;

loss of revenue; and

the inability to commercialize any products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Seasonality may cause fluctuations in our financial results.

We generally experience some effects of seasonality due to increases in demand for cough and cold products during the winter season. Accordingly, sales of cough and cold products and associated revenue have generally increased at a higher rate immediately prior and during the winter season. This seasonality may cause fluctuations in our financial results. In addition, other seasonality trends may develop and the existing seasonality that we experience may change.

Risks Related to Our Dependence on Third Parties

If the manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture our marketed products, and we do not currently plan to develop any capacity to do so. We rely on third party manufacturers for our products. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling

up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our manufacturers may not perform as agreed or may terminate their agreements with us. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to sell our marketed products or any other product candidate that we commercialize would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our marketed products will result in the loss of potential revenues.

In connection with our acquisition of the rights to Treximet intellectual property in August 2014, we discovered short-term supply constraints for the product. Our failure to obtain sufficient supply of Treximet to meet anticipated demand in the future may result in the loss of potential revenues.

All manufacturers of pharmaceutical products must comply with current good manufacturing practice, or cGMP, requirements enforced by the FDA through its facilities inspection program. The FDA is also likely to conduct inspections of our manufacturers' facilities as part of their review of any marketing applications we submit. These cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of our supply of our marketed products. We do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for production.

Any of these factors could adversely affect the commercial activities for our marketed products, and required approvals for any other product candidate that we develop, or entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our manufacturers failed to deliver the required commercial quantities of raw materials, including bulk drug substance, or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

We rely entirely on GSK as the sole supplier of Treximet. GSK's inability to continue manufacturing adequate supplies of Treximet, or its refusal to supply us with commercial quantities of Treximet, may materially harm our business and financial condition and adversely impact our commercialization and sales efforts with respect to the product.

We have entered into a supply agreement with GSK pursuant to which GSK will manufacture and supply to us commercial quantities of Treximet. GSK is currently our sole source for Treximet We may from time to time experience disruptions by GSK in the manufacture or supply of Treximet, or may experience disruptions in our business relationship with GSK. For example, in connection with our acquisition of the rights to Treximet intellectual property in August 2014, we discovered short-term supply constraints for the product. In addition, as of December 31, 2014 GSK has claimed damages of approximately $8.5 million stemming from an alleged breach of a covenant contained in the Asset Purchase Agreement pursuant to which we purchased the Treximet assets pertaining to a pre-existing customer agreement. The failure by GSK for any reason to provide us with sufficient commercial quantities of Treximet may materially harm our business and financial condition and adversely impact our commercialization and sales efforts with respect to the product.

If GSK fails to provide us with commercial quantities of Treximet, the process of changing or adding a new contract manufacturer or supplier may require additional testing and prior FDA approval and may be expensive and time-consuming. If we were unable to manage such changes effectively, we could face supply disruptions that could result in significant costs and delays, damage to our reputation or commercial prospects and cause us to lose potential revenues relating to the product.

The concentration of our product sales to only a few wholesale distributors increases the risk that we will not be able to effectively distribute our products if we need to replace any of these customers, which would cause our sales to decline.

The majority of our sales are to a small number of pharmaceutical wholesale distributors, which in turn sell our products primarily to retail pharmacies, which ultimately dispense our products to the end consumers. For the year ended December 31, 2014, McKesson Corporation accounted for 37% of our total gross sales, AmerisourceBergen Drug Corporation accounted for 31% of our total gross sales and Cardinal Health accounted for 23% of our total gross sales. For the year ended December 31, 2013, McKesson Corporation accounted for 35% of our total gross sales, AmerisourceBergen Drug Corporation accounted for 20% of our total gross sales and Cardinal Health accounted for 24% of our total gross sales. For the year ended December 31, 2012, McKesson Corporation accounted for 26% of our total gross sales, AmerisourceBergen Drug Corporation accounted for 10% of our total gross sales and Cardinal health accounted for 39% of our total gross sales.

If any of these customers cease doing business with us or materially reduce the amount of product they purchase from us and we cannot conclude agreements with replacement wholesale distributors on commercially reasonable terms, we might not be able to effectively distribute our products through retail pharmacies. The possibility of this occurring is exacerbated by the recent significant consolidation in the wholesale drug distribution industry, including through mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

Any collaboration arrangements that we enter into may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We enter into collaboration arrangements from time to time on a selective basis. Our collaborations may not be successful. Of our current product portfolio, we market Omeclamox-Pak, Khedezla, Cedax, Zutripro, Rezira, Vituz and certain of our generic products pursuant to collaboration arrangements. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Our business could suffer as a result of a failure to manage and maintain our distribution network with our wholesale customers.

We depend on the distribution abilities of our wholesale customers to ensure that our products are effectively distributed through the supply chain. If there are any interruptions in our customers' ability to distribute products through their distribution centers, our products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution.

We intend to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not intend to independently conduct clinical trials for our product candidates. We will rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We are subject to various legal proceedings and business disputes that could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our common stock

to decline.

We are subject to various legal proceedings and business disputes and additional claims may arise in the future. In particular, as of December 31, 2014 GSK has claimed damages of approximately $8.5 million stemming from an alleged breach of a covenant contained in the Asset Purchase Agreement pursuant to which we purchased the Treximet assets pertaining to a pre-existing customer agreement. Our dispute with GSK and other legal proceedings and disputes that may arise in the future, may be complex and extended and may occupy the resources of our management and employees. These proceedings may also be costly to prosecute and defend and may involve substantial awards or damages payable by us if not found in our favor. We may also be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings. Defending against or settling such claims and any unfavorable legal decisions, settlements or orders could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline. For more information regarding legal proceedings and contingencies, see Note 24, Commitments and Contingencies, to our consolidated financial statements included in the Annual Report on Form 10-K.

Risks Related to Intellectual Property

If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.

Our success will depend in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of pharmaceuticals is highly uncertain and involves complex legal and scientific questions. We rely upon patents, trade secret laws and confidentiality agreements to protect our technology and products. We may not be able to obtain additional patent rights relating to our technology or products and pending patent applications to which we have rights may not issue as patents or if issued, may not issue in a form that will be advantageous to us. Even if issued, any patents issued to us or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. For example, the principal patent protection that covers Silenor consists of method of use patents. This type of patent protects the product only when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical or similar to Silenor for an indication that is outside of the patented method. Moreover, physicians may prescribe such a competitive or similar product for off-label indications that are covered by the applicable patents. Some physicians are prescribing generic 10mg doxepin capsules and generic oral solution doxepin for insomnia on such an off-label basis in lieu of prescribing Silenor. In addition, some managed healthcare plans are requiring the substitution of these generic doxepin products for Silenor, and some pharmacies are suggesting such substitution. Although such off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Our patent rights also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a U.S. patent application covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position. In addition, patents generally expire, regardless of the date of issue, 20 years from the earliest non-provisional effective U.S. filing date.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act did not become effective until 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An

inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Trademark protection of our products may not provide us with a meaningful competitive advantage.

We use trademarks on most of our currently marketed branded products and believe that having distinctive marks is an important factor in marketing those products. Trademarks are also an important factor in marketing products of other parties under license or co-promotion agreements. Distinctive marks may also be important for any additional products that we successfully develop and commercially market. However, we generally do not expect our marks to provide a meaningful competitive advantage over other branded or generic products. We believe that efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third party payors are and are likely to continue to be more important factors in the commercial success of our products. For example, physicians and patients may not readily associate our trademark with the applicable product or active pharmaceutical ingredient. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy, resulting in a significant loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Competitors also may use marks or names that are similar to our trademarks. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We have acquired rights to products and product candidates under license and co-promotion agreements with third parties and expect to enter into additional licenses and co-promotion agreements in the future. Our existing licenses impose, and we expect that future licenses will impose, various development and commercialization, purchase commitment, royalty, sublicensing, patent protection and maintenance, insurance and other obligations on us.

If we fail to comply with our obligations under a license agreement, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any product that is covered by the licensed patents. Even if we contest any such termination or claim and are ultimately successful, our results of operations and stock price could suffer. In addition, upon any termination of a license agreement, we may be required to license to the licensor any related intellectual property that we developed.

For example, we in-licensed rights to Silenor through an exclusive licensing arrangement, and may enter into similar licenses in the future. Under our license agreement for Silenor, we are required to use commercially reasonable efforts to commercialize Silenor. In addition, our licensor has the contractual right to terminate the license agreement upon the breach by us or a specified insolvency event. In the event that our licensor for Silenor terminates the license agreement, even though we would maintain ownership of our clinical data and the other intellectual property we developed relating to Silenor, we would be unable to continue our commercialization activities relating to Silenor and our business and financial condition may be materially harmed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect our unpatented proprietary information in part by confidentiality agreements with our employees, consultants and third parties. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, third parties, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate.

In addition, the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. To the extent that our intellectual property protection is inadequate, we are exposed to a greater risk of direct competition. If our intellectual property is not adequately protected against competitors' products, our competitive position could be adversely affected, as could our business. We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our consultants and third parties, when appropriate, to execute confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us be kept confidential and not disclosed to third parties except in specific circumstances and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this

information to develop products that compete with our products, which could adversely impact our business.

If we infringe or are alleged to infringe intellectual property rights of third parties, it may adversely affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and/or abroad. Such third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any relevant claims of third-party patents that we are alleged to infringe are upheld as valid and enforceable in any litigation or administrative proceeding, we or our potential future collaborators could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign our products, and could be liable for monetary damages. There can be no assurance that such licenses would be available or, if available, would be available on acceptable terms or that we would be successful in any attempt to redesign our products. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us or our future collaborators from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition and results of operations.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. The cost to us of any patent litigation or other proceedings, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Financial Position

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs, commercialization efforts or acquisition strategy.

We make significant investments in our currently-marketed products for sales, marketing, and distribution. We have used, and expect to continue to use, revenue from sales of our marketed products to fund acquisitions (at least partially), for development costs and to establish and expand our sales and marketing infrastructure.

Our future capital requirements will depend on many factors, including:

- our ability to successfully integrate the operations of newly acquired businesses and assets into our product portfolio;
- the level of product sales from our currently marketed products and any additional products that we may market in the future;
- the extent to which we acquire or invest in products, businesses and technologies;
- the scope, progress, results and costs of clinical development activities for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the extent to which we choose to establish additional collaboration, co-promotion, distribution or other similar arrangements for our products and product candidates; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims.

We intend to obtain any additional funding we require through public or private equity or debt financings, strategic relationships, including the divestiture of non-core assets, assigning receivables, milestone payments or royalty rights, or other arrangements and we cannot assure such funding will be available on reasonable terms, or at all. Additional equity financing will be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Any exploration of strategic alternatives may not result in an agreement or transaction and, if completed, any agreement or transaction may not be successful or on attractive terms. The inability to enter into a strategic transaction, or a strategic transaction that is not successful or on attractive terms, could accelerate our need for cash and make securing funding on reasonable terms more difficult. In addition, if we raise additional funds through collaborations or other strategic transactions, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If our efforts in raising additional funds when needed are unsuccessful, we may be required to delay, scale-back or eliminate plans or programs relating to our business, relinquish some or all rights to our products or renegotiate less favorable terms with respect to such rights than we would otherwise choose or cease operating as a going concern. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we were successful in defending against these potential claims, litigation could

result in substantial costs and be a distraction to management, and may result in unfavorable results that could further adversely impact our financial condition.

If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investments.

If the estimates that we make, or the assumptions upon which we rely, in preparing our financial statements prove inaccurate, our future financial results may vary from expectations.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders' equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated charge backs, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves For new products, these sales adjustments may be estimated based on information available on any similar products in the marketplace or specific information provided by business partners or if management is not able to derive a reasonable estimate for the adjustments, gross revenue can be deferred and recognized as the product is prescribed.

Actual sales allowances may vary from our estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. We cannot assure you, therefore, that there may not be material fluctuations between our estimates and the actual results.

If we fail to meet all applicable continued listing requirements of the NASDAQ Global Market and it determines to delist our common stock, the market liquidity and market price of our common stock could decline.

If we fail to meet all applicable listing requirements of the NASDAQ Global Market and it determines to delist our common stock, trading, if any, in our shares may continue to be conducted on the Over-the-Counter Bulletin Board or in a non-NASDAQ over-the-counter market, such as the "pink sheets". Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest and confidence in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than $5.00 per share, our shares could be subject to Rule 15g-9 under the Exchange Act which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital.

If significant business or product announcements by us or our competitors cause fluctuations in our stock price, an investment in our stock may suffer a decline in value.

The market price of our common stock may be subject to substantial volatility as a result of announcements by us or other companies in our industry, including our collaborators. Announcements that may subject the price of our common stock to substantial volatility include announcements regarding:

- our operating results, including the amount and timing of sales of our products and our ability to successfully integrate the operations of newly acquired businesses or products;
- the availability and timely delivery of a sufficient supply of our products;

the safety and quality of our products or those of our competitors;

our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;

the results of discoveries, preclinical studies and clinical trials by us or our competitors;

the acquisition of technologies, product candidates or products by us or our competitors;

the development of new technologies, product candidates or products by us or our competitors;

regulatory actions with respect to our product candidates or products or those of our competitors; and

significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We did not make any distributions for the years ended December 31, 2014, 2013 and 2012. We are currently investing in our promoted product lines and product candidates and do not anticipate paying dividends in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our credit agreement with MidCap and the indentures governing our outstanding notes prohibit us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Holders of our outstanding February 2014 Convertible Notes have the ability to exercise significant influence over our management and affairs and matters requiring stockholder approval.

Upon conversion of our outstanding February 2014 Convertible Notes, the February 2014 Convertible Note holders will own an aggregate of 18,055,555 shares of our common stock, which represents approximately 32% of our outstanding common stock upon conversion. In addition, two of these holders have each been granted the right to nominate a member of our board of directors. As a result, these February 2014 Convertible Note holders have the ability to exercise significant influence over our management and affairs and matters requiring stockholder approval. The interests of these holders may differ from or conflict with the interests of our other stockholders.

Sales of a substantial number of shares of our common stock or equity-linked securities could cause our stock price to fall.

Sales of a substantial number of shares of our common stock or equity-linked securities in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-linked securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Our operating results are likely to fluctuate from period to period.

We anticipate that there may be fluctuations in our future operating results. Potential causes of future fluctuations in our operating results may include:

- period-to-period fluctuations in financial results due to seasonal demands for certain of our products;
- unanticipated potential product liability or patent infringement claims;
- new or increased competition from generics;
- the introduction of technological innovations or new commercial products by competitors;
- changes in the availability of reimbursement to the patient from third-party payers for our products;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the initiation of litigation to enforce or defend any of our intellectual property rights;
- the loss of key employees;
- the results of pre-clinical testing, IND application, and potential clinical trials of some product candidates;
- regulatory changes;
- the results and timing of regulatory reviews relating to the approval of product candidates;
- the results of clinical trials conducted by others on products that would compete with our products and product candidates;

failure of any of our products or product candidates to achieve commercial success;

general and industry-specific economic conditions that may affect research and development expenditures;

future sales of our common stock; and

changes in the structure of health care payment systems resulting from proposed healthcare legislation or otherwise.

Our stock price is subject to fluctuation, which may cause an investment in our stock to suffer a decline in value.

The market price of our common stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

If we become subject to unsolicited public proposals from activist stockholders due to our shifting strategic focus or otherwise, we may experience significant uncertainty that would likely be disruptive to our business and increase volatility in our stock price.

Public companies, particularly those in volatile industries such as the pharmaceutical industry, have been the target of unsolicited public proposals from activist stockholders. The unsolicited and often hostile nature of these public proposals can result in significant uncertainty for current and potential licensors, suppliers, patients, physicians and other constituents, and can cause these parties to change or terminate their business relationships with the targeted company. Companies targeted by these unsolicited proposals from activist stockholders may not be able to attract and retain key personnel as a result of the related uncertainty. In addition, unsolicited proposals can result in stockholder class action lawsuits. The review and consideration of an unsolicited proposal as well as any resulting lawsuits can be a significant distraction for management and employees, and may require the expenditure of significant time, costs and other resources.

If we were to receive unsolicited public proposals from activist stockholders, we may encounter all of these risks and, as a result, may be delayed in executing our core strategy. We could be required to spend substantial resources on the evaluation of the proposal as well as the review of other opportunities that never come to fruition. If we were to receive any of these unsolicited public proposals, the future trading price of our common stock is likely to be even more volatile than in the past, and could be subject to wide price fluctuations based on many factors, including uncertainty associated with the proposals.

We may become involved in securities or other class action litigation that could divert management’s attention and harm our business.

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, following periods of volatility in the market price of a particular company’s securities, securities class action litigation has often been brought against that company. Any securities or other class action litigation asserted against us could have a material adverse effect on our business.

The historical and pro forma financial statements we have filed with the SEC relating to Treximet may not be an indication of our ability to commercialize Treximet

In August 2014, we completed the acquisition of the intellectual property rights to Treximet in the United States from GSK. In October 2014, we filed historical financial statements and pro forma financial information relating to the Treximet product line, and the SEC stated that it would not object to our conclusion that the filing of the historical financial statements relating to the Treximet product line represents substantial compliance with the requirements of Rule 3-05 of Regulation S-X, or Rule 3-05. However, we were advised by GSK that the Treximet product line had not been a separate legal entity of GSK and was never operated as a stand-alone business, division or subsidiary. GSK

also advised us that it had never prepared full stand-alone or full carve-out financial statements for the Treximet business, and that GSK has never maintained the distinct and separate accounts necessary to prepare financial statements that fully comply with the requirements of Rule 3-05. As a result, these historical statements may not be an indication of the performance of Treximet under GSK for the periods indicated. In addition, the assumptions used in preparing the pro forma financial information may not prove to be accurate or relevant to the Treximet product line, in particular on a go-forward basis, and therefore should not be relied upon as a measure of our ability to commercialize Treximet.

Risks Related to Product Development

We may invest a significant portion of our efforts and financial resources in the development of our product candidates and there is no guarantee we will obtain requisite regulatory approvals or otherwise timely bring these product candidates to market.

Our ability to bring any of our product candidates to market depends on a number of factors including:

- successful completion of pre-clinical laboratory and animal testing;
- an FDA approved investigational new drug application or IND application, becoming effective, which must occur before human clinical trials may commence;
- successful completion of clinical trials;
- submission of an NDA;
- receipt of marketing approvals from the FDA;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- launching commercial sales of the product;
- acceptance of the product by patients, the medical community and third party payors;
- competition from other therapies;
- achieving and maintaining compliance with all regulatory requirements applicable to the product; and
- a continued acceptable safety profile of the product following approval.

There are no guarantees that we will be successful in completing these tasks. If we are not successful in commercializing any of our product candidates, or are significantly delayed in doing so, our business will be harmed, possibly materially.

If our clinical trials do not demonstrate safety and efficacy in humans, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Before obtaining regulatory approval for the sale of some of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. In the United States, we must demonstrate with substantial evidence gathered in well-controlled studies, and to the satisfaction of the FDA, that each product candidate is safe and effective for use in the target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. The outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if early phase clinical trials are successful, it is necessary to conduct additional clinical trials in larger numbers of patients taking the drug for longer periods before seeking approval from the FDA to market and sell a drug in the United States. Clinical data is often susceptible to varying interpretations, and companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. Similarly, even if clinical trials of a product candidate

are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. A failure of one or more of our clinical trials can occur at any stage of testing.

Failures or delays in the commencement or completion of our clinical trials could result in increased costs to us and delay or limit our ability to generate revenues.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Commencement or completion of clinical trials can be delayed or prevented for a number of reasons, including:

- FDA or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- difficulty complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our clinical trials may produce negative or inconclusive results, and we may decide, or the FDA or analogous foreign governmental entities may require us, to conduct additional clinical trials or we may abandon projects that we expect to be promising;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates in addition to those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for one or more of our product candidates;
- not be able to obtain marketing approval; or

obtain approval for indications that are not as broad as intended.

Our product development costs also will increase if we experience delays in testing or approvals. Significant clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates. In addition, failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may also result in the ineligibility to use the data to support market approval.

Risks Related to Regulatory Matters

Some of our specialty pharmaceutical products are now being marketed without FDA approvals.

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has historically refrained from taking enforcement action against some marketed, unapproved new drugs. Specifically, some marketed prescription and nonprescription drugs are not the subject of an approved marketing application because they are thought to be identical, related, or similar to historically-marketed products, which were thought not to require pre-market review and approval, or which were approved only on the basis of safety, at the time they entered the marketplace. When enacted in 1938, the FDCA required proof of safety but not efficacy for new drugs. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar to the approved drug to be covered by that approval, and allowed those drugs to be marketed without independent approval. In 1962, Congress amended the FDCA to require that a new drug be proven effective, as well as safe, to obtain FDA approval. The FDA established the Drug Efficacy Study Implementation, or DESI, program, which was established to determine the effectiveness of drug products approved before 1962. Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, the FDA created a program, known as the Prescription Drug Wrap-Up, also known as DESI II, to address the remaining unapproved drugs. Most of these drugs contain active pharmaceutical ingredients that were first marketed prior to 1938. The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement discretion because all prescription drugs must be the subject of an approved drug application.

There are a few narrow exceptions. Under the 1938 grandfather clause, a drug product that was on the market prior to the passage of the FDCA in 1938 and which contains in its labeling the same representations concerning the conditions of use as it did prior to passage of the FDCA was not considered a “new drug” and therefore was exempt from the requirement of having an approved NDA. The 1962 grandfather clause exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the FDCA at that time, and (c) not covered by an effective application. The FDA and the courts have interpreted these two grandfather clauses very narrowly. The FDA believes that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population. It is a company’s burden to prove that its product is grandfathered.

The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. While all such drugs are considered to require FDA approval, FDA enforcement against such products as unapproved new drugs prioritizes products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved.

Some of our specialty pharmaceutical products are marketed in the United States without an FDA-approved marketing application because they have been considered by us to be identical, related or similar to products that have existed in the market without an NDA or ANDA. These products are marketed subject to the FDA’s regulatory discretion and enforcement policies, and it is possible that the FDA could disagree with our determination that one or more of these products is identical, related or similar to products that have existed in the marketplace without an NDA or ANDA. On March 3, 2011, the FDA announced its intent to remove certain unapproved prescription cough, cold, and allergy products from the U.S. market and named products from two cough and cold product families that Pernix sold, as well as certain Cypress products. The FDA provided three dates for the cessation of manufacturing, shipping or other introduction or delivery into commerce – March 3, 2011 for drugs not listed with the FDA under Section 510 of the FDCA, June 1, 2011 for cessation of manufacturing of listed drugs and August 31, 2011 for cessation of shipping of listed drugs covered by the notice. Manufacturing or shipping of the drug products covered by the notice beyond the date specified can result in enforcement action, including seizure, injunction, or other judicial or administrative proceedings. The time periods will not be extended for those who have submitted but not yet received approval of an NDA or ANDA application for a drug product covered by the notice. The Company completed the conversion of the ALDEX and BROVEX product families, two of our legacy cough and cold product families, to OTC monograph from DESI drugs in 2011. The Company believes it has appropriately marketed these lines as OTC monograph products. If the FDA were to disagree with our determination, it could require the removal of our unapproved products from the market. We voluntarily discontinued these products in 2013.

The Company’s authorized generic products that are OTC monograph products have not been affected by the FDA announcement. Certain Macoven generic products that were not marketed as OTC monograph were converted, and we did not experience any suspension, delay or interruption in our sales of these products. Our remaining generic DESI cough and cold products that were not being converted to OTC monograph were phased out by 2011 and did not have a material impact on the results of operations or financial condition of the Company. If the FDA were to disagree with our determination, it could ask or require the removal of our unapproved products from the market; however, this would no longer have a material impact on our gross sales.

In addition, if the FDA issues an approved NDA for one of the drug products within the class of drugs that includes one or more of our unapproved products or completes the efficacy review for that drug product, it may require us to also file an NDA or ANDA application for its unapproved products in that class of drugs in order to continue

marketing them in the United States. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and could ask or require that the unapproved products be removed from the market immediately. In addition, the time it takes us to complete the necessary clinical trials and submit an NDA or ANDA to the FDA may exceed any applicable grace period, which would result in an interruption of sales of such unapproved products. If the FDA asks or requires that the unapproved products be removed from the market, our financial condition and results of operations would be materially and adversely affected.

If the FDA disagrees with our determination that several of our products meet the over-the-counter requirements, those products may be removed from the market.

Drugs must meet all of the general conditions for OTC drugs and all of the conditions contained in an applicable final monograph to be considered generally recognized as safe and effective (GRAS/GRAE) and to be marketed without FDA approval of a marketing application. The general conditions include, among other things, compliance with cGMP, establishment registration and labeling requirements. Any product which fails to comply with the general conditions and a monograph is liable to regulatory action. We believe our promoted branded products comply with FDA OTC monograph requirements. However, if the FDA determines that our products do not comply with the monograph or if we fail to meet the general conditions, the products may be removed from the market and we may face actions including, but not limited to, restrictions on the marketing or distribution of such products, warning letters, fines, product seizure, or injunctions or the imposition of civil or criminal penalties. Any of these actions would reduce our gross sales.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate increased revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, the DEA and other regulatory agencies in the United States. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our future products may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, recordkeeping, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements may result in actions such as:

withdrawal of the products from the market;

restrictions on the marketing or distribution of such products;

restrictions on the manufacturers or manufacturing processes;

warning letters;

refusal to approve pending applications or supplements to approved applications that we submit;

recalls;

fines;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, or for the indications specified in an applicable OTC monograph and in accordance with the monograph's labeling requirements. An organization that is found to have improperly promoted off-label uses may be subject to significant liability by the FDA and other agencies that actively enforce laws and regulations prohibiting the promotion of off-label uses. The Federal Trade Commission regulates advertising for OTC drug products and advertising for these products must be truthful, not misleading and adequately substantiated. If we are found to have promoted off-label uses, our OTC products may be deemed out of compliance with the applicable OTC monograph, we may be enjoined from such off-label promotion and become subject to significant liability, which would have an adverse effect on our reputation, business and revenues, if any.

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of our products.

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs, varies but coverage is similar to other products within the same class of drugs. For example, Cedax is covered by private insurance plans similar to other marketed, branded cephalosporins. However, the position of any of our branded products that requires a higher patient copayment may make it more difficult to expand the current market share for such product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for a branded product. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, some of our products are purchased under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center lookalikes and qualified disproportionate share hospitals.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, created a new Medicare benefit for prescription drugs. More recently, the Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business.

In March 2010, the President signed the PPACA, which makes extensive changes to the delivery of healthcare in the U.S. This act includes numerous provisions that affect pharmaceutical companies, some of which were effective immediately and others of which will be taking effect over the next several years. For example, the act seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The act also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The act also contains cost-containment measures that could reduce reimbursement levels for healthcare items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching

hospitals. These measures could result in decreased net revenues from our pharmaceutical products and decreased potential returns from our development efforts. Although the PPACA was recently upheld by the U.S. Supreme Court, it is possible that the PPACA may be modified or repealed in the future.

In addition, private insurers, such as MCOs, may adopt their own reimbursement reductions in response to federal or state legislation. Any reduction in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product and the amount for which that product will be reimbursed are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products may change at any time.

The MMA established a voluntary prescription drug benefit, called Part D, which became effective in 2006 for all Medicare beneficiaries. We cannot be certain that our currently marketed products will continue to be, or any of our product candidates still in development will be, included in the Medicare prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

If we succeed in bringing additional products to the market, these products may not be considered cost-effective and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of our products and product candidates.

Our relationships with customers and payors are subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputation harm, and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulation that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products. Applicable federal and state healthcare laws and regulations, include but are not limited to, the following:

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

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

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

the Foreign Corrupt Practices Act and similar anit-bribery laws in countries outside of the U.S., such as the U.K. Bribery Act of 2010, prohibit companies and their intermediaries from making, or offering or promising to make, improper payments for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

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

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

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

guidelines and the relevant compliance guidance promulgated by the federal government.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. These include proposals to permit reimportation of pharmaceutical products from other countries and proposals concerning safety matters. For example, in an attempt to protect against counterfeiting and diversion of drugs, a bill was introduced in a previous Congress that would establish an electronic drug pedigree and track-and-trace system capable of electronically recording and authenticating every sale of a drug unit throughout the distribution chain. This bill or a similar bill may be introduced in Congress in the future. California has already effected legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. Compliance with California and any future federal or state electronic pedigree requirements will likely require an increase in our operational expenses and will likely be administratively burdensome. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

We, as well as many other pharmaceutical companies, sponsor prescription drug coupons and other cost-savings programs to help reduce the burden of co-payments and co-insurance. During 2012, lawsuits have been filed against several pharmaceutical companies alleging, among other things, that the drug-makers violated anti-trust laws and the Racketeer Influenced and Corrupt Organizations Act, or RICO, when they provided coupon programs to privately-insured consumers that subsidize all or part of the cost-sharing obligation (co-pay or co-insurance) for a branded prescription drug or drugs. We cannot be certain as to whether we will be named in any future similar lawsuit or concerning the potential outcome of the ongoing litigation.

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

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

The Food and Drug Administration Amendments Act of 2007 may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute our existing products.

The Food and Drug Administration Amendments Act of 2007, or the FDAAA, grants a variety of new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. The amendments, among other things, require some new drug applicants to submit risk evaluation and minimization strategies to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Companies that violate the law are subject to substantial civil monetary penalties. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. While the FDAAA has had, and is expected to have, a substantial effect on the pharmaceutical industry, the full extent of that effect is not yet known. As the FDA issues further regulations, guidance and interpretations relating to this legislation, the impact on the industry as well as our business will become clearer. The requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products. Our and our partners' ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

We may be subject to investigations or other inquiries concerning our compliance with reporting obligations under federal healthcare program pharmaceutical pricing requirements.

Under federal healthcare programs, some state governments and private payors investigate and have filed civil actions against numerous pharmaceutical companies alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated average wholesale price, which in turn may be alleged to have improperly inflated

the reimbursements paid by Medicare, private insurers, state Medicaid programs, medical plans and others to healthcare providers who prescribed and administered those products or pharmacies that dispensed those products. These same payors may allege that companies do not properly report their “best prices” to the state under the Medicaid program. Suppliers of outpatient pharmaceuticals to the Medicaid program are also subject to price rebate agreements. Failure to comply with these price rebate agreements may lead to federal or state investigations, criminal or civil liability, exclusion from federal healthcare programs, contractual damages, and otherwise harm our reputation, business and prospects.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

In June 2014, we began leasing 6,428 square feet of office space in Morristown, New Jersey, which serves as our corporate headquarters. The term of this lease expires July 2020 and our lease payment per month is approximately $15,000 per month, which is subject to certain annual escalators.

In November 2014, we began leasing 5,249 square feet of office space in Mount Pleasant, South Carolina, which serves as our accounting office. The term of this lease expires in January 2020 and our lease payment per month is approximately, $7,000 per month, which is subject to certain annual escalators. Prior to November 2014, we leased 3,184 square feet of office space in Mount Pleasant, South Carolina, which served as our accounting office. The lease was terminated in November 2014 and prior to termination our lease payments were approximately $4,000 per month.

We own approximately 118 acres of undeveloped land in Charleston County, South Carolina which we acquired in our merger with Golf Trust America, Inc. in March 2010.

ITEM 3. LEGAL PROCEEDINGS

In re Somaxon Pharmaceuticals, Inc. Shareholder Litigation (Lead Case No. 37-201200087821-CU-SLCTL)

A purported class action lawsuit was filed in the Superior Court of California County of San Diego by Daniele Riganello, who, prior to the consummation of the merger between Pernix and Somaxon on March 6, 2013 (the "Merger"), was an alleged stockholder of Somaxon (Riganello v. Somaxon, et al., No. 37-201200087821-CU-SLCTL). A second purported class action was also filed in the court by another alleged stockholder (Wasserstrom vs. Somaxon, et al., No. 37-2012-00029214-CU-SL-CTL). Both plaintiffs filed amended complaints on January 18, 2013. The lawsuits were consolidated into a single action captioned In re Somaxon Pharmaceuticals, Inc. Shareholder Litigation (Lead Case No. 37-201200087821-CU-SLCTL). The operative complaint named as defendants Somaxon, Pernix, Pernix Acquisition Corp. I, as well as each of the former members of Somaxon's board of directors (the "Individual Defendants"). It alleged, among other things, that (i) the Individual Defendants breached fiduciary duties they assertedly owed to Somaxon's former stockholders in connection with the Merger (ii) Somaxon and Pernix aided and abetted the purported breaches of fiduciary duty; (iii) the merger consideration was unfair and inadequate; and (iv) the disclosures regarding the Merger in the Registration Statement on Form S-4, initially filed with the Securities and Exchange Commission ("SEC") on January 7, 2013 (as amended, the "Proxy Statement/Prospectus"), were inadequate.

On January 24, 2013, solely to avoid the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, Pernix and the other named defendants in such litigation signed a memorandum of understanding (the "MOU") to settle such litigation. The MOU resolves the claims brought in such litigation and provides a release and settlement by the purported class of Somaxon's former stockholders of all claims against the defendants and their affiliates and agents in connection with the Merger. The parties executed a stipulation of settlement setting forth a plaintiff's fee of $185,000 on July 3, 2013. The court entered a preliminary approval of the settlement on January 17, 2014 and the final settlement approval hearing occurred on April 25, 2014. We paid the $185,000 plaintiff's fee and attorney's fees of $15,000 and the case has been dismissed.

Texas Attorney General Medicaid Investigation RE Cypress Pharmaceuticals

On May 9, 2013, our subsidiary, Cypress Pharmaceuticals, Inc., received notice from the Office of the Attorney General of the State of Texas that it had completed its initial analysis of transaction data provided by Cypress during 2012 to the Attorney General's office and offering to settle all claims that the Attorney General alleged arose from Cypress's prior actions under the Texas Medicaid Fraud Prevention Act. Cypress and the Texas Attorney General entered into a Settlement Agreement effective February 6, 2014 finally settling all claims against Cypress through the effective date for an aggregate payment of $12 million, with $2 million paid up front, and $2 million due on the first five anniversaries of the effective date.

Stanton Keith Pritchard, as Sellers' Agent v. Pernix Therapeutics Holdings, Inc. (U.S.D.C., So. Dist. Of TX)

On December 18, 2013, the selling shareholders of Cypress Pharmaceuticals, Inc. filed suit against Pernix to require Pernix to pay into the existing unfunded escrow account the $5.5 million holdback payment and the $4.5 million escrow payment that allegedly became due on December 16, 2013 under the Securities Purchase Agreement between the selling shareholders and Pernix dated November 12, 2012, as amended. The parties entered into a settlement agreement dated January 27, 2014 pursuant to which each party waived and released all claims against the other party pursuant to the Securities Purchase Agreement (including Pernix' put obligation pursuant to the agreement) in exchange for a one-time payment of $1.33 million to the Cypress shareholders by Pernix. The payment was made, and the case was dismissed effective January 29, 2014.

Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals, Inc. (C.D. Calif.)

On August 1, 2012, a complaint for patent infringement was filed against Somaxon (now Pernix Sleep) by Classen Immunotherapies, Inc. in the United States District Court for the Central District of California. The complaint alleges that Somaxon infringed one or more claims of two of plaintiff's patents by conducting one or more clinical studies relating to Silenor and seeking FDA approval for Silenor. The plaintiff seeks damages, including for willful infringement, and attorneys' fees. We believe that none of Somaxon's activities has infringed plaintiff's patents. We also do not believe that any potential damages in this case, given the nature of the patents, would amount to a material impact on Pernix. Finally, Somaxon was granted a motion for summary judgment giving the plaintiff leave to amend its complaint, which it did. Recently, Somaxon was granted a second motion for summary judgment to dismiss the amended complaint. Plaintiff appealed in mid-July 2013, and Somaxon filed its brief in response on September 12, 2013. The parties had oral arguments on January 9, 2014 on the plaintiff's appeal of the second motion for summary judgment. On January 17, 2014, the court affirmed the district court's favorable ruling for us. The plaintiff petitioned the court for a rehearing, which was denied by the Court on March 21, 2014.

Frontline Pharmaceuticals LLC vs. Pernix Therapeutics Holdings, Inc. (S.D. NY)

On October 24, 2014, a complaint was filed by Frontline Pharmaceuticals LLC ("Frontline") asserting claims against Pernix for breach of contract and unjust enrichment, alleging that Frontline was promised warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share in connection with work allegedly performed by Frontline in connection with the our February 2014 convertible note offering. The parties entered into a settlement agreement effective as of December 31, 2014 pursuant to which we issued to Frontline warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

On January 16, 2013, Pernix received approval from the NASDAQ Stock Market to transfer its common stock listing from the NYSE MKT LLC to the NASDAQ Global Market effective January 28, 2013. Pernix's common stock is listed on the NASDAQ Global Market under the symbol "PTX." On February 23, 2015, the most recent practicable date prior to the filing of this Annual Report on Form 10-K, the closing price of Pernix's common stock as reported on the NASDAQ Global Market was $9.58 per share. The following table sets forth, for the fiscal quarters indicated, the high and low intraday sales prices per share of Pernix's common stock as quoted on the NYSE MKT LLC through January 27, 2013 and as quoted on the NASDAQ Global Market commencing January 28, 2013.

	Price range of common stock	
	High	Low
Year Ended December 31, 2013:		
First Quarter	8.34	4.57
Second Quarter	5.18	2.93
Third Quarter	4.30	2.64
Fourth Quarter	3.59	1.68
Year Ended December 31, 2014:		
First Quarter	6.02	2.05
Second Quarter	9.36	4.07
Third Quarter	9.56	6.06
Fourth Quarter	11.68	7.10

Stockholder Information

On February 25, 2015, Pernix had 38,386,381 shares of common stock outstanding. As of February 23, 2015, those shares were held of record by approximately 91 registered holders. Because substantially all of our common shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividends

Pernix did not declare or pay any cash dividends for the years ended December 31, 2014, 2013 and 2012, and we do not anticipate paying dividends in the foreseeable future. Additionally, our Amended Credit Agreement with MidCap and the Indentures governing the February 2014 Convertible Notes and the Treximet Notes include restrictions on our ability to make dividends and distributions. For additional information, see Note 16, Debt and Lines of Credit, to our consolidated financial statements included in this Annual Report on Form 10-K.

Stock Performance Graph

The following stock performance graph illustrates a comparison of the annual percentage change in the cumulative total stockholder return on our common stock. The graph assumes an initial investment of $100 on December 31, 2009.

Issuer Purchases of Equity Securities

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly-announced plans or programs (1)	Maximum approximate dollar value of shares that may yet be purchased under the plans or programs
October 1, 2014 through October 31, 2014	—	$ —	—	$ 1,150,130
November 1, 2014 through November 30, 2014	—	$ —	—	$ 1,150,130
December 1, 2014 through December 31, 2014	—	$ —	—	$ 1,150,130
Total	—	$ —	—	$ 1,150,130

(1) On May 12, 2010, our Board of Directors authorized the repurchase of up to $5.0 million in shares of our common stock. As of December 31, 2014, approximately $1,150,130 remained available under the repurchase plan. The repurchase plan does not have a termination date and may be eliminated by our Board at any time.

Equity Compensation Plan Information

The following table sets forth information with respect to our common stock that has been authorized for issuance under all of Pernix's equity compensation plans as of December 31, 2014. Pernix does not have any equity compensation plans which were not approved by its stockholders.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a) (1)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c) (2)
Equity Compensation Plans Approved by Security Holders	4,691,084	5.35	2,043,820
Equity Compensation Plans Not Approved by Security Holders	-		-
Total	4,691,084	5.35	2,043,820

(1) Includes 139,950 restricted shares that have vesting dates up to February 11, 2018; 48,000 options, in the aggregate, issued under GTA's 2007 Stock Incentive Plan; and 4,503,134 options, in the aggregate, issued under our Amended and Restated 2009 Stock Incentive Plan (the "Plan").

(2) Includes 1,212,127 shares remaining available for issuance under our 2009 Plan, which may be issued as options, stock appreciation rights, restricted stock, restricted stock units or performance awards, and 831,693 shares remaining to be granted under our 2010 Employee Stock Purchase Plan.

Recent Sales of Unregistered Securities

During 2014, we issued an aggregate of 70,000 shares of common stock to ParaPRO, LLC pursuant to the exercise of stock options for cash consideration with aggregate exercise proceeds of approximately $255,000.

As of December 31, 2014 we issued to Frontline Pharmaceuticals LLC (“Frontline”) warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share. The warrants were issued as compensation for services Frontline provided us in connection with the sale of $65.0 million of February 2014 Convertible Notes and in connection with the settlement of a lawsuit instituted by Frontline against us in October 2014. The exercise price of the warrant equals the conversion price of the convertible notes.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2014, 2013, and 2012 and at December 31, 2014 and 2013 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this Annual Report on Form 10-K. The selected financial data for the years ended December 31, 2011 and 2010 and as of December 31, 2012, 2011, and 2010 are derived from our audited financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2014 (1,2,3,4,5,6,7)	2013 (2,3,4,5,6,7,8)	2012 (4,5,6,7,8)	2011 (7,8)	2010 (8)
	(In thousands, except per share data)				
Statement of Operations Data:					
Net revenues	$ 121,747	$ 84,872	$ 61,313	$ 60,606	$ 33,227
Expenses:					
Cost of sales	45,156	43,870	23,377	20,921	6,182
Selling, general and administrative expenses	62,967	62,551	35,452	22,158	15,188
Research and development	3,938	4,798	732	922	998
Loss from operations of the joint venture	–	–	240	814	–
Loss disposal of assets, impairments of intangibles	242	19,638	–	380	–
Loss on sale of PML (including impairment charge)	6,659				
Depreciation and amortization expense	32,999	8,676	3,201	2,303	1,239
Total costs and expenses	151,961	139,533	63,002	47,498	23,607
Income (loss) from operations	(30,214)	(54,661)	(1,689)	(13,308)	9,620
Other income (expense)	(18,797)	8,269	(95)	(171)	1,175
Income (loss) before income taxes	(49,011)	(46,392)	(1,784)	12,937	10,795
Income tax expense (benefit)	(13,725)	(20,757)	(374)	4,589	1,486
Net income (loss)	$ (35,286)	$ (25,635)	$ (1,410)	$ 8,348	$ 9,309
Net income (loss) per share - basic	$ (0.93)	$ (0.70)	$ (0.05)	$ 0.35	$ 0.40
Net income (loss) per share - diluted	$ (0.93)	$ (0.70)	$ (0.05)	$ 0.34	$ 0.40

	2014 (1,2,3,4,5,6,7)	2013 (2,3,4,5,6,7)	2012 (4,5,6,7)	2011 (7)	2010
Balance Sheet Data:					
Cash and cash equivalents	$ 34,855	$ 15,647	$ 23,023	$ 34,551	$ 8,260
Total assets	487,413	211,386	251,447	82,564	46,034
Debt (current and non-current)	292,345	18,310	43,636	6,000	–
	11,229	19,791	15,896	1,890	4,000

Contractual obligations (current and non-current)					
Stockholders' equity	$ 83,592	$ 110,722	$ 78,539	$ 49,624	$ 18,905

(1) On August 20, 2014, we completed the acquisition of the U.S. intellectual property rights to the pharmaceutical product, Treximet. The results of operations have been included in our consolidated financial statements since the acquisition date.

(2) On March 6, 2013, we acquired all of the outstanding common stock of Pernix Sleep. The Somaxon acquisition broadened our product portfolio to include Silenor, a non-controlled substance approved for the treatment of insomnia characterized by difficulty with sleep maintenance. The results of operations have been included in our consolidated financial statements since the acquisition date.

(3) On September 11, 2013, we completed the sale of certain of our generic assets held by Cypress.

(4) On December 31, 2012, we completed the acquisition of Cypress Pharmaceuticals, Inc., a privately-owned generic pharmaceutical company and its subsidiary, Hawthorn Pharmaceuticals, Inc., a privately owned, branded pharmaceutical company. The assets and liabilities assumed from this acquisition are included in our consolidated balance sheet as of December 31, 2012. The results of operations have been included in our consolidated financial statements since January 1, 2013.

(5) On July 2, 2012, we acquired the business assets of Great Southern Laboratories, or GSL, a pharmaceutical contract manufacturing company located in Houston, Texas. The results of operations have been included in our consolidated financial statements since the acquisition date. On April 21, 2014, we closed on the sale of this facility. The impact of the sale of this facility was a decrease in expense due to the costs related to the employees transferred to the buyer of $3.0 million.

(6) On February 10, 2012, we entered into a controlled equity offering sales agreement. We sold 2,966,739 shares of common stock under this controlled equity program for total net proceeds of approximately $23.8 million and closed the controlled equity offering on May 1, 2012.

(7) On July 27, 2011, we completed an underwritten registered direct offering of 4,000,000 shares of common stock (3,000,000 shares of which were sold by Pernix and 1,000,000 shares of which were sold by certain selling shareholders). Net proceeds from the transaction were approximately $19.3 million.

(8) Certain reclassifications have been made to prior period amounts in our consolidated statements of income to conform to the current period presentation. These reclassifications related to the classification of cost of samples as a selling expense instead of including in cost of product sales and the classification of coupon processing and program administrative fees as selling expense instead of being included in net sales. In addition, royalty expense was reclassified from a separate line item to cost of product sales. These reclassifications had no effect on net income as previously reported.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion below contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of current or historical fact, including statements regarding our current expectations of our future growth, results of operations, financial condition, cash flows, performance and business prospects, and opportunities and any other statements about management's future expectations, beliefs, goals, plans or prospects, constitute forward-looking statements. We have tried to identify forward-looking statements by using words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "target," "will," "would," "anticipate," words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the rate and degree of market acceptance of, and our ability and our distribution and marketing partners' ability to obtain reimbursement for, any approved products; our ability to successfully execute our sales and marketing strategy, including to continue to successfully recruit and retain sales and marketing personnel in the U.S.; our ability to obtain additional financing; our ability to maintain regulatory approvals for our products; the accuracy of our estimates regarding expenses, future revenues and capital requirements; our ability to manage our anticipated future growth; the ability of our products to compete with generic products as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products; the performance of our manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to operate our business without infringing the intellectual property rights of others; the success and timing of our clinical development efforts; the loss of key scientific or management personnel; regulatory developments in the U.S. and foreign countries; our ability to either acquire or develop and commercialize other product candidates in addition to our current products and other risks detailed above in Part I—Item 1A "Risk Factors."

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. In addition, any forward-looking statements in this Annual Report on Form 10-K represent our views only as of the date of this Annual Report on Form 10-K and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so unless required by law, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make in the future.

Overview

We are a specialty pharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

- Growing sales of the existing products in our portfolio in various ways, including identifying new growth opportunities;
- Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure; and
- Pursuing targeted development of a pipeline of post-discovery specialty product candidates.

We target underserved segments, such as central nervous system (CNS) indications, including neurology and psychiatry, as well as other specialty therapeutic areas. We promote our core branded products to physicians through our sales force. We promote our non-core branded products, such as our cough and cold products, through contracted sales organizations, and we market our generic products through our wholly owned subsidiaries, Macoven and Cypress.

Our branded products include Treximet, a medication indicated for the acute treatment of migraine attacks, with or without aura, in adults, Silenor, a non-controlled substance and approved medication indicated for the treatment of insomnia characterized by difficulty with sleep maintenance, Cedax, an antibiotic for middle ear infections, and a family of prescription treatments for cough and cold (Zutripro, Rezira, and Vituz). During the third quarter we engaged a contract sales team to promote Cedax and entered into an agreement with a third party to promote Zutripro, Rezira, and Vituz. The term of these agreements cover the cough and cold season and currently terminate on March 31, 2015. We also promote Khedezla, for major depressive disorder through an Exclusive License Agreement with Osmotica Pharmaceutical Corp. See Part I, Item 1 – Business included in this Annual Report on Form 10-K for additional information regarding our products and product candidates.

Annual Update

The following significant transactions and/or events occurred during 2014:

Completed our acquisition of the United States intellectual property rights to the pharmaceutical product, Treximet through our wholly owned subsidiary PIL for an aggregate acquisition cost of $257.3 million. See Note 4, Business Combinations and Other Acquisitions, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for further discussion.

Issued $220.0 million aggregate principal amount of our 12.0% Senior Secured Notes due 2020 during August 2014 (“Treximet Notes”). For additional information see Note 16, Debt and Lines of Credit, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K and herein under the heading “Liquidity and Capital Resources”.

During February 2014, issued $65.0 million aggregate principal amount of our 8.00% Convertible Senior Notes due 2019 (“February 2014 Convertible Notes”). For additional information see Note 16, Debt and Lines of Credit, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K and herein under the heading “Liquidity and Capital Resources”.

In November 2014, we filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to $300.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and units. The shelf registration statement includes a sales agreement prospectus covering the offering, issuance and sale of up to $100.0 million of shares of our common stock that may be issued and sold under the Controlled Equity Offering Sales Agreement, dated November 7, 2014, between us and Cantor Fitzgerald & Co. as agent. This program will provide us with financial flexibility and the ability to opportunistically access the capital markets. Also in November 2014, we filed an acquisition shelf registration statement on Form S-4 with the SEC, which will enable us to issue up to 12.0 million shares of our common stock in one or more acquisition transactions. These transactions may include the acquisition of assets, businesses or securities, whether by purchase, merger or any other form of business combination. We currently have no immediate plans to issue securities pursuant to either of these registration statements. For additional information see Note 19, Stockholders’ Equity, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K and herein under the heading “Liquidity and Capital Resources”.

During April 2014 we completed our disposition of the business assets of PML a pharmaceutical contract manufacturing company located in Houston, Texas. We received approximately $1.2 million in proceeds net of the assumed mortgage and working capital liabilities at closing and expect to realize approximately $5.0 million in annualized costs savings from the divestiture. As part of the agreement, the purchaser will continue to manufacture the existing Pernix products under a long-term supply agreement with terms similar to those provided to us by other third-party manufacturers. For additional information see Note 5, Asset Dispositions, to our consolidated financial

statements included in Item 8 of this Annual Report on Form 10-K .

During 2014 we relocated our corporate headquarters to Morristown, New Jersey and replaced our entire senior management team as well as reconfigured our board of directors to replace insiders with independent directors that each have over fifteen years of experience in the pharmaceutical industry.

See further discussion herein under the heading “Liquidity and Capital Resources”.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2014, 2013 and 2012 (in thousands):

	Years Ended December 31,				Years Ended December 31,			
	2014	2013	Increase / (Decrease)		2013	2012	Increase / (Decrease)	
Net revenues	$121,747	$84,872	43	%	$84,872	$61,313	38	%
Cost of product sales	45,156	43,870	3	%	43,870	23,377	88	%
Selling, general and administrative								
Expense	62,967	62,551	1	%	62,551	35,452	76	%
Research and development expense	3,938	4,798	(18	)%	4,798	732	555	%
Loss from operations of joint venture			N/A	(1)		240	N/A	(1)
Loss on disposal of assets	242	19,638	N/A	(1)	19,638		N/A	(1)
Loss on sale of PML (including								
impairment charge)	6,659		N/A	(1)			N/A	(1)
Depreciation and amortization								
Expense	32,999	8,676	280	%	8,676	3,201	171	%
Change in fair value of put right		8,361	N/A	(1)	8,361		N/A	(1)
Change in fair value of contingent								
consideration		(805)	N/A	(1)	(805)			
Gain on contingent consideration								
and put right		(16,269)	N/A	(1)	(16,269)		N/A	(1)
Interest expense, net	18,797	4,049	364	%	4,049	95	4,162	%
Gain on sale of investment		(3,605)	N/A	(1)	(3,605)		N/A	(1)
Income tax benefit	(13,725)	(20,757)	(34	)%	(20,757)	(374)	5,450	%

(1) Comparison to prior period not meaningful.

Comparison of the Year Ended December 31, 2014 and 2013

Net Revenues

Net revenues consist of net product sales and revenue from co-promotion and other revenue sharing agreements, as well as revenue from PML until our manufacturing operations were sold on April 21, 2014. We recognize product sales net of estimated allowances for product returns, price adjustments (customer rebates, managed care rebates, service fees, chargebacks, coupons and other discounts), government program rebates (Medicaid, Medicare and other government sponsored programs) and prompt pay discounts. The primary factors that determine our net product sales are the level of demand for our products, unit sales prices, the applicable federal and supplemental government program rebates, contracted rebates, service fees, chargebacks and other discounts that we may offer such as consumer

coupon programs. In addition to our own product portfolio, we have entered into co-promotion agreements and other revenue sharing arrangements with various parties in return for a percentage of revenue on sales we generate or on sales they generate.

The following table sets forth a summary of our net revenues for the years ended December 31, 2014, 2013 and 2012 (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Net product sales – Treximet	$ 54,775	$ —	$ —
Net product sales – Silenor	15,302	7,774	—
Net product sales - Other	47,929	69,758	51,375
Net product sales	118,006	77,532	51,375
Manufacturing revenue	1,025	3,011	5,424
Co-promotion and other revenue	2,716	4,329	4,514
Total Net Revenues	$ 121,747	$ 84,872	$ 61,313

Net product sales – Treximet increased by $54.8 million during the year ended December 31, 2014 compared to the year ended December 31, 2013, as Treximet was acquired in August 2014, with the first sale occurring on September 2, 2014. Net product sales Silenor increased by $7.5 million, or 97%, during the during the year ended December 31, 2014 compared to the year ended December 31, 2013, as Silenor was acquired in March 2013, so there was a full year of sales in 2014 in addition to a price increase implemented in 2014 and the focused selling and marketing strategy implemented in 2014 to create more market awareness and grow sales. Net product sales – other decreased by $21.8 million, or 31%, during the year ended December 31, 2014 compared to the year ended December 31, 2013. Declining net product sales - other was due to (i) the sale of certain Cypress generic products to Breckenridge in September 2013, (ii) the discontinuation of certain less profitable products, primarily generics, and certain OTC monograph seasonal cough and cold products (iii) the termination of certain contracts pursuant to which we marketed and distributed products for others and invoiced those sales and (iv) the increase of certain deductions such as managed care rebates and government rebates on certain brand products due to Consumer Price Index for All Urban Customers ("CPI-U") penalties resulting from price increases. The decrease in net product sales – other was offset by price increases on certain products. Manufacturing revenue decreased by $2.0 million during the year ended December 31, 2014 compared to the year ended December 31, 2013, as we sold our manufacturing subsidiary, PML, in April 2014. Co-promotion and other revenue decreased by $1.6 million during the year ended December 31, 2014 compared to the year ended December 31, 2013. The decrease in co-promotion and other revenue was primarily attributable to the termination of the co-promotion agreement on Natroba and was partially offset by the increase in co-promotion revenue from our agreement with Cumberland that began in October 2013.

Cost of Product Sales

Cost of product sales increased by $1.3 million, or 3%, during the year ended December 31, 2014, compared to the year ended December 31, 2013. The increase was primarily driven by an increase in royalty and collaboration expense of $11.7 million, of which $9.9 million was attributable to the royalty due to the patent holder of Treximet, equal to 18% of the product's net sales. To a lesser extent, the increase was due to an increase in the allowance for obsolete and slow moving inventory, included in cost of sales, of $2.3 million and the cost of Treximet of $1.4 million. The increase was partially offset by a decrease in the cost of our products, excluding Treximet, of $7.3 million, a decrease in PML's cost of product sales of $3.2 million and a decrease in the acquisition cost basis of the inventory sold of $3.7 million, as the majority of the Cypress and Somaxon acquired inventory has been sold. Gross profit margin as a percentage of net revenues (excluding costs of sales attributed to sales of the acquired inventory which has a significantly higher basis than the inventory purchased post-closing) was 65.1% during the year ended December 31, 2014, compared to 55.8% for the year ended December 31, 2013. The increase in our gross profit margin percentage during the year ended December 31, 2014 was primarily due to a change in product mix, in particular, the addition of the Treximet product line. We expect cost of product sales to increase in 2015 over 2014, primarily due to expected growth in the sales of Treximet and Silenor, which will result in an increase in royalty expense as well as the costs of the Treximet and Silenor products.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses increased by $416,000, or 1%, during the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was driven by an increase in marketing campaign costs of $6.7 million related to our Silenor and Treximet products, increased stock-based compensation of $2.6 million as well as increased compensation costs of our expanded management team. We also realized increases in consulting, professional fees, cost of samples, 3PL costs and coupon program administrative fees. These increases were partially offset by a decrease in litigation settlements and reserves of $7.2 million, a decrease in costs related to the employees transferred to the buyer in the sale of our manufacturing facility, PML, of $3.0 million and the effect of the cancellation of the ParaPRO, LLC stock options of previously recognized stock compensation expense of $1.7 million. We also realized decreases in deal costs, legal fees, freight fees and vehicle expense.

Research and Development

Research and Development ("R&D") expenses decreased by $860,000, or 18%, during the year ended December 31, 2014 compared to the year ended December 31, 2013, primarily due to the reduction of expenses incurred related to the in-process research and development at Cypress as certain of these projects were transferred to Breckenridge connected with the sale of certain generic assets to them in September 2013 and others were discontinued.

Depreciation and Amortization Expense

Depreciation and amortization expense increased by $24.3 million, or 280%, during the twelve months ended December 31, 2014 compared to the twelve months ended December 31, 2013. The increase was primarily as a result of $24.6 million of amortization related to the Treximet developed technologies acquired. The increase was partially offset by a decrease in depreciation expense of $340,000, due to the sale of Pernix Manufacturing and its related fixed assets in April 2014.

Interest Expense, net

Interest expense, net, increased $14.7 million, or 364%, during the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was primarily driven by an increase in interest expense of $15.0 million, which was primarily due to the recognition of interest expense related to our $220.0 million Treximet Notes, issued in August 2014 and $65.0 million February 2014 Convertible Notes, issued in February 2014, of $9.8 million and $4.5 million, respectively. The increase was partially offset by a $220,000 increase in interest income primarily attributable to the implied interest of our promissory notes with Breckenridge. For further discussion, see Note 16, Debt and Lines of Credit, to our consolidated financial statements included in this Annual Report on Form 10-K.

Income Tax Provision

During 2014, we recognized an income tax benefit of $13.7 million. Our 2014 effective rate from continuing operations rate was 28.0%. This tax benefit included a deferred tax benefit of approximately $11.8 million and an income tax provision of approximately $2.0 million. During 2013 we recognized an income tax benefit of $20.7 million. This tax benefit included a deferred tax benefit of $22.5 million offset by an income tax provision of $1.8 million. The change in the 2014 effective tax rate relates mainly to the tax effect of permanent difference on our pre-tax loss. The 2013 effective income tax rate on continuing operations before utilization of our Federal net operating loss carryforwards, or NOLs and tax credit carryforwards in 2013 of 44.7% was higher than the statutory rate of 35% due to a number of factors, including various expenses not deductible for tax purposes. The decrease in the effective tax rate in 2014 compared to 2013 was primarily due to changes in income mix among the various jurisdictions in which we operate, as well as higher taxes in 2013 related to acquisition restructuring.

Comparison of the Year Ended December 31, 2013 and 2012

Net Revenues

Net revenues increased $23.6 million, or 38%, for the year ended December 31, 2013, compared to the year ended December 31, 2012. The Cypress and Hawthorn product portfolio, acquired on December 31, 2012, contributed approximately $34.5 million in net revenues and the Somaxon product, acquired on March 6, 2013, contributed approximately $6.7 million in net revenues. These increases were offset by a decrease in the net revenues of our legacy portfolio (pre-acquisition portfolio) of products of approximately $15.2 million and a decrease in the manufacturing revenue of approximately $2.4 million. This decrease was due in part to (i) the discontinuation of the sale of certain generic products due to patent litigation settlement, (ii) the discontinuation of certain cough and cold products, and (iii) the change in the terms of the co-promotion agreement for Natroba with ParaPRO pursuant to which we no longer recognize the gross sales of Natroba. Gross to net deductions as a percent of gross product sales have increased by approximately 10% primarily due to rebates under managed care contracts as well as coupon programs initiated on more of our products and increased utilization under our coupon programs.

Cost of Product Sales

Cost of product sales increased $20.5 million, or 88% for the year ended December 31, 2013, compared to the year ended December 31, 2012. Approximately $6.4 million of this amount is from the increased basis of the inventory acquired in connection with the Cypress and Somaxon acquisitions that was recognized for products sold during the year ended December 31, 2013. The remaining increase in basis of the inventory acquired in connection with the Cypress and Somaxon acquisitions is approximately $2.7 million, which is amortized on a pro-rata basis as the acquired inventory is sold and included in cost of sales in future periods. The allowance for obsolete and slow moving inventory, included in cost of sales, was approximately $3.0 million in the year ended December 31, 2013 compared to approximately $822,000 in the year ended December 31, 2012. Gross profit margin on the net sales of our products was 55.8% (excluding the increase in the cost of sales attributed to sales of the acquired inventory which has a significantly higher basis than the inventory purchased post-closing) and 61.9% for the years ended December 31, 2013 and 2012, respectively, a decrease of approximately 6.1%. This decrease in gross margin is due to an increase in obsolete and slow moving inventory as well as an increase in the number of products subject to profit sharing arrangements.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $27.1 million, or 76%, during the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was driven by an increase in overall

compensation expense of $8.9 million, which was primarily due to the addition of Cypress employees effective January 1, 2013, and the addition of Pernix Manufacturing employees in July 2012, offset by decreases resulting from the reorganization of the consolidated company and the elimination and consolidation of certain management level and staff positions. Other selling, general and administrative expenses were increased by $18.3 million, or 101%, during the year ended December 31, 2013 compared to the year ended December 31, 2012. This increase was primarily due to the incremental increase of the SG&A expenses from the acquisitions of Cypress, Somaxon and the manufacturing facility. In addition, during the year ended December 31, 2013, Pernix recorded the fair value of the settlement of the Texas Medicaid litigation of approximately $9.8 million.

Research and Development Expenses

Research and development expenses increased $4.1 million, or 555%, during the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was primarily due to expenses incurred related to the in-process research and development, including the compensation of the individuals in the R&D department, acquired in connection with the acquisition of Cypress and furthering the development of a late-stage pediatric product.

Depreciation and Amortization Expense

Depreciation and amortization expense increased $5.5 million, or 171%, for the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was primarily driven by an increase in amortization expense of $5.1 million that was attributable to the amortization related to the intangible assets obtained in the acquisitions of Cypress and Somaxon. To a lesser extent, the increase was driven by an increase in depreciation expense of $348,000. For further discussion, see Note 12, Intangible Assets and Goodwill, to our consolidated financial statements included in Item 8 this Annual Report on Form 10-K.

Interest Expense, net

Interest expense, net, increased $4.0 million for the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was primarily driven by an increase in interest expense of $4.0 million that was attributable to interest and related financing costs from the Midcap Amended and Restated Credit Agreement. The increase in interest expense, net, was partially offset by an increased in interest income of $60,000. For further discussion, see Note 16, Debt and Lines of Credit, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K.

Non-GAAP Financial Measures

To supplement our financial results determined by U.S. generally accepted accounting principles (“GAAP”), we have also disclosed in the tables below the following non-GAAP information: (a) adjusted earnings before interest, taxes, depreciation and amortization (“EBITDA”) and (b) adjusted EBITDA per basic and diluted common share. This financial measure excludes the impact of certain items and, therefore, has not been calculated in accordance with GAAP. These non-GAAP financial measures exclude depreciation and amortization, net interest, taxes, deal expenses, share-based compensation expense, amortization of inventory step-up included in cost of product sales, change in fair value of put right, change in fair value of contingent consideration, gain on waiver of put right, gain on contingent consideration, loss on sale of PML (including impairment charge), loss on disposal of equipment gain on sale of investments, impairment of intangibles, loss from operations – joint venture, one-time litigation settlement, one-time contract termination fee, impact on returns from FDA reclassification of Hydrocodone products from C3 to C2, Treximet supplemental New Drug Application (“sNDA”) fee and severance expenses (comprehensively “Adjustment Items”). In addition, from time to time in the future there may be other items that we may exclude for the purposes of our non-GAAP financial measures; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of our non-GAAP financial measures. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our operating results because they exclude amounts that management and the board of directors do not consider part of core operating results or that are non-recurring when assessing the performance of the organization. We believe that inclusion of these non-GAAP financial measures provides consistency and comparability with past reports of financial results and provides consistency in calculations by outside analysts reviewing our results. Accordingly, we believe these non-GAAP financial measures are useful to investors in allowing for greater transparency of supplemental information used by management.

We believe that non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, there are limitations associated with the use of these non-GAAP financial measures. These non-GAAP financial measures are not prepared in accordance with GAAP, do not reflect a comprehensive system of accounting and may not be completely comparable to similarly titled measures of other companies due to potential differences in the exact method of calculation between companies. Adjustment Items that are excluded from our non-GAAP financial measures can have a material impact on net earnings. As a result, these non-GAAP financial measures have limitations and should not be considered in isolation from, or as a substitute for, net loss, cash flow from operations or other measures of performance prepared in accordance with GAAP. We compensate for these

limitations by using these non-GAAP financial measures as supplements to GAAP financial measures and by reconciling the non-GAAP financial measures to their most comparable GAAP financial measure. Investors are encouraged to review the reconciliations of the non-GAAP financial measures to their most comparable GAAP financial measures that are included elsewhere in this Annual Report on Form 10-K.

Reconciliation of GAAP reported net loss to adjusted EBITDA and the related per share amounts are as follows (in thousands, except per share amounts):

	Year Ended December 31,					
	2014		2013		2012	
GAAP net loss	$(35,286)		$(25,635)		$(1,410)	
Adjustments:						
Interest expense, net	18,797		4,049		95	
Depreciation and amortization	32,999		8,676		3,201	
Income tax expenses (benefit)	(13,725)		(20,756)		(374)	
EBITDA	2,785		(33,666)		1,512	
Net revenues adjustments	1,257	(1)				
Cost of product sales adjustments	2,617	(2)	6,359	(2)		
Selling, general and administrative adjustments	9,118	(3)	14,288	(3)	4,359	(3)
Research and development adjustments	1,168	(4)				
Loss from operations of the joint venture					240	
Loss on disposal of assets, impairment of intangibles	242		19,638			
Loss on sale of PML (including impairment charge)	6,659					
Change in fair value of put right			8,361			
Change in fair value of contingent consideration			(805)			
Gain on contingent consideration and put right			(16,269)			
Gain on sale of investment			(3,605)			
Adjusted EBITDA	$23,846		$(5,699)		$6,111	
Basic adjusted EBITDA per common share	$0.63		$(0.16)		$0.22	
Diluted adjusted EBITDA per common share	$0.44		$(0.16)		$0.21	
Weighted average number common shares outstanding	37,871		36,444		28,146	
Weighted average number common shares outstanding assuming dilution	54,792	(5)	36,444		28,683	

(1) To exclude one-time contract termination fee of $700 and impact on returns from FDA reclass of Hydrocodone products from C3 to C2 classification of $557 for the year ended December 31, 2014
(2) To exclude amortization of inventory step-up of $2,617 and $6,359, for the year ended December 31, 2014 and 2013, respectively.
(3) To exclude deal expenses of $1,027, $1,371 and $1,001; stock compensation expense of $4,687, $2,048 and $2,654; stock compensation – ParaPRO of ($1,175), $548, and $685; severance expense of $1,078, $540 and $18 and non-recurring litigation settlement expense of $3,500, $9,780 and $0 for the year ended December 31, 2014, 2013 and 2012, respectively.
(4) To exclude expense associated with Treximet's sNDA of $1,168 for the year ended December 31, 2014.
(5) Includes the dilutive effect of the February 2014 Convertible Notes, warrants and stock awards of 15,533 shares, 116 shares and 1,272 shares, respectively.

Liquidity and Capital Resources

As of December 31, 2014, we had cash and cash equivalents of $34.9 million, borrowing availability of $32.7 million under our $20.0 million revolving loan and a related $20.0 million uncommitted accordion feature and long-term debt of $285.0 million.

During February 2014 we entered into Amendment No. 1 to the Amended and Restated Credit Agreements (the "Agreement" and together with the Amended and Restated Credit Agreement, as amended by the Amendment, the "Amended Credit Agreement") with MidCap Funding IV, LLC, as Agent and as a lender ("MidCap"), and the other lenders from time to time parties thereto. The Amendment provided for the addition of a $20.0 million uncommitted accordion feature to the lenders' existing $20.0 million revolving loan commitment. Our long-term debt included $220.0 million aggregate principal amount of our 12.0% Senior Secured Notes issued August 19, 2014 and due August 1, 2020 ("Treximet Notes") and $65.0 million aggregate principal amount of our 8.0% Convertible Senior Notes, issued February 21, 2014 and due February 15, 2019, ("February 2014 Convertible Notes") unless earlier converted. See Note 16, Debt and Lines of Credit, to our consolidated financial statements included in this report for additional information regarding our MidCap credit facility, the February 2014 Convertible Notes and the Treximet Notes.

During 2014 we generated cash flows from operations of $8.9 million. During 2013 and 2012 we utilized cash from operations of ($6.5) million and ($1.9) million, respectively. We expect to continue to generate positive cash flow from operations. On August 20, 2014, we, through our wholly owned subsidiary Pernix Ireland Limited ("PIL"), formerly known as Worrigan Limited, completed the acquisition of the U.S. intellectual property rights to the pharmaceutical product, Treximet, from GlaxoSmithKline plc and certain of its related affiliates (together "GSK"). There were no other tangible or intangible assets acquired or liabilities assumed related to Treximet intellectual property from GSK. The total purchase price consisted of an upfront cash payment of $250.0 million paid to GSK upon closing of the transaction, and $17.0 million payable to GSK upon receipt of an updated Written Request for pediatric exclusivity from the FDA, subject to certain deductions based on delays in supplying the commercial product to us. Subsequently, the deductions resulting from delays in supplying the commercial product reduced the $17.0 million payable amount to $1.95 million. We funded the acquisition with $220.0 million in debt, the Treximet Notes, plus approximately $32.0 million from available cash.

In November 2014, we filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to $300.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and units. The shelf registration statement includes a sales agreement prospectus covering the offering, issuance and sale of up to $100.0 million of shares of our common stock that may be issued and sold under the Controlled Equity Offering Sales Agreement, dated November 7, 2014, between us and Cantor Fitzgerald & Co. as agent. This program will provide us with financial flexibility and the ability to opportunistically access the capital markets.

Also in November 2014, we filed an acquisition shelf registration statement on Form S-4 with the SEC, which will enable us to issue up to 12.0 million shares of our common stock in one or more acquisition transactions. These transactions may include the acquisition of assets, businesses or securities, whether by purchase, merger or any other form of business combination.

We currently have no immediate plans to issue securities pursuant to either of these registration statements. For additional information see Note 19, Stockholders' Equity, to our consolidated financial statements in Item 8 of this Annual Report on Form 10-K.

Our future capital requirements will depend on many factors, including:

the level of product sales of its currently marketed products and any additional products that we may market in the future;

the extent to which we acquire or invests in products, businesses and technologies;

the level of inventory purchase commitments under supply, manufacturing, license and/or co-promotion agreements;

the scope, progress, results and costs of development activities for our current product candidates;

the costs, timing and outcome of regulatory review of our product candidates;

the number of, and development requirements for, additional product candidates that we pursue;

the costs of commercialization activities, including product marketing, sales and distribution;

the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

A significant portion of our planned expenditures for 2015 are expenses in connection with our development programs, notably our planned OTC launch for a pediatric product which is expected to end phase II development in 2015 and our planned Rx to OTC switch for Silenor. As of February 23, 2015, we believe that our existing cash balance, cash from operations and funds remaining available under our Midcap $20.0 million revolving loan and related $20.0 million uncommitted accordion feature will be sufficient to fund our existing level of operating expenses, current development activities and general capital expenditure requirements through 2015.

GSK has claimed that we owe them damages relating to an alleged breach by us of a covenant contained in the Asset Purchase and Sale Agreement dated as of May 13, 2014 by and among GSK and its affiliates and us pertaining to a pre-existing customer agreement. As of December 31, 2014, GSK alleged damages of approximately of $8.5 million. We intend to vigorously contest GSK's allegations that its damages are a result of our breach and that they are compensable under the Asset Purchase and Sale Agreement or otherwise. As of December 31, 2014, a settlement reserve of $3.5 million has been recorded. Any material liability resulting from this claim could negatively impact the Company’s financial results.

On each Payment Date, commencing August 1, 2015, the Company will pay an installment of principal on the Treximet Notes in an amount equal to 50% of net sales of Treximet for the two consecutive fiscal quarters immediately preceding such Payment Date (less the amount of interest paid on the Treximet Notes on such Payment Date of $6.6 million per quarter). Pursuant to the August 2014 Indenture, there is no principal payment applicable to Treximet sales in the third and fourth quarters of the fiscal year ended December 31, 2014. The first principal payment is due on August 1, 2015 and will be calculated on net sales for the first and second quarters of 2015, less interest paid during those same two quarters. At each month-end beginning with January 2015, the net sales of Treximet will be calculated, the monthly interest accrual amount will then be deducted from the net sales and this resulting amount will be recorded as the current portion of the Treximet Notes. If the Treximet net sales less the interest due at each month-end of each six-month period does not result in any excess over the interest due, no principal payment must be paid at that time. The balance outstanding on the Treximet Notes, or the full amount of the $220 million principal of the notes if the calculation as described does not result in any principal payments during the term of the Treximet Notes, will be due on the maturity date of the Treximet Notes which is August 1, 2020. Based on the calculation of the principal payments and the fact that under the circumstance where the calculation does not result in any excess to be applied to principal then no principal would be due, the Company has recorded the $220 million of Treximet Notes as long term as of December 31, 2014.

To continue to grow our business over the longer term, we may need to commit substantial resources to one or more of product acquisition, product development and clinical trials of product candidates, business acquisition, technology acquisition and expansion of other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or the expansion of our existing operations.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2014, 2013 and 2012 (in thousands).

	Year Ended December 31, (in thousands)		
Cash (used in) provided by	2014	2013	2012
Operating activities	$ 8,896	$ (6,531)	$ (1,926)

Investing activities	(249,922)	23,386	(64,897)
Financing activities	260,234	(24,231)	55,295
Net increase (decrease) in cash and cash equivalents	$ 19,208	$ (7,376)	$ (11,528)

Comparison of the Year Ended December 31, 2014 and 2013

Net cash provided by (used in) operating activities

Net cash provided by (used in) operating activities during 2014 was $8.9 million, an increase of $15.4 million from cash used in operating activities during 2013 of ($6.5) million. The $8.9 million provided by operating activities during 2014 was driven by: net loss of $35.3 million, adjusted by non-cash expenses totaling $45.5 million, offset by a non-cash deferred income tax benefit of $11.8 million and $10.5 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities. The $6.5 million used in operating activities during 2013 was primarily driven by: net loss of $25.6 million, adjusted by non-cash expenses totaling $19.8 million, offset by a non-cash deferred income tax benefit of $22.5 million and $21.8 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities.

Net cash provided by (used in) investing activities

Net cash provided by (used in) investing activities during 2014 was ($249.9) million, which represents a decreased of $273.3 million from the cash provided by investing activities during 2013 of $23.4 million. The $249.9 million used in investing activities during 2014 was primarily driven by $255.0 million related to the acquisition of Treximet, partially offset by $4.9 million related to payments received on our notes receivable from Breckenridge. The $23.4 million cash provided by investing activities during 2013 was primarily driven by $19.6 million of proceeds from the sale of certain Cypress assets and $4.6 million in proceeds from the sale of TherapeuticsMD stock.

Net cash provided by (used in) financing activities

Net cash provided by (used in) financing activities during 2014 was $260.2 million, which represents an increase of $284.5 million from cash used in financing activities during 2013 of ($24.2) million. The $260.2 million provided by financing activities during 2014 was primarily attributable to proceeds from the issuance of our February 2014 Convertible Notes and Treximet Notes, of $65.0 and $220.0 million, respectively, partially offset by financing cost payments, primarily related to the issuance of the February 2014 Convertible Notes and the Treximet Notes, of $14.1 million and net proceeds from our revolving credit facility of $9.5 million. The $24.2 million used in financing activities during 2013 was primarily attributable to prepayments of $12.5 million related to the term loan that had previously been outstanding under our original credit agreement with MidCap and $10.0 million of principal payments on the new term loan.

Comparison of the Year Ended December 31, 2013 and 2012

Net cash provided by (used in) operating activities

Net cash provided by (used in) operating activities during 2013 was ($6.5) million, an increase of $4.6 million from cash used in operating activities during 2012 of ($1.9 million). The $6.5 million used in operating activities during 2013 was primarily driven by: net loss of $25.6 million, adjusted by non-cash expenses totaling $19.8 million, offset by a non-cash deferred income tax benefit of $22.5 million and $21.8 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities. The $1.9 million used in operating activities during 2012 was primarily driven by: net loss of $1.4 million, adjusted by non-cash expenses totaling $6.8 million, partially offset by a non-cash deferred income tax benefit of $1.8 million and $5.5 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities.

Net cash provided by (used in) investing activities

Net cash provided by (used in) investing activities during 2013 was $23.4 million, which represents an increase of $88.3 million from the cash used in investing activities during 2012 of ($64.9) million. The $23.4 million cash provided by investing activities during 2013 was primarily driven by $19.6 million of proceeds from the sale of certain Cypress assets and $4.6 million in proceeds from the sale of TherapeuticsMD stock. The ($64.9) million cash used in investing activities during 2012 was primarily attributable to cash used in the acquisition of Cypress Pharmaceuticals and Great Southern Laboratories of $51.7 million and $4.7 million, respectively as well as the acquisitions of the license from SEEK for the non-codeine antitussive drug in development and the Omeclamox license of $5.0 million and $2.4 million, respectively.

Net cash provided by (used in) financing activities

Net cash provided by (used in) financing activities during 2013 was ($24.2) million, which represents a decrease of $79.5 million from cash provided by financing activities during 2012 of $55.3 million. The $24.2 million used in financing activities during 2013 was primarily attributable to prepayments of $12.5 million related to the term loan that had previously been outstanding under our original credit agreement with MidCap and $10.0 million of principal payments on the new term loan. The $55.3 million used in financing activities during 2012 was primarily driven by $40.0 million in proceeds from our original credit agreement with MidCap, net of capitalized loan costs of approximately $1.9 million, and $23.8 million in net proceeds from our controlled equity offerings which was partially offset by $6.0 million in payments on our line or credit and $3.5 million in payments on contracts.

Critical Accounting Policies and Significant Estimates

Management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires our management to make estimates and assumptions that affect our reported assets and liabilities, revenues and expenses and other financial information. Reported results could differ significantly under different estimates and assumptions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We regard an accounting estimate or assumption underlying its financial statements as a "critical accounting estimate" where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on its financial condition or operating performance is material.

Our significant accounting policies are described in Notes 2, Summary of Significant Accounting Policies to our consolidated financial statements in Item 8 of this Annual Report on Form 10-K. Not all of these significant accounting policies, however, fit the definition of "critical accounting estimates." We believe that our estimates relating to revenue recognition, sales allowances such as returns on product sales, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, depreciation, stock-based compensation, the determination of fair values of assets and liabilities in connection with business combinations and deferred income taxes fit the definition of "critical accounting estimates."

Revenue Recognition

Revenues are recognized when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been performed and are billable; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured. At the time of a product sale, estimates for a variety of sales deductions, such as returns on product sales, government program rebates, price adjustments and prompt pay discounts are recorded.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of selling price ("BESP"). The BESP reflects the best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In most cases we expect to use TPE or BESP for allocating consideration to each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a

right or license to use an asset, or another performance obligation.

We recognize revenue from milestone payments when earned, provided that (i) the milestone event is substantive in that it can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance and its achievability was not reasonably assured at the inception of the collaboration arrangement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone earned and (iii) it would result in additional payments being due to us. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone. Any amounts received under the promotion arrangement in advance of performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as we complete our performance obligations. See Note 21, Other Revenue Sharing Arrangements, to our consolidated financial statements included in this Annual Report on Form 10-K for analysis of milestone events deemed to be substantive or non-substantive.

Manufacturing revenue is recognized when the finished product is shipped to the customer.

Net Product Sales

Product sales revenue is recognized when the customer takes ownership and assumes risk of loss (free-on-board destination).

Items deducted from gross product sales. Revenues from sales of products are recorded net of governmental rebates and rebates under managed care plans, estimated allowances for product returns, government chargebacks, prompt pay discounts, patient coupon programs and specialty distributor and wholesaler fees. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulation and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data. We review the adequacy of our provision for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are product returns, rebates and chargebacks.

Allowances for Prompt Pay Discounts, Product Returns, Price Adjustments, and Medicaid Rebates

The following table sets forth a summary of our allowances for product returns, government program rebates and price adjustments as of December 31, 2014:

	Product Returns	Government Program Rebates	Price Adjustments
		(in thousands)	
Balance at December 31, 2011	5,712	5,843	5,451
Allowances assumed in acquisition of Cypress	5,901	1,175	4,586
Current provision:			
Adjustments to provision for prior year sales	1,840	(1,075)	(272)
Provision – current year sales	5,426	7,689	15,368
Payments and credits	(6,822)	(6,595)	(14,173)
Balance at December 31, 2012	12,057	7,037	10,960
Allowances assumed in acquisition of Somaxon	776	479	1,113
Post-closing opening balance sheet adjustments	1,374	391	416
Allowances for certain co-agreements (1)	58	110	483
Reclass from contingent consideration	3,934	—	—
Current provision:			
Adjustments to provision for prior year sales	1,611	(921)	(300)
Provision – current year sales	9,394	6,335	48,567
Payments and credits	(17,155)	(9,495)	(42,938)
Balance at December 31, 2013	$ 12,049	3,936	18,301
Increase in allowance for certain agreement (1)	2,841	542	486
Current provision:			
Adjustments to provision for prior year sales	—	475	—
Provision – current year sales	16,469	13,978	76,298
Payments and credits	(21,668)	(8,963)	(62,140)
Balance at December 31, 2014	$ 9,691	$ 9,968	$ 32,945

(1) Allowances to be recognized by other parties or under certain co-promotion agreements and other third party arrangements pursuant to which the expense is the responsibility of the other party. However, since we are responsible for the remittance of the payment of these deduction items to the billing third party, these items are included in accrued allowances on our balance sheet.

Product Returns. Consistent with industry practice, we offer contractual return rights that allow our customers to return short-dated or expiring products within an 18-month period, commencing from six months prior to and up to twelve months subsequent to the product expiration date. Our products have a 15 to 42 month expiration period from the date of manufacture. We account for product returns as a reduction in net revenue at the time of sale and is recognized by establishing an accrual in an amount equal to the estimated value of the products expected to be returned. We adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the forecast of future sales of the product, competitive issues such as new product entrants and other known changes in sales trends. We estimate returns at percentages up to 10% of sales of branded products and generic products and, from time to time, higher on launch return percentages for sales of new products. Returns estimates are based upon historical data and

other facts and circumstances that may impact future expected returns to derive an average return percentage for our products. The returns reserve may be adjusted as sales history and returns experience is accumulated on this portfolio of products. We review and adjust these reserves quarterly. If estimates regarding product demand are inaccurate, if changes in the competitive environment affect demand for certain products, or if other unforeseen circumstances affect a product's salability, actual returns could differ and such differences could be material. Product returns were $16.5 million, $10.7 million and $7.3 million for the years ended December 31, 2014, 2013 and 2012, respectively. If estimates regarding product demand are inaccurate, if changes in the competitive environment effect demand for certain products, or if other unforeseen circumstances effect a product's salability, actual returns could differ and such differences could be material. For example, a one percent difference in our provision assumption for the year ended December 31, 2014 would have affected pre-tax earnings by approximately $2.3 million.

Government Program Rebates. The liability for Medicaid, Medicare and other government program rebates is estimated based on historical and current rebate redemption and utilization rates contractually submitted by each state's program administrator and assumptions regarding future government program utilization for each product sold. As we become aware of changing circumstances regarding the Medicaid, Medicare or other government-sponsored program coverage of our products, we will incorporate such changing circumstances into the estimates and assumptions that we use to calculate government program rebates. Estimating these rebates is complex, in part due to the time delay between the date of sale and the actual settlement of the liability. We believe that the methodology we use to estimate rebates on product sales made under governmental pricing programs is reasonable and appropriate given current facts and circumstances. However, estimates may vary from actual expense. Governmental program rebates were $14.5 million, $5.4 million and $6.6 million for the years ended December 31, 2014, 2013 and 2012, respectively. If our estimates and assumptions prove inaccurate, we may be subject to higher or lower government program rebates. For example, with respect to the provision for the year ended December 13, 2014, a one percent difference in the provision assumptions based on utilization would have affected pre-tax earnings by approximately $1.9 million and a one percent difference in the provision based on reimbursement rates would have affected pre-tax earnings by approximately $2.8 million.

Price Adjustments. Our estimates of price adjustments which include coupons, customer rebates, service fees, chargebacks, shelf stock adjustments, fees and other discounts are based on our estimated mix of sales to various third-party payors who are entitled either contractually or statutorily to discounts from the listed prices of our products and contracted service fees with our wholesalers. We account for the costs of these special promotional programs as a reduction of gross revenue when applicable products are sold to the wholesalers or other retailers. Any price adjustments that are not contractual but that are offered at the time of sale are recorded as a reduction of revenue when the sales order is recorded. These adjustments are not accrued as they are offered on a non-recurring basis at the time of sale and are recorded as an expense at the time of the sale. These allowances may be offered at varying times throughout the year or may be associated with specific events such as a new product launch or to reintroduce a product. Price adjustments, including prompt pay discounts, were $81.0 million, $51.4 million and $16.8 million, for the years ended December 31, 2014, 2013 and 2012, respectively. In the event that the sales mix to third-party payors or the contract fees paid to the wholesalers are different from our estimates, we may be required to pay higher or lower total price adjustments that originally estimated. For example, for the year ended December 31, 2014, a one percent difference in the assumptions based on the applicable sales would have affected pre-tax earnings by approximately $5.6 million. Additional information regarding types of price adjustments are discussed below:

Coupons: To help patients afford our products, we have various co-pay coupon programs for certain products. We estimate our liabilities for these coupon programs based on redemption information provided by a third party claims processing organization.

Customer rebates: We offer customer rebates on many of our products. We generally account for these programs by establishing an accrual based on our estimate of the rebate incentives attributable to a sale. We accrue our estimates on historical experience and other relevant factors. We adjust our accruals periodically throughout each quarter based on actual experiences and changes in other factors, if any, to ensure the balance is fairly stated.

Service fees: As a result of consolidation amount wholesale distributors, as well as rapid growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. Some wholesale distributors have required that pharmaceutical companies, including us, enter into distribution service agreements (“DSA”) pursuant to which the wholesale distributors provide the pharmaceutical companies with specific services, including the provision of period retail demand information and current inventory levels and other information. We generally account for these fees by establishing and accrual based on our estimate of the services fees attributable to a sale.

Chargebacks: These deductions relate to our contractual agreements to sell products to group purchasing organization and other indirect customers at contractual prices that are lower than the list prices we charge wholesales. When these group purchasing organizations or other indirect customers purchase our products through a wholesaler at a reduced price, the wholesaler charges for the difference between the price they paid us and the price at which they sold the product to the indirect customer. The primary factors we consider in developing and evaluating our provision for chargebacks includes: (i) the average historical chargeback credits, (ii) estimated future sales trends and (iii) an estimate of the inventory held by our wholesalers based on internal analysis of a wholesaler’s historical purchases and contract sales.

Shelf stock adjustments: These deductions are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer’s inventory cost to better reflect current market prices. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include: (i) the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence, (ii) the estimated decline in the market price of our product, which we determine based on historical experience and customer input and (iii) the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based

upon historical experience and customer input.

Prompt Payment Discounts. We typically require our customers to remit payments within the first 30 days for branded products and within 60 to 120 days for generics, depending on the customer and the products purchased. We offer wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally two percent, but may be higher in some instances due to product launches and/or industry expectations. As our wholesale distributors typically take advantage of the prompt pay discount, we accrue 100% of the prompt pay discounts, based on the gross amount of each invoice, at the time of our original sale, and apply earned discounts at the time of payment. This allowance is recorded as a reduction of accounts receivable and revenue. We adjust the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. We do not anticipate that future changes to our estimates of prompt payment discounts will have a material impact on our net revenue. Prompt pay discounts were $4.7 million, $3.1 million and $1.7 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Stock Based Compensation

Stock based compensation expense is determined by reference to the fair value of an award on the date of grant and is recognized, net of an estimated forfeiture rate on a straight-line basis over requisite service period, which is the vesting period. We account for our stock based compensation pursuant to Accounting Standards Codification (“ASC”) 718, Accounting for Stock Options and Other Stock Based Compensation. ASC 718 also establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. See Note 22, Stock Benefit Plans and Stock-Based Compensation, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K, regarding the calculation of the value of options issued and other details regarding stock based compensation awarded in the years then ended.

Inventory

Inventory primarily consists of finished goods which include pharmaceutical products ready for commercial sale or distribution as samples. Prior to the sale of PML, on April 21, 2014, inventory also consisted of Pernix Manufacturing's inventory of raw materials and packaging supplies for the manufacture of products. Inventory is stated at the actual cost per bottle determined under the specific identification method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material impact on our financial condition and results of operations in any reporting period. An allowance for slow-moving or obsolete inventory or declines in the value of inventory is determined based on management's assessments. The raw materials we have in inventory are provided to certain of our manufacturers to utilize in the manufacture of our products and, from time to time, are sold to other companies to utilize in their own products. As of December 31, 2014 and 2013, we had approximately $11.4 million and $13.8 million in inventory, respectively, which is net of a reserve of approximately $2.2 million and $2.6 million as of December 31, 2014 and 2013, respectively. Inventory at December 31, 2014 and 2013 includes an increase in the basis of acquired inventory from the Cypress and Somaxon acquisitions of approximately $97,000 and $2.7 million, respectively.

Off-Balance Sheet Arrangements

Since its inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

Effects of Inflation

We do not believe that inflation has had a significant impact on its revenues or results of operations since inception.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. Further, obligations under employment agreements contingent upon continued employment are not included in the table below. The following table summarizes our contractual obligations as of December 31, 2014 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases(1)	$ 1,638	$ 316	$ 638	$ 616	68
Professional services agreements(2)	7,569	6,104	1,465	—	—
Supply agreements and purchase obligations(3)	8,906	2,413	1,998	1,998	2,497
License and development agreements(4)	51,750	15,000	32,750	4,000	—
S Short-term borrowings(5)	8,695	8,695	—	—	—
Long-term debt obligations(6)	438,450	31,600	63,200	343,650	—
Settlement obligations(7)	13,500	2,750	5,500	5,000	250
Total contractual obligations	$ 530,508	$ 66,878	$ 105,551	$ 355,264	$ 2,815

(1) Operating leases include minimum payments under leases for our facilities and certain equipment.

(2) Professional service agreements include agreements with a specific term for consulting, information technology, telecom and software support, data and sales reporting tools and services.

(3) Supply agreements and purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers and other providers of goods and services. The contractual obligations table set forth above does not reflect certain minimum sales requirements related to our co-promotion agreements nor does it include supply agreements for which the failure to meet the purchase or sale requirements under such agreements generally allows the counterparty to terminate the agreement and/or results in a loss of our exclusivity rights.

(4) Future scheduled or specific payments pursuant to license or development agreements. Future payments for which the date of payments or amount cannot be determined are excluded.

(5) Short-term borrowings represent amounts outstanding under our senior secured notes and Mid-Cap Credit Facility as of December 31, 2014 and the minimum interest payments that must be paid on 75% of the total amount available, $20.0 million before consideration of the accordion feature, under the revolver regardless of the balance outstanding. As of December 31, 2014 we had borrowings of approximately $7.3 million under our revolving credit facility.

(6) The long-term debt obligations represent the principle repayments on the February 2014 Convertible Notes and the Treximet Notes and the associated contractual interest payments assuming that principle payments are made only on each issuances' respective maturity date based on the terms of these notes. See Note 16, Debt and Lines of Credit, and Note 17, Senior Secured Notes – Treximet – Current, for further information on the classification of this long-term debt.

(7) Settlement obligations represent remaining payments due under settlement agreements.

See Note 16, Debt and Lines of Credit and Note 24, Commitments and Contingencies, to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

In addition to the material contractual cash obligations included the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution, acquisition and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. As the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets and have not been included in the table above. See Notes 4, Business Combinations and Other Acquisitions, and 14, Intangible Assets and Goodwill, to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in this Annual Report on Form 10-K.

Seasonality

We generally experience a higher volume of cough and cold product sales during the months of September through March due to the corresponding cough and cold season.

Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet or non-consolidated special purpose entity arrangements as defined by the applicable Securities and Exchange Commission rules.

ITEM 7A. QUANTITAIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is contained in the financial statements set forth in Item 15 (a) under the caption “Consolidated Financial Statements and Supplementary Data” as a part of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the “Exchange Act”). The rules refer to the controls and other procedures designed to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As of December 31, 2014, management, including the CEO and our principal financial officer, performed an evaluation of the effectiveness of our disclosure controls and procedures. Based on that evaluation, management, including the CEO and our principal financial officer, concluded that as of December 31, 2014, our disclosure controls and procedures were effective.

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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 in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control system is designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated 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 (iii) 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 consolidated 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessment and the COSO criteria, we believe that, as of December 31, 2014, the Company maintained effective internal control over financial reporting.

The Company's independent registered public accounting firm has audited the Company's internal control over financial reporting as of December 31, 2014, as stated in the Report of Independent Registered Public Accounting Firm, appearing under Item 9A, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2014.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item will be contained in our definitive proxy statement, or the Definitive Proxy Statement, to be filed with the SEC in connection with our 2015 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2014, under the headings "Election of Directors," "Corporate Governance," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

We have a written Code of Conduct and Ethics that applies to our principal executive officer, principal financial officer and our principal accounting officer and every other director, officer and employee of Pernix. The Code of Conduct and Ethics is available on our Internet website at www.pernixtx.com. A copy of the Code of Conduct and Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our Internet website within four business days at www.pernixtx.com.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this item may be found in our Definitive Proxy Statement under the heading "Executive Compensation" and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Information required by this item may be found in our Definitive Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners" and "Security Ownership of Directors and Executive Officers" and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item may be found in our Definitive Proxy Statement under the headings "The Board of Directors and Board Committees" and "Certain Relationships and Related-Party Transactions" and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item may be found in our Definitive Proxy Statement under the heading "Proposal to Ratify the Appointment of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements and Supplementary Data

2. Financial Statement Schedules.

Schedule II –Valuation and Qualifying Accounts

All other financial statement schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits.

The exhibits listed in the accompanying Index to Exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

PERNIX THERAPEUTICS HOLDINGS, INC.

Date: March 2, 2015

By: /s/ Douglas Drysdale
Douglas Drysdale
President, Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Douglas Drysdale Douglas Drysdale	President, Chief Executive Officer and Chairman (Principal Executive Officer)	March 2, 2015
/s/ Sanjay S. Patel Sanjay S. Patel	Chief Financial Officer (Principal Financial Officer)	March 2, 2015
/s/ Tracy S. Clifford Tracy S. Clifford	Vice President of Accounting and Corporate Controller (Principal Accounting Officer)	March 2, 2015
/s/ Steven A. Elms Steven A. Elms	Director	March 2, 2015
/s/ John Sedor John Sedor	Director	March 2, 2015
/s/ Tasos Konidaris Tasos Konidaris	Director	March 2, 2015

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors
Pernix Therapeutics Holdings, Inc.
Morristown, New Jersey

We have audited Pernix Therapeutics Holdings, Inc.'s and subsidiaries 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). Pernix Therapeutics Holdings, Inc.'s and subsidiaries management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Pernix Therapeutics Holdings, Inc. and subsidiaries 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).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States of America), the consolidated balance sheets of Pernix Therapeutics Holdings, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014, and the related consolidated financial statement schedule as of December 31, 2014, 2013, and 2012, and our report dated March 2, 2015 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

March 2, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors
Pernix Therapeutics Holdings, Inc.
Morristown, New Jersey

We have audited the accompanying consolidated balance sheets of Pernix Therapeutics Holdings, Inc. and subsidiaries (collectively, the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of income (loss) and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. We have also audited the accompanying consolidated financial statement schedule for each of the three years in the period ended December 31, 2014 listed in the index at Item 15. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with 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 consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pernix Therapeutics Holdings, Inc. and subsidiaries at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related consolidated financial statement schedule for each of the three years in the period ended December 31, 2014, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company'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), and our report dated March 2, 2015 expressed an unqualified opinion thereon.

/s/ Cherry Bekaert LLP

Atlanta, Georgia
March 2, 2015

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Per Share Data)

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,855	$ 15,647
Accounts receivable, net	44,127	25,681
Inventory, net	11,362	13,810
Prepaid expenses and other current assets	10,346	5,879
Note receivable, net of unamortized discount of $127 and $101, respectively	4,723	4,749
Prepaid income taxes	7,911	1,318
Deferred income tax assets – current	15,933	9,301
Total current assets	129,257	76,385
Property and equipment, net	1,514	6,872
Other assets:		
Goodwill	44,900	42,497
Intangible assets, net	300,489	80,022
Note receivable, net of unamortized discount of $0 and $319, respectively	—	4,531
Other long-term assets	11,253	1,079
Total assets	$ 487,413	$ 211,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,399	$ 3,444
Accrued personnel expense	3,573	3,803
Accrued allowances	52,604	34,286
Other accrued expenses	15,333	5,386
Interest payable	10,159	147
Contingent consideration - Cypress acquisition	—	1,330
Other liabilities	3,264	4,072
Debt – current	7,345	17,000
Senior secured notes – Treximet – current	—	—
Total current liabilities	97,677	69,468
Long-term liabilities		
Other liabilities	11,755	14,386
Debt – long term	—	1,310
Senior convertible notes – long-term	65,000	—
Senior secured notes – Treximet – long-term	220,000	—
Deferred income taxes	9,389	15,499
Total liabilities	403,821	100,663
Commitments and contingencies (Note 24)		
STOCKHOLDERS' EQUITY		
	383	372

Common stock $0.01 par value, 90,000 shares authorized, 40,805 and 39,318 issued, and 38,341 and 37,189 outstanding at December 31, 2014 and 2013, respectively		
Treasury stock, at cost (2,464 and 2,129 shares held at December 31, 2014 and 2013, respectively)	(5,431)	(4,001)
Additional paid-in capital	129,128	119,554
Retained deficit	(40,488)	(5,202)
Total stockholders' equity	83,592	110,723
Total liabilities and stockholders' equity	$ 487,413	$ 211,386

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE (LOSS) INCOME
(In Thousands, Except Per Share Data)

	Years Ended December 31,		
	2014	2013	2012
Net revenues	$ 121,747	$ 84,872	$ 61,313
Cost and expenses:			
Cost of product sales	45,156	43,870	23,377
Selling, general and administrative expenses	62,967	62,551	35,452
Research and development expense	3,938	4,798	732
Loss from operations of the joint venture	—	—	240
Loss on disposal of assets, impairments of intangibles	242	19,638	—
Loss on sale of PML (including impairment charge)	6,659	—	—
Depreciation and amortization expense	32,999	8,676	3,201
Total costs and operating expenses	151,961	139,533	63,002
Loss from operations	(30,214)	(54,661)	(1,689)
Other income (expense):			
Change in fair value of put right	—	(8,361)	—
Change in fair value of contingent consideration	—	805	—
Gain on contingent consideration and put right	—	16,269	—
Interest expense, net	(18,797)	(4,049)	(95)
Gain on sale of investment	—	3,605	—
Total other income (loss), net	(18,797)	8,269	(95)
Loss before income taxes	(49,011)	(46,392)	(1,784)
Income tax benefit	(13,725)	(20,757)	(374)
Net loss	(35,286)	(25,635)	(1,410)
Other comprehensive income (loss)			
Unrealized gains (loss) during period, net of tax of $0, ($411) and $1,060, respectively	—	(702)	1,886
Reclassification adjustment for net gains included in net loss, net of tax of $0, ($1,332) and $0, respectively	—	(2,273)	—
Comprehensive income (loss)	$ (35,286)	$ (28,610)	$ 476
Net loss per share, basic	$ (0.93)	$ (0.70)	$ (0.05)
Net loss per share, diluted	$ (0.93)	$ (0.70)	$ (0.05)
Weighted-average common shares, basic	37,871	36,444	28,146
Weighted-average common shares, diluted	37,871	36,444	28,146

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In Thousands)

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2011	25,749	$ 257	$ 30,185	$ (3,752)	$ 21,844	$ 1,089	$ 49,623
Stock-based compensation							
Restricted stock	668	7	1,037	—	—	—	1,044
Cancelled/reclass par value of unvested restricted stock	(728)	(7)	7				—
Stock options	—	—	1,547	—	—	—	1,547
Employee stock purchase plan	—	—	63	—	—	—	63
Issuance of stock options for services from non-employees	—	—	685	—	—	—	685
Issuance of common stock in lieu of cash bonus	21	—	200	—	—	—	200
Issuance of common stock upon the exercise of stock options	171	2	665	—	—	—	667
Forfeit of restricted common stock in payment of income tax liability	—	—	—	(20)	—	—	(20)
Issuance of common stock in connection with employee stock purchase plan	27	—	189	—	—	—	189
Income tax benefit on stock based awards	—	—	315	—	—	—	315
Issuance of common stock	2,967	30	23,720	—	—	—	23,750

upon additional public offering, net of issuance costs of $846							
Net loss	—	—	—	—	(1,410)		(1,410)
Unrealized gain on securities, net	—	—	—	—	—	1,886	1,886
Balance at December 31, 2012	28,875	$ 289	$ 58,613	$ (3,772)	$ 20,434	$ 2,975	$ 78,539
Stock-based compensation							
Restricted stock	285	3	1,533	—	—	—	1,536
Cancelled/reclass par value of unvested restricted stock	(219)	(2)	2	—	—	—	—
Stock options	—	—	442	—	—	—	442
Employee stock purchase plan	—	—	71	—	—	—	71
Issuance of stock options for services from non-employees	—	—	548	—	—	—	548
Issuance of common stock upon the exercise of stock options	40	1	111	—	—	—	112

Forfeit of restricted common stock in payment of income tax liability	(39)	(1)	—	(229)	—	—	(230)
Issuance of common stock in connection with employee stock purchase plan	65	1	149	—	—	—	150
Issuance of restricted stock in lieu of cash payment	97	1	161	—	—	—	162
Issuance of common stock in connection with the Somaxon acquisition	3,658	36	23,804	—	—	—	23,840
Reclass of shares (previously subject to the put right of the former Cypress shareholders in connection with the Cypress acquisition) from temporary equity	4,427	44	34,266	—	—	—	34,310
Income tax benefit on stock based awards	—	—	(147)	—	—	—	(147)
Net loss	—	—	—	—	(25,635)	—	(25,635)
Unrealized gain on securities, net	—	—	—	—	—	(2,975)	(2,975)
Balance at December 31, 2013	37,189	$ 372	$ 119,554	$ (4,001)	$ (5,202)	$ —$	110,723
Stock-based compensation							
Restricted stock	—	—	1,796	—	—	—	1,796
Stock options	—	—	2,766	—	—	—	2,766
Employee stock purchase plan	—	—	124	—	—	—	124

Issuance of stock options for services from non-employees	—	—	119	—	—	—	119
Cancellation of ParaPRO stock options in connection with termination of contract	—	—	(1,294)	—	—	—	(1,294)
Issuance of common stock upon the exercise of stock options, net of tax	749	7	2,474	(321)	—	—	2,160
Issuance of common stock upon the vesting of restricted stock	554	5	(5)	—	—	—	—
Forfeit of restricted common stock in payment of income tax liability	(229)	(3)	3	(1,109)	—	—	(1,109)
Issuance of common stock in connection with employee stock purchase plan	42	1	140	—	—	—	141
Issuance of common stock upon the cashless exercise of options from non-employees	35	1	(1)	—	—	—	—
Issuance warrants in connection with the acquisition of Treximet	—	—	2,359	—	—	—	2,359
Issuance warrants in connection with the issuance of the February 2014 Convertible Notes	—	—	841	—	—	—	841
Stock issuance costs	—	—	(152)	—	—	—	(152)
Income tax benefit on stock based awards	—	—	404	—	—	—	404

Net loss		—		—		—		—	(35,286)		—	(35,286)
Balance at December 31, 2014	38,340	$	383	$	129,128	$	(5,431)	$	(40,488)	$	—$	83,592

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Years Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$ (35,286)	$ (25,635)	$ (1,410)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	331	672	324
Amortization of intangibles and interest accretion of contingent consideration	32,668	8,004	2,878
Amortization of deferred financing costs	2,333	1,295	—
Interest accretion on notes receivable	(292)	(114)	—
Deferred income tax benefit	(11,753)	(22,516)	(1,836)
Gain on sale of investment	—	(3,605)	—
Stock compensation expense	4,686	2,049	2,654
Expense for stock options issued in exchange for services	119	548	685
Cancellation of ParaPRO stock options in connection with termination of contract	(1,294)	—	—
Change in fair value of contingent consideration and put right	—	7,556	—
Gain on contingent consideration and put right	—	(16,269)	—
Loss on impairment of certain intangible assets	—	19,429	—
Loss on sale of PML (including impairment)	6,659	—	—
Loss on disposal of software and equipment	242	208	26
Loss from the operations of the joint venture	—	—	240
Changes in operating assets and liabilities, net of effects of acquisitions			
Accounts receivable	(18,480)	12,163	(3,886)
Income taxes	(6,592)	642	(1,335)
Inventory	1,880	7,406	(650)
Prepaid expenses and other assets	(2,144)	(2,180)	(180)
Accounts payable	2,051	(3,544)	(1,843)
Accrued allowances	18,318	(3,075)	1,544
Accrued expenses and personnel expenses	10,110	146	863
Interest payable	10,012	100	—
Other liabilities	(4,672)	10,189	—
Net cash provided by (used in) operating activities	8,896	(6,531)	(1,926)

Cash flows from investing activities:			
Proceeds from sale of investment	—	4,605	—
Acquisitions	(254,950)	(310)	(63,729)
Proceeds from the sale of PML	1,137	—	—
Payments received on note receivable	4,850	—	—
Proceeds from sale of certain Cypress assets	175	19,588	—
Other intangibles	—	—	(850)
Proceeds from sale of equipment	43	31	8
Purchase of software and equipment	(1,177)	(528)	(326)
Net cash provided by (used in) investing activities	(249,922)	23,386	(64,897)
Cash flows from financing activities:			
Cash acquired in connection with acquisition of Somaxon	—	2,881	—
Payments on original Midcap loan	—	(12,497)	—
Payments on term loan	—	(10,000)	—
Stock issuance costs	(152)	—	—
Proceeds from issuance of the Treximet Notes	220,000	—	—
Proceeds from issuance of the February 2014 Convertible Notes	65,000	—	—
Net payments on revolving credit facility	(9,515)	(2,656)	(6,000)
Payments on financing costs	(14,149)	—	—
Proceeds from credit facility, net of capitalized loan costs	—	—	40,054
Payments on contracts payable	(2,500)	(1,700)	(3,540)
Proceeds from issuance of stock in additional offering, net of issuance costs of $846 for the year ended December 31, 2012	—	—	23,751
Payments on mortgages and capital leases	(46)	(144)	(121)
Proceeds from issuance of common stock, net of tax	2,301	262	836
Tax benefit on stock-based awards	404	(147)	315
Payment of employee income tax liability with surrender of employee restricted stock	(1,109)	(230)	—
Net cash provided by (used in) financing activities	260,234	(24,231)	55,295
Net increase (decrease) in cash and cash equivalents	19,208	(7,376)	(11,528)
Cash and cash equivalents, beginning of year	15,647	23,023	34,551
Cash and cash equivalents, end of year	$ 34,855	$ 15,647	$ 23,023
Supplemental Disclosure of Cash Flow Information:			
Cash paid for income taxes	4,217	$ 1,265	$ 2,482
Interest paid during the period	6,451	2,733	200
Non-cash investing and financing activities:			
Acquisition of product licenses – contract payable balance	—	500	630
Accrued bonus paid in unrestricted stock	—	—	200
Accrued severance paid in restricted common stock	—	142	—
Acquisition of Cypress and Somaxon – Purchase price adjustment (see Note 4)	(990)	5,412	—
Acquisition of Somaxon – Fair value of common stock	—	24,840	—
Acquisition of Treximet - warrants issued to Pozen	2,359	—	—
Warrants issued to Frontline in connection with the issuance of the February 2014 Convertible Notes	841	—	—
Acquisition of Cypress – fair value of common stock	—	—	34,300

Acquisition of GSL – liabilities assumed	—	—	1,700

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Company Overview

Pernix Therapeutics Holdings, Inc. (“Pernix”, the “Company”, “we”, “our” and "us") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of prescription drugs, primarily for the U.S. market. The Company targets underserved therapeutic areas, such as central nervous system (CNS), including neurology and psychiatry, and has an interest in expanding into additional specialty segments. The Company promotes its branded products to physicians through its Pernix sales force, uses contracted sales organizations to market its non-core cough and cold products, and markets its generic portfolio through its wholly owned subsidiaries, Macoven Pharmaceuticals, LLC (“Macoven”) and Cypress Pharmaceuticals, Inc. (“Cypress”).

The Company’s branded products include Treximet, a medication indicated for the acute treatment of migraine pain and inflammation, Silenor, a non-controlled substance and approved medication for the treatment of insomnia characterized by difficulty with sleep, Cedax, an antibiotic for middle ear infections, and a family of prescription products for cough and cold (Zutripro, Rezira, and Vituz). The Company recently entered into an agreement with a third party to promote Zutripro, Rezira and Vituz. The Company also has an Exclusive License Agreement with Osmotica Pharmaceutical Corp. to promote Khedezla, a prescription medication for major depressive disorder. As described below, the Company completed the acquisition of the U.S. intellectual property rights to the migraine product, Treximet on August 20, 2014.

Acquisition of Treximet

On August 20, 2014, the Company, through a wholly owned subsidiary Pernix Ireland Limited (“PIL”), formerly known as Worrigan Limited, completed the acquisition of the U.S. intellectual property rights to the pharmaceutical product, Treximet from GlaxoSmithKline plc and certain of its related affiliates (together “GSK”). See Note 4, Business Combinations and Other Acquisitions, for further discussion.

Acquisition of Somaxon Pharmaceuticals, Inc.

On March 6, 2013, the Company acquired all of the outstanding common stock of Somaxon Pharmaceuticals, Inc. (“Somaxon”) pursuant to an agreement and plan of merger dated December 10, 2012. At the time of acquisition, Somaxon was only marketing Silenor. The company’s name was changed from Somaxon to Pernix Sleep, Inc (“Pernix Sleep”). See Note 4, Business Combinations and Other Acquisitions, for further discussion.

Acquisition of Cypress Pharmaceuticals, Inc.

On December 31, 2012, the Company completed the acquisition of Cypress Pharmaceuticals, Inc., a generic pharmaceutical company, and its subsidiary Hawthorn Pharmaceuticals, Inc., a branded pharmaceutical company, both of which were privately owned companies, collectively referred to herein as Cypress. Cypress offers a wide array of branded and generic pharmaceutical products in the areas of cough and cold, nutritional supplements, analgesics, urinary tract, women’s health, pre-natal vitamins and dental health, as well as allergy, respiratory, iron deficiency, nephrology and pain management. See Note 4, Business Combinations and Other Acquisitions, for further information.

Acquisition of Great Southern Laboratories

On July 2, 2012, the Company completed the acquisition of the business assets of Great Southern Laboratories ("GSL"), a pharmaceutical contract manufacturing company located in Houston, Texas. See Note 4, Business Combinations and Other Acquisitions, for further information. Pernix acquired the GSL assets through its wholly owned subsidiary, Pernix Manufacturing, LLC, ("PML"). See Note 4, Business Combinations and Other Acquisitions.

Asset Dispositions

On April 21, 2014, the Company closed on the sale of its manufacturing operations (acquired on July 2, 2012), PML, to Woodfield Pharmaceutical LLC. See Note 5, Asset Dispositions, for further information.

On September 11, 2013, the Company completed the sale of certain of its generic assets held by Cypress to Breckenridge Pharmaceutical, Inc. ("Breckenridge"). See Note 5, Asset Dispositions, for further information.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Pernix and its wholly-owned subsidiaries after elimination of all intercompany balances and transactions. The results of operations of the acquired PML (sold on April 21, 2014), Cypress, Pernix Sleep, a Treximet business, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, are included in the consolidated financial statements since the effective dates of the respective acquisitions.

Basis of Accounting

The accompanying consolidated financial statements have been prepared in accordance with GAAP. The Financial Accounting Standards Board ("FASB") has established the FASB Accounting Standards Codification ("ASC") as the single source of authoritative GAAP.

Management's Estimates and Assumptions

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of the Company include: revenue recognition, sales allowances such as returns on product sales, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, stock-based compensation, the determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes.

Business Acquisitions

Our consolidated financial statements include the operations of an acquired business after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, with limited exceptions, and that the fair value of acquired in-process research and development ("IPR&D"), be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the acquisition consideration over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings.

Financial Instruments, Credit Risk Concentrations and Economic Dependency

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents, and accounts receivable.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. Most of Pernix's manufacturing arrangements are not subject to long-term agreements and generally may be terminated by either party without penalty at any time. For the year ended December 31, 2014,

approximately 38% of the inventory purchases, excluding the generic lice product, Spinosad, which is purchased exclusively from ParaPRO, were from three primary suppliers, allocated 14%, 13% and 11% respectively, and approximately 14% of the inventory purchases were manufactured by Woodfield Pharmaceuticals (the purchaser of PML). For the year ended December 31, 2013, approximately 42% of the inventory purchases, excluding Natroba and its generic, Spinosad, which was purchased exclusively from ParaPRO, were from three primary suppliers, allocated 21%, 13% and 8%, respectively, and approximately 16% of the inventory purchases were manufactured by PML. For the year ended December 31, 2012, approximately, 35% of the inventory purchases, including Cypress inventory purchases but excluding Natroba and its generic, Spinosad, which is purchased exclusively from ParaPRO, were from four primary suppliers, allocated 10%, 9%, 8% and 8%, respectively, and approximately 17% of the inventory purchases were manufactured by PML. The Company believes that it has good relationships with its current suppliers, and could secure the services of alternative suppliers if necessary or required.

Trade accounts receivable are unsecured and are due primarily from wholesalers and distributors that sell to individual pharmacies. The Company primarily sold to three major customers in 2014, 2013 and 2012. See Note 20, Concentrations, for additional information. The Company continually evaluates the collectability of accounts receivable and maintains allowances for potential losses when deemed necessary.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. The Company places its cash and cash equivalents on deposit with financial institutions in the United States. Included in cash and cash equivalents is approximately $22.7 million invested by Regions Morgan Keegan Trust in short-term securities which are secured by government securities at an amount not less than 105% of the amount invested. The Federal Deposit Insurance Corporation (“FDIC”) covers $250,000 for substantially all depository accounts. The Company from time to time may have amounts on deposit in excess of the insured limits, but maintains its cash and cash equivalents with high quality financial institutions. As of December 31, 2014, the Company had approximately $11.8 million, excluding the Regions Morgan Keegan Trust funds, on deposit in such accounts which exceeded these insured amounts.

Accounts Receivable

Accounts receivable result primarily from sales of pharmaceutical products and amounts due under revenue sharing arrangements. Credit is extended based on each customer's financial condition, and generally collateral is not required. The Company ages its accounts receivable using the corresponding sale date of the transaction and considers accounts past due based on terms agreed upon in the transaction, which is generally 30 days for brand sales and 60 to 120 days for generic sales, depending on the customer and the products purchased.

Current earnings are charged with a provision for bad debt expense based on experience and evaluation of the individual accounts. Write-offs of accounts are charged against this allowance once the amount is determined to be uncollectible by management. Recoveries of trade receivables previously written off are recorded when recovered. At December 31, 2014 and 2013, the allowance for doubtful accounts was approximately $228,000 and $84,000, respectively.

Inventories

Inventory is valued at the lower of cost or market, with cost determined by using the specific identification method. Allowances for slow-moving, obsolete, and/or declines in the value of inventory are determined based on management's assessments. Sample inventory utilized for promoting the Company's products is expensed and included in Selling, general and administrative ("SG&A") expenses when the sample units are distributed to the Company's sales representatives.

Property, Equipment and Depreciation

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which ranges from three to seven years. Leasehold improvements are amortized over the shorter of the noncancelable term of the operating lease or their economic useful lives. Maintenance and repairs are charged against earnings when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings.

Goodwill

The Company tests goodwill for impairment annually in December and when events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Company has determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The test for goodwill impairment is a two-step process. Step 1 is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If the carrying value of the reporting unit exceeds the reporting unit's fair value, we report Step 2 of the goodwill impairment test to determine the amount of impairment loss by comparing the implied fair value of the reporting unit's goodwill with the carrying amount of that goodwill. Under such evaluation, if the carrying value of the reporting unit's goodwill exceeds the implied fair value of the goodwill, the impairment loss is recognized as an operating expense as the amount equal to the excess. There were no impairment charged recorded to goodwill during the periods presented.

Intangible Assets

Intangible assets with finite useful lives consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from 6 to 12 years. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized over their estimated useful lives.

During the years ended December 31, 2014, 2013 and 2012, the Company recorded impairment charges of $0.0, $19.4 million and $0.0. See Note 12, Intangible Assets and Goodwill, for further information.

Impairment of Long-lived Assets

The Company reviews long-lived assets, such as property and equipment, subject to amortization, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. If any long-lived assets are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the asset exceeds its fair value. In connection with the sale of PML, the Company recorded impairment charges of $6.5 million against the net assets of PML in March 2014. See Note 5, Asset Dispositions, for additional information.

Equity Method of Accounting

The Company’s investment in the joint venture with SEEK was accounted for at cost and adjusted for the Company’s share (46%) of the joint venture’s undistributed earnings or losses through May 14, 2012. See Note 11, Investment in Joint Venture, for further discussion.

Revenue Recognition

Net Product Sales

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the seller’s price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product,

(iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

Revenues from sales of products are recorded net of estimated allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Provisions for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans are included within current liabilities in our consolidated balance sheets. Provision for prompt payment discounts are generally shown as a reduction in accounts receivable. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data.

Co-promotion, Royalties and Other Product Related Revenues

We receive royalties from third parties based on sales of our products under licensing and distribution arrangements. For those arrangements where royalties are reasonably estimable, we recognize revenues based on estimates of royalties earned during the applicable period, and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been significant.

Our contract revenues consist of fees and milestone payments. Non-refundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. In situations where we have continuing performance obligations, non-refundable fees are deferred and are recognized ratably over our projected performance period. Sales-based milestone payments are typically payments made to us that are triggered when aggregate net sales of a product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. We recognize sales-based milestone payments from a collaborator when the event which triggers the obligation of payment has occurred, there is no further obligation on our part in connection with the payment, and collection is reasonably assured.

The following table sets forth a summary of Pernix's consolidated net revenues for the years ended December 31, 2014, 2013 and 2012 (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Net product sales – Treximet	$ 54,775	$ —	$ —
Net product sales – Silenor	15,302	7,774	—
Net product sales – Other	47,929	69,758	51,375
Net product sales	118,006	77,532	51,375
Manufacturing revenue	1,025	3,011	5,424
Co-promotion, royalty and other revenues	2,716	4,329	4,514
Net revenues	$ 121,747	$ 84,872	$ 61,313

Cost of Product Sales

Cost of product sales is comprised of (i) costs to manufacture or acquire products sold to customers; (ii) royalty, co-promotion and other revenue sharing payments under license and other agreements granting the Company rights to sell related products; (iii) direct and indirect distribution costs incurred in the sale of products; and (iv) the value of any write-offs or donations of obsolete or damaged inventory that cannot be sold. The Company acquired the rights to sell certain of its commercial products through license and assignment agreements with the original developers or other parties with interests in these products. These agreements obligate the Company to make payments under varying payment structures based on its net revenue from related products.

In connection with the acquisitions of Cypress and Somaxon, the Company adjusted the predecessor cost basis increasing inventory to fair value as required by ASC No. 820, Fair Value Measurements and Disclosures. As a result, the Company recorded adjustments to increase the inventory to fair value in the amount of $8.6 million and $695,000 at the time of acquisition for Cypress and Somaxon, respectively. Cost of product sales for the years ended December 31, 2014, 2013 and 2012 included $2.6 million, $6.4 million and $0, respectively of inventory costs associated with the increase in the basis of the inventory that was amortized as the inventory was subsequently sold. In addition, approximately $222,000 of the Cypress inventory basis was subsequently adjusted to goodwill as the result of the re-valuation of the Cypress intangible assets during 2013. The remaining balance of the increase in the basis of the inventory acquired was approximately $97,000 as of December 31, 2014.

Freight

The Company includes freight costs for outgoing shipments in SG&A, except for the outgoing freight costs for PML which were included in cost of goods. Outgoing freight costs included in selling expenses were approximately $1.2 million, $1.2 million and $376,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

Research and Development

Research and development costs in connection with the Company's internal programs for the development of products are expensed as incurred. Pernix either expenses research and development costs as incurred or will advance third parties a research and development fee which is amortized over the term of the related agreement. Research and development expenses were approximately $3.9 million, $4.8 million and $732,000 during the years ended December 31, 2014, 2013 and 2012, respectively.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for 2014, 2013 and 2012 were $5.8 million $21,500, and $49,700, respectively. The increase is due to advertising programs for Treximet and Silenor that were developed during 2014.

Stock-Based Compensation

Stock-based compensation expense is recognized, net of an estimated forfeiture rate, on a straight-line basis over the requisite service period, which is the vesting period. See Note 22, Stock Benefit Plans and Stock-Based Compensation, for additional information.

Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization and the related amortization expense is included in interest expense, net in the consolidated statements of loss and comprehensive (loss) income. Financing costs amortized during years ended December 31, 2014, 2013 and 2012 were $2.3 million, $1.3 million and $0.0, respectively. Unamortized deferred financing costs were $14.3 million and $1.7 million as of December 31, 2014 and 2013, respectively.

Segment Information

The Company currently markets two major product lines: a branded pharmaceuticals product line and a generic pharmaceuticals product line. These product lines qualify for reporting as a single segment in accordance with GAAP because they are similar in the nature of the products and services, production processes, types of customer, distribution methods and regulatory environment. The Company had a manufacturing subsidiary, PML, until April 21, 2014, when it was divested. See Note 5, Asset Dispositions for further discussion. However, the majority of its revenue was generated through intercompany sales and were eliminated in consolidation. It is deemed immaterial for segment reporting purposes. The Company believes that its divesture of PML does not qualify as discontinued operations in accordance with ASC 205, Presentation of Financial Statements.

Income Taxes

Temporary differences are differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities. Deferred taxes represent the future tax consequences on income taxes when the reported amount of the asset or liability is recovered or settled. Deferred taxes are measured using the enacted tax rates expected to apply to taxable income in periods in which the deductible or taxable temporary difference is expected to be recovered or settled. The effect on changes in tax rates and laws are recognized in income from continuing operations in the period that includes the enactment date. The Company will recognize deferred tax assets for deductible temporary differences, operating loss and tax credit carryforwards. In assessing the realizability of deferred tax assets, the Company’s management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Future realization of deferred tax assets ultimately is dependent on the existence of sufficient taxable income of the appropriate character in either the carryback or carryforward period under the tax law. The Company’s management considers the four sources of taxable income in making this assessment. The Company’s Management believes that it is more likely than not that the Company will realize the benefits. The Company’s management has also evaluated the potential impact in accounting for uncertainties in income taxes and has determined that it has no significant uncertain income tax positions as of December 31, 2014. Income tax returns subject to review by taxing authorities include 2010, 2011, 2012, and 2013.

Contingencies

Periodically, the Company may be involved in claims and other legal matters. The Company records accruals for loss contingencies to the extent that management concludes that it is probable that a liability has been occurred and the amount of the related loss can be reasonably estimated. Legal fees and other expenses related to litigation are expensed as incurred and included in SG&A. See Note 24, Commitments and Contingencies, for additional information.

Earnings per Share

Earnings per common share is presented under two formats: basic earnings per common share and diluted earnings per common share. Basic earnings per common share is computed by dividing net income attributable to common

shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of common shares outstanding during the period, plus the potentially dilutive impact of common stock equivalents (i.e. restricted stock, stock options, warrants and convertible notes). Dilutive common share equivalents consist of the incremental common shares issuable upon exercise of stock options.

The following table sets forth the computation of basic and diluted net income per share (in thousands, except per share data):

	Year Ended December 31,		
	2014	2013	2012
Numerator:			
Net loss	$ (35,286)	$ (25,635)	$ (1,410)
Denominator:			
Weighted-average common shares, basic	37,871	36,444	28,146
Dilutive effect of stock options	—	—	—
Weighted-average common shares, diluted	37,871	36,444	28,146
Net loss per share, basic	$ (0.93)	$ (0.70)	$ (0.05)
Net loss per share, diluted	$ (0.93)	$ (0.70)	$ (0.05)

During the years ended December 31, 2014, 2013 and 2012, stock options and awards to purchase 4.7 million, 2.2 million, and 2.4 million shares, respectively, were excluded from the diluted earnings per share calculation because they were anti-dilutive. See Note 22, Stock Benefit Plans and Stock-Based Compensation, for additional information.

During the years ended December 31, 2014, 2013 and 2012, warrants to purchase 1.5 million, 469,000 and 0 shares of the Company's common stock, respectively, were excluded from the diluted earnings per share calculation as they were anti-dilutive. See Note 22, Stock Benefit Plans and Stock-Based Compensation, for additional information.

As discussed in Note 16, Debt and Lines of Credit, in February 2014, the Company issued the February 2014 Convertible Notes, pursuant to Rule Regulation D and Section 4(2) under the Securities Act. Upon conversion, the February 2014 Convertible Notes may be settled in shares of the Company's common stock. During the years ended December 31, 2014, 2013 and 2012, the conversion of 18.1 million, 0 and 0 shares of the Company's common stock, respectively, were excluded from diluted earnings per share calculation as they were anti-dilutive. See Note 16, Debt and Lines of Credit, for additional information,

Investments in Marketable Securities and Other Comprehensive Income

On October 5, 2011, the Company acquired 2.6 million shares of TherapeuticsMD for a purchase price of $1.0 million, or $0.38 per share, representing approximately 3.2% of TherapeuticsMD's outstanding common stock at that time. The Company held investments in marketable equity securities as available-for-sale and the change in the market value gave rise to other comprehensive income. The components of other comprehensive loss are recorded in consolidated statements of income (loss), net of the related income tax effect. On June 14, 2013, the Company sold all its shares of TherapeuticsMD for approximately $4.6 million in cash proceeds, recognizing a gain on the investment of approximately $3.6 million.

Recent Accounting Pronouncements

In April 2014, the FASB issued Accounting Standards Update ("ASU") 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360) which changes the requirements for reporting discontinued operations. ASU 2014-08 changes the threshold for disclosing discontinued operations and the related disclosure requirements. Pursuant to ASU 2014-08, only disposals representing a strategic shift, such as a major line of business, a major geographical area or majority equity investment, should be presented as a discontinued operation. If the disposal does qualify as a discontinued operation under ASU 2014-08, the entity will be required to provide expanded disclosures. The guidance will be applied prospectively to new disposals and new classifications of disposal groups held for sale after the effective date. ASU 2014-08 is effective for annual periods beginning on or after December 15, 2014 with early adoption permitted but only for disposals or classifications as held for sale which have not been reported in financial statements previously issued or available for issuance. The Company adopted ASU 2014-08 as of January 1, 2014. The Company believes its sale of PML does not qualify as discontinued operations upon its adoption of ASU 2014-08 as the Company's manufacturing facility was not a major line of business and was not a significant component of its financial results during our period of ownership, July 1, 2012 through April 21, 2014. See Note 5, Asset Dispositions, for additional information.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after

December 15, 2016. Early application is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company is currently evaluating the effect of the new revenue recognition guidance.

On August 27, 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which requires an entity to evaluate whether conditions or events, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern for one year from the date the financial statements are issued or are available to be issued. The guidance will become effective January 1, 2017. The adoption of ASU 2014-15 is not expected to have an impact on our consolidated financial position, results of operations or cash flows.

There were no other recent accounting pronouncements that have not yet been adopted by the Company that are expected to have a material impact on the Company’s consolidated financial statements.

Note 3. Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value as follows:

Level 1	Quoted prices in active markets for identical assets or liabilities as of the reporting date.
Level 2	Inputs other than level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities as of the reporting date.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables summarize the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 and December 31, 2013 (in thousands):

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Money market fund and trust cash sweep investments (1)	$26,297	$	$	$26,297
Total Assets	$26,297	$	$	$26,297

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
Assets				
Money market fund and trust cash sweep investments (1)	$6,312	$	$	$6,312
Total Assets	$6,312	$	$	$6,312
Liabilities				
Contingent consideration (2)	$	$	$1,330	$1,330
Total Liabilities	$	$	$1,330	$1,330

(1) The Company's money market and trust cash sweep investments are included in cash and cash equivalents within its consolidated balance sheets.

(2) Contingent consideration consists of certain holdback payments and contingent cash and equity payments with respect to our acquisition of Cypress. The fair value of the contingent consideration is included in contingent consideration within the consolidated balance sheets. The fair value of contingent consideration was originally estimated using probability weighted discounted cash flow models ("DCF"). The DCF incorporates level 3 inputs including estimated discount rates that the Company believes market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements

specific to the Cypress acquisition agreement. The Company analyzes and evaluates these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements. Any increases or decreases in discount rates would have an inverse impact on the value of related fair value measurements, while increases or decreases in expected cash flows would result in a corresponding increase or decrease in fair value measurements. The Company settled the matter of contingent consideration and paid the former shareholders of Cypress $1.3 million in January 2014.

For the Company's assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3), the following table provides a reconciliation of the beginning and ending balances for each category therein, and gains or losses recognized during the years ended December 31, 2014 and 2013 (in thousands).

	2014	2013
Liabilities:	Contingent Liability Consideration	Contingent Liability Consideration
Beginning balance at January 1,	$ 1,330	$ 14,328
Interest accretion of Cypress contingent consideration		670
Change in fair value of Cypress contingent consideration		(805)
Change in fair value of Cypress put right		8,361
Reclass of contingent consideration against indemnification claims pursuant to settlement with the former Cypress Shareholders		(4,955)
Gain on Cypress contingent consideration		(4,543)
Payment of contingent consideration – Cypress	(1,330)	
Contingent consideration in connection with the acquisition of Treximet	1,950	
Payment of contingent consideration – Treximet	(1,950)	
Gain from the waiver of the put right pursuant to settlement with the former Cypress Shareholders		(11,726)
Ending balance at December 31, 2014	$	$ 1,330

Note 4. Business Combinations and Other Acquisitions

Consideration paid by the Company for the businesses it purchases is allocated to the assets and liabilities acquired based upon their estimated fair values as of the date of the acquisition. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed is recorded as goodwill.

Treximet Acquisition

On August 20, 2014, the Company, through a wholly owned subsidiary PIL, formerly known as Worrigan Limited, completed the acquisition of the U.S. intellectual property rights to the pharmaceutical product, Treximet, from GSK. There were no other tangible or intangible assets acquired or liabilities assumed related to Treximet intellectual property from GSK.

The total purchase price consisted of an upfront cash payment of $250.0 million paid to GSK upon closing of the transaction, and $17.0 million payable to GSK upon receipt of an updated Written Request for pediatric exclusivity from the FDA, subject to certain deductions based on delays in supplying the commercial product to the Company. Subsequently, the deductions resulting from delays in supplying the commercial product reduced the $17.0 million payable amount to $1.95 million, which was paid during the fourth quarter of 2014. The Company funded this acquisition with $220.0 million in debt, plus approximately $32.0 million from available cash.

Treximet is a medication indicated for the acute treatment of migraine pain and inflammation and is manufactured by GSK under a license from Pozen. In June 2003, Pozen licensed the U.S. only rights to Treximet to GSK. GSK was responsible for all commercialization activities in the U.S. The product was approved by the FDA in April 2008. In November 2011, Pozen sold most of the future royalty and milestone payments covering Treximet sales in the U.S. to CPPIB Credit Investments Inc. ("CPPIB"). Treximet is covered by three patents in the U.S. which expire August 14, 2017. In addition, the Company will be seeking pediatric exclusivity and other potential FDA exclusivity options which may provide an additional six months to three years of exclusivity.

In connection with the transaction, GSK assigned to PIL the Product Development and Commercialization Agreement, (the "PDC Agreement") between GSK and Pozen. In connection with the assignment of the PDC Agreement, PIL paid $3.0 million to CPPIB (which owns the rights to the royalty payments under the PDC Agreement), and the Company granted Pozen a warrant (the "Warrant") to purchase 500,000 shares of the Company's common stock at an exercise price of $4.28 per share (the closing price of the Company's common stock on May 13, 2014 as reported on NASDAQ). The Warrant is exercisable from the closing date (August 20, 2014) of the PDC Agreement until February 28, 2018. The Company will continue to pay a royalty to Pozen under the PDC Agreement, equal to 18% of Treximet net sales with quarterly minimum royalty amounts of $4.0 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018.

The Treximet acquisition was accounted for as a business combination in accordance with ASC No. 805, Business Combinations which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The purchase price allocation is preliminary with respect to taxes and certain accruals and includes the use of estimates based on information that was available to management at the time these unaudited condensed consolidated financial statements were prepared. The Company believes the estimates used are reasonable and the significant effects of the Treximet acquisition are properly reflected. However, the estimates are subject to change as additional information becomes available and is assessed by the Company.

The following table summarizes the consideration paid to acquire Treximet and the estimated values of assets acquired and liabilities assumed in the accompanying unaudited condensed consolidated balance sheet based on their fair values on August 20, 2014 (in thousands):

Purchase price:		
Cash consideration paid to GSK	$	250,000
Fair value of contingent consideration payable to GSK(i)		1,950
Cash paid to CPPIB (ii)		3,000
Fair value of Warrant issued to Pozen (ii)		2,359
Total purchase price	$	257,309

Estimated fair value of assets acquired:		
Intangible assets (iii):		
Developed technologies	$	230,000
In-process research and development		23,000
Amount attributable to assets acquired	$	253,000
Goodwill (iv)	$	4,309

(i) Represents fair value of the contingent consideration payable to GSK upon receipt of an updated Written Request for pediatric exclusivity from the FDA after certain deductions based on delays in supplying the commercial product to the Company.

(ii) Cash payment of $3.0 million to CPPIB and issuance of Warrant with fair value of $2.4 million to Pozen are considered as consideration paid by the Company to acquire the exclusive U.S. rights to Treximet. These payments were made in exchange for the consent of the respective parties to permit GSK to transfer the U.S. rights to Treximet to the Company. The $2.4 fair value of the warrants was calculated using a Black-Scholes valuation model with assumptions for the following variables: price of Pernix stock on the closing date of the acquisition ($4.28); risk free interest rates (1.16%); and expected volatility (45.45%). The warrants have been classified as equity.

(iii) As of the effective time of the acquisition, the identifiable intangible assets are required to be measured at fair value and these assets could include assets that are not intended to be used or sold or that are intended to be used in a manner other than their highest and best use. For purposes of the valuation, it is assumed that all assets will be used in the manner that represents the highest and best use of those assets, but it is not assumed that any market synergies will be achieved. The consideration of synergies has been excluded because they are not considered to be factually supportable.

The fair value of identifiable assets is determined primarily using the “income method,” which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of product sales, research and development costs, sales and marketing expenses, income tax expense, capital expenditures and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset’s life cycle and the competitive trends impacting the asset, among other factors.

The consolidated balance sheets include estimated identifiable intangible assets representing core technology intangibles valued at $230.0 million, and in-process research and development (“IPR&D”) intangibles valued at $23.0 million. The core technology intangible assets represent developed technology of products approved for

sales in the market, which we refer to as marketed products, and have a finite useful lives. They are amortized on a straight line basis over a weighted average of 3.5 years. These estimates will be adjusted accordingly if the final identifiable intangible asset valuation generates results, including corresponding useful lives and related amortization methods, which differ from the pro forma estimates, or if the above scope of intangible assets is modified. The IPR&D are considered indefinite-lived intangible assets until the completion of abandonment of the associated research and development efforts. Accordingly, during the development period, these assets are not amortized but subject to an annual impairment review. The final valuation is expected to be completed within 12 months from the completion of the acquisition, based on any updated assumptions and information related to facts and circumstances that existed as of the acquisition date.

(iv) Goodwill is calculated as the difference between the purchase price of the consideration expected to be transferred and the fair values assigned to the assets acquired. Goodwill is not amortized but tested for impairment on an annual basis or when indications for impairment exist. Goodwill is not deductible for tax purposes

Pro forma Impact of Acquisition

The following pro forma combined results of operations are provided for the years ended December 31, 2014 and 2013, as though the Treximet acquisition had been completed as of January 1, 2013. These supplemental pro forma results of operations are provided for illustrative purposes only and do not purport to be indicative of the actual results that would have been achieved by the combined company for the periods presented or that may be achieved by the combined company in the future. The pro forma results of operations do not include any cost savings or other synergies that resulted, or may result, from the Treximet acquisition or any estimated costs that will be incurred to integrate the Treximet product line. Future results may vary significantly from the results in this pro forma information because of future events and transactions, as well as other factors.

(in thousands, except per share data)	December 31	
	2014 (unaudited)	2013 (unaudited)
Revenue	$ 158,419	$ 163,707
Net loss	$ (52,673)	$ (44,026)
Pro forma net loss per common share		
Basic	$ (1.39)	$ (1.21)
Diluted	$ (1.39)	$ (1.21)

The Company's historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the Treximet acquisition and factually supportable. The unaudited pro forma consolidated results include historical revenues and expenses of assets acquired in the acquisition with the following adjustments:

- Adjustment to recognize incremental amortization expense based on the fair value of intangibles acquired;
- Adjustment to recognize interest expense for debt issued in connection with the acquisition
- Eliminate transaction costs and non-recurring charges directly related to the acquisition that were included in the historical results of operations for Pernix
- Adjustment to recognize pro forma income tax based on income tax benefit on the amortization of intangible asset at the statutory tax rate of Ireland (12.50%), and the income tax benefit on the interest expense at the statutory tax rate of the United States (36.95%).

The Company has recognized net product sales and earnings for Treximet subsequent to the closing of August 20, 2014 in the amount of $54.8 million. Non-recurring transaction costs of approximately $836,000 related to the acquisition for the year ended December 31, 2014 are included in the consolidated statements of operations in selling, general and administrative expenses; these non-recurring transaction costs have been excluded from the pro forma results in the above table.

Somaxon Acquisition

On March 6, 2013, Pernix completed an acquisition of Somaxon pursuant to an agreement and plan of merger dated December 10, 2012. As a result of the transaction, each outstanding share of Somaxon common stock was converted into the right to receive 0.477 shares of Pernix common stock. Somaxon stockholders received approximately 3.7 million shares of Pernix common stock which was calculated based on a weighted average price of Pernix stock and a common stock value consideration of $25 million. Upon completion of the merger all unexercised and unexpired warrants to purchase Somaxon common stock were assumed by Pernix and were estimated to have a fair value of $0.9 million at the closing date.

The Somaxon acquisition broadened the Company's product portfolio and provides the opportunity for OTC development of Silenor, a non-controlled substance approved for the treatment of insomnia characterized by difficulty with sleep maintenance.

The Somaxon acquisition was accounted for as a business combination in accordance with ASC No. 805 Business Combinations, which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The initial purchase price allocation was preliminary with respect to taxes and certain accruals and included the use of estimates based on information that was currently available at the time. The Company believes the estimates used are reasonable and the significant effects of the Somaxon acquisition are properly reflected. Since the date of the acquisition, the Company made adjustments to recognize previously unrecorded liabilities of approximately $1.6 million offset by adjustments to increase intangible asset values by $0.3 million and establish deferred tax assets of approximately $11.6 million.

The following table summarizes the consideration paid to acquire Somaxon and the estimated values of assets acquired and liabilities assumed in the accompanying unaudited consolidated balance sheet based on their fair values on March 6, 2013 (in thousands, except stock price):

	March 6, 2013 (as initially reported)	Measurement Period Adjustment (i)	March 6, 2013 (As adjusted)
Consideration (ii) :			
Shares of Pernix common stock issued to Somaxon' stockholders	3,665		3,665
Pernix common stock price	$6.26	$	$6.26
Fair value of common stock issued	$22,945		$22,945
Fair value of warrants (iii)	895		895
Total consideration	$23,840	$	$23,840
Fair Value of Liabilities Assumed:			
Current liabilities	$8,764	$ 1,607	$10,371
Long-term liabilities	3,403		3,403
Long-term deferred tax liability (iv)	11,342	(11,559)	(217)
Amount attributable to liabilities assumed	$23,509	$ (9,952)	$13,557
Total purchase price plus liabilities assumed	$47,349	$ (9,952)	$37,397
Fair Value of Assets Acquired:			
Current assets, excluding inventory	$4,782	$	$4,782
Inventory (v)	1,090		1,090
Intangible assets (vi)	30,729	300	31,029
Amount attributable to assets acquired	$36,601	$ 300	$36,901
Goodwill (vii)	$10,748	$ (9,262)	$496

(i) After the March 31, 2013 condensed consolidated financial statements were filed, the Company updated certain estimates used in the purchase price allocation, primarily with respect to fair value of the consideration, deferred tax amounts and other accruals due to more current information. The adjustments are based on updated assumptions and information related to facts and circumstances that existed as of the acquisition date as well as confirmatory information related to accruals.

(ii) Under the terms of the merger agreement, consideration paid by Pernix consisted of approximately 0.477 shares of Pernix common stock for each share of Somaxon common stock and assumption of Somaxon's warrants. The fair value of the total purchase price was based upon the NASDAQ closing price of Pernix common stock on the day immediately prior to the closing date of the transaction, March 6, 2013. The Company issued a total of approximately 3.7 million shares of its common stock to former Somaxon stockholders in exchange for their shares of Somaxon common stock and assumed approximately 469,000 outstanding warrants.

(iii) The $895,000 fair value of the assumed warrants was calculated using a Black-Scholes valuation model with assumptions for the following variables: closing price of Pernix stock on the closing date of the merger ($6.16); risk-free interest rates (1.95%); and expected volatility (68.17%). The assumed warrants have been classified as equity.

(iv)

The Company received carryover tax basis in Somaxon's assets and liabilities because the acquisition was not a taxable transaction under the United States Internal Revenue Code of 1986, as amended. Based upon the preliminary purchase price allocation, an increase in financial reporting carrying value related to the intangible assets and the inventory acquired from Somaxon was expected to result in a deferred tax liability of approximately $11.3 million. Subsequently, during 2013 the net deferred tax liability related to Somaxon was reduced by $11.6 million to a deferred tax asset of $217,000 due to the re-allocation of the purchase price to recognize the utilizable deferred tax assets associated with the transaction. During the fourth quarter of 2014, the Company completed a study, under section 382 of the Internal Revenue Code ("IRC"), for Somaxon resulting in an adjustment to the estimate at closing of $990,000.

(v) As of the effective date of the acquisition, inventories are required to be measured at fair value. The fair value of inventory was estimated based on estimated percentage of completion of work-in-progress inventory and selling costs left to incur.

(vi) As of the effective date of the Somaxon acquisition, identifiable intangible assets are required to be measured at fair value and these acquired assets could include assets that are not intended to be used or sold or that are intended to be used in a manner other than their highest and best use. For purposes of the valuation, it is assumed that all assets will be used and that all assets will be used in a manner that represents the highest and best use of those assets, but it is not assumed that any market participant synergies will be achieved. The consideration of synergies has been excluded because they are not considered to be factually supportable.

The fair value of identifiable intangible assets is determined primarily using the income method, which starts with a forecast of all the expected future net cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including revenue, cost of sales, research and development costs, sales and marketing expenses, capital expenditures and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, among other factors.

The consolidated financial statements include estimated identifiable intangible assets representing in-process research and development, or IPR&D, intangibles valued at $22.3 million, core technology intangibles valued at $8.0 million and a product license valued at $700,000. The IPR&D are considered indefinite-lived intangible assets until the completion or abandonment of the associated research and development efforts. Accordingly, during the development period, these assets are not amortized but are subject to impairment review. The core technology intangible assets represent developed technology of products approved for sale in the market, which we refer to as marketed products, and have finite useful lives. They are amortized on a straight line basis over a weighted average period of 4 years.

(vii) Goodwill is calculated as the difference between the acquisition date purchase price of the consideration transferred and the fair values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but tested for impairment on an annual basis or when indications of impairment exist. Goodwill is not deductible for tax purposes. Goodwill specifically includes the expected synergies and other benefits that the Company believes will result from combining its operations with those of Somaxon and other intangible assets that do not qualify for separate recognition, such as assembled workforce in place at the date of acquisition.

We did not provide pro forma financial information because we do not believe the information is material, as Somaxon's net income is included within the Company's consolidated statement of income for approximately ten months of the year ended December 31, 2013 and for the entire twelve months for the year ending December 31, 2014.

Cypress Acquisition

On December 31, 2012, the Company completed the acquisition of Cypress by purchasing all the outstanding capital stock of Cypress from the former stockholders of Cypress. The Company paid $52.0 million in cash and issued approximately 4.4 million shares of the Company's common stock with a market value equal to approximately $34.3 million based on the closing price per share of $7.75 as reported on the NYSE MKT LLC on December 31, 2012. In addition, the Company agreed to pay a holdback payment up to $5.5 million on December 15, 2013, a $1.0 million payment contingent on Cypress' 2013 gross sales, $4.5 million to be deposited in escrow on December 15, 2013 and $5.0 million in shares of Company's common stock upon the occurrence of a milestone event, for an aggregate purchase price up to $102.3 million. The Company also granted a put right to the sellers pursuant to which the sellers could have put the acquisition shares to the Company at approximately $5.38 per share, exercisable from January 1, 2014 to January 31, 2014 under certain circumstances.

As the result of a settlement agreement between the Company and the former Cypress Shareholders entered into during January of 2014, the put right has been waived and the terms of the contingent consideration have been modified. As part of the settlement, the Company agreed to pay $1.3 million to the Plaintiff Shareholders on or before February 7, 2014, which amount was accrued at the time of the Cypress acquisition as a contingent consideration in our financial statements. This payment was made according to these terms. In exchange for this payment, both parties released all claims against the other parties, which includes the Plaintiff Shareholders waiving any rights to the put obligation of the Company included in the Purchase Agreement. Additionally, this payment repays in full all currently existing obligations by us to fund the escrow account or to pay the holdback amount under the Purchase Agreement. The settlement also modified the language relating to the milestone payment payable to the Plaintiff Shareholders pursuant to the Purchase Agreement but still reflects a one-time payment of $5.0 million, payable in cash or stock, upon the achievement of one of such milestones related to the development or sale of certain in-process research and development.

See Note 5, Asset Dispositions, for discussion of the sale of certain of the generic assets and Abbreviated New Drug Application (ANDAs) which were acquired in the Cypress acquisition.

The Cypress acquisition was accounted for as a business combination in accordance with ASC No. 805 Business Combinations, which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values.

A preliminary allocation of the purchase price as of December 31, 2012 was prepared in connection with the Company's annual financial statements filed on Form 10-K for the period ended December 31, 2012. Concurrent with the sale of the Cypress assets to Breckenridge (see Note 5, Asset Dispositions) in September 2013, the Company obtained an updated valuation summary of the purchase consideration which was compared to the preliminary fair value estimates that were used to prepare the initial purchase price allocation. With this information, the Company updated the assets acquired, as well as certain other estimates used in the initial purchase price allocation related to deferred tax amounts and other accruals based on the updated valuation. The Company believes the estimates used are reasonable and the significant effects of the acquisition are properly reflected. During the year ended December 31, 2013, the Company made adjustments to reallocate the fair value of the consideration of approximately $1.5 million and to recognize deferred taxes of approximately $2.3 million. The adjustments are based on updated assumptions and information related to facts and circumstances that existed as of the acquisition date as well as confirmatory information related to accruals.

Cypress' operating results are included in the Company's consolidated statements of loss and comprehensive (loss) income for the years ended December 31, 2013 and 2014 and therefor proforma information is not applicable.

Acquisition of GSL

On July 2, 2012, the Company acquired the business assets of GSL, a pharmaceutical contract manufacturing company located in Houston, Texas. The Company closed on the related real estate on August 30, 2012. Upon the final closing, the Company paid an aggregate of approximately $4.9 million (including $300,000 deposited to an escrow that was subsequently refunded to the Company as payment for unrecorded liabilities), and assumed certain liabilities totaling approximately $5.9 million for substantially all of GSL's assets including the land and buildings in which GSL operates. GSL has an established manufacturing facility for the pharmaceutical industry, which was expected to provide the Company with potential cost savings going forward. The Company acquired the GSL assets through a wholly-owned subsidiary, Pernix Manufacturing, LLC. The results of operations of Pernix Manufacturing have been included in the Company's consolidated financial statements since the acquisition date.

The GSL Acquisition was accounted for as a business combination in accordance with ASC No. 805 Business Combinations which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The purchase price allocation was preliminary and was based on estimates of fair values at the date of the acquisition. The Company evaluated the preliminary purchase price allocation, which was adjusted as additional information relative to the fair value of assets and liabilities became available.

GSL's operating results are included in the Company's consolidated statements of loss and comprehensive (loss) income for the years ended December 31, 2013 and 2014 and therefore proforma information is not necessary.

Note 5. Asset Dispositions

Disposal of PML

On March 31, 2014, the Company entered into a definitive agreement to divest its manufacturing operations, PML, to Woodfield Pharmaceutical LLC. Accordingly, during the three months ended March 31, 2014, the Company adjusted PML's net assets to fair value and, as a result, recorded the assets as held for sale, net of an impairment charge of approximately $6.5 million. The Company closed on the sale of PML on April 21, 2014. The Company received approximately $1.2 million in proceeds, net of the assumed mortgage and working capital liabilities at closing. The entire PML operation and the mortgage was assumed by the acquirer. The Company recorded an additional loss on the sale of approximately $202,000 at closing. The Company does not believe the disposal of PML qualifies as discontinued operations as the manufacturing facility was not a major line of business and was not a significant

component of the Company's financial results during our period of ownership.

Disposition of Certain Cypress Assets

On September 11, 2013, the Company completed the sale of certain of its generic assets held by Cypress to Breckenridge pursuant to the Purchase Agreement, as amended. The assets included seven previously marketed products, eight ANDAs filed at the FDA, and certain other ANDAs in various stages of development and the transfer of $1.0 million in inventory.

Breckenridge paid the Company $2.0 million in cash upon execution of the Purchase Agreement, approximately $17.9 million, before customary closing costs of approximately $173,000, in cash at the closing of the transaction, and issued two promissory notes, each in an amount of approximately $4.9 million, net of a present value discount (at an assumed rate of 3.1% on the one-year note and 4.25% on the two-year note) of approximately $505,000 in the aggregate, with one due on the first anniversary after the closing and the other due on the second anniversary after the closing, for an aggregate purchase price of up to approximately $29.6 million.

Note 6. Derivative Instruments

In connection with the acquisition of Cypress effective December 31, 2012, the Company issued a put right to Cypress' former shareholders. The put right, which had an expiration date of January 31, 2014, was exercisable during the thirty-day period immediately following the one-year anniversary date of the business acquisition, which if exercised would have enabled the put right holders to sell any of the shares they still held at the time of exercise (3.5 million as of December 31, 2013 from the underlying 4.4 million shares of the Company's common stock they received as part of the purchase consideration), back to the Company at a price of $5.38 per share, which represents a 30% discount off of the per-share value established on the effective date of the closing of the acquisition. In accordance with the relevant authoritative accounting literature a portion of the total purchase consideration was allocated to this put liability based on its initial fair value, which was determined to be $3.4 million using a Black-Scholes model. The inputs used in the valuation of the put right include term, stock price volatility, current stock price, exercise price, and the risk free rate of return. The Company has classified the put right, for which the fair value is re-measured on a recurring basis at each reporting date as a Level 3 instrument, which the Company believes is the most appropriate level within the fair value hierarchy based on the inputs used to determine its fair value at the measurement date. In connection with the settlement between the Company and the former Cypress shareholders, pursuant to which the rights under the put option were waived (See Note 5, Asset Dispositions), the fair value of the put right liability was written off as of December 31, 2013 and recorded as a gain to contingent consideration and is included in other non-operating income in the accompanying consolidated statement of income (loss) and comprehensive income (loss).

Note 7. Accounts Receivable

Accounts receivable consist of the following (in thousands):

	December, 2014	December 31, 2013
Trade accounts receivable	$ 42,565	$ 25,585
Less allowance for prompt pay discounts	(893)	(532)
Less allowance for doubtful accounts	(228)	(84)
Total trade receivables	41,444	24,969
Receivables from third parties	2,601	655
Other miscellaneous receivables	82	57
Total accounts receivable	$ 44,127	$ 25,681

The Company typically requires customers to remit payments within the first 30 days for brand purchases and 60 to 120 days for generic purchases (depending on the customer and the products purchased). The Company offers wholesale distributors a prompt payment discount, which is typically two percent as an incentive to remit payment within this timeframe. Accounts receivable are stated net of the estimated prompt pay discount.

Note 8. Notes Receivable

The Company received two promissory notes from Breckenridge in connection with the sale of its generic assets held by Cypress to Breckenridge on September 11, 2013. The notes mature on the first and second anniversary dates of the closing. The one year promissory note was paid in full during the year ended December 31, 2014 in the amount of $4.9 million. The remaining two year promissory note in the amount of $4.9 million matures on September 11, 2015. The promissory note is recorded net of a present value discount (at an assumed rate of 4.25% on the two year note).

Note 9. Inventory

Inventories consist of the following (in thousands):

	December 31, 2014	December 31, 2013
Raw materials	$ 417	$ 1,460
Packaging materials	82	841
Samples	883	732
Finished goods	12,200	13,411
Inventory, gross	13,582	16,444
Reserve for obsolescence	(2,220)	(2,634)
I Inventory, net	$ 11,362	$ 13,810

An increase in the basis of inventory related to the acquisitions of Cypress and Somaxon is included in the balances above as of December 31, 2014 and 2013. The increase included in raw materials from the Somaxon acquisition was approximately $97,000 and $220,000 as of December 31, 2014 and 2013, respectively. The increase included in finished goods from the Cypress and Somaxon acquisitions was approximately $0 and $2.7 million, in the aggregate, as of December 31, 2014 and 2013, respectively (in thousands):

Note 10. Property, Plant & Equipment

	December 31, 2014	December 31, 2013
Land	$ 572	$ 1,356
Buildings and improvements	12	3,986
Vehicles		15
Equipment	253	2,344
Furniture and fixtures	339	189
Computer software and website	517	94
Total carrying value of property, plant & equipment, gross	1,693	7,984
Less accumulated depreciation	(179)	(1,112)
Total plant, property & equipment, net	$ 1,514	$ 6,872

Depreciation expense amounted to approximately $331,000, $672,000 and $324,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

During 2014, as discussed in Note 5, Asset Dispositions, the company disposed of its manufacturing facility, PML, resulting in impairment charges of $6.5 million. Approximately, $5.8 million of this impairment charge related to impairments on the PML plant, property and equipment. During the year ended December 31, 2013, we recognized an impairment charge to capitalized software of approximately $98,000 and equipment of approximately $113,000.

Note 11. Investment in Joint Venture

On December 17, 2010, the Company entered into a Joint Venture Agreement with SEEK, a United Kingdom drug discovery group, to form a joint venture structured as a private company limited by shares incorporated in the United Kingdom (the “JV”). The purpose of the JV was to develop and obtain regulatory approval in both Europe and the United States for BC 1036, an antitussive cough suppressant pharmaceutical product utilizing theobromine as an active ingredient. Pernix contributed approximately $1.5 million to the JV, in consideration for 50% of the voting interest and approximately 46% of the total economic interest in the JV. On September 26, 2011, the Company funded an additional $1.0 million in cash to the JV for continuing operations.

On May 14, 2012, in connection with its withdrawal from the JV, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture’s intellectual property (IP) in the areas of cough, cold, sinus and allergy in the United States and Canada for $5.0 million. The investment in the JV at termination was approximately $1.4 million and approximately $2.7 million arising from a deferred tax liability. The total value of the license recorded was approximately $9.1 million. Under the terms of the agreement, Pernix would have paid royalties to SEEK on sales of products utilizing the joint venture IP in the United States and Canada. Pernix would have also received royalties from SEEK for product sales outside of the United States and Canada. As a result, the Company no longer shared in the development costs outside the United States and Canada.

Effective August 30, 2013, the Company re-licensed all of our rights to these assets in the United States and licensed the Dr. Cocoa trademark and logo to infirst+ in exchange for a royalty of 5% of net sales in the United States through 2019 and 2.5% of net sales in the United States and Canada from 2020 through 2029. Our former subsidiary, PML, entered into a supply agreement with infirst+ to supply certain of infirst+'s manufactured products in the United States. As a result of this transaction, the Company no longer has any rights to a royalty for products utilizing the intellectual property described above outside of the United States and Canada. Because the fair value of the expected royalty stream supports the carrying value of the related intangibles and the Company had not yet launched the product, there was no financial impact.

Note 12. Intangible Assets and Goodwill

Intangible assets consist of the following (in thousands, except years):

		As of December 31, 2014		
	Weighted Average Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Non-amortizable intangible assets:				
Trademark rights	Indefinite	$ 400		$ 400
In-process research and development	Indefinite	48,300		48,300
Total Non-amortizable intangible assets		48,700		48,700
Amortizable intangible assets:				
Patents	11.0 years	500	(355)	145
Brand	8.0 years	3,887	(2,308)	1,579
Product licenses	11.0 years	17,581	(4,058)	13,523
Non-compete and supplier contracts	5.3 years	5,194	(4,342)	852
Acquired developed technologies	4.4 years	269,826	(34,136)	235,690
Total amortizable intangible assets		296,988	(45,199)	251,789
Total intangible assets		$ 345,688	$ (45,199)	$ 300,489

		As of December 31, 2013		
	Weighted Average Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Non-amortizable intangible assets:				
Trademark rights	Indefinite	$ 400	$	$ 400
In-process research and development	Indefinite	25,300		25,300
Total non-amortizable intangible assets		25,700		25,700
Amortizable intangible assets:				
Patents	11.0 years	500	(306)	194
Brand	8.0 years	3,887	(1,822)	2,065
Product licenses	11.0 years	15,964	(2,383)	13,581
Customer relationships	6.0 years	1,848	(462)	1,386
Non-compete and supplier contracts	5.3 years	5,194	(3,609)	1,585
Acquired developed technologies	12.2 years	40,000	(4,489)	35,511
Total amortizable intangible assets		67,393	(13,071)	54,322
Total intangible assets		$ 93,093	$ (13,071)	$ 80,022

As of December, 2014, the weighted average life for our definite-lived intangible assets in total was approximately 4.86 years.

In connection with the acquisition of the Treximet intangible assets (see Note 4, Business Combinations and Other Acquisitions, for further information), the Company recorded, at fair value, intangible assets consisting of intellectual property valued at $230.0 million and IPR&D intangibles valued at $23.0 million. Intellectual property will be amortized on a straight line basis over 3.5 years. IPR&D will be amortized on a straight line basis over its useful life once the receipt of regulatory approval is obtained.

During 2013, the Company recorded impairment charges of approximately $213,000 against product licenses, $545,000 against patents, $239,000 against trademark rights and $18.4 million against IPR&D. The impairment charges against IPR&D consist of $8.9 million related to projects the Company acquired in the acquisition of Cypress that we have elected not to continue to pursue and a write-down of approximately $9.5 million on one project for which the Company is pursuing an alternative strategic path.

Estimated amortization expense related to intangible assets with definite lives for each of the five succeeding years and thereafter is as follows (in thousands):

	Amount
2015	$ 73,734
2016	72,881
2017	71,214
2018	12,904
2019	4,364
Thereafter	16,692
Total	$ 251,789

Amortization expense was $32.7 million, $7.3 million and $2.9 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Goodwill

Changes in the carrying amount of goodwill for the years ended December 31, 2014 and 2013 are as follows (in thousands):

	December 31,	
	2014	2013
Beginning Balance	$ 42,497	$ 37,161
Goodwill acquired – Somaxon	—	10,748
Goodwill acquired – Treximet	4,309	—
Goodwill impairment – PML (see Note 5)	(916)	—
Adjustments (1)	(990)	(5,412)
Total	$ 44,900	$ 42,497

(1) Primarily reflects the impact of measurement period adjustments related to the Cypress and Somaxon acquisitions composed of a tax adjustment related to the completion of a study, under section 382 of the IRC, for Somaxon that was completed in the fourth quarter of 2014 resulting in an adjustment to the estimate at closing, a deferred tax asset on the increase in the basis of the acquired inventory, an increase in certain accrued allowances and the impact of the re-evaluation of the opening balance sheet

Cypress intangible assets and inventory. See Note 4, Business Combinations and Other Acquisitions and Note 5, Asset Dispositions, for further information.

Note 13. Accrued Allowances

Accrued allowances consist of the following (in thousands):

	December 31, 2014	December 31, 2013
Accrued returns allowance	$ 9,691	$ 12,049
Accrued price adjustments	32,945	18,301
Accrued government program rebates	9,968	3,936
Total	$ 52,604	$ 34,286

Note 14. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2014	December 31, 2013
Due to third parties (revenue sharing arrangements)	$ 9,153	$ 3,654
Accrued legal reserve	3,500	
Other accrued expenses	2,680	1,732
Total	$ 15,333	$ 5,386

Note 15. Other Liabilities

Other liabilities consist of the following (in thousands):

	December 31, 2014	December 31, 2013
Settlement obligations (see Note 24)	$ 11,229	$ 14,115
Deferred revenue	3,743	4,279
Other	47	64
Total contracts payable and other obligations	$ 15,019	$ 18,458
Other liabilities – current	$ 3,264	$ 4,072
Other liabilities – long term	$ 11,755	$ 14,386

Note 16. Debt and Lines of Credit

Debt consists of the following (in thousands):

	December 31, 2014	December 31, 2013
Amounts outstanding under the Midcap Credit Facility	$ 7,345	$ 16,860
StanCorp mortgage		1,450
Senior secured notes (the “Treximet Notes”)	220,000	

Senior convertible notes (the “February 2014 Convertible Notes”)	65,000	
Total debt	$ 292,345	$ 18,310
Debt – short-tem	$ 7,345	$ 17,000
Debt – long term	$ 285,000	$ 1,310

The following table represents, by year, the future maturity schedule of the outstanding debt and line of credit as of December 31, 2014 (in thousands):

2015 (line of credit classified as current debt)	$7,345
2016	
2017	
2018	
2019	65,000
2020 and thereafter	220,000
Total maturities	$292,345

Interest expense, gross of interest income, amounted to $19.1 million, $4.2 million and $169,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

Credit Facility – MidCap Funding V, LLC

In connection with the purchase of all of the capital stock of Cypress, the Company, together with its subsidiaries, entered into a Credit and Guaranty Agreement, dated December 31, 2012, with MidCap Funding V, LLC, as administrative agent, a lender and as a co-bookrunner, and Business Development Corporation of America, as co-bookrunner, and additional lenders from time to time party thereto (the "Original Credit Agreement"). The Original Credit Agreement provided for a term credit facility of $42.0 million. Subject to certain permitted liens, the obligations under this facility were secured by a first priority perfected security interest in substantially all of the assets of the Company and its subsidiaries. The proceeds from this facility were used to fund a portion of the cash consideration of the acquisition of Cypress. On May 8, 2013, the Company, together with its subsidiaries, entered into an Amended and Restated Credit Agreement with MidCap Financial, LLC, as Administrative Agent and as a lender, and additional lenders from time to time party thereto (the “Amended and Restated Credit Agreement”). The May 2013 amendments were treated as a modification of debt under GAAP, and the Company expensed $630,000 of deferred financing fees and recorded approximately $670,000 of new deferred financing fees for the year ended December 31, 2013.

On February 21, 2014, in connection with the February 2014 Convertible Notes offering discussed below, the Company entered into Amendment No. 1 to the Amended and Restated Credit Agreement (the “Amendment” and together with the Amended and Restated Credit Agreement, as amended by the Amendment, the “Amended Credit Agreement”) with MidCap Funding IV, LLC, as Agent and as a lender (“MidCap”), and the other lenders from time to time parties thereto. In addition to allowing for the note issuance, the Amendment provides for the addition of a $20.0 million uncommitted accordion feature to the lenders’ existing $20.0 million revolving loan commitment. Pursuant to the Amendment, MidCap and the other lenders released their liens on certain Company assets. The obligations under the Amended Credit Agreement are secured by a first priority security interest in the Company’s accounts, inventory, deposit accounts, securities accounts, securities entitlements, permits and cash. On April 23, 2014 the Company entered into Amendment No. 2 to the Amended and Restated Credit Agreement with MidCap to increase the letter of credit sublimit from $0 to $750,000. On August 19, 2014 the Company, MidCap, and certain subsidiaries of the Company entered into Amendment No. 3 to the Amended and Restated Credit Agreement dated as of May 8, 2013 to permit the Company to consummate the purchase of the Treximet assets from GSK.

The covenants contained in the Amended Credit Agreement required the Company to maintain a minimum amount of earnings before interest, tax, depreciation and amortization (“EBITDA”) and net invoiced revenues unless the Company demonstrate minimum liquidity of at least $30.0 million through June 30, 2014. This was revised and not required with Amendment No. 3. Beginning with the calendar month ending March 31, 2015, the Company with be

required to meet a minimum fixed charge coverage ratio. The Amended Credit Agreement also continues to include customary covenants for a secured credit facility, which include, among other things, (a) restrictions on (i) the incurrence of indebtedness, (ii) the creation of or existence of liens, (iii) the incurrence or existence of contingent obligations, (iv) making certain dividends or other distributions, (v) certain consolidations, mergers or sales of assets and (vi) purchases of assets, investments and acquisitions; and (b) requirements to deliver financial statements, reports and notices to the agent and the other lenders, provided that, the restrictions described in (a)(i)-(vi) above are subject to certain exceptions and permissions limited in scope and dollar value. The Amended Credit Agreement also contains customary representations and warranties and event of default provisions for a secured credit facility.

The loans under this facility bear interest at a rate equal to the sum of the LIBOR (with a floor of 1.5%) plus an applicable margin of 7.50% per annum (9% at December 31, 2014). The expiration date of the agreement has been extended to February 21, 2017. The Company is required to maintain a lockbox for which all funds deposited into the lockbox account shall be transferred for payment by the close of each business day to reduce the balance of the revolving loan. In addition, upon the occurrence and during the continuance of an event of default and if requested by MidCap, the amounts due under the revolving loan commitment shall become immediately due and payable. Therefore, amounts outstanding under this agreement are recorded on the balance sheet as current debt as of December 31, 2014 and 2013.

February 2014 Convertible Note Offering

On February 21, 2014, the Company issued $65.0 million aggregate principal amount 8.0% Convertible Senior Notes. The February 2014 Convertible Notes mature on February 15, 2019, unless earlier converted. The Company received net proceeds from the sale of the February 2014 Convertible Notes of $58.8 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Interest on the February 2014 Convertible Notes is payable on March 15, June 15, September 15 and December 15 of each year, beginning June 15, 2014. The note balance of $65.0 million is recorded as long term debt on the balance sheet as of December 31, 2014 and is payable on February 15, 2019.

The February 2014 Convertible Notes are governed by the terms of an indenture (the “February 2014 Indenture”), between the Company and Wilmington Trust, National Association (the “February 2014 Trustee”), each of which were entered into on February 21, 2014.

The February 2014 Convertible Notes are senior unsecured obligations and are: senior in right of payment to the Company’s future indebtedness that is expressly subordinated in right of payment to the February 2014 Convertible Notes; equal in right of payment to the Company’s existing and future unsecured indebtedness that is not so subordinated; effectively junior to any of the Company’s secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness (including trade payables) incurred by the Company’s subsidiaries.

The Company may not redeem the February 2014 Convertible Notes prior to the maturity date (February 15, 2019). However, the holders may convert their February 2014 Convertible Notes at any time prior to the close of business on the business day immediately preceding February 15, 2019. Upon conversion, the Company will deliver a number of shares of the Company’s common stock equal to the conversion rate in effect on the conversion date. The initial conversion rate will be 277.7778 shares of the Company’s common stock for each $1,000 principal amount of the February 2014 Convertible Notes, which represents an initial conversion price of approximately $3.60 per share. Following certain corporate transactions that can occur on or prior to the stated maturity date, the Company will increase the conversion rate for a holder that elects to convert its February 2014 Convertible Notes in connection with such a corporate transaction.

As the Company was not required to separate the conversion option in the February 2014 Convertible Notes under ASC 815, Derivatives and Hedging , it considered whether the cash conversion guidance contained in ASC 470-20, Debt with Conversion and Other Options, is applicable to the February 2014 Convertible Notes. However, as the conversion option may not be settled in cash upon the Company’s election, the Company concluded that the cash conversion guidance is not applicable to the February 2014 Convertible Notes, and the Company therefore recorded the entire proceeds of the February 2014 Convertible Notes as a liability, without allocating any portion to equity.

Because the conversion option is not bifurcated as a derivative pursuant to ASC 815 and is not separately accounted for under the cash conversion guidance, the Company further evaluated the conversion option to determine whether it is considered a beneficial conversion option at inception. The Company determined the effective conversion price at issuance to be $3.60 per share. Because the fair value of the common stock at the close of trading on the date of issuance was $3.08, no beneficial conversion feature existed at the issuance date.

For the year ended December 31, 2014, total interest expense related to the outstanding principal balance of the February 2014 Convertible Notes was $4.5 million at the stated interest rate of 8.0% per annum. As of December 31, 2014, the Company had outstanding borrowings of $65.0 million related to the February 2014 Convertible Notes. The Company has $5.8 million in deferred financing costs related to the February 2014 Convertible Notes as of December 31, 2014. This is recorded on the balance sheet in Prepaid Expenses and Other Current Assets and Other Long-Term

Assets.

Treximet Note Offering

On August 19, 2014, the Company issued $220.0 million aggregate principal amount of its 12% Senior Secured Notes due 2020 (the "Treximet Notes") pursuant to an Indenture (the "August 2014 Indenture") dated as of August 19, 2014 among the Company, certain of its subsidiaries (the "Guarantors") and U.S. Bank National Association (the "August 2014 Trustee"), as trustee and collateral agent.

The Treximet Notes mature on August 1, 2020 and bear interest at a rate of 12.0 % per annum, payable in arrears on February 1 and August 1 of each year (each, a "Payment Date"), beginning on February 1, 2015. On each Payment Date, commencing August 1, 2015, the Company will also pay an installment of principal on the Treximet Notes as further described below in Note 17, Senior Secured Notes – Treximet – Current.

The Treximet Notes are unconditionally guaranteed, jointly and severally, by the Guarantors. The Treximet Notes and the guarantees of the Guarantors are secured by a continuing first-priority security interest in substantially all of the assets of the Company and the Guarantors related to Treximet, other than inventory and certain inventory related assets, including accounts arising from the sale of the inventory.

The Company may redeem the Treximet Notes at its option, in whole at any time or in part from time to time, on any business day, on not less than 30 days' nor more than 60 days prior notice provided to each holder's registered address. If such redemption is prior to August 1, 2015, the redemption price is equal to the greater of (i) the principal amount of the Treximet Notes being redeemed and (ii) the present value, discounted at the applicable treasury rate of the principal amount of the Treximet Notes being redeemed plus 1.00%, of such principal payment amounts and interest at the rate per annum shown above on the outstanding principal balance of the Treximet Notes being redeemed assuming the principal balances are amortized at the times and in the assumed amounts set forth on Schedule A to the August 2014 Indenture. If such redemption occurs (i) on or after August 1, 2015 and prior to August 1, 2016, the redemption price will equal 106% of the outstanding principal amount of Treximet Notes being redeemed plus accrued and unpaid interest thereon, (ii) on or after August 1, 2016 and prior to August 1, 2017, the redemption price will equal 103% of the outstanding principal amount of the Treximet Notes being redeemed plus accrued and unpaid interest thereon and (iii) on or after August 1, 2017, the redemption price will equal 100% of the outstanding principal amount of the Treximet Notes being redeemed plus accrued and unpaid interest thereon.

The August 2014 Indenture contains covenants that limit the ability of the Company and the Guarantors to, among other things: incur certain additional indebtedness pay dividends on, redeem or repurchase stock or make other distributions in respect of its capital stock repurchase, prepay or redeem certain indebtedness make certain investments create restrictions on the ability of the Guarantors to pay dividends to the Company or make other intercompany transfers create liens transfer or sell assets consolidate, merge or sell or otherwise dispose of all or substantially all of its assets and enter into certain transactions with affiliates. Upon the occurrence of certain events constituting a change of control, the Company is required to make an offer to repurchase all of the Treximet Notes (unless otherwise redeemed) at a purchase price equal to 101% of their principal amount, plus accrued and unpaid interest, if any to the repurchase date.

The August 2014 Indenture provides that an Event of Default (as defined in the August 2014 Indenture) will occur if, among other things, (a) the Company defaults in any payment of interest on any note when due and payable, and such default continues for a period of 30 days (b) the Company defaults in the payment of principal of or premium, if any, on any note when due and payable on the maturity date, upon declaration of acceleration or otherwise, or to pay the change of control repurchase price, when due and payable, and such default continues for a period of five days; (c) failure to make a repurchase offer in the event of a change in control when required under the August 2014 Indenture, which continues for three business days; (d) the Company or any Guarantor fails to comply with certain covenants after receiving written notice from the August 2014 Trustee or the holders of more than 25% of the principal amount

of the outstanding Treximet Notes; (e) the Company or any Guarantor defaults with respect to other indebtedness for borrowed money in excess of $8.0 million and such default is not cured within 30 days after written notice from the August 2014 Trustee or the holders of more than 25% of the principal amount of the outstanding Treximet Notes; (f) the Company or any Guarantor has rendered against it a final judgment for the payment of $8.0 million (or its foreign currency equivalent) or more (excluding any amounts covered by insurance) under certain circumstances; (g) certain bankruptcy, insolvency, liquidation, reorganization or similar events occur with respect to the Company or any Guarantor; (h) a guarantee of the Treximet Notes (with certain exceptions) is held to be unenforceable or invalid in a judicial proceeding or ceases to be in full force and effect or a Guarantor disaffirms its obligations under its guarantee of the Treximet Notes, and (i) certain changes in control of a Guarantor.

On August 19, 2014, the Company entered into the First Supplemental Indenture to the August 2014 Indenture for the Company's February 2014 Convertible Notes due 2019 (the "First Supplemental Indenture") to permit the Company to consummate the purchase of the Treximet assets from GSK described in Note 4, Business Combinations and Other Acquisitions, and to issue the Treximet Notes. On August 19, 2014, the Company also entered into the Second Supplemental Indenture to the August 2014 Indenture for the Company's February 2014 Convertible Notes due 2019 (the "Second Supplemental Indenture") to add PIL, a wholly owned subsidiary of the Company, as a guarantor.

For the year ended December 31, 2014, total interest expense related to the outstanding principal balance of the Treximet Notes was $9.8 million at the stated interest rate of 12.0% per annum. As of December 31, 2014, the Company had outstanding borrowings of $220.0 million related to the Treximet Notes included as long-term debt on the accompanying balance sheet. The Company has $7.3 million in deferred financing costs related to the Treximet Notes as of December 31, 2014. This is recorded on the balance sheet in Prepaid Expenses and Other Current Assets and Other Long-Term Assets.

Note 17. Senior Secured Notes – Treximet – Current

On each Payment Date, commencing August 1, 2015, the Company will pay an installment of principal on the Treximet Notes in an amount equal to 50% of net sales of Treximet for the two consecutive fiscal quarters immediately preceding such Payment Date (less the amount of interest paid on the Treximet Notes on such Payment Date of $6.6 million per quarter). Pursuant to the August 2014 Indenture, there is no principal payment applicable to Treximet sales in the third and fourth quarters of the fiscal year ended December 31, 2014. The first principal payment is due on August 1, 2015 and will be calculated on net sales for the first and second quarters of 2015, less interest paid during those same two quarters. At each month-end beginning with January 2015, the net sales of Treximet will be calculated, the monthly interest accrual amount will then be deducted from the net sales and this resulting amount will be recorded as the current portion of the Treximet Notes. If the Treximet net sales less the interest due at each month-end of each six-month period does not result in any excess over the interest due, no principal payment must be paid at that time. The balance outstanding on the Treximet Notes, or the full amount of the $220 million principal of the notes if the calculation as described does not result in any principal payments during the term of the Treximet Notes, will be due on the maturity date of the Treximet Notes which is August 1, 2020. Based on the calculation of the principal payments and the fact that under the circumstance where the calculation does not result in any excess to be applied to principal then no principal would be due, the Company has recorded the $220 million of Treximet Notes as long term as of December 31, 2014.

Note 18. Temporary Equity

The Company issued 4,427,084 shares of its common stock as consideration to the sellers for the Cypress acquisition. These shares were subject to a put option that would have allowed the sellers of Cypress to sell Pernix the common stock received as consideration to Pernix at a per share price of $5.376, representing 70% of the volume weighted average trading price of Pernix common stock for the 30 trading days prior to November 13, 2012.

The $3.4 million fair value of the put option was calculated using a Black-Scholes valuation model with assumptions for the following variables: the closing Pernix stock price 30 days prior to November 13, 2012 ($7.75), risk-free interest rates (1.84%), and expected volatility (68.34%). As the put right provides the sellers of Cypress a cash settlement option, this cash redemption feature is bifurcated from common stock issued as a consideration and classified as current liability. In connection with the Company’s settlement with the former Cypress shareholders, pursuant to which the cash settlement option to the put right was waived, the fair value of the put right was therefore recognized as a gain on contingent commission and the temporary equity was reclassed to shareholders’ equity as of December 31, 2013. See Note 4, Business Combinations and Other Acquisitions, for further information.

Note 19. Stockholders' Equity

Controlled Equity Offering

On February, 10, 2012, the Company entered into a controlled equity offering program with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company sold 3.0 million shares of common stock for total net proceeds of approximately $23.8 million. The offering was made pursuant to a shelf registration statement filed with the SEC on May 31, 2011. The Company used the proceeds of this financing to fund acquisitions and for general corporate purposes in 2012. This program was closed on May 1, 2012.

In November 2014, the Company filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to $300.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and units. The shelf registration statement includes a sales agreement prospectus covering the offering, issuance and sale of up to $100.0 million of shares of our common stock that may be issued and sold under the Controlled Equity Offering Sales Agreement, dated November 7, 2014, between us and Cantor as agent. This program will provide us with financial flexibility and the ability to opportunistically access the capital markets.

Also in November 2014, we filed an acquisition shelf registration statement on Form S-4 with the SEC, which will enable us to issue up to 12,000,000 shares of our common stock in one or more acquisition transactions. These transactions may include the acquisition of assets, businesses or securities, whether by purchase, merger or any other form of business combination.

The Company currently has no immediate plans to issue securities pursuant to either of these registration statements.

Stock Repurchase Contract with Related Party

On September 10, 2010, Pernix entered into an agreement, pursuant to a stock repurchase authorization from our board of directors on May 12, 2010, to purchase 2.0 million shares of its common stock from an employee of Pernix at $1.80 per share. The aggregate purchase price of $3.6 million was paid in equal quarterly installments of $300,000 over three years, ending on April 1, 2013. No amounts were due under this agreement at December 31, 2013 and 2014.

Warrants Issued in Acquisition of Somaxon

In connection with the acquisition of Somaxon in March 2013, the Company assumed approximately 469,000 outstanding warrants in the acquisition of Somaxon. These warrants have exercise prices ranging from $7.70 to $90.72 and expiration dates ranging from July 2016 through August 2021.

Warrants Issued in Acquisition of Treximet

In connection with the acquisition of Treximet in August 2014, the Company granted Pozen a warrant to purchase 500,000 shares of the Company's common stock at an exercise price of $4.28 per share (equal to the closing price of the Company's common stock on May 13, 2014 as reported on NASDAQ). The Warrant is exercisable from the closing date (August 20, 2014) of the Agreement until February 28, 2018. The warrants were recorded at fair value to stockholders' equity as part of the purchase price allocation as of December 31, 2014. See Note 4, Business Combinations and Other Acquisitions, for further information.

Warrants Issued in connection with Issuance of the February 2014 Convertible Notes

As of December 31, 2014 we issued to Frontline Pharmaceuticals LLC warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share. The warrants were issued as compensation for services Frontline provided us in connection with the sale of $65.0 million of our February 2014 Convertible Notes and in connection with the settlement of a lawsuit instituted by Frontline against us in October 2014. The exercise price of the warrant equals the conversion price of the convertible notes. The warrants were record at a fair value of $841,000 to stockholders' equity as additional paid in capital and to prepaid expenses and other current assets and other long-term assets as capitalized financing costs on the consolidated balance sheet as of December 31, 2014.

Treasury Shares

Treasury shares increased by 335,357 shares from restricted share awards that vested during 2014 that were forfeited to cover personal income tax liabilities as a result of the vesting.

Note 20. Concentrations

The Company's customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. The Company primarily sells products directly to drug wholesalers, which in turn, distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. The following tables list the Company's customers that individually comprise greater than 10% of total gross product sales (before gross to net deductions) and their aggregate percentage of the Company's total gross product sales for the years ended December 31, 2014, 2013 and 2012, and the customers that comprise more than 10% of total accounts receivable and such customers' aggregate percentage of the Company's total accounts receivable as of the years ended December 31, 2014 and 2013:

	For the years ended December 31,		
Gross Product Sales	2014	2013	2012
McKesson Corporation	37%	35%	26%
AmerisourceBergen Drug Corporation	31%	20%	10%
Cardinal Health, Inc.	23%	24%	39%
Total	91%	79%	75%

	As of December 31,	
Accounts Receivable	2014	2013
AmerisourceBergen Drug Corporation	42%	23%
McKesson Corporation	29%	35%
Cardinal Health, Inc.	18%	16%
Total	89%	74%

Note 21. Other Revenue Sharing Arrangements

The Company enters into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities might include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the product. Revenues related to products sold by the Company pursuant to these arrangements are included in product sales, while other sources of revenue such as royalties and profit share receipts are included in collaboration, royalty and other revenue as further discussed below. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item.

Co-promotion Agreements

The Company seeks to enter into co-promotion agreements to enhance the promotional efforts and sales of products. The Company may enter into co-promotion agreements whereby it obtains rights to market other parties' products in return for certain commissions or percentages of revenue on the sales Pernix generates. Alternatively, Pernix may enter into co-promotion agreements with respect to its products whereby it grants another party certain rights to market or otherwise promote one or more of its products. Typically, the Company will enter into this type of co-promotion arrangement when a particular product is not aligned with its product focus or it lacks sufficient sales force representation in a particular geographic area. Co-promotion revenue is included in net revenues. Expense from co-promotion agreements is included in cost of products sold. For the years ended December 31, 2014, 2013 and 2012, we recognized approximately $18.5 million, $6.9 million and $4.2 million, respectively, in expense included in cost of goods sold from payments pursuant to co-promotion and other revenue sharing arrangements. Co-promotion,

royalty and other revenues were $2.7 million, $4.3 million and $4.5 million for the years ended December 31, 2014, 2013, and 2012.

In September 2013, the Company amended the terms of our co-promotion agreement with ParaPRO. ParaPRO assumed responsibility for distribution of Natroba and related activities, and the Company and its subsidiaries no longer purchase quantities of Natroba at a discount for sale to customers. The Company continued to provide promotion services for Natroba in its assigned territories for co-promotion fees based on prescriptions generated by its sales force through April 2014. With respect to generic products covered by the agreement, the Company continued to provide co-promotion services through April 2014 for fees based on prescriptions dispensed in defined territories and distribution services through July 31, 2014 for fees based on units distributed.

On October 28, 2013, the Company entered into an agreement with Cumberland Pharmaceuticals Inc. to promote Omeclamox-Pak. Pursuant to the agreement, Cumberland will promote Omeclamox-Pak to gastroenterologists in the United States, and the Company will continue to promote the product to certain primary care physicians. This agreement provides for various types of payments, including non-refundable upfront license fees, milestone payments, and future royalties on Cumberland's net product sales of Omeclamox. We received a non-refundable upfront payment of $4.0 million upon execution of the agreement. The terms of the arrangement with Cumberland include continuing performance obligations that were conditions to Cumberland's decision to pursue promotion of this product. Due to these ongoing performance obligations, the Company determined that the promotion rights did not have stand-alone value. The Company also did not have objective and reliable evidence of the fair value of these undelivered obligations. Accordingly, amounts received upfront under the license agreement were recorded as deferred revenue and are being recognized on a straight-line basis over the term of the agreement. Current deferred revenue represents amounts, which are expected to be recognized within one year. There are also additional milestones at the first and second anniversary dates of the execution of the agreement totaling $4.0 million in the aggregate. The first milestone was not met. Royalty payments ranging from 15% to 20% based on tiered levels of gross profits will be paid by Cumberland to the Company monthly.

In connection with an amendment to the license and supply agreement between the Company and GastroEntero-Logic, LLC ("GEL") effective May 15, 2014, the Company must remit to GEL a minimum royalty payment of $750,000 per quarter from sales of Omecalmox-Pak.

In connection with the acquisition of Treximet, the Company is responsible for the payment of royalties to Pozen of 18% of net sales with quarterly minimum royalty amounts of $4.0 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018. See Note 4, Business Combinations and Other Acquisitions, for additional information.

On February 27, 2014, the Company entered into an exclusive license agreement with Osmotica Pharmaceutical Corporation to promote Khedezla (desvenlafaxine) Extended-Release (ER) Tablets. The sales and marketing of Khedezla is supported by the Company's team of approximately 97 sales professionals, promoting the product to high desvenlafaxine prescribing physicians. Khedezla is indicated for the treatment of major depressive disorder (MDD). Pursuant to the agreement, the Company agreed to make an upfront payment for the license and Osmotica's existing inventory of Khedezla in the amount of $4,000,000 in the aggregate which has been paid. There are also additional milestones based on certain levels of net profits achieved. Royalty payments equivalent to 60% of net profits will be paid by the Company to Osmotica quarterly. The royalty payments reduce to 55% in the second contract year and 50% for each year thereafter.

Profit Sharing Agreements Assumed in the Acquisition of Cypress

Hawthorn Pharmaceuticals was a party to a development, license, and supply agreement with Pharmaceutical Associates, Inc., a developer, manufacturer, and distributor of pharmaceutical products, for the exclusive promotion and distribution of (i) hydrocodone bitrate and acetaminophen oral solution 10/325 mg/15mL (promoted under the brand name Zamicet), and (ii) prednisolone sodium phosphate oral solution 20mg/5 mL (promoted under the brand name Veripred). Under the terms of the agreement entered into on July 18, 2008, Pharmaceutical Associates received a royalty of 50% of profits obtained on these products. On February 21, 2013, Hawthorn received a notice effectively terminating its promotion and distribution rights to Zamicet effective August 25, 2013. On June 12, 2013, Hawthorn received a notice effectively terminating its promotion and distribution rights to Veripred effective December 12, 2013.

Note 22. Stock Benefit Plans and Stock-Based Compensation

The Company participates in a 401(k) plan, which covers substantially all full-time employees. This plan is funded by employee contributions and discretionary matching contributions determined by management. At the Company's discretion, it may match up to 100 percent of each employee's contribution, not to exceed the first six percent of the employee's individual salary. The 401(k) plan currently meets the minimum requirements of a Safe Harbor 401(k) plan. There is a six-month waiting period from date of hire to participate in the plan. Employees are 100 percent vested in employee and employer contributions once they are eligible to participate. Contribution expense was $361,000, $450,000 and $346,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

The Company's 2009 Stock Incentive Plan (the "2009 Plan") was approved concurrent with its merger with Golf Trust of America ("GTA"), Inc. on March 9, 2010 and subsequently amended. The maximum number of shares that can be offered under this plan, as amended, is 7.75 million. Incentives may be granted under the 2009 Plan to eligible participants in the form of (a) incentive stock options, (b) non-qualified stock options, (c) restricted stock, (d) restricted stock units, (e) stock appreciation rights and (f) other stock-based awards. Incentive grants under the 2009 Plan generally vest based on four years of continuous service and have 10-year contractual terms. All plans prior to the 2009 Plan, with the exception of the Company's 2007 Stock Option Plan (the "2007 Plan"), which was approved by shareholder and permits the grant of share options and shares to its employees for up to 700,000 shares of common

stock, have been terminated. As of December 31, 2014, the 2007 Plan had 48,000 options outstanding.

Stock-Based Compensation

Stock-based compensation expense is recognized, net of an estimated forfeiture rate, on a straight-line basis over the requisite service period, which is the vesting.

The Company currently uses the Black-Scholes option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company's expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

The weighted average fair value of stock options granted during the periods and the assumptions used to estimate those value using the Black-Scholes option pricing mode were as follows:

	Year Ended December 31,		
	2014	2013	2012
Weighted average expected stock price volatility	74.7 %	66.8 %	64.7 %
Estimated dividend yield	0.0 %	0.0 %	0.0 %
Risk-free interest rate	1.9 %	1.0 %	1.1 %
Expected life of option (in years)	6.2	6.0	6.0
Weighted-average grant-date fair value per share	$3.44	$4.64	$5.33

The expected stock price volatility for the stock options is based on historical volatility of the Company's stock. The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate is assumed to be 0%. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of the stock options granted was estimated based on the historical exercise patterns over the option lives.

The Company measures the grant date fair value of restricted stock units using the company's closing common stock price on the trading date immediately preceding the grant date.

Stock Options

As of December 31, 2014, approximately 4.6 million options are outstanding that have been issued to current officers and employees under the 2007 Plan and 2009 Plan.

The following table shows the option activity, described above, during the year ended December 31, 2014 (share and intrinsic values in thousands):

	Shares	Average Exercise Price	Weighted Average Remaining Contractual Life Years	Aggregate Intrinsic Value
Options outstanding at December 31, 2013	1,605	$4.45		
Granted	4,524	5.12		
Exercised(1)	(926)	3.38		$2,917
Cancelled(1)	(652)	4.37		
Expired				
Options outstanding at December 31, 2014	4,551	$5.35	9.2	$18,482
Options vested and expected to vest as of December 31, 2014	3,708	$5.31	9.1	$15,215
Options vested and exercisable as of December 31, 2014	436	$5.02	7.2	$1,927

(1) Cancelled includes 390,000 options granted to ParaPRO, LLC ("ParaPRO") on August 3, 2011, that were to vest over seven years, pursuant to the commercial terms of the co-promotion arrangement between the Company and ParaPRO for the marketing and sale of Natroba which was terminated on April 30, 2014. Exercised includes 70,000 vested options exercised by ParaPRO in June 2014.

The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 were $2.9 million, $132,000 and $637,000, respectively.

The vesting schedule of the Company's options was graded vesting over three years through January 2014. Options issued subsequent to January 2014 have a graded vesting schedule over four years. The Company's stock option grants expire ten years from the date of grant.

As of December 31, 2014, there was approximately $10.2 million of total unrecognized compensation cost related to non-vested stock options issued to employees and directors of the Company, which is expected to be recognized ratably over a weighted-average period of 3.5 years.

Restricted Stock

The following table shows the Company's non-vested restricted stock activity during the nine months ended December 31, 2014 (share and intrinsic values in thousands):

	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Non-vested restricted stock outstanding at December 31, 2013	629	$5.60	
Granted	150	4.51	
Vested	(554)	5.29	$2,871
Forfeited	(85)	7.52	
Non-vested restricted stock outstanding at December 31, 2014	140	$4.52	

The total intrinsic value of restricted stock vested during the years ended December 31, 2014, 2013 and 2012 were $2.9 million, $795,000 and $546,000.

The vesting schedule of the Company’s restricted stock was graded vesting over three years through January 2014. Options issued subsequent to January 2014 have a graded vesting schedule over four years.

As of December 31, 2014, there was approximately $445,000 of total unrecognized compensation cost related to non-vested restricted stock issued to employees and directors of the Company, which is expected to be recognized ratably over a weighted-average period of 1.3 years.

Employee Stock Purchase Plan

Effective July 22, 2010, the Company adopted the 2010 Employee Stock Purchase Plan to provide substantially all employees an opportunity to purchase shares of its common stock through payroll deduction, up to 10% of eligible compensation with a $25,000 maximum deferral. Semi-annually (on May 1 and November 1), participant account balances will be used to purchase shares of stock at the lesser of 85 percent of the fair market value of shares at the beginning or end of such six-month period. The Employee Stock Purchase Plan expires on July 22, 2020. A total of 1.0 million shares are available for purchase under this plan of which 170,403 have been issued. Compensation expense related to the Employee Stock Purchase Plan was $124,000, $71,000 and $63,000 for the years ended December 31, 2014, 2013, and 2012, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense was $4.7 million, $2.0 million and $2.7 million for the years ended December 31, 2014, 2013 and 2012, respectively. Stock-based compensation expense for the periods presented are included within the selling, general and administrative expenses line of the consolidated statements of comprehensive loss and comprehensive (loss) income.

Note 23. Income Taxes

The components of the provision (benefit) for income taxes are as follows for the years ending December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
Current:			
Federal	$ (1,817)	$ 1,176	$ 1,718
State	232	583	(255)
Foreign	(387)	—	—
Total current provision (benefit)	(1,972)	1,759	1,463
Deferred Provision			
Federal	(9,497)	(18,985)	(1,758)
State	(952)	(3,531)	(79)
Foreign	(1,304)	—	—
Total deferred provision (benefit)	(11,753)	(22,516)	(1,837)
Total	$ (13,725)	$ (20,757)	$ (374)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The sources of the temporary differences and their effect on deferred taxes are as follows:

	Year Ended December 31,	
	2014	2013
Deferred tax assets:		
Accounts receivable	$ 415	$ 230
Differences in carrying value of property and equipment	93	81
Accruals	18,800	13,082
Inventory	958	—
Stock awards	2,060	2,272
Net operating loss carryovers	9,045	7,303
Gross deferred tax assets	31,371	22,968
Deferred tax liabilities:		
Inventory	—	(79)
Other	(497)	(475)
Intangibles	(22,577)	(25,106)
Installment sale	(1,753)	(3,506)
Gross deferred tax liability	(24,827)	(29,166)
Net deferred tax asset/(liability)	6,544	(6,198)
Included in consolidated balance sheet:		
Deferred income tax assets/(liabilities)–current	15,933	9,301
Deferred income tax assets/(liabilities)–long-term	(9,389)	(15,499)
Net deferred tax asset/(liability)	$ 6,544	$ (6,198)

Somaxon has federal net operating loss carryforwards (NOL's) of approximately $246.5 million at December 31, 2014 ranging in expiration from 2023 to 2032. However, based on the change in ownership provision of IRC Section 382, $21.9 million of those NOL are expected to be available for utilization.

Pernix Therapeutics Holdings, Inc. has federal NOL's of approximately $520,000 at December 31, 2014 with an expiration of 2031.

GTA GP, Inc. has federal NOL's of approximately $85.3 million at December 31, 2014 ranging in expiration from 2024 to 2033. However, based on the change in ownership provisions of IRC Section 382, none of those NOL are expected to be available for utilization.

Somaxon has federal research and development credit carryovers of approximately $4.3 million at December 31, 2014. However, based on the change in ownership provision of IRC Section 382, none of those credits are expected to be available for utilization.

It should be noted that only those amounts that are expected to be utilized are included in the deferred tax assets (Somaxon and Pernix NOL's noted above).

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon our projections for future taxable income over the periods that the deferred tax assets are deductible, management believes that it is more likely than not that the Company will realize the benefits of these deductible differences. The amount of the deferred tax assets at the Company level are considered realizable based on the reversal of deferred tax liabilities and the Company's projected levels of taxable income.

The effective income tax rate from continuing operations is different from the federal statutory rate for the years ended December 31, 2014, 2013 and 2012 for the following reasons:

	December 31,		
	2014	2013	2012
Expected taxes at statutory rates	35.0%	35.0%	35.0%
State taxes, net of federal tax benefit	1.0%	4.1%	12.2%
Foreign income tax rate differential	(7.5)%	—	—
Cypress put option – change in value	—	(6.3)%	—
Cypress put option – contingent gain	—	12.3%	—
Non-deductible transaction costs	—	—	(22.3)%
Permanent differences and other	(0.5)%	(0.4)%	(3.9)%
	28.0%	44.7%	21.0%

Changes in tax laws or in their application or interpretation, such as to the transfer pricing between the Company's non-U.S. operations and the U.S., could increase our effective tax rate and negatively affect our results of operations.

Approximately $11.1 million and $12.3 million of the deferred tax liability at December 31, 2014 and 2013, respectively, relates to the difference between the financial statement and tax basis of the intangibles acquired in the Cypress acquisition. The deferred tax liability related to these Cypress intangibles is reduced on an annual basis by the financial statement amortization of such intangibles.

Note 24. Commitments and Contingencies

Purchase Commitments

Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers and other providers of goods and services. Our failure to satisfy minimum sales requirements under our co-promotion agreements generally allows the counterparty to terminate the agreement and/or results in a loss of our exclusivity rights. In addition to minimum sales requirements under our co-promotion agreements, the Company has commitments under open purchase orders for inventory that can be cancelled without penalty of approximately $10.6 million.

Leases

The Company leases facilities space and equipment under operating lease arrangements that have terms expiring at various dates through 2020. Certain lease arrangements include renewal options and escalation clauses. In addition, various lease agreements to which the Company is a party require that it complies with certain customary covenants throughout the term of the leases. If the Company is unable to comply with these covenants and cannot reach a satisfactory resolution in the event of noncompliance, these agreements could terminate.

During the second quarter of 2014 the Company signed a lease for office space for its corporate headquarters in Morristown, New Jersey. The lease agreement is a seven year lease, beginning on or about May 19, 2014. The total lease obligation is approximately $1.1 million over the term of the lease.

During the third quarter of 2014, the Company entered in to a lease for office space in Mount Pleasant, South Carolina where the Company’s accounting functions are based. The term of this lease is 62 months and the total financial obligation under this lease is approximately $593,000. This lease will replace an existing office lease.

Future minimum lease payments under non-cancelable operating leases are as follows as of December 31, 2014 (in thousands):

2015	$	286
2016		308
2017		295
2018		305
2019		312
Thereafter		68
Total	$	1,574

Total rent expense was approximately $553,000, $730,000 and $375,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

Capital leases on certain pharmaceutical manufacturing equipment assumed in the acquisition of GSL had terms to November 2013.

Milestone Payments

As discussed in Note 4, Business Combinations and Other Acquisitions, and in Note 21, Other Revenue Sharing Agreements, the Company is party to certain license agreements and acquisition agreements. Generally, these agreements require that the Company make milestone payments in cash upon the achievement of certain product development and commercialization goals and payments of royalties upon commercial sales. The amount and timing of future milestone payments may vary depending on when related milestones will be attained, if at all.

Other Revenue Sharing Arrangements

As discussed in Note 21, Other Revenue Sharing Arrangements, the Company has entered into certain revenue sharing arrangements that require payments based on a specified percentage of net sales or a specified cost per unit sold. See Note 21 for further information.

Other Commitments

During the fourth quarter of 2014, the Company entered into a services agreement for services to conduct a clinical development program for Treximet in order for the Company to submit the sNDA for Treximet by July 1, 2016. The estimate for the costs associated with this agreement is approximately $2.3 million, which does not include hourly rates that will be billed as incurred on a time and materials basis. There were no services performed related to this agreement during 2014.

In August 2014, the Company entered into an agreement with PDI, Inc. for services related to the promotion of Cedax and its authorized generic. The Company is required to pay monthly installments of $259,000. The agreement terminates on December 31, 2015.

In July 2012 and January 2013, Somaxon settled two patent litigation claims with parties seeking to market generic equivalents of Silenor. As of December 31, 2014, remaining payment obligations owed under these settlement agreements are $1.25 million, payable in equal annual installments of $250,000 through 2019, and $1.5 million, payable in equal installments of $500,000 through 2017. These settlement agreements are recorded in other liabilities (both current and long-term) on the balance sheet as of December 31, 2014

Texas Attorney General Medicaid Investigation. The Company reached an agreement with the Attorney General of the State of Texas to settle all claims arising from certain actions by Cypress under the Texas Medicaid Fraud Prevention Act prior to its acquisition by us in connection with a Civil Investigative Demand made on Cypress. As part of the settlement, the Company has agreed to pay $12.0 million to the State of Texas. As discussed in Note 5, Asset Dispositions, the Company recorded the fair value of this settlement in the amount of $9.8 million in our financial statements at December 31, 2013 and recorded as an expense during the quarter ended December 31, 2013. An initial payment of $2.0 million was due and payable within ten business days of the effective date of the final settlement agreement (the “Effective Date”) and was paid accordingly. Thereafter, the Company will make subsequent payments of $2.0 million on each of the first five anniversaries of the Effective Date. The balance of this obligation was $8.2 million and $9.8 million as of December 31, 2014 and 2013 and is included in other liabilities on the consolidated balance sheet.

Resignation of Executive Officer. Effective October 3, 2014, the Company's Senior Vice President Research & Development and a named executive officer ("Former Employee") of the Company terminated his employment with the Company. In connection with such resignation, the Company and the Former Employee entered into an agreement pursuant to which, among other things, the Former Employee agreed to provide certain transition services to the Company and the Company agreed to issue to the Former Employee 50,000 shares of common stock of the Company that were previously issuable subject to satisfaction of certain conditions and the Company released restrictions on approximately 30,000 additional shares of common stock of the Company that had previously been issued to the Former Employee. The financial impact of the accelerated vesting of the common stock in the fourth quarter of 2014 is approximately $377,000 of stock compensation expense. In addition, the Company agreed to provide severance compensation in the amount of approximately $200,000 payable semi-monthly through May of 2015 and is in accrued expenses on the consolidated balance sheet as of December 31, 2014.

Contingencies

GSK has claimed that we owe them damages relating to an alleged breach by us of a covenant contained in the Asset Purchase and Sale Agreement dated as of May 13, 2014 by and among GSK and its affiliates and us pertaining to a pre-existing customer agreement. As of December 31, 2014, GSK alleged damages of approximately of $8.5 million. We intend to vigorously contest GSK's allegations that its damages are a result of our breach and that they are compensable under the Asset Purchase and Sale Agreement or otherwise. As of December 31, 2014, a settlement reserve of $3.5 million has been recorded. Any material liability resulting from this claim could negatively impact the Company's financial results.

Legal Proceedings

In re Somaxon Pharmaceuticals, Inc. Shareholder Litigation (Lead Case No. 37-201200087821-CU-SLCTL)

A purported class action lawsuit was filed in the Superior Court of California County of San Diego by Daniele Riganello, who, prior to the consummation of the merger between Pernix and Somaxon on March 6, 2013 (the "Merger"), was an alleged stockholder of Somaxon (Riganello v. Somaxon, et al., No. 37-201200087821-CU-SLCTL). A second purported class action was also filed in the court by another alleged stockholder (Wasserstrom vs. Somaxon, et al., No. 37-2012-00029214-CU-SL-CTL). Both plaintiffs filed amended complaints on January 18, 2013. The lawsuits were consolidated into a single action captioned In re Somaxon Pharmaceuticals, Inc. Shareholder Litigation (Lead Case No. 37-201200087821-CU-SLCTL). The operative complaint named as defendants Somaxon, Pernix, Pernix Acquisition Corp. I, as well as each of the former members of Somaxon's board of directors (the "Individual Defendants"). It alleged, among other things, that (i) the Individual Defendants breached fiduciary duties they assertedly owed to Somaxon's former stockholders in connection with the Merger (ii) Somaxon and Pernix aided and abetted the purported breaches of fiduciary duty; (iii) the merger consideration was unfair and inadequate; and (iv) the disclosures regarding the Merger in the Registration Statement on Form S-4, initially filed with the SEC on January 7, 2013 (as amended, the "Proxy Statement/Prospectus"), were inadequate.

On January 24, 2013, solely to avoid the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, Pernix and the other named defendants in such litigation signed a memorandum of understanding (the "MOU") to settle such litigation. The MOU resolves the claims brought in such litigation and provides a release and settlement by the purported class of Somaxon's former stockholders of all claims against the defendants and their affiliates and agents in connection with the Merger. The parties executed a stipulation of settlement setting forth a plaintiff's fee of $185,000 on July 3, 2013. The court entered a preliminary approval of the settlement on January 17, 2014 and the final settlement approval hearing occurred on April 25, 2014. We paid the $185,000 plaintiff's fee and attorney's fees of $15,000, and the case has been dismissed.

Texas Attorney General Medicaid Investigation RE Cypress Pharmaceuticals

On May 9, 2013, our subsidiary, Cypress Pharmaceuticals, Inc., received notice from the Office of the Attorney General of the State of Texas that it had completed its initial analysis of transaction data provided by Cypress during 2012 to the Attorney General's office and offering to settle all claims that the Attorney General alleged arose from Cypress's prior actions under the Texas Medicaid Fraud Prevention Act. Cypress and the Texas Attorney General entered into a Settlement Agreement effective February 6, 2014 finally settling all claims against Cypress through the effective date for an aggregate payment of $12 million, with $2 million paid up front, and $2 million due on the first five anniversaries of the effective date.

Stanton Keith Pritchard, as Sellers' Agent v. Pernix Therapeutics Holdings, Inc. (U.S.D.C., So. Dist. Of TX)

On December 18, 2013, the selling shareholders of Cypress Pharmaceuticals, Inc. filed suit against Pernix to require Pernix to pay into the existing unfunded escrow account the $5.5 million holdback payment and the $4.5 million escrow payment that allegedly became due on December 16, 2013 under the Securities Purchase Agreement between the selling shareholders and Pernix dated November 12, 2012, as amended. The parties entered into a settlement agreement dated January 27, 2014 pursuant to which each party waived and released all claims against the other party pursuant to the Securities Purchase Agreement (including Pernix' put obligation pursuant to the agreement) in exchange for a one-time payment of $1.33 million to the Cypress shareholders by Pernix. The payment was accrued as of December 31, 2013 in contingent consideration on the consolidated balance sheet. The payment was made during January of 2014 and the case was dismissed effective January 29, 2014.

Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals, Inc. (C.D. Calif.)

On August 1, 2012, a complaint for patent infringement was filed against Somaxon (now Pernix Sleep) by Classen Immunotherapies, Inc. in the United States District Court for the Central District of California. The complaint alleges that Somaxon infringed one or more claims of two of plaintiff's patents by conducting one or more clinical studies relating to Silenor and seeking FDA approval for Silenor. The plaintiff seeks damages, including for willful infringement, and attorneys' fees. The Company believes that none of Somaxon's activities has infringed plaintiff's patents. We also do not believe that any potential damages in this case, given the nature of the patents, would amount to a material impact on Pernix. Finally, Somaxon was granted a motion for summary judgment giving the plaintiff leave to amend its complaint, which it did. Somaxon was granted a second motion for summary judgment to dismiss the amended complaint. Plaintiff appealed in mid-July 2013, and Somaxon filed its brief in response on September 12, 2013. The parties had oral arguments on January 9, 2014 on the plaintiff's appeal of the second motion for summary judgment. On January 17, 2014, the court affirmed the district court's favorable ruling for us. The plaintiff petitioned the court for a rehearing, which was denied by the Court on March 21, 2014. The plaintiff has one final opportunity to request a writ of certiorari to the U.S. Supreme Court.

Frontline Pharmaceuticals LLC vs. Pernix Therapeutics Holdings, Inc. (S.D. NY)

On October 24, 2014, a complaint was filed by Frontline Pharmaceuticals LLC asserting claims against Pernix for breach of contract and unjust enrichment, alleging that Frontline was promised warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share in connection with work allegedly performed by Frontline in connection with the our February 2014 convertible note offering. The parties entered into a settlement agreement effective as of December 31, 2014 pursuant to which we issued to Frontline warrants to purchase 500,000 shares of Pernix common stock at an exercise price of $3.60 per share. The fair value of the warrants was recorded to stockholders' equity in the amount of $841,000.

Uninsured Liabilities

The Company is exposed to various risks of losses related to torts, theft of, damage to, and destruction of assets, errors and omissions, injuries to employees, and natural disasters for which the Company maintains general liability insurance with limits and deductibles that management believes prudent in light of the exposure of the Company to loss and the cost of the insurance.

The Company is subject to various claims and litigation arising in the ordinary course of business. In the opinion of management, the outcome of such matters will not have a material effect on the consolidated financial position or results of operations of the Company.

Note 25. Quarterly Financial Data (Unaudited)

Selected quarterly consolidated financial data are shown below (in thousands, except per share data, unaudited).

	Three Months Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Net revenues	$ 19,052	$ 17,382	$ 31,479	$ 53,834
Operating expenses	33,195	25,131	37,181	56,454
Loss from operations	(14,143)	(7,749)	(5,702)	(2,620)
Other (expense) income, net	(1,265)	(2,233)	(5,335)	(9,964)
Income tax (benefit) provision	(5,866)	(3,749)	655	(4,765)
Net loss	$ (9,542)	$ (6,233)	$ (11,692)	$ (7,819)
Net loss per share—basic	$ (0.26)	$ (0.16)	$ (0.31)	$ (0.20)
Net loss per share - diluted	$ (0.26)	$ (0.16)	$ (0.31)	$ (0.20)

	Three Months Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Net revenues	$ 22,078	$ 20,573	$ 18,295	$ 23,926
Operating expenses	30,188	28,378	24,259	56,708
Loss Income from operations	(8,110)	(7,805)	(5,964)	(32,782)

Other (expense) income, net	(2,934)	143	(2,406)	13,466
Income tax (benefit) provision	(3,134)	(1,985)	(2,547)	(13,090)
Net (loss) income	$ (7,910)	$ (5,677)	$ (5,823)	$ (6,226)
Net loss income per share—basic	$ (0.23)	$ (0.15)	$ (0.16)	$ (0.17)
Net loss income per share - diluted	$ (0.23)	$ (0.15)	$ (0.16)	$ (0.17)

Schedule II
Pernix Therapeutics Holdings, Inc.

Valuation and Qualifying Accounts
Years Ended December 31, 2014, 2013 and 2012
(in thousands)

		Balance and beginning of period	Additions charged to costs and expenses	Other Additions	Deductions	Balance at end of period
For the year ended December 31, 2014						
Allowance for doubtful accounts	(1)	$84	$211	$-	$(67)	$228
Allowance for prompt pay discounts	(1)	532	4,693	-	(4,332)	893
Inventory obsolescence allowance	(2)	2,634	5,157	-	(5,571)	2,220
For the year ended December 31, 2013						
Allowance for doubtful accounts	(1)	39	98	-	(53)	84
Allowance for prompt pay discounts	(1)	728	3,053	-	(3,249)	532
Inventory obsolescence allowance	(2)	1,057	2,856	-	(1,279)	2,634
For the year ended December 31, 2012						
Allowance for doubtful accounts	(1)	-	43	-	(4)	39
Allowance for prompt pay discounts	(1)	393	1,713	-	(1,378)	728
Inventory obsolescence allowance	(2)	-	540	661	(144)	1,057

(1) Shown as a reduction of accounts receivable. Charges related to prompt pay discounts are reflected as a reduction of revenue.
(2) Shown as a reduction of inventory. Charges related to obsolescence of inventory are reflected in "cost of product sales" in the consolidated statements of loss and comprehensive (loss) income.

INDEX TO EXHIBITS

No.	Description	Filed or Furnished with this Form 10-K	Incorporated by Reference	
			Form	Date Filed
2.1	Securities Purchase Agreement, dated as of November 13, 2012, by and among Pernix Therapeutics Holdings, Inc., Cypress Pharmaceuticals, Inc., all of the stockholders of Cypress Pharmaceuticals, Inc. and an individual as agent of all of the stockholders of Cypress Pharmaceuticals, Inc.		8-K	11/15/2012
2.2	First Amendment to Securities Purchase Agreement dated December 28, 2012 among Pernix Therapeutics Holdings, Inc., on the one hand, and Cypress Pharmaceuticals, Inc., a Mississippi corporation, all of the stockholders of Cypress, and for limited purposes set forth therein, an individual as agent of the Sellers, on the other hand.		8-K	01/04/2013
2.3	Agreement and Plan of Merger dated December 10, 2012 by and among Pernix Therapeutics Holdings, Inc., Pernix Acquisition Corp I. and Somaxon Pharmaceuticals, Inc.		8-K	12/12/2012
2.4	Asset Purchase Agreement by and among Breckenridge Pharmaceutical, Inc. (“Breckenridge”), on the one hand, and the Company and Cypress Pharmaceuticals, Inc. (“Cypress”), on the other hand, dated as of August 5, 2013		10-Q	08/09/2013
2.5	Joinder Agreement and First Amendment to Asset Purchase Agreement dated September 11, 2013 among the Company and Cypress, on the one hand, and Breckenridge, on the other hand		8-K	09/17/2013
3.1	Articles of Incorporation of Pernix Therapeutics Holdings, Inc.		8-K	03/15/2010
3.2	Bylaws of Pernix Therapeutics Holdings, Inc.		8-K	03/15/2010
4.1	Form of certificate representing shares of common stock of Pernix Therapeutics Holdings, Inc.		10-K	03/29/2012
4.2	Indenture, dated February 21, 2014, by and between Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association		8-K	02/26/2014
4.3	Form of 8.00% Convertible Senior Note due 2019 (included in Exhibit 4.2)		8-K	02/26/2014
4.4	Common Stock Purchase Warrant dated May 13, 2014 issued to Pozen, Inc.		8-K	05/16/2014

4.6	Indenture, dated August 19, 2014, among Pernix Therapeutics Holdings, Inc., the Guarantors named therein and U.S. Bank National Association, as Trustee and as Collateral Agent	8-K	08/22/2014
4.7	Forms of 12% Senior Secured Notes due 2020 (included in Exhibit 4.6)	8-K	08/22/2014
4.8	First Supplemental Indenture, dated as of August 19, 2014, among Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	08/22/2014
4.9	Second Supplemental Indenture, dated as of August 19, 2014, among Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	08/22/2014
4.10	Form of Warrant to Purchase Common Stock, dated as of December 31, 2014, issued by Pernix Therapeutics Holdings, Inc.	S-3/A (No. 333-200011)	01/30/2015
10.1*	2009 Stock Incentive Plan	8-K	03/15/2010
10.2*	2010 Employee Stock Purchase Plan	8-K	08/16/2010
10.3*	Golf Trust of America, Inc. 2007 Stock Option Plan	S-8	06/04/2010
10.4*	2007 Stock Option Plan	Def14A	11/16/2007
10.5*	Employment and Non-Compete Agreement, dated December 31, 2008, by and between Pernix Therapeutics, Inc. and Michael Venters	8-K	03/15/2010

10.6*	Employment Offer Letter, dated May 10, 2013, by and between Pernix Therapeutics, Inc. and Cooper Collins	10-Q	08/09/2013
10.7*	Amended and Restated Employment and Non-Compete Agreement, dated March 14, 2011, by and among Pernix Therapeutics Holdings, Inc., Macoven Pharmaceuticals, LLC. and John McMahon	10-K	03/30/2011
10.8*	Amendment No. 1 to Amended and Restated Employment and Non-Compete Agreement, dated March 23, 2012, by and among Pernix Therapeutics Holdings, Inc., Macoven Pharmaceuticals, LLC. and John McMahon	10-K	03/29/2012
10.9*	Employment Offer Letter, dated May 10, 2013, by and between Pernix Therapeutics Holdings, Inc., and Michael Pearce	10-Q	08/09/2013
10.10	Form of Amended and Restated Merger Partner Stockholder Agreement	8-K	05/31/2011
10.11	Amended and Restated Credit Agreement dated as of May 8, 2013 by and among Pernix Therapeutics Holdings, Inc., together with its subsidiaries, Midcap Financial, LLC., as Administrative Agent and Lender and the additional lenders from time to time party thereto.	8-K	05/13/2013
10.12*	Severance Letter, dated July 19, 2013, by and between Pernix Therapeutics Holdings, Inc. and Tracy S. Clifford	10-Q	08/09/2013
10.13*	Employment Offer Letter, dated April 19, 2013, by and between Pernix Therapeutics Holdings, Inc. and Brian T. Dorsey	8-K	04/25/2013
10.14	Amended and Restated License Agreement by and between Pernix Sleep, Inc. (formerly Somaxon Pharmaceuticals, Inc.) and ProCom One, Inc. dated September 15, 2010.	10-Q	11/12/2013
10.15	Form of Securities Purchase Agreement, dated February 4, 2014.	8-K	02/07/2014
10.16*	Employment Agreement dated as of February 5, 2014 by and between Pernix Therapeutics Holdings, Inc. and Douglas Drysdale.	8-K	02/07/2014
10.17	Amendment No. 1 to the Amended and Restated Credit Agreement, dated February 21, 2014, between Pernix Therapeutics Holdings, Inc. and MidCap Funding IV, LLC, as Agent and as a lender, and the other lenders from time to time parties thereto	8-K	02/26/2014
10.18	Amended and Restated Security and Pledge Agreement, dated February 21, 2014, by and between Pernix Therapeutics Holdings, Inc. and MidCap Funding IV, LLC, as Agent.	8-K	02/26/2014
10.19	Form of Representation Agreement, dated February 21,2014, by and between Pernix Therapeutics Holdings, Inc. and the Investors party	8-K	02/26/2014

	thereto		
10.20	Form of Registration Rights Agreement, dated February 21,2014, by and between Pernix Therapeutics Holdings, Inc. and the Investors party thereto	8-K	02/26/2014
10.21*	Amendment No. 1 to the Pernix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan	10-K	03/17/2014
10.22 *	Employment Agreement dated as of March 9, 2014 by and between Pernix Therapeutics Holdings, Inc. and Terence Novak	10-Q	05/12/2014

10.23 *	Pernix Therapeutics Holdings, Inc. Amended and Restated 2009 Stock Incentive Plan		DEF 14A	04/28/2014
10.24	Amendment No. 2 to the Amended and Restated Credit Agreement, dated April 23, 2014, between Pernix Therapeutics Holdings, Inc. and MidCap Funding IV, LLC, as Agent and as a lender, and the other lenders from time to time parties thereto		10-Q	05/12/2014
10.25	Asset Purchase and Sale Agreement, dated as of May 13, 2014, by and among Glaxo Group Limited, GlaxoSmithKline, LLC, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline Intellectual Property Management Limited, (collectively, the “Sellers”) and Pernix Therapeutics Holdings, Inc.		8-K	05/16/2014
10.26 *	Employment Offer Letter, dated June 20, 2014 , by and between Pernix Therapeutics Holdings, Inc. and Sanjay S. Patel		8-K	06/25/2014
10.27	Amendment No. 3 to the Amended and Restated Credit Agreement, dated as of August 19, 2014, among MidCap Funding IV, LLC, as Agent, Pernix Therapeutics Holdings, Inc. and the subsidiary guarantors identified therein.		8-K	08/22/2014
10.28	Letter Agreement dated August 14, 2014 among Pernix Therapeutics Holdings, Inc., Worrigan Limited, Glaxo Group, Limited, GlaxoSmithKline Intellectual Property Management Limited, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline, LLC		8-K	08/22/2014
10.29	Controlled Equity OfferingSM Sales Agreement, dated November 7, 2014, by and between Pernix Therapeutics Holdings, Inc. and Cantor Fitzgerald & Co.		S-3 (No. 333-200005)	11/07/2014
21.1	Subsidiaries of the Company	√		
23.1	Consent of Cherry Bekaert L.L.P.	√		
31.1	Certification by Douglas Drysdale (Principal Executive Officer) pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	√		
31.2	Certification by Sanjay S. Patel (Principal Financial Officer) pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	√		
32.1	Certification by Douglas Drysdale and Sanjay S. Patel pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	√		
101.INS	XBRL Instance Document			

101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Indicates a management contact or compensatory plan or arrangement