

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2015**

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

(State or Other Jurisdiction of Incorporation)

33-0724736

(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

Common Stock, par value \$0.01 per share

Name of each exchange on which registered

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 No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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). Yes No

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.

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

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

(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 No

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2015 (the last business day of the registrant's most recently completed second quarter) was approximately \$359,884,000, based upon the \$5.92 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 March 3, 2016, the registrant had 61,127,615 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 2016 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, 2015.

PERNIX THERAPEUTICS HOLDINGS, INC. Annual Report on Form 10-K for the Year Ended December 31, 2015 TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1. Business	3
Item 1A. Risk Factors	27
Item 1B. Unresolved Staff Comments	51
Item 2. Properties	51
Item 3. Legal Proceedings	52
Item 4. Mine Safety Disclosures	53
PART II	
Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	53
Item 6. Selected Financial Data	55
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	56
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	72
Item 8. Financial Statements and Supplementary Data	73
Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	117
Item 9A. Controls and Procedures	117
Item 9B. Other Information	118
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	118
Item 11. Executive Compensation	118
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	119
Item 13. Certain Relationships and Related Transactions, Director Independence	119
Item 14. Principal Accounting Fees and Services	119
PART IV	
Item 15. Exhibits, Financial Statement Schedules	119

PART I

Unless the context indicates otherwise, references in the report to "Pemix[®]," "Company," "we," "us" and "our" and similar terms mean Pemix Therapeutics Holdings, Inc., a Maryland corporation, and its subsidiaries.

This Annual Report on Form 10-K and the documents incorporated by reference into this report contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform act of 1995. These statements are based on our current expectations and are subject to uncertainty and changes in circumstances. We cannot guarantee the accuracy of such statements, and you should be aware that results and events could differ materially from those contained in such statements. You should consider carefully the statements set forth in Item 1A of this report entitled "Risk Factors" and Item 7 of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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, pain and psychiatry, as well as other specialty therapeutic areas. We promote our core branded products to physicians through our sales force. We promote selected non-core branded products, such as our cough and cold products, through co-promotion arrangements with established third-party 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 growth in 2015, as a result of the following:

- Growth in full year sales of Treximet, which was acquired in August 2014;
- Acquisition of Zohydro® ER with BeadTek™ in April 2015;
- Expansion of the Pemix sales force by more than 100 sales representatives in May 2015 in connection with the Company's acquisition of Zohydro ER with BeadTek in May 2015;
- Cross-trained the Pemix sales force to market Treximet®, Silenor® and Zohydro ER with BeadTek;

As a result, in 2015, Pemix reported its highest net revenues since becoming a pharmaceutical company through a reverse merger in March 2010. Going into 2016, we have a portfolio of approved products that address medical needs in several therapeutic areas, including:

- **Migraine:** Treximet (sumatriptan/naproxen sodium), the only fixed dose combination product indicated for acute migraine;
- **Pain:** Zohydro ER (hydrocodone bitartrate) with BeadTek, an extended-release opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate;
- **Insomnia:** Silenor (doxepin), the only nonnarcotic, non-scheduled and non-addictive prescription sleep aid for the treatment of insomnia characterized by difficulty with sleep maintenance; and

- **Depression:** Khedezla® (desvenlafaxine extended-release tablets), for major depressive disorder.

In addition, we made significant progress and investment in expanding our product development pipeline. We received approval for our 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 Zohydro ER 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 sodium)

Treximet is the only fixed dose combination sumatriptan and naproxen sodium product approved by the U.S. Food and Drug Administration ("FDA"). Sumatriptan, one of the two active ingredients in Treximet, belongs 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 estimated 17% of females and 6% of males in the United States. Based on current U.S. 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 an acute medication that combines the benefits of both of these commonly used classes of drugs to provide a synergistic effect that is not found when the individual components are used alone.

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. On May 15, 2015, we announced that the FDA had approved Treximet for use in pediatric patients 12 years of age and older for the acute treatment of migraine with or without aura.

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 U.S. rights for Treximet to GSK. Prior to our acquisition of Treximet, GSK was responsible for all commercialization activities in the U.S. 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 in the primary position. Treximet is exclusively licensed to us for U.S. marketing, sales and distribution. We currently have two qualified suppliers of Treximet. Treximet is covered by five patents in the U.S., licenses to which are currently held by our subsidiary, Pernix Ireland Limited ("PIL"). Including six months of pediatric exclusivity, four of

the patents expire on February 14, 2018, and one expires on April 2, 2026. Six companies have filed abbreviated new drug applications (ANDAs) with the FDA seeking approval to market a generic version of Treximet. Three generic filers are enjoined from launching until the conclusion of our exclusivity period in 2026.

Zohydro ER with BeadTek

Zohydro ER with BeadTek is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Zohydro ER does not contain acetaminophen, unlike many immediate-release hydrocodone products, reducing the risk for potential liver toxicity due to overexposure of acetaminophen. Zohydro ER with BeadTek is available in strengths 10 mg, 15 mg, 20 mg, 30 mg, 40 mg and 50 mg. On January 30, 2015, the FDA approved this updated formulation that features BeadTek, a technology encompassing an indistinguishable mix of inactive beads, active immediate-release hydrocodone beads and active extended-release hydrocodone beads. Zohydro ER with BeadTek delivers an extended release of hydrocodone that provides 12-hour dose duration. When taken as directed, the inactive beads contained in Zohydro ER with BeadTek remain inert. The inactive beads dissolve independently of the active hydrocodone beads and are designed not to change the 12-hour release properties of the medication when taken as directed. However, when crushed and dissolved in liquids or solvents, the inactive beads are designed to avoid opioid abuse by immediately forming a viscous gel.

As part of the acquisition, which closed on April 24, 2015, we retained key members of Zogenix's commercial team, who will oversee the sales, marketing and contracting of Zohydro ER with BeadTek, most notably a significant number of Zogenix's approximately 100-person sales team.

It is estimated that about 100 million Americans suffer from chronic pain, defined as pain that lasts longer than three months. Chronic pain can be mild or excruciating, episodic or continuous, merely inconvenient or totally incapacitating. With chronic pain, signals of pain remain active in the nervous system for months or even years. This can take both a physical and emotional toll on a person. The most common sources of pain stem from lower back pain, joint pain or pain from injury. Other kinds of chronic pain include pain affecting specific parts of the body, such as the shoulders, pelvis, and neck. Generalized muscle or nerve pain can also develop into a chronic condition. Chronic pain may originate with an initial trauma/injury or infection, or there may be an ongoing cause of pain. Some people suffer chronic pain in the absence of any past injury or evidence of body damage. Chronic pain is complex, so there are many treatment options including opioid pain medications such as Zohydro ER with BeadTek, we believe Zohydro ER with BeadTek is an excellent option for patients who have pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate because of its true 12-hour formulation ensuring patients are able to get pain control without the risk of end of dose failure.

We promote Zohydro ER with BeadTek in the United States through our nationwide specialty sales force, which covers approximately 100 territories. Zohydro ER with BeadTek is manufactured by and licensed from Recro Pharma, Inc. Prior to our acquisition of the Zohydro ER franchise, Zogenix, Inc. was responsible for all commercialization activities in the U.S. During this time, Zogenix paid milestones and royalties on sales to Alkermes plc. On March 3, 2015, Alkermes announced the sale of the manufacturing facility and royalty revenue associated with Zohydro ER to Recro. Recro is our sole supplier. Zohydro ER with BeadTek is covered by four issued U.S. patents, which our subsidiary, Pemix Ireland Pain Limited ("PIPL") either owns or has rights to. Two of these patents expire November 1, 2019, one expires July 25, 2033 and a fourth expires September 12, 2034.

Silenor (doxepin)

Silenor is the only non-narcotic, non-scheduled and non-addictive 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 know 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 Pemix Sleep, Inc. (f/k/a Somaxon Pharmaceuticals, Inc.), or "Pemix 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 temazepam (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 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.

We promote Silenor in the United States through both of our nationwide specialty sales force, which covers approximately 200 territories. This sales force is also responsible for selling Treximet as well as Zohydro ER with BeadTek to specific customers. We market and sell Silenor through Paladin Labs (a division of Endo Pharmaceuticals plc) in Canada, and are currently working with CJ Healthcare Corporation which launched Silenor in South Korea in 2015. Silenor is covered by four issued U.S. patents, the latest expiring 2030, three of which are exclusively licensed from ProCom One, Inc. ("ProCom"). Four companies have filed abbreviated new drug applications (ANDAs) with the FDA seeking approval to market a generic version of Silenor, with an earliest potential generic entry date of 2020. 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. Mylan is our supplier of commercial product for distribution in the U.S. 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.

Khedeza (desvenlafaxine extended-release tablets)

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

Khedeza competes directly with Pristiq. In 2014, Pristiq had U.S. sales of approximately \$737 million. Khedeza also competes with other treatments for depression such as Effexor XR[®] (venlafaxine) (Pfizer), Cymbalta[®] (duloxetine) (Eli Lilly) and Lexapro[®] (escitalopram) (Forest). We believe that Khedeza is an economically attractive alternative to Pristiq that we can promote cost-effectively, with simple market positioning and favorable contracting with Managed Care companies.

We received the rights to Khedeza 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 Khedeza.

Externally Promoted and Non-Promoted Products

We market and sell our non-core products through contract sales arrangements with third-party organizations. 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 U.S. that compete with our Cedax line include Suprax®, Amoxicillin®, Omnicef®, Cefzil®, Ceclor® and Ceftin®. We believe that the manufacturing barrier related to Cedax and the fact that we market an authorized generic version of Cedax have so far provided barriers to generic entrants to the market. We also own a trademark on the name Cedax in the U.S.

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 possess) 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 Pemix 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. In May 2015, the FDA approved Treximet in adolescents aged 12 to 17.
- *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. We announced positive interim results from this study on November 12, 2015, and full study results are expected in the first quarter of 2016.
- *Silenor OTC.* We are evaluating an OTC formulation of Silenor.

For the years ended December 31, 2015, 2014 and 2013, we recorded \$8.2 million, \$3.9 million and \$4.8 million, respectively, in research and development expenses. For 2016 and beyond, we expect that our research and development expenses will increase from the expenses we recorded in year ended December 31, 2015, 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 Zohydro ER with BeadTek. 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 two sales forces; each of which consists of approximately 100 independent territories nationwide. Our teams of experienced sales professionals detail our products to physicians in specialties appropriate for each marketed product.

Our commercial activities include marketing, managed care contracting 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 Zohydro ER with BeadTek

On April 24, 2015, through our wholly-owned subsidiary, Pemix Ireland Pain Limited, we completed the acquisition of the pharmaceutical product line, Zohydro ER, including an abuse-deterrent pipeline and rights to all related intellectual property, a supplier contract and an associated liability payable and a specified quantity of inventory associated therewith, from Zogenix, Inc. ("Zogenix"). There were no other tangible or intangible assets acquired and liabilities assumed related to the Zohydro ER product line from Zogenix. The total purchase price consisted of an upfront cash payment of \$80.0 million including a deposit of \$10.0 million in an escrow fund, 1,682,086 shares of Common Stock of Pemix, \$927,000 for a specified quantity of inventory, and regulatory and commercial milestone payments of up to \$283.5 million, including a \$12.5 million milestone payment upon approval of ZX007 abuse-deterrent extended-release hydrocodone tablet and up to \$271.0 million in potential sales milestones if the Zohydro ER product line achieves certain agreed-upon net sales targets. We funded the cash portion of the purchase price from our issuance of \$130 million aggregate principal amount of convertible notes ("4.25% Convertible Notes").

Acquisition of Treximet

On August 20, 2014, we, through our 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.

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 was exercisable from the closing date (August 20, 2014) of the Agreement until February 28, 2018. In March 2015, an assignee of POZEN exercised the warrant on a cashless basis, resulting in the issuance of 315,835 shares of common stock to such assignee. 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. We were required to purchase 100% of our requirements of Treximet product from GSK until December 31, 2015. 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 have qualified 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.

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 and second notes in the amounts of \$4.85 million in September of 2014 and 2015, respectively.

Financing Activities

Convertible Notes:

4.25% Convertible Notes

On April 22, 2015, the Company issued \$130.0 million aggregate principal amount 4.25% Convertible Senior Notes (the "4.25% Convertible Notes"). The 4.25% Convertible Notes mature on April 1, 2021, unless earlier converted, redeemed or repurchased. The Company received net proceeds from the sale of the 4.25% Convertible Notes of \$125.0 million, after deducting placement agent fees and commissions and offering expenses payable by the Company. Interest on the 4.25% Convertible Notes is payable on April 1 and October 1 of each year, beginning October 1, 2015. See further discussion under the heading "Liquidity and Capital Resources" in Part II, Item 7 of this Annual Report on Form 10-K.

8.00% 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 ("8.00% Convertible Notes") 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. During the year ended December 31, 2015, the holders of the 8.00% Convertible Notes converted the outstanding notes at a conversion price of \$3.60 per share. We issued 18.1 million shares pursuant to this conversion and retired the \$65.0 million of the outstanding 8.00% Convertible Notes. See further discussion under the heading "Liquidity and Capital Resources" in Part II, Item 7 of this Annual Report on Form 10-K.

Secured Notes:

Treximet Secured Notes

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

The Treximet Secured 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 Secured 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 Secured Notes on such Payment Date). As of December 31, 2015, the aggregate principal amount of the Treximet Secured Notes was approximately \$210.0 million.

Credit Facilities:

Wells Fargo

On August 21, 2015, we entered into a Credit Agreement with Wells Fargo, National Association, as Administrative Agent and the lenders party thereto for a \$50.0 million, three-year senior secured revolving credit facility (the "Wells Fargo Credit Facility"), which may be increased by an additional \$20.0 million in the lenders' discretion.

Our obligations under the Wells Fargo Credit Facility are secured by, among other things, our and certain of our subsidiaries' inventory and accounts receivable, and are guaranteed by certain of our subsidiaries. As of December 31, 2015, \$15.0 million is outstanding under the Wells Fargo Credit Facility and classified as Credit facilities - long-term on the consolidated balance sheet. Borrowing availability under the Wells Fargo Credit Facility was \$15.3 million as of December 31, 2015. Availability of borrowings under the Wells Fargo Credit Facility from time to time is subject to a borrowing base calculation based upon a valuation of our eligible inventories and eligible accounts receivable, each multiplied by an applicable advance rate. Borrowings under the Wells Fargo Credit Facility will bear interest at our election at (i) the rate of LIBOR plus 1.5% to LIBOR plus 2.0% or (ii) the Base Rate (as defined in our Wells Fargo Credit Facility) plus 0.5% to the Base Rate plus 1.0%. The applicable interest rate margin percentage will be determined by the average daily availability of borrowings under the Wells Fargo Credit Facility. In addition, we are required to pay a commitment fee on the undrawn commitments under the Wells Fargo Credit Facility from time to time at an applicable rate of 0.25% per annum according to the average daily balance of

borrowings under the Wells Fargo Credit Facility during any month. The Wells Fargo Credit Facility contains representations and warranties, affirmative, restrictive and financial covenants, and events of default (applicable to us and certain of our subsidiaries) which are customary for credit facilities of this type.

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.

On August 21, 2015, we terminated the Amended and Restated Credit Agreement, dated as of May 8, 2013, as amended, by and among MidCap Funding IV, LLC, and certain subsidiaries of the Company and repaid all outstanding loans thereunder (the "MidCap Credit Facility").

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 launched Zohydro ER with BeadTek and re-launched Treximet, Silenor and Khedezla in the U.S. market, and we intend to expand upon and leverage our early commercial success. We have also launched Permex Prescriptions Direct™, a prescription processing service that provides benefit verification, prescription adjudication and mail order delivery of the prescription directly to the patient. We believe that our Permex Prescriptions Direct program offers patients and healthcare professionals improved convenience and health plan management that we believe will result in better compliance and reduced prescription abandonment among those participating in the program. 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, cannot 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.

Patents

We own or have rights to 24 issued U.S. patents and 24 pending U.S. Patent Applications relating to our products and technology. Further detail with respect to our patents pertaining to Treximet, Zohydro ER with BeadTek and Silenor are described below.

Our Treximet patent portfolio broadly covers the pharmaceutical formulation, including the proprietary combination of a 5-HT agonist (i.e. sumatriptan) and a long-acting NSAID (i.e. naproxen) and bilayer tablet formulation, as well as method of treatment and kit claims. The portfolio comprises five issued U.S. patents (U.S. patent nos. 6,060,499, 6,586,458, 7,322,183, 8,022,095, and 5,872,145), all of which are listed in the United States Food and Drug Administration's ("FDA's") *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") and all of which benefit from six months pediatric exclusivity. Four of the U.S. patents expire February 14, 2018, including six months pediatric exclusivity, and one expires April 2, 2026, including pediatric exclusivity. The adult and pediatric strengths have separate Orange Book listings. There are no pending applications in the U.S. All five patents are in-licensed from Pozen.

Zohydro ER with BeadTek is covered by three licensed issued U.S. patents and one patent owned solely by Pemix Ireland Pain Limited. An additional half dozen U.S. patent applications relating to Zohydro ER with BeadTek are pending. U.S. patent nos. 6,228,398 and 6,902,742, both of which expire on November 1, 2019 and both of which are in-licensed from Recro Gainseville, LLC, broadly cover the multiparticulate modified release composition and are listed in the Orange Book. U.S. patent no. 9,132,096, also in-licensed from Recro Gainseville, LLC and also Orange Book listed, is directed to the abuse deterrent technology (BeadTek) and expires September 12, 2034. Recently issued U.S. patent no. 9,265,760 is directed to a method of dosing patients with mild or moderate hepatic impairment where no adjustment in start dose is required relative to patients without hepatic impairment. U.S. patent no. 9,265,760 expires July 25, 2033 and is Orange Book listed. Further, we own or have rights to over a half dozen pending U.S. patent applications that related to Zohydro ER with BeadTek.

Silenor benefits from four issued U.S. patents, all of which are listed in the Orange Book and broadly cover methods of treating insomnia, with the latest expiring in 2030. U.S. patent no. 6,211,229 is broadly directed to the treatment of insomnia with doxepin and expires February 17, 2020. U.S. patent no. 7,915,307 is directed to method of providing sleep therapy by administering doxepin several hours after a meal and expires August 24, 2027. U.S. patent nos. 9,107,898 and 8,513,299, expiring May 1, 2028 and September 7, 2030, respectively, are directed to a method of treating sleep maintenance insomnia by administering doxepin to reduce fragmented sleep or early awakenings. Three of the issued U.S. patents will likely cover the proposed OTC version. Further, we own or have rights to eleven pending U.S. patent applications that relate to Silenor.

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; exclusivity has been extended until February 14, 2018 in light of the FDA's approval of a pediatric formulation of Treximet. 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.

In a license agreement dated August 2003 and amended and restated in September 2010, Pemix 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.

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 or have rights to approximately 25 trademarks registered with the United States Patent and Trademark Office, including PERNIX, SILENOR, TREXIMET, ZOHYDRO, ZOHYDRO ER, BEADTEK, KHEDEZLA, VITUZ, CEDAX, ZUTRIPRO, REZIRA, and many more. The trademark registrations we own or hold rights to include registrations covering our company name and product names, services, logos and slogans used for marketing of our products. In addition to our registered marks, we remain committed to branding our good will and continuously file new trademarks used to brand and market our products and services and currently have approximately six pending trademark registrations, including pending registrations to our Silenor logo and marketed slogan.

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 93%, 91% and 79% of gross product sales in 2015, 2014 and 2013, respectively, are all drug wholesalers. Each customer and its respective percentage of our gross product sales are listed by year below:

Gross Product Sales	<u>2015</u>	<u>2014</u>	<u>2013</u>
McKesson Corporation	38%	37%	35%
AmerisourceBergen Drug Corporation	27%	31%	20%
Cardinal Health, Inc.	<u>28%</u>	<u>23%</u>	<u>24%</u>
Total	<u><u>93%</u></u>	<u><u>91%</u></u>	<u><u>79%</u></u>

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.

Reimbursement

In the U.S. 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 ("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, psychiatry, 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, Depomed, Purdue Pharma, Pfizer 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 U.S. 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 U.S. 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 U.S., 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 U.S., (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.

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.

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 U.S. 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.

Regulation of Controlled Substances

We, our third party manufacturers and certain of our products including Zohydro ER with BeadTek, 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. All of our products containing hydrocodone, including Zohydro ER, Zutripro, Rezira and Vituz are 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 U.S. 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 U.S. 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 U.S. 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 health 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, 2015, we had 274 full-time employees, including a field sales force that covers 200 territories nationwide. We have 66 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.

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.

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 Zohydro ER product line in 2015, the rights to Treximet intellectual property in 2014, Pernix Sleep in 2013 and Cypress in 2012. As part of our ongoing expansion strategy, we plan to make additional strategic acquisitions of assets and businesses. However, our credit agreement with Wells Fargo and the indentures governing our outstanding notes contain 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, among other things. In addition to these restrictive covenants our credit agreement with Wells Fargo contains certain financial covenants. For additional information see the notes to our audited consolidated financial statements for the years ended December 31, 2015, 2014 and 2013 contained in Part II, Item 8 of this Annual Report on Form 10-K. 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 Wells Fargo 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 Pemix 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 Pemix 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, the rights to Treximet intellectual property and the Zohydro product line 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, 2015, after giving effect to our issuance of an aggregate of \$130.0 million of 4.25% Convertible Notes, our outstanding Wells Fargo Credit Facility of \$15.0 million and an aggregate of \$210.0 million of Treximet Secured Notes in August 2014, we had approximately \$328.8 million of debt outstanding and the ability to borrow approximately \$15.3 million under our credit agreement with Wells Fargo, 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 Wells Fargo 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 Wells Fargo 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 Wells Fargo 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 waiver and a number of qualifications and exceptions and, under certain circumstances, debt incurred following receipt of a waiver or 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 Wells Fargo 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 Wells Fargo 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 Wells Fargo 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 the Treximet Secured Notes require us to maintain a minimum liquidity of \$8.0 million at all times.

Upon the occurrence of a fundamental change, as described in the indenture governing the 4.25% Convertible Notes, holders of the 4.25% Convertible Notes may require us to repurchase for cash all or part of their 4.25% Convertible Notes at a repurchase price equal to 100% of the principal amount of the 4.25% Convertible Notes to be repurchased, plus accrued and unpaid interest. If a holder elects to convert its 4.25% Convertible Notes for shares in excess of the conversion cap, as described in the indenture governing the 4.25% Convertible Notes, 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 4.25% Convertible Notes surrendered therefor in connection with a fundamental change or payments of cash on 4.25% Convertible Notes converted in excess of the conversion cap. In addition, our ability to repurchase the 4.25% Convertible Notes or to pay cash upon conversions of the 4.25% Convertible Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the 4.25% Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 4.25% Convertible Notes as required by the indenture would constitute a default under the indenture. A default under the indenture could also lead to a default under agreements governing our other outstanding 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 4.25% Convertible Notes or make cash payments upon conversions as required by the indenture.

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 Wells Fargo 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 Wells Fargo.

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 April 2015 acquisition of Zohydro ER and the 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 Zohydro ER in April 2015 and 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 and existing 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. We have also experienced, and expect to continue to experience, turnover of some of our sales representatives that we hired or will hire, requiring us to train new sales representatives. The members of our sales force may have no prior experience promoting the pharmaceutical products that we own or may acquire in the future. As a result, we 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. If we are unable to effectively train our sales force and equip them with effective materials relating to our pharmaceutical products, 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 four 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, 2015, our sales force consisted of approximately 200 sales territories. In August 2015, we entered into an agreement with Poly Pharmaceuticals, Inc. for services related to the promotion of Cedax and its authorized generic.

We 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. 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 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 Zohydro ER with BeadTek, 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 Zohydro, 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.

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, 2015, McKesson Corporation, Cardinal Health and AmerisourceBergen Drug Corporation accounted for 38%, 28% and 27%, respectively, of our total gross sales. For the year ended December 31, 2014, McKesson Corporation, AmerisourceBergen Drug Corporation and Cardinal Health accounted for 37%, 31% and 23%, respectively, of our total gross sales. For the year ended December 31, 2013, McKesson Corporation, AmerisourceBergen Drug Corporation and Cardinal Health accounted for 35%, 20% and 24%, respectively, 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 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, 2015, GSK has claimed aggregate damages of approximately \$32.0 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. We have an escrow of \$5.7 million against potential liability in this suit. 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 22, *Commitments and Contingencies*, to our consolidated financial statements included in this 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, trademarks, trade secrets 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. 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, including a transition from a first to invent to a first inventor to file system. 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 invent or file patent applications to the inventions claimed in our or their issued patents or pending 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 at the United States Patent and Trademark Office. The specific type of proceeding will be determined by the filing date of the application for patent. If the application for patent was filed prior to March 15, 2013, such a proceeding would be an interference proceeding. For all applications filed after March 15, 2013, such a proceeding would be a derivation proceeding. 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.

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, trade secrets 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 15c-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, 2015, 2014 and 2013. 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 Wells Fargo 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.

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 Zohydro and Treximet may not be an indication of our ability to commercialize Zohydro and or Treximet.

In May 2015 and August 2014, we completed the acquisition of Zohydro and the intellectual property rights to Treximet in the United States from GSK, respectively. We filed historical financial statements and pro forma financial information relating to these products and the SEC stated that it would not object to our conclusion that the filing of the historical financial statements relating to Zohydro and 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 Zogenix and GSK that the Zohydro and Treximet product lines, respectively, had not been a separate legal entity of Zogenix and GSK and was never operated as a stand-alone business, division or subsidiary. Zogenix and GSK also advised us that they had never prepared full stand-alone or full carve-out financial statements for either business, and that Zogenix and GSK have 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 either product 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 product lines, in particular on a go-forward basis, and therefore should not be relied upon as a measure of our ability to commercialize these products.

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 Pemix 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 promoted products are generally well 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 anti-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 antitrust 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

None.

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 original lease expired July 2020 and our lease payment was approximately \$15,000 per month, which is subject to certain annual escalators. In January 2015, we amended our lease to add 9,562 square feet of office space for a total of 15,990 square feet for approximately \$40,000 per month, which is subject to certain annual escalators and extend the original term of the lease to expire July 31, 2022.

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 is approximately \$7,000 per month, which is subject to certain annual escalators. Due to the restructuring and relocation of the accounting department from Mount Pleasant to our corporate headquarters in Morristown, New Jersey we have subleased this office space to a third party for substantially the same lease payments and terms as our original lease.

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

GlaxoSmithKline Arbitration

In December 2014, GlaxoSmithKline asserted a claim against Pernix for damages arising from an alleged breach by Pernix of Section 8.15 of the Asset Purchase Agreement between the parties. GSK has alleged approximately \$32 million of additional damages. Pernix has asserted a setoff under the Asset Purchase Agreement, as well as its own claims for GSK's alleged breach of a Supply Agreement between the parties, amounting to in excess of \$50 million. Pernix and GSK have entered into an Interim Settlement Agreement under which Pernix has paid GSK an amount equal to 35.7% and deposited into an escrow account an additional 21.4% of the amount GSK claims are owed as rebates on Caremark business. On August 24, 2015, the parties submitted this matter to binding arbitration before the International Chamber of Commerce International Court of Arbitration. Discovery in the matter has begun and hearings are scheduled for April and August 2016. A decision in the arbitration is expected in September or October 2016.

Recro Gainseville LLC v. Actavis Laboratories FL, Inc., District of Delaware Case Nos. 14-1118, 15-413, and 15-1196; *Recro Gainseville LLC v. Alvogen Malta Operations Ltd.*, District of Delaware Case No. 14-1364

Recro is the owner of U.S. Patent Nos. 6,228,398 ("the '398 Patent") and 6,902,742 ("the '742 Patent"), both of which expire on November 1, 2019, and U.S. Patent No. 9,132,096 ("the '096 Patent"), which expires on September 12, 2034. All three patents (collectively, "the Orange Book Patents") are listed in the United States Food and Drug Administration's ("FDA's") *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering Zohydro ER. Actavis and Alvogen each filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval of proposed generic versions of Zohydro ER in 10, 15, 20, 30, 40, and 50 mg dosage strengths. Those ANDAs and amendments thereto contained certifications asserting that the Orange Book Patents are invalid and not infringed. Pursuant to the Hatch-Waxman Act, Recro brought suit against Actavis on September 3, 2014 and May 21, 2015 for declaratory judgment of infringement of the '398 and '742 Patents, and on December 23, 2015 for declaratory judgment of infringement of the '096 Patent. In response, Actavis filed counterclaims seeking declaratory judgments of noninfringement and invalidity of all three Orange Book Patents. Pursuant to the Hatch-Waxman Act, Recro brought suit against Alvogen on November 3, 2014 for declaratory judgment of infringement of the '398 and '742 Patents. In response, Alvogen filed counterclaims seeking declaratory judgments of noninfringement and invalidity of those two patents. All of these related cases are pending in the United States District Court for the District of Delaware, where they are currently in the fact discovery stage. We continue to monitor the cases closely. Trial is currently scheduled to begin on October 3, 2016.

Pernix Ireland Pain, Ltd. and Pernix Therapeutics, LLC v. Actavis Laboratories FL, Inc., District of Delaware Case No. 16-138; *Pernix Ireland Pain, Ltd. and Pernix Therapeutics, LLC v. Alvogen Malta Operations, Ltd.*, District of Delaware Case No. 16-139.

Pernix Ireland Pain, Ltd. is the owner of U.S. Patent No. 9,265,760 ("the '760 Patent"), which issued on February 23, 2016 and expires on July 25, 2033, and which is listed in the Orange Book as covering Zohydro® ER. Pernix Therapeutics, LLC ("Pernix") is the exclusive licensee of the '760 Patent and is the sole distributor of Zohydro® ER in the United States. As discussed above, Actavis and Alvogen ("Defendants") each filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval of proposed generic versions of Zohydro® ER in 10, 15, 20, 30, 40, and 50 mg dosage strengths, and litigation regarding those ANDAs is ongoing in the District of Delaware. Pernix brought suit against Defendants in the District of Delaware on March 4, 2016, seeking declaratory judgment of infringement of the '760 Patent. The complaints in those matters were served on March 7, 2016, and Defendants' respective answers are due on March 28, 2016.

U.S. ex. Rel. Conrad v. Abbott Labs, Inc., et al. (U.S.D.C. Mass.)

On December 21, 2009, Cypress Pharmaceuticals and its wholly owned subsidiary Hawthorn Pharmaceuticals were served with a partially sealed *qui tam* complaint in *U.S. ex. rel. Conrad v. Abbott Labs, Inc., et al.*, filed in the United States District Court for the District of Massachusetts. The complaint alleged violations of the False Claims Act by more than 20 pharmaceutical manufacturers, claiming that each had made false submissions to CMS and/or the FDA which asserted that certain of their products were covered outpatient drugs and eligible for Medicaid program reimbursement when those products were actually either unapproved drugs, over the counter medications, or nutritional supplements not eligible for reimbursement. The government did not intervene with respect to the claims brought against either Cypress or Hawthorn. The complaint alleged single damages against Cypress and Hawthorn in excess of \$71 million. On February 29, 2012, the plaintiffs voluntarily dismissed their claims with respect to four products in response to Cypress and Hawthorn's individual motion to dismiss. On February 26, 2013, the Court granted the defendants' joint motion to dismiss the case in its entirety on the grounds that the Court had no jurisdiction to hear the matter due to the application of the public disclosure bar. The joint defense team continues to wait for the plaintiff to make a motion in order to help determine the next steps. While the complaint alleges \$71 million in damages, we believe the likelihood of success on the merits is extremely low as evidenced by the most recent decision by the Court to grant the defendants' motion to dismiss.

State of Louisiana v. Abbott Laboratories, Inc., et al (U.S.D.C., M.D. La.)

On September 23, 2013, Pernix was served as a defendant (along with its subsidiaries, Cypress and Hawthorn and its predecessor-in-interest, Zyber Pharmaceuticals) in this suit by the State of Louisiana against over 50 defendants with similar allegations to those made by Conrad in the suit described in No. 1 above but with respect to Louisiana state law regarding false submissions of unapproved drugs. Just as in No. 1 above, Pernix and its affiliated defendants joined a Joint Defense Team with the other defendants in this case to minimize defense costs. On September 21, 2015, the trial court granted the joint defendants' Exception of No Right of Action dismissing the State of Louisiana as plaintiff in the case. The State has appealed this ruling and a decision is not expected until March or April 2016. The Louisiana Department of Health and Hospitals ("DHH") is now deemed to be the proper party plaintiff and can file the same suit. That suit, if filed, will be subject to a prescription argument (statute of limitations) which may possibly eliminate several of the pending claims. The same prescription argument was not available to the joint defendants as long as the State was the plaintiff. While the judge has ordered discovery in this case, no significant discovery has taken place since the decision in September 2015.

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, Pemix 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. Pemix's common stock is listed on the NASDAQ Global Market under the symbol "PTX." The following table sets forth, for the periods indicated, the high and low closing sales prices for our common stock, as reported on the NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
2014		
First Quarter	\$ 5.93	\$ 2.09
Second Quarter	9.17	4.24
Third Quarter	9.23	6.63
Fourth Quarter	11.35	7.17
2015		
First Quarter	\$ 11.89	\$ 7.64
Second Quarter	10.58	5.30
Third Quarter	6.19	2.99
Fourth Quarter	4.06	2.43

Holdings

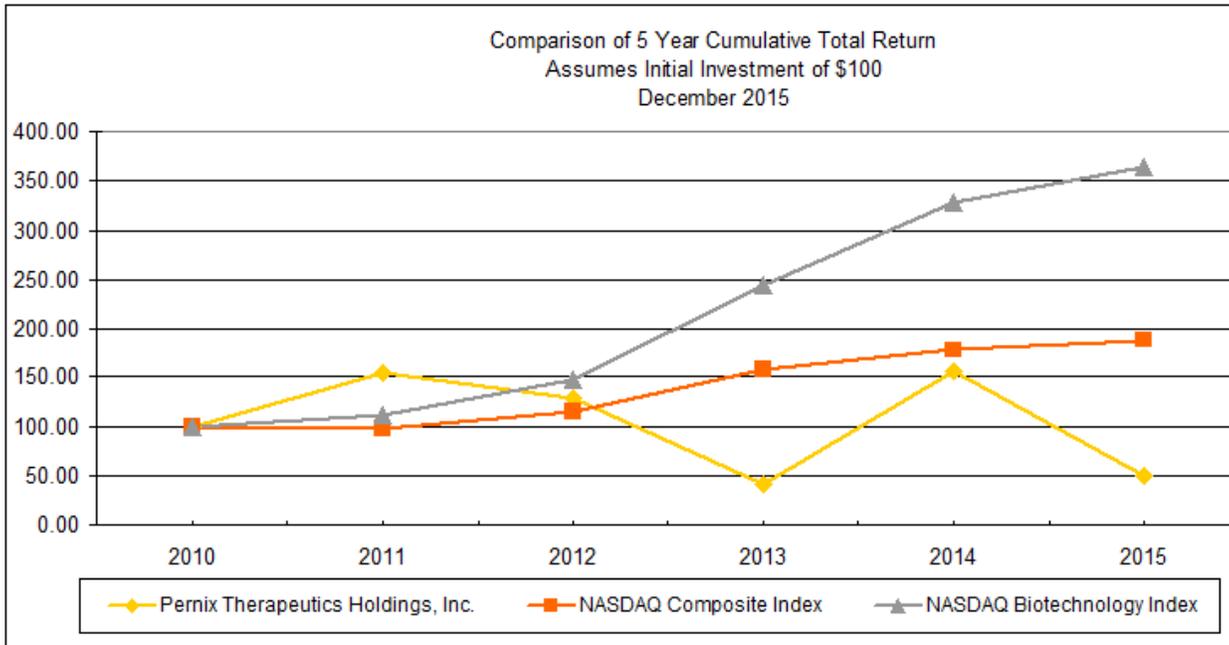
As of March 3, 2016, there were approximately 111 holders of record of our common stock.

Dividends

We have not declared or paid any cash dividends for the years ended December 31, 2015, 2014 and 2013. We intend to retain any future earnings to finance growth and development and therefore do not anticipate paying cash dividends in the foreseeable future.

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, 2010.



Issuer Repurchases of Equity Securities

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, 2015, \$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. We did not repurchase any of our shares of common stock during the fourth quarter of 2015.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 11 for information regarding securities authorized for issuance under our equity compensation plans. Such information is incorporated by reference to our definitive proxy statement pursuant to Regulation 14A, which we intend to file with the SEC not later than 120 days after the close of our year ended December 31, 2015.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2015, 2014 and 2013 and at December 31, 2015 and 2014 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in the Annual Report on Form 10-K. The selected financial data for the years ended December 31, 2012 and 2011 and as of December 31, 2013, 2012 and 2011 are derived from our audited financial statements not included in this Annual Report on Form 10-K.

Consolidated Statements of Operations Data:

(in thousands, except per share amounts)	Years Ended December 31,				
	2015 (1,2,3,4,5)	2014 (2,3,4,5,6)	2013 (3,4,5,6)	2012 (4,5,6)	2011 (6)
Net revenues	\$ 175,850	\$ 121,747	\$ 84,872	\$ 61,313	\$ 60,606
Costs and operating expenses:					
Cost of product sales	51,408	45,156	43,870	23,377	20,921
Selling, general and administrative expenses	97,421	62,967	62,551	35,452	22,158
Research and development expenses	8,229	3,938	4,798	732	922
Loss from operations of the joint venture	-	-	-	240	814
Loss from disposal of assets, impairments of intangibles	24,352	242	19,638	-	380
Loss on sale of PML (including impairment charge)	-	6,659	-	-	-
Depreciation and amortization expense	94,695	32,999	8,676	3,201	2,303
Change in fair value of contingent consideration	(138)	-	(805)	-	-
Restructuring costs	1,137	-	-	-	-
Total costs and operating expenses	<u>277,104</u>	<u>151,961</u>	<u>138,728</u>	<u>63,002</u>	<u>47,498</u>
(Loss) income from operations	(101,254)	(30,214)	(53,856)	(1,689)	13,108
Other (expense) income	<u>(39,999)</u>	<u>(18,797)</u>	<u>7,464</u>	<u>(95)</u>	<u>(171)</u>
(Loss) income before income taxes	(141,253)	(49,011)	(46,392)	(1,784)	12,937
Income tax expense (benefit)	<u>7,062</u>	<u>(13,725)</u>	<u>(20,757)</u>	<u>(374)</u>	<u>4,589</u>
Net (loss) income	<u>\$ (148,315)</u>	<u>\$ (35,286)</u>	<u>\$ (25,635)</u>	<u>\$ (1,410)</u>	<u>\$ 8,348</u>
Net (loss) income per common and potential common share					
Basic	\$ (2.78)	\$ (0.93)	\$ (0.70)	\$ (0.05)	\$ 0.35
Diluted	\$ (2.78)	\$ (0.93)	\$ (0.70)	\$ (0.05)	\$ 0.34

Consolidated Balance Sheet Data:

(in thousands)	Years Ended December 31,				
	2015 (1,2,3,4,5)	2014 (2,3,4,5)	2013 (3,4,5)	2012 (4,5)	2011
Cash and cash equivalents	\$ 56,135	\$ 34,855	\$ 15,647	\$ 23,023	\$ 34,551
Working capital	23,247	31,580	6,917	41,768	36,630
Total assets	511,158	487,413	211,386	251,447	82,564
Debt (current and non-current)	328,793	292,345	18,310	43,636	6,000
Accumulated (deficit) earnings	(188,803)	(40,488)	(5,202)	20,433	21,843
Stockholder's equity	33,097	83,592	110,722	78,539	49,624

1. On April 24, 2015, we completed the acquisition of the pharmaceutical product line, Zohydro ER®. The results of operations have been included in our consolidated financial statements since the acquisition date.
2. 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.
3. On March 6, 2013, we acquired all of the outstanding common stock of Permex 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.
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.
6. Certain reclassifications have been made to prior period amounts in our consolidated statements of operations to conform to the current period presentation. These reclassifications related to the classification of shipping costs and FDA fees which are now included in cost of goods sold instead of selling costs. In addition, the change in fair value of contingent consideration was reclassified to operating expenses from other income (expense). 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.

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements by terminology such as "anticipate," "believe," "could," "continue," "estimate," "expect," "intend," "may," "plan," "potential," "project," "predict," "should," "target," "will," "would," "anticipate," "expect" or the negative of these terms or other words if similar import, although some forward-looking statements are expressed differently. All statements other than statements of historical fact included in this Annual Report on Form 10-K regarding our financial position, business strategy and plans or objective for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding 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, pain 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 co-promotion arrangements with established third-party 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, Zohydro ER with BeadTek, an extended-release opioid agonist indicated for the management of pain, Silenor, a non-controlled substance and approved medication indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. During the third quarter of 2015, we engaged a contract sales team to promote Cedax, an antibiotic for middle ear infections. The term of this agreement covers the cough and cold season and can be renewed each year. We also sell 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 2015:

- During March 2015, through our wholly-owned subsidiary Pernix Ireland Pain Limited (f/k/a Ferrimill Limited), we entered into an asset purchase agreement, with Zogenix, pursuant to which we acquired certain assets related to the product Zohydro ER from Zogenix, including, among other things, the registered patents and trademarks, certain contracts, the new drug application and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER (collectively, the "Purchased Assets"). Upon closing of this transaction on April 24, 2015, we paid Zogenix \$70.0 million in cash, deposited \$10.0 million in escrow to fund potential indemnification claims for a period of 12 months following the closing and issued approximately 1.7 million shares of our common stock, with an approximate value of \$20.0 million, based on the closing price of \$11.89 on March 9, 2015, the trading day immediately preceding the execution date of the Asset Purchase Agreement. We recorded measurement period adjustments subsequent to the purchase date and recorded them during the year ended December 31, 2015. The measurement period adjustments consisted of an additional \$31.4 million allocated to developed technologies, an additional liability of \$2.9 million for a supplier contract, and an increase in goodwill of \$6.9 million. We also reduced the allocation to in-process research and development by \$50.4 million and the fair value of contingent consideration by \$15.1 million. See Note 4, *Business Combination and Other Acquisitions*, for additional information.
- On March 16, 2015, we decided to institute an initiative to restructure operations and shut down the Charleston, South Carolina site. This step was done to consolidate operations within the Company's headquarters located in Morristown, New Jersey.
- On April 22, 2015, we sold a private offering of \$130.0 million aggregate principal amount of our 4.25% Convertible Debt due 2021. The notes are general unsecured obligations. The interest will be paid on the notes semi-annually at a rate of 4.25% per annum and will mature on April 1, 2021, unless redeemed, repurchased or converted in accordance with their terms prior to such date. The notes have an initial conversion rate, subject to adjustment, of 87.2030 shares of our common stock per \$1,000 principal amount of the notes, representing a conversion price of approximately \$11.47 per share of our common stock, based on the last reported sale price of \$8.34 per share of our common stock on April 16, 2015.

The gross proceeds from the offering were \$130.0 million. We used approximately \$80.9 million of the gross proceeds from the offering to finance the cash consideration portion of the consideration necessary to consummate its previously announced acquisition of the Zohydro ER franchise, and used approximately \$8.3 million to pay fees and expenses related to such acquisition and the offering, \$2.2 million to pay the consent fee related to our consent solicitation of our 12.00% Treximet senior secured notes due 2020 and the remainder for working capital and other general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products, services and technologies.

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

Results of Operations

The following table summarizes selected operating statement data for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Net revenues	\$ 175,850	\$ 121,747	\$ 84,872
Operating expenses			
Cost of product sales	51,408	47,965	43,870
Selling, general and administrative expense	97,421	60,158	62,551
Research and development expense	8,229	3,938	4,798
Loss from disposal of assets, impairments of intangibles	24,352	242	19,638
Loss on sale of PML (including impairment charge)	-	6,659	-
Depreciation and amortization expense	94,695	32,999	8,676
Change in fair value of contingent consideration	(138)	-	(805)
Restructuring costs	1,137	-	-
Other income (expense):			
Interest income	157	353	134
Change in fair value of put right	-	-	(8,361)
Gain on contingent consideration and put right	-	-	16,269
Gain on sale of investment	-	-	3,605
Cost of inducement	(19,500)	-	-
Loss on extinguishment of debt	(1,112)	-	-
Foreign currency transaction loss	(582)	-	-
Change in fair value of derivative liability	19,315	-	-
Interest expense	(38,277)	(19,150)	(4,183)
Income tax expense (benefit)	7,062	(13,725)	(20,757)

Comparison of the Year Ended December 31, 2015 and 2014

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, services fees, and 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, 2015, 2014 and 2013 (in thousands):

	Year ended December 31,		
	2015	2014	2013
Treximet	\$ 101,753	\$ 54,775	\$ -
Silenor	20,913	15,302	7,774
Zohydro	16,545	-	-
Other	<u>32,047</u>	<u>47,929</u>	<u>69,758</u>
Net product sales	171,258	118,006	77,532
Manufacturing revenue	-	1,025	3,011
Co-promotion and other revenue	<u>4,592</u>	<u>2,716</u>	<u>4,329</u>
Total net revenues	<u>\$ 175,850</u>	<u>\$ 121,747</u>	<u>\$ 84,872</u>

Net product sales - Treximet increased by \$47.0 million, or 86% during the year ended December 31, 2015 compared to the year ended December 31, 2014, as Treximet was acquired in August 2014, with the first sale occurring on September 2, 2014. The Zohydro franchise was acquired in April 2015 and we launched Zohydro ER with BeadTek on May 4, 2015. Net product sales of Silenor increased by \$5.6 million, or 37%, during the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase in sales of Silenor was primarily driven by a 58% increase in sales volume and the focused selling and marketing strategy implemented to create more market awareness and grow sales. The increase in Silenor was partially offset by higher managed care rebates paid. Net product sales - other decreased by \$15.9 million, or 33%, during the year ended December 31, 2015 compared to the year ended December 31, 2014. Declining net product sales - other was due to (i) the discontinuation of certain less profitable products, primarily generics, and certain OTC monograph seasonal cough and cold products and (ii) the termination of certain contracts pursuant to which we marketed and distributed products for others and invoiced those sales. The decrease in net product sales - other was partially offset by price increases on certain products. Manufacturing revenue decreased by \$1.0 million during the year ended December 31, 2015 compared to the year ended December 31, 2014, as we sold our manufacturing subsidiary, PML, in April 2014. Co-promotion and other revenue increased by \$1.9 million during the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase in co-promotion and other revenue was primarily attributable to the termination of the co-promotion agreement with one of our partners.

Cost of Product Sales

Cost of product sales increased by \$3.4 million, or 7%, during the year ended December 31, 2015, compared to the year ended December 31, 2014. The increase was primarily driven by an increase in royalty and collaboration expense of \$6.8 million and an increase of \$2.9 million in product costs related to higher sales volumes in 2015. The increases were partially offset by a decrease of \$3.7 million for write-offs of obsolete and slow moving inventory due to improved inventory management and a \$2.5 million expense recorded in 2014 for the acquisition cost basis of Cypress and Somaxon inventory which did not reoccur in 2015. We expect cost of product sales to increase in 2016 over 2015, primarily due to expected growth in the sales of Treximet, Zohydro and Silenor, which will result in an increase in royalty expense as well as the costs of the Treximet, Zohydro and Silenor products.

Selling, General and Administrative Expense

Selling, general and administrative ("SG&A") expense increased by \$37.3 million, or 62%, during the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase was driven by an increase in selling and marketing costs of \$21.2 million and \$11.2 million, respectively, primarily focused on our Silenor, Treximet and newly acquired Zohydro ER with BeadTek products. We also realized increases in deal costs, professional fees, consulting, legal fees as well as increased compensation costs of our expanded sales team. These increases were partially offset by a decrease in litigation settlements and reserves.

Research and Development Expense

Research and Development ("R&D") expense increased by \$4.3 million, or 109%, during the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily due to the on-going work for new formulations of Treximet and Zohydro.

Loss from Disposal of Assets, Impairments of Intangibles

Loss from disposal of assets, impairments of intangibles was \$24.4 million for the year ended December 31, 2015 compared to \$242,000 for the year ended December 31, 2014. The increase was attributable to our initiative launched in 2015 to focus on our primary branded products, Treximet, Zohydro, Silenor and Khedezla and discontinue the promotion of our non-core products.

Depreciation and Amortization Expense

Depreciation and amortization expense increased by \$61.7 million, or 187%, during the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase was primarily as a result of an increase of \$46.3 million of amortization related to the Treximet developed technologies acquired in 2014 and an increase of \$14.7 million for Zohydro ER with BeadTek which was acquired in 2015.

Change in Fair Value of Contingent Consideration

In April 2015 with the acquisition of Zohydro ER, we recorded \$29.3 million of contingent consideration. The acquisition date fair value of the contingent consideration linked to FDA approval was \$10.3 million and the fair value of the contingent consideration linked to achievement of the net sales target was \$19.0 million. During the year ended December 31, 2015, we recorded measurement period adjustments of \$15.1 million, which adjusted the carrying value to \$14.2 million. The adjusted values of the contingent consideration linked to FDA approval and net sales targets were \$2.7 million and \$11.5 million, respectively. As of December 31, 2015, the current fair value of the contingent consideration is approximately \$14.1 million. We recorded \$138,000 as change in fair value of contingent consideration in the year ended December 31, 2015. For further discussion, see Note 4, *Business Combinations and Other Acquisitions*, to our consolidated financial statements included in this Annual Report on Form 10-K.

Restructuring Costs

Restructuring costs were \$1.1 million during the year ended December 31, 2015. The increase is due to the costs related to the initiative to restructure operations and shut down the Charleston, South Carolina site.

Cost of Inducement

In April 2015, we entered into the Inducement Agreement with all of the holders of the 8.00% Convertible Notes, pursuant to which such holders agreed to the removal of substantially all of the material restrictive covenants in the indenture governing the notes and to convert their notes in accordance with the provisions of such indenture in exchange for an aggregate of 2,338,129 shares of our common stock. We recorded \$19.5 million as cost of inducement expense in the year ended December 31, 2015. 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.

Loss on Extinguishment of Debt

During the year ended December 31, 2015, we terminated the MidCap Credit Facility and recorded a \$1.1 million loss on extinguishment of debt for the deferred financing costs that had been capitalized at the time of acquisition of this debt.

Change in Fair Value of Derivative Liability

We recorded a benefit of \$19.3 million for the change in fair value of derivative liability in other expense, net in the year ended December 31, 2015. 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.

Interest Expense

Interest expense increased \$19.1 million, or 100%, during the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase was primarily driven by an increase in interest expense of \$16.1 million related to our Treximet Secured Notes, issued in August 2014 and an increase of \$6.1 million related to our 4.25% Convertible Notes, issued in April 2015. The increase in interest expense was partially offset by a decrease in interest expense of \$2.9 million related to the April 2015 retirement of the 8.00% Convertible Notes.

Income Tax Provision

During 2015, we recognized an income tax expense of \$7.1 million. Our 2015 effective rate from continuing operations was (5.0%). This tax expense included a current income tax provision of approximately \$7.6 million and a deferred tax benefit of approximately \$576,000. 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. The change in the 2015 effective tax rate relates mainly to the tax effect of permanent difference on our pre-tax loss and income tax expense related to uncertain tax position. The 2014 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.

Comparison of the Year Ended December 31, 2014 and 2013

Net Revenues

Net revenues increased \$36.9 million, or 43% for the year ended December 31, 2014, compared to the year ended December 31, 2013. Sales of 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. Sales of Silenor increased by \$7.5 million, or 97%, 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 \$4.1 million, or 9%, 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 also partially due certain reclassifications of costs from selling, general and administrative expenses to cost of goods sold as discussed in Note 1. *Organization and Nature of Business*, of \$2.8 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.

Selling, General and Administrative Expense

Selling, general and administrative expenses decreased by \$2.4 million, or 4%, during the year ended December 31, 2014 compared to the year ended December 31, 2013. The decrease was driven primarily by certain reclassifications of costs from selling, general and administrative expenses to cost of goods sold as discussed in Note 1. *Organization and Nature of Business*, of \$2.8 million. Also, there were decreases in litigation settlements and reserves of \$7.2 million, and the effect of the cancellation of the ParaPRO, LLC stock options of previously recognized stock compensation expense of \$1.7 million. These decreases were partially offset 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 and coupon program administrative fees.

Research and Development Expense

Research and Development 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 Pemix Manufacturing and its related fixed assets in April 2014.

Interest Expense

Interest expense increased \$15.0 million 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 Treximet Secured Notes, issued in August 2014 and 8.00% Convertible Notes, issued in February 2014, of \$9.8 million and \$4.5 million, respectively.

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.

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: adjusted earnings before interest, taxes, depreciation and amortization ("EBITDA"). 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 are as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
GAAP net loss	\$ (148,315)	\$ (35,286)	\$ (25,635)
Adjustments:			
Interest expense, net	38,120	18,797	4,049
Depreciation and amortization	94,695	32,999	8,676
Income tax expense (benefit)	7,062	(13,725)	(20,757)
EBITDA	<u>(8,438)</u>	<u>2,785</u>	<u>(33,667)</u>
Net revenue adjustments (1)	303	1,257	-
Cost of product sales adjustments (2)	97	2,617	6,359
Selling, general and administrative adjustments (3)	11,518	9,118	14,288
Research and development adjustments (4)	500	1,168	-
Cost of inducement	19,500	-	-
Change in fair value of contingent consideration	(138)	-	(805)
Change in fair value of derivative liability	(19,315)	-	-
Loss from disposal of assets, impairments of intangibles	24,352	242	19,638
Foreign currency transaction loss	582	-	-
Loss on extinguishment of debt	1,112	-	-
(Gain) loss on sale of PML (including impairment charge)	-	6,659	-
Restructuring costs (5)	1,137	-	-
Change in fair value of put right	-	-	8,361
Gain on contingent consideration and put right	-	-	(16,269)
Gain on sale of investment	-	-	(3,605)
Adjusted EBITDA	<u>\$ 31,210</u>	<u>\$ 23,846</u>	<u>\$ (5,700)</u>

(1) To exclude impact on returns from FDA reclass of Hydrocodone products from C3 to C2 classification of \$303,000 for the year ended December 31, 2015. To exclude one-time contract termination fee of \$700,000 and impact on returns from FDA reclass of Hydrocodone products from C3 to C2 classification of \$557,000 for the year ended December 31, 2014.

(2) To exclude amortization of inventory step-up from acquisitions.

(3) To exclude deal expenses of \$4.3 million, \$1.0 million, and \$1.4 million; stock compensation expense of \$5.3 million, \$4.7 million and \$2.0 million; stock compensation - ParaPRO of \$0, (\$1.2 million) and \$548,000; severance expense of \$0, \$1.1 million and \$540,000 and non-recurring litigation settlement expense of \$1.9 million, \$3.5 million and \$9.8 million for the years ended December 31, 2015, 2014 and 2013, respectively.

- (4) To exclude expense associated with contractual milestone assumed as part of the Zohydro ER acquisition for the twelve months ended December 31, 2015. To exclude expense associated with the Treximet sNDA of \$1.2 million for the year ended December 31, 2014.
- (5) To exclude expense related to the initiative to restructure operations and shut down the Charleston, South Carolina site.

Liquidity and Capital Resources

The following table summarizes selected financial data (amounts in thousands):

	December 31,	
	2015	2014
Cash and cash equivalents	\$ 56,135	\$ 34,855
Total current assets	157,399	129,257
Current debt	15,044	7,345
Non-current debt	313,749	285,000
Stockholders' equity	\$ 33,097	\$ 83,592

During August 2015, we entered into a Credit Agreement with Wells Fargo, National Association, as Administrative Agent and the lenders party thereto for a \$50.0 million, three-year senior secured revolving credit facility (the "Wells Fargo Credit Facility"), which may be increased by an additional \$20.0 million in the lenders' discretion. Our debt included \$210.0 million aggregate principal amount of our 12.0% Treximet Secured Notes issued August 19, 2014 and due August 1, 2020 ("Treximet Secured Notes") and \$130.0 million aggregate principal amount of our 4.25% Convertible Notes, issued April 22, 2015 and due April 1, 2021, ("4.25% Convertible Notes") unless earlier converted.

During 2015 and 2013 we utilized cash from operations of (\$14.7) million and (\$6.5) million, respectively. During 2014 we generated cash flows from operations of \$8.9 million. On April 24, 2015, we, through our wholly owned subsidiary Pemix Ireland Pain Limited ("PIPL"), formerly known as Ferrimill Limited, completed the acquisition of the pharmaceutical product line, Zohydro ER, including an abuse-deterrent pipeline and all related intellectual property, a favorable supplier contract and an associated liability payable, and a specified quantity of inventory associated therewith, from Zogenix, Inc. ("Zogenix"). There were no other tangible or intangible assets acquired and liabilities assumed related to the Zohydro ER product line from Zogenix. The total purchase price consisted of an upfront cash payment of \$80.0 million including a deposit of \$10.0 million in an escrow fund, stock consideration of \$11.9 million issued in common stock of Pemix, \$927,000 for specified quantity of inventory, and regulatory and commercial milestones of up to \$283.5 million including a \$12.5 million milestone payment upon approval of ZX007 abuse-deterrent extended-release hydrocodone tablet and up to \$271.0 million in potential sales milestones if the Zohydro ER product line achieves certain agreed-upon net sales targets.

We have an effective 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.

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 invest 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 2016 are expenses in connection with our selling and marketing of Treximet, Zohydro ER with BeadTek, and Silenor brands. As of March 3, 2016, we believe that our existing cash balance, cash from operations, net proceeds from the offering of our \$130.0 million 4.25% Convertible Notes due 2021 and funds remaining available under our Wells Fargo Credit agreement of \$50.0 million, which may be increased by an additional \$20.0 million in the lenders' discretion, will be sufficient to fund our existing level of operating expenses, current development activities, non-operating payments of debt, interest, accrued settlement and arbitration payments and general capital expenditure requirements through at least the next year.

GSK has claimed that we owe GSK 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. We have entered into an Interim Settlement Agreement under which we will continue to make payments to GSK and escrow additional funds and the parties will submit the dispute to binding arbitration. We have paid to GSK approximately \$9.6 million through December 31, 2015 and have deposited an additional approximately \$5.7 million into an escrow account on account of the settlement of disputed amounts. The amounts paid by us to GSK and escrowed represent approximately 57% of the amounts GSK claims are owed to them as a result of our alleged breach. The amounts paid and escrowed by us for GSK claims are consistent with the amounts accrued by us for managed care rebates and fees during the year ended December 31, 2015. While 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, any material liability resulting from this claim could negatively impact our financial results.

On each Payment Date, commencing August 1, 2015, we will pay an installment of principal on the Treximet Secured 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 Secured Notes on such Payment Date). Pursuant to the August 2014 Indenture, the first principal payment was due on August 1, 2015 and was 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 during January 2015, the net sales of Treximet will be calculated, and 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 Secured 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 will be paid at that time. The balance outstanding on the Treximet Secured Notes will be due on the maturity date of the Treximet Secured Notes, which is August 1, 2020. Based on the calculation of the principal payments as described, the Company has recorded \$194.9 million of Treximet Secured Notes as long-term debt and \$15.0 million as short-term debt as of December 31, 2015.

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, 2015, 2014 and 2013 (in thousands).

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Cash (used in) provided by			
Operating activities	\$ (14,749)	\$ 8,896	\$ (6,531)
Investing activities	(84,348)	(249,922)	23,386
Financing activities	120,377	260,234	(24,231)
Net increase (decrease) in cash and cash equivalents	<u>\$ 21,280</u>	<u>\$ 19,208</u>	<u>\$ (7,376)</u>

Net cash (used in) provided by operating activities

Net cash used in operating activities during 2015 and 2013 was \$14.7 million and \$6.5 million, respectively. Net cash provided by operating activities during 2014 was \$8.9 million. The \$14.7 million used in operating activities during 2015 was primarily driven by: net loss of \$148.3 million, adjusted by non-cash expenses totaling \$137.8 million and \$4.2 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities. 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 (used in) provided by investing activities

Net cash used in investing activities during 2015 and 2014 was \$84.3 million and \$249.9 million, respectively. Net cash provided by investing activities during 2013 was \$23.4 million. The \$84.3 million used in investing activities during 2015 was primarily driven by \$85.2 million related to the acquisition of Zohydro, partially offset by \$4.9 million related to payments received on our notes receivable from Breckenridge. 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 financing activities during 2015 and 2014 was \$120.4 million and \$260.2 million, respectively. Net cash used in financing activities during 2013 was \$24.2 million. The \$120.4 million provided by financing activities during 2015 was primarily attributable to proceeds from the issuance of our 4.25% Convertible Notes of \$130.0 million, partially offset by financing cost payments related to the issuance of the 4.25% Convertible Notes of \$5.0 million. Net cash provided by financing activities for 2015 was also due to net proceeds from our revolving credit facility of \$7.7 million. The net cash provided by financing activities during 2015 was partially offset by principal payments on our Treximet Secured Notes of \$10.0 million. The \$260.2 million provided by financing activities during 2014 was primarily attributable to proceeds from the issuance of our 8.00% Convertible Notes and Treximet Secured Notes, of \$65.0 million and \$220.0 million, respectively, partially offset by financing cost payments, primarily related to the issuance of the 8.00% Convertible Notes and the Treximet Secured Notes, of \$14.1 million and net proceeds from our revolving credit facilities 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.

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. As the achievement of milestones is neither probable nor reasonably estimable, such contingent

payments have not been recorded, except for the contingent consideration discussed in Note 4, *Business Combination and Other Acquisitions*, for the acquisition of Zohydro in April 2015, on our consolidated balance sheets. 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, 2015 (in thousands):

Contractual obligations:	<u>Total</u>	<u>Less than 1 year</u>	<u>2-3 Years</u>	<u>4-5 Years</u>	<u>More than 5 Years</u>
Operating leases (1)	\$ 3,913	\$ 677	\$ 1,245	\$ 1,158	\$ 833
Professional service agreements (2)	29,982	28,721	1,261	-	-
Supply agreements and purchase obligations (3)	6,710	6,710	-	-	-
License and development agreements (4)	36,000	16,000	20,000	-	-
Short-term borrowings (5)	15,000	-	15,000	-	-
4.25% Convertible Notes	130,000	-	-	-	130,000
Interest on 4.25% Convertible Notes	30,848	5,525	11,050	11,050	3,223
Treximet Secured Notes (6)	209,987	39,506	131,097	39,384	-
Interest on Treximet Secured Notes	56,649	24,304	29,475	2,870	-
Contingent consideration (7)	14,055	-	-	-	14,055
Settlement obligations	10,000	2,750	5,000	2,250	-
Total contractual obligations	<u>\$ 543,144</u>	<u>\$ 124,193</u>	<u>\$ 214,128</u>	<u>\$ 56,712</u>	<u>\$ 148,111</u>

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 Wells Fargo Credit Facility as of December 31, 2015.
6. Amounts show as contractual commitments under our Treximet Secured Notes represent our estimate of expected principal repayment based on anticipated Treximet net sales. Amounts shown in Interest on Treximet Secured Notes include our estimated interest payments based on estimated net sales of Treximet.
7. Contingent consideration is estimated based on the probability of achieving certain milestones in the development of Zohydro ER.

See Note 16, *Debt and Lines of Credit* and Note 22, *Commitments and Contingencies*, to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

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 these financial statements requires us to make estimates and judgements that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue and other costs. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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 believe the following critical accounting policies affect the significant judgements and estimates used in the preparation of our consolidated financial statements:

- revenue recognition;

- inventory valuation;
- share-based payments; and
- valuation of long-lived assets, intangibles and goodwill.

Revenue Recognition

Net product sales. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, we have no further performance obligations, and returns can be reasonably estimated. 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.

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, 2015, 2014 and 2013:

	Product Returns	Government Program Rebates	Price Adjustments
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	<u>(17,155)</u>	<u>(9,495)</u>	<u>(42,938)</u>
Balance at December 31, 2013	12,049	3,936	18,301
Allowances for certain co-agreements(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	<u>(21,668)</u>	<u>(8,963)</u>	<u>(62,140)</u>
Balance at December 31, 2014	9,691	9,968	32,945
Allowances for certain co-agreements(1)	326	194	-
Current provision:			
Provision - current year sales	17,807	6,166	138,306
Payments and credits	<u>(15,928)</u>	<u>(9,646)</u>	<u>(127,151)</u>
Balance at December 31, 2015	<u>\$ 11,896</u>	<u>\$ 6,682</u>	<u>\$ 44,100</u>

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 consolidated balance sheets.

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.

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. If our estimates and assumptions prove inaccurate, we may be subject to higher or lower government program rebates.

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. 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. 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 third party claims processing organizations.

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 based 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.

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 wholesalers. 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 include: (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 75 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.

Milestone payments. 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.

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

Inventory Valuation

Inventory primarily consists of finished goods which include pharmaceutical products ready for commercial sale. Prior to the sale of PML, on April 21, 2014, inventory also consisted of Pemix 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.

Share-based Payments

We grant options to purchase our common stock to our employees and directors under our stock option plans. For options with market conditions we use the Monte Carlo simulation to value the awards. For other options which vest based on the passage of time, we estimate the fair value on the date of grant using a Black-Scholes pricing model (Black-Scholes model). The determination of the fair value of share-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period.

Estimates of share-based compensation expenses are significant to our financial statements, but these expenses are based on option valuation models and will never result in the payment of cash by us.

There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

For purposes of estimating the fair value of stock options granted using the Black-Scholes model, we have made an estimate regarding our stock price volatility. We consider the historical volatility and the implied volatility of market-traded options in our stock for the expected volatility assumption input to the Black-Scholes model. The risk-free interest rate is based on the yield curve of U.S. Treasury strip securities for a period consistent with the expected term of the option in effect at the time of grant. The dividend yield assumption is based on our history and expectation of dividend payouts. The expected term is estimated considering historical option information.

Valuation of Long-lived Assets, Intangibles and Goodwill

We assess the impairment of long-lived assets, intangibles and goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;
- significant decline in our stock price for a sustained period; and
- our market capitalization relative to net book value.

When we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on a probability weighted projected discounted cash flow method using a discount rate determined to be commensurate with the risk inherent in our current business model.

Intangibles represent the fair value of product rights purchased. Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur.

Goodwill represents the excess of costs over fair value of net assets of businesses acquired. Goodwill acquired in a purchase business combination is not amortized, but instead tested for impairment at least annually, or sooner if circumstances indicate that an impairment might have occurred.

Off-Balance Sheet Arrangements

Since our 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 our revenues or results of operations since inception.

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. In addition, we expect that sales in the first quarter of each year will be lower than they may otherwise be due to increased patient out-of-pocket costs until deductibles under applicable plans are met.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies and Recent Accounting Pronouncements* to the consolidated financial statements for a full description of recent accounting pronouncements including the respective expected dates of adoption and expected effect on results of operations and financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our interest rate risk exposure results from our convertible notes, and our Treximet Secured Notes.

Our Treximet Secured Notes have a fixed interest rate. As of December 31, 2015, our Treximet Secured Notes had \$210.0 million in aggregate principal amount outstanding. The fair value of the Treximet Secured Notes is affected by changes in interest rates and by historical and projected rates of net sales of Treximet.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**Pernix Therapeutics Holdings, Inc. and Subsidiaries
Table of Contents**

	Page
Reports of Independent Registered Public Accounting Firm	74
Consolidated Balance Sheets	76
Consolidated Statements of Operations and Comprehensive Loss	77
Consolidated Statements of Stockholders' Equity	78
Consolidated Statements of Cash Flows	79
Notes to Consolidated Financial Statements	80
Schedule II - Valuation and Qualifying Accounts	117

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Permex Therapeutics Holdings, Inc.'s and subsidiaries internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Permex 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, Permex Therapeutics Holdings, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, 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 Permex Therapeutics Holdings, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015, and the related consolidated financial statement schedule as of December 31, 2015, 2014, and 2013, and our report dated March 10, 2016 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

March 10, 2016

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, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. We have also audited the accompanying consolidated financial statement schedule for each of the three years in the period ended December 31, 2015 listed in the index at Item 8. 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 audit 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, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 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, 2015, 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, 2015, 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 10, 2016 expressed an unqualified opinion thereon.

/s/ Cherry Bekaert LLP

Atlanta, Georgia
March 10, 2016

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

December 31, 2015 and 2014

(in thousands, except share and per share data)

Assets	<u>2015</u>	<u>2014</u>
Current assets:		
Cash and cash equivalents	\$ 56,135	\$ 34,855
Restricted cash	10,002	-
Accounts receivable, net	61,209	44,127
Inventory, net	10,035	10,479
Prepaid expenses and other current assets	13,283	16,550
Income tax receivable	6,735	2,590
Note receivable, net of unamortized discount of \$0 and \$127, respectively	-	4,723
Deferred income tax assets — current	-	6,544
Total current assets	<u>157,399</u>	<u>119,868</u>
Property and equipment, net	2,346	1,514
Goodwill	54,865	44,900
Intangible assets, net	285,943	300,489
Other	10,605	11,253
Total assets	<u>\$ 511,158</u>	<u>\$ 478,024</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 14,081	\$ 5,399
Accrued personnel expense	4,336	3,573
Accrued allowances	62,678	52,604
Other accrued expenses	9,355	15,333
Interest payable	11,903	10,159
Credit facilities — current	-	7,345
Treximet Secured Notes — current	15,044	-
Restricted cash payable	10,002	-
Other liabilities	6,753	3,264
Total current liabilities	<u>134,152</u>	<u>97,677</u>
Convertible notes — long-term	103,806	65,000
Derivative liability	9,165	-
Contingent consideration	14,055	-
Treximet Secured Notes — long-term	194,943	220,000
Credit facilities — long-term	15,000	-
Deferred income tax liability — long-term	202	-
Other liabilities	6,738	11,755
Total liabilities	<u>478,061</u>	<u>394,432</u>
Commitments and contingencies (notes 1, 3, 13, 15, 16, 22 and 23)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, authorized 10,000,000 shares; no shares issued and outstanding	-	-
Common stock, \$0.01 par value, 140,000,000 and 90,000,000 shares authorized, 63,874,549 and 40,805,659 issued and 61,112,527 and 38,341,352 outstanding at December 31, 2015 and 2014, respectively	611	383
Additional paid-in capital	226,837	129,128
Treasury stock, at cost, 2,762,022 and 2,464,307 shares held at December 31, 2015 and 2014, respectively	(5,548)	(5,431)
Accumulated deficit	(188,803)	(40,488)
Total stockholders' equity	<u>33,097</u>	<u>83,592</u>
Total liabilities and stockholders' equity	<u>\$ 511,158</u>	<u>\$ 478,024</u>

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Years ended December 31, 2015, 2014 and 2013

(in thousands, except per share data)

	2015	2014	2013
Net revenues	\$ 175,850	\$ 121,747	\$ 84,872
Costs and operating expenses:			
Cost of product sales	51,408	47,965	43,870
Selling, general and administrative expense	97,421	60,158	62,551
Research and development expense	8,229	3,938	4,798
Loss from disposal of assets, impairments of intangibles	24,352	242	19,638
Loss on sale of PML (including impairment charge)	-	6,659	-
Depreciation and amortization expense	94,695	32,999	8,676
Change in fair value of contingent consideration	(138)	-	(805)
Restructuring costs	1,137	-	-
Total costs and operating expenses	277,104	151,961	138,728
Loss from operations	(101,254)	(30,214)	(53,856)
Other income (expense):			
Interest income	157	353	134
Change in fair value of put right	-	-	(8,361)
Gain on contingent consideration and put right	-	-	16,269
Gain on sale of investment	-	-	3,605
Cost of inducement	(19,500)	-	-
Loss on extinguishment of debt	(1,112)	-	-
Foreign currency transaction loss	(582)	-	-
Change in fair value of derivative liability	19,315	-	-
Interest expense	(38,277)	(19,150)	(4,183)
Total other (expense) income, net	(39,999)	(18,797)	7,464
Loss before income tax expense (benefit)	(141,253)	(49,011)	(46,392)
Income tax expense (benefit)	7,062	(13,725)	(20,757)
Net loss	(148,315)	(35,286)	(25,635)
Other comprehensive loss			
Unrealized loss during period, net of tax of \$0, \$0 and (\$411), respectively	-	-	(702)
Reclassification adjustment for net gains included in net loss, net of tax of \$0, \$0, and (\$1,332), respectively	-	-	(2,273)
Comprehensive loss	\$ (148,315)	\$ (35,286)	\$ (28,610)
Net loss per common and potential common share			
Basic	\$ (2.78)	\$ (0.93)	\$ (0.70)
Diluted	\$ (2.78)	\$ (0.93)	\$ (0.70)
Weighted-average common and potential common shares outstanding:			
Basic	53,321	37,871	36,444
Diluted	53,321	37,871	36,444

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years ended December 31, 2015, 2014 and 2013
(in thousands)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Treasury Stock</u>	<u>Retained Earnings (Deficit)</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balance at December 31, 2012	-	\$ -	28,876	\$ 289	\$ 58,614	\$ (3,772)	\$ 20,433	\$ 2,975	\$ 78,539
Net proceeds from issuance of restricted stock	-	-	66	1	1,535	-	-	-	1,536
Compensation expense on share-based awards	-	-	-	-	513	-	-	-	513
Net proceeds from sale of shares	-	-	163	2	421	(229)	-	-	194
Issuance of stock options for services from non-employees	-	-	-	-	548	-	-	-	548
Stock issued 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 share-based awards	-	-	-	-	(147)	-	-	-	(147)
Net loss	-	-	-	-	-	-	(25,635)	-	(25,635)
Unrealized gain on securities, net	-	-	-	-	-	-	-	(2,975)	(2,975)
Balance at December 31, 2013	-	-	37,190	372	119,554	(4,001)	(5,202)	-	110,723
Net proceeds from issuance of restricted stock	-	-	325	2	(2)	(1,109)	-	-	(1,109)
Compensation expense on share-based awards	-	-	-	-	4,686	-	-	-	4,686
Net proceeds from sale of shares	-	-	826	9	2,613	(321)	-	-	2,301
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 warrants in connection with the acquisition of Treximet	-	-	-	-	2,359	-	-	-	2,359
Issuance of warrants in connection with the issuance of the February 2014 Convertible Notes, net	-	-	-	-	689	-	-	-	689
Income tax benefit on share-based awards	-	-	-	-	404	-	-	-	404
Net loss	-	-	-	-	-	-	(35,286)	-	(35,286)
Balance at December 31, 2014	-	-	38,341	383	129,128	(5,431)	(40,488)	-	83,592
Net proceeds from issuance of restricted stock	-	-	49	-	-	(117)	-	-	(117)
Compensation expense on share-based awards	-	-	-	-	5,944	-	-	-	5,944
Net proceeds from sale of shares	-	-	647	7	388	-	-	-	395
Conversion of 8.0% convertible notes	-	-	18,056	181	59,991	-	-	-	60,172
Issuance of stock for inducement	-	-	2,338	23	19,477	-	-	-	19,500
Stock issued in connection with the purchase of Zohydro ER	-	-	1,682	17	11,909	-	-	-	11,926
Net loss	-	-	-	-	-	-	(148,315)	-	(148,315)
Balance at December 31, 2015	-	\$ -	61,113	\$ 611	\$ 226,837	\$ (5,548)	\$ (188,803)	\$ -	\$ 33,097

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2015, 2014 and 2013
(in thousands)

	2015	2014	2013
Cash flows from operating activities:			
Net loss	\$ (148,315)	\$ (35,286)	\$ (25,635)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation	361	331	672
Amortization of intangibles and interest accretion of contingent consideration	94,334	32,668	8,004
Amortization of deferred financing costs	2,730	2,333	1,295
Accretion of debt discount	2,286	-	-
Interest accretion of notes receivable	(127)	(292)	(114)
Deferred income tax expense (benefit)	6,746	(11,753)	(22,516)
Gain on sale of investment	-	-	(3,605)
Loss on disposal of software and equipment	19	242	208
Loss on extinguishment of debt	1,112	-	-
Stock compensation expense	5,944	4,686	2,049
Expense for stock options issued in exchange for services	-	119	548
Cancellation of ParaPRO stock options in connection with termination of contract	-	(1,294)	-
Fair market value change in derivative liability	(19,315)	-	-
Fair market value change in contingent consideration and put right	(138)	-	7,556
Gain on contingent consideration and put right	-	-	(16,269)
Issuance of stock for inducement	19,500	-	-
Loss on impairment	24,352	-	19,429
Loss on sale of PML (including impairment)	-	6,659	-
(Increase) decrease in operating assets (net of effect of acquisitions):			
Accounts receivable	(17,082)	(18,480)	12,163
Income taxes	(4,145)	(6,592)	642
Inventory	444	1,880	7,406
Prepaid expenses and other assets	2,471	(2,144)	(2,180)
Increase (decrease) in operating liabilities (net of effect of acquisitions):			
Accounts payable and accrued expenses	6,682	12,161	(3,398)
Accrued allowances	10,074	18,318	(3,075)
Interest payable	2,291	10,012	100
Other liabilities	(4,973)	(4,672)	10,189
Net cash (used in) provided by operating activities	(14,749)	8,896	(6,531)
Cash flows from investing activities:			
Acquisitions	(87,986)	(254,950)	(310)
Proceeds from the sales of investment	-	-	4,605
Payments received on notes receivable	4,850	4,850	-
Proceeds from sale of PML	-	1,137	-
Proceeds from sale of certain Cypress assets	-	175	19,588
Proceeds from sale of equipment	-	43	31
Purchase of software and equipment	(1,212)	(1,177)	(528)
Net cash (used in) provided by investing activities	(84,348)	(249,922)	23,386
Cash flows from financing activities:			
Proceeds from issuance of Convertible Notes	130,000	65,000	-
Cash acquired in connection with acquisition of Somaxon	-	-	2,881
Payments on contracts payable	-	(2,500)	(1,700)
(Payments) proceeds from Treximet Secured Notes	(10,013)	220,000	-
Net drawdowns (payments) on credit facilities	7,655	(9,515)	(25,153)
Payments for financing costs	(5,349)	(14,149)	-
Payment of consent fee	(2,150)	-	-
Payments on mortgages and capital leases	(44)	(46)	(144)
Proceeds from issuance of common stock, net of tax and costs	395	2,149	262
Tax benefit on stock-based awards	-	404	(147)
Shares withheld for the payment of taxes	(117)	(1,109)	(230)
Net cash provided by (used in) financing activities	120,377	260,234	(24,231)
Net increase (decrease) in cash and cash equivalents	21,280	19,208	(7,376)
Cash and cash equivalents, beginning of period	34,855	15,647	23,023
Cash and cash equivalents, end of period	\$ 56,135	\$ 34,855	\$ 15,647

See accompanying notes to consolidated financial statements

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2015, 2014 and 2013

Note 1. Organization and Nature of Business

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, pain 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, 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, and Zohydro ER with BeadTek, an extended-release opioid agonist indicated for the management of pain. The Company also has an exclusive license agreement with Osmotica Pharmaceutical Corp. to promote Khedezla, a prescription medication for major depressive disorder.

Acquisition of Zohydro

On April 24, 2015, the Company, through a wholly owned subsidiary Pernix Ireland Pain Limited ("PIPL"), formerly known as Ferrimill Limited, completed the acquisition of the pharmaceutical product line Zohydro ER, including an abuse-deterrent pipeline and all related intellectual property, a supplier contract, an associated liability payable and a specified quantity of inventory associated therewith, from Zogenix, Inc. ("Zogenix"). See Note 4, *Business Combinations and Other Acquisitions*, for further discussion.

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.

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.

Reclassifications

Certain reclassifications have been made to prior period amounts in our consolidated statements of income to conform to the current period presentation. The Company reclassified certain regulatory and distribution costs of \$2.8 million from selling, general and administrative expense to cost of product sales and reclassified the change in fair value of contingent consideration of \$805,000 to operating expenses from other income (expense) on the consolidated statements of loss and comprehensive (loss) income during the years ended December 31, 2014 and 2013, respectively. The Company also reclassified \$883,000 of product samples from inventory, net to prepaid expenses and other current assets on the consolidated balance sheets as of December 31, 2014.

Note 2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), applied on a consistent basis.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Management's Estimates and Assumptions

The preparation of consolidated financial statements 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; useful lives of amortizable intangible assets; provisions for income taxes; uncertain tax positions, and realizability of deferred tax assets; expected future cash flows used in evaluating intangible assets for impairment; stock-based compensation; and the allocation of the purchase price for acquired assets and businesses, including the fair value of contingent consideration. On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company's business and new information as it becomes available. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company's consolidated financial statements could be materially impacted.

Business Acquisitions

Acquired businesses are accounted for 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. If the acquired net assets do not constitute a business under the acquisition method of accounting, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, the amount allocated to acquired IPR&D with no alternative future is charged to expense at the acquisition date.

Fair Value of Financial Instruments

The estimated fair values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their carrying values due to their short maturity periods. The fair value of acquisition-related contingent consideration is based on estimated discounted future cash flows and assessment of the probability of occurrence of potential future events. The fair value of long-term debt is based on quoted market prices, if available, or estimated discounted future cash flows.

Cash and Cash Equivalents

Cash and cash equivalents include certain money-market funds with maturities of three months or less when purchased.

The restricted cash amount at December 31, 2015 consists of amounts escrowed for the purchase of Zohydro ER with BeadTek. In accordance with the asset purchase agreement, the Company has deposited \$10.0 million in an escrow fund to be held for a period of 12 months from the closing date as a security to pay, or be applied against, any losses incurred by the Company that are subject to the general representations, warranties and indemnification obligations of Zogenix. The Company is considered to be the legal and tax owner of the fund until the expiration of the escrow period of 12 months. Accordingly, the

amount of \$10.0 million in the escrow fund is recognized as restricted cash and consideration payable to Zogenix. Restricted cash and the restricted cash payable are presented separately under current assets and current liabilities, respectively, in the consolidated balance sheets. See Note 4, *Business Combinations and Other Acquisitions*, for additional information.

Concentrations of Credit Risk 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 invests its excess cash in high quality, money market instruments. The Company maintains its cash and cash equivalents with a major financial institution. At times, such amounts may exceed federally insured limits. The Company has not experienced any significant losses on its cash or cash equivalents.

The Company's accounts receivable primarily represent amounts due from drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. The Company performs periodic credit evaluations of customers and does not require collateral. An allowance for doubtful accounts is maintained for potential credit losses based on the aging of accounts receivable, historical bad debts experience, and changes in customer payment patterns. Accounts receivables balances are written off against the allowance when it is probable that the receivable will not be collected. The Company primarily sold to three major customers in 2015, 2014 and 2013. See Note 18, *Concentrations*, for additional information. At December 31, 2015 and 2014, the allowance for doubtful accounts was approximately \$15,000 and \$228,000, respectively.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. Most of the Company'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, 2015, approximately 25% of the inventory purchases, were from two primary suppliers - GSK and Aphenia Pharma Solutions, allocated 15% and 10%, respectively. 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. The Company believes that it has good relationships with its current suppliers, and could secure the services of alternative suppliers if necessary or required.

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 is included in prepaid expenses and other current assets on the consolidated balance sheets and are expensed to selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss when the sample units are distributed to the Company's sales representatives.

The Company evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared with quantities on hand, the price the Company expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

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 it operates in a single segment and has 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 charges 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 3 to 13 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, 2015, 2014 and 2013, the Company recorded impairment charges of \$24.4 million, \$0, and \$19.4 million. See Note 12, *Goodwill and Intangible Assets*, 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 \$6.7 million against the net assets of PML in March 2014. See Note 5, *Asset Dispositions*, for additional information.

Deferred Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization, and are recorded in prepaid expenses and other current assets and other long-term assets. Amortization expense is included in interest expense. Deferred financing costs amortized during years ended December 31, 2015, 2014 and 2013 were \$2.7 million, \$2.3 million and \$1.3 million, respectively. Unamortized deferred financing costs were \$12.8 million and \$14.3 million as of December 31, 2015 and 2014, respectively.

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

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.

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, 2015, 2014 and 2013 included \$97,000, \$2.6 million and \$6.4 million, 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 year ended December 31, 2013. The remaining balance of the increase in the basis of the inventory acquired was approximately \$0 as of December 31, 2015.

Research and Development

Research and development costs in connection with the Company's internal programs for the development of products are expensed as incurred. Pemix 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.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred in SG&A. Advertising expenses for 2015, 2014 and 2013 were \$9.7 million \$5.8 million, and \$50,000, respectively. The increase is due to advertising programs for Treximet and Silenor that were developed during 2015.

Share-Based Compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options and restricted share units ("RSUs"), at estimated fair value. The Company amortizes the fair value of stock option or RSU grants on a straight-line basis over the requisite service period of the individual stock option or RSU grant, which generally equals the vesting period. Stock option and RSU forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 divestiture of PML does not qualify as discontinued operations in accordance with ASC 205, *Presentation of Financial Statements*.

Acquisition-Related Contingent Consideration

Acquisition-related contingent consideration, which consists primarily of potential milestone payments and royalty obligations, is recorded in the consolidated balance sheets at its acquisition date estimated fair value, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of income (loss). The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting.

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.

The Company must also make judgments regarding the realizability of deferred tax assets. The carrying value of the Company's net deferred tax assets is based on its view of whether it is more likely than not that the Company will generate sufficient future taxable income in certain jurisdictions to realize these deferred tax assets. A valuation allowance has been established for deferred tax assets which the Company does not believe meet the "more likely than not" criteria. The Company's judgments regarding future taxable income may change due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If the Company's assumptions and consequently its estimates change in the future, the valuation allowances it has established may be increased or decreased, resulting in a respective increase or decrease in income tax expense. The Company's effective tax rate is highly dependent upon the geographic distribution of its worldwide earnings or losses, the tax regulations and tax holidays in each geographic region, the availability of tax credits and carryforwards, and the effectiveness of its tax planning strategies.

The Company used a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with the guidance on judgments regarding the realizability of deferred taxes. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes.

Income tax returns subject to review by taxing authorities include 2012 through 2015.

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 22, *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 and warrants, conversion of notes or vesting of restricted stock.

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

	Year ended December 31,		
	2015	2014	2013
Numerator:			
Net loss	\$ (148,315)	\$ (35,286)	\$ (25,635)
Denominator:			
Weighted-average common shares, basic	53,321	37,871	36,444
Dilutive effective of stock options	-	-	-
Weighted-average common shares, diluted	<u>53,321</u>	<u>37,871</u>	<u>36,444</u>
Net loss per share, basic and diluted	\$ (2.78)	\$ (0.93)	\$ (0.70)

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income (loss) per share because to do so would have been anti-dilutive for the periods presented (in thousands):

	Year ended December 31,		
	2015	2014	2013
4.25% Convertible Notes	7,887	-	-
8.00% Convertible Notes	-	18,056	-
Stock options and restricted stock	3,948	4,691	2,233
Warrants	469	1,500	469
Total potential dilutive effect	<u>12,304</u>	<u>24,247</u>	<u>2,702</u>

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 February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02 *Leases (Topic 842)*. ASU 2016-02 is intended to improve financial reporting about leasing transactions. The ASU affects all companies and other organizations that lease assets such as real estate, airplanes, and manufacturing equipment. The ASU will require organizations that lease assets referred to as "Lessees" to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require both types of leases (i.e. operating and capital) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases.

The leasing standard will be effective for calendar year-end public companies beginning after December 15, 2018. Public companies will be required to adopt the new leasing standard for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption will be permitted for all companies and organizations upon issuance of the standard. For calendar year-end public companies, this means an adoption date of January 1, 2019 and retrospective application to previously issued annual and interim financial statements for 2018 and 2017. See Note 22, *Commitments and Contingencies*, for the Company's current lease commitments. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its financial statements.

In January 2016, the FASB issued Accounting Standards Update ("ASU") 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In November 2015, the FASB issued ASU 2015-17 *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The ASU eliminates the current requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. The amendments apply to all organizations that present a classified balance sheet. For public companies, the amendments are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted and the Company adopted this ASU retrospectively in its fiscal year ended December 31, 2015 resulting in the reclassification of \$9.4 million from deferred income tax liability - long-term to deferred income tax assets - current as of December 31, 2014.

In September 2015, the FASB issued ASU 2015-16 *Simplifying the Accounting for Measurement-Period Adjustments*. The amendments in this update require that during the measurement period, the acquirer shall recognize adjustments to the provisional amounts with a corresponding adjustment to goodwill in the reporting period in which the adjustments to the provisional amounts are determined. ASU 2015-16 requires an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. ASU 2015-16 is effective for annual reporting periods beginning after December 15, 2015. Early application is permitted. Effective September 30, 2015, the Company early adopted ASU 2015-16.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs* which changes the presentation of debt issuance costs in financial statements. Under the new standard, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs is reported as interest expense. The accounting standard is effective for annual reporting periods beginning after December 15, 2015 and interim periods beginning after December 15, 2016. Early adoption is allowed for all entities for financial statements that have not been previously issued. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In July 2015, the FASB issued, ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Prior to the issuance of the standard, inventory was measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin). The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2016. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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.

In May 2014, the FASB issued Accounting Standards Update ("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, 2017 and interim periods therein. Early adoption is permitted as early as the original effective date (i.e. annual reporting periods beginning after December 15, 2016 and interim periods therein). Early adoption prior to that date 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.

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 - Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 - Inputs are other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 - Inputs are unobservable and reflect the Company's assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Summary of Assets Recorded at Fair Value

In accordance with the fair value hierarchy described above, the following table shows the fair value of the Company's financial assets that are required to be measured at fair value as of December 31, 2015 and December 31, 2014 (in thousands):

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Money market fund and trust cash sweep investments ⁽¹⁾	\$ 4,367	\$ -	\$ -	\$ 4,367
Total assets	\$ 4,367	\$ -	\$ -	\$ 4,367

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Money market fund and trust cash sweep investments ⁽¹⁾	\$ 26,297	\$ -	\$ -	\$ 26,297
Total assets	\$ 26,297	\$ -	\$ -	\$ 26,297

⁽¹⁾ The Company's money market and trust cash sweep investments are included in cash and cash equivalents within the Consolidated Balance Sheets.

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices or broker or dealer quotations for similar assets. These investments are initially valued at the transaction price and subsequently valued utilizing third-party pricing providers or other market observable data. Data used in the analysis include reportable trades, broker/dealer quotes, bids and offers, benchmark yields and credit spreads. The Company validates the prices provided by its third-party pricing providers by reviewing their pricing methods, analyzing pricing inputs and confirming that the securities have traded in normally functioning markets. The Company did not adjust or override any fair value measurements provided by its pricing providers as of December 31, 2015 or December 31, 2014.

As of December 31, 2015 and December 31, 2014, the Company did not have any investments in Level 3 securities.

There were no transfers of assets or liabilities between Level 1 and Level 2 during the years ended December 31, 2015 and 2014.

The carrying amounts reflected in the consolidated balance sheets for certain short-term financial instruments including accounts receivable, accounts payable, accrued expenses, and other liabilities approximate fair value due to their short-term nature.

Summary of Liabilities Recorded at Carrying Value and Fair Value

The fair and carrying value of the Company's debt instruments are detailed as follows (in thousands):

	<u>As of December 31, 2015</u>		<u>As of December 31, 2014</u>	
	<u>Fair Value</u>	<u>Carrying Value</u>	<u>Fair Value</u>	<u>Carrying Value</u>
4.25% Convertible Notes	\$ 68,637	\$ 103,806	\$ -	\$ -
Derivative liability	9,165	9,165	-	-
8.00% Convertible Notes	-	-	129,320	65,000
Contingent consideration	14,055	14,055	-	-
Treximet Secured Notes	179,518	209,987	167,114	220,000
Total	<u>\$ 271,375</u>	<u>\$ 337,013</u>	<u>\$ 296,434</u>	<u>\$ 285,000</u>

Convertible Notes

The fair values of the Convertible notes were estimated using the (i) terms of the convertible notes; (ii) rights, preferences, privileges, and restrictions of the underlying security; (iii) time until any restriction(s) are released; (iv) fundamental financial and other characteristics of the Company; (v) trading characteristics of the underlying security (exchange, volume, price, and volatility); (vi) valuation of derivative liability; and (vii) precedent sale transactions.

Derivative Liability

The fair value of the derivative liability was determined using a "with and without" scenario. Under this methodology, valuations are performed on the convertible note inclusive of all terms as well as for a convertible note that has identical terms and features but excluding the conversion option. The difference between the two valuations is equal to the fair value of the conversion option. Significant increases or decreases in these inputs would result in a significant change in the fair value of the derivative liability.

Contingent Consideration

The fair value of contingent consideration is based on two components - a regulatory milestone and commercial milestone.

For the regulatory milestone, the expected regulatory earn out payment was discounted taking into account (a) the Company's cost of debt, (b) the expected timing of the payment and (c) subordinate nature of the earn out obligation.

The fair value of the commercial milestone was determined using a Monte Carlo simulation. This simulation assumed a risk-neutral framework, whereby future net revenue was simulated over the earn out period using the Geometric Brownian Motion. For each simulation path, the earn out payments were calculated based on the achievement of the revenue milestone and then were discounted to the valuation date. Significant increases or decreases in these unobservable inputs and/or the probability of achievement of these milestones would result in a significant change in the fair value of the contingent consideration.

Treximet Secured Notes

The fair value of the Company's Treximet Secured Notes was estimated using a discounted cash flow model.

Within the hierarchy of fair value measurements, these are Level 3 fair values.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

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, 2015 and 2014 (in thousands).

	December 31, 2015	December 31, 2014
Convertible notes:		
Beginning balance	\$ 65,000	\$ -
Issuance of convertible notes	130,000	65,000
Conversion of notes to shares	(65,000)	-
Initial measurement of derivative liability	(28,480)	-
Amortization of debt discount	2,286	-
Ending balance	<u>\$ 103,806</u>	<u>\$ 65,000</u>

Treximet secured notes:		
Beginning balance	\$ 220,000	\$ -
Issuance of secured notes	-	220,000
Payments	(10,013)	-
Ending balance	<u>\$ 209,987</u>	<u>\$ 220,000</u>

	December 31, 2015	December 31, 2014
Derivative liability:		
Beginning balance	\$ -	\$ -
Initial measurement of derivative liability	28,480	-
Remeasurement adjustments - gains included in earnings	(19,315)	-
Ending balance	<u>\$ 9,165</u>	<u>\$ -</u>

Contingent consideration:		
Beginning balance	\$ -	\$ 1,330
Initial measurement of contingent consideration	14,193	1,950
Payment of contingent consideration	-	(3,280)
Remeasurement adjustments - gains included in earnings	(138)	-
Ending balance	<u>\$ 14,055</u>	<u>\$ -</u>

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.

Zohydro ER Acquisition

On April 24, 2015, the Company completed the acquisition of the pharmaceutical product line, Zohydro ER, including an abuse-deterrent pipeline and all related intellectual property, a supplier contract, an associated liability payable, and a specified quantity of inventory associated therewith, from Zogenix, Inc. ("Zogenix"). There were no other tangible or intangible assets acquired and liabilities assumed related to the Zohydro ER product line from Zogenix. The total purchase price consisted of an upfront cash payment of \$80.0 million including a deposit of \$10.0 million in an escrow fund, stock consideration of \$11.9 million issued in common stock of Pemix, \$927,000 for specified quantity of inventory, and regulatory and commercial milestones of up to \$283.5 million including a \$12.5 million milestone payment upon approval of ZX007 abuse-deterrent extended-release hydrocodone tablet and up to \$271.0 million in potential sales milestones if the Zohydro ER product line achieves certain agreed-upon net sales targets.

Zohydro ER is an extended-release form of hydrocodone indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Zohydro ER does not contain acetaminophen, unlike many immediate-release hydrocodone products, such as Vicodin and Lortab, reducing the risk for potential liver toxicity due to overexposure of acetaminophen. The active ingredient, hydrocodone, is the most commonly prescribed opioid in the U.S., with over 114 million prescriptions in 2014. The FDA approved the New Drug Application ("NDA") for Zohydro ER in October 2013 and the product was launched in March 2014.

The Zohydro ER product line acquisition was accounted for as a business combination in accordance with ASC 805 *Business Combinations* ("ASC 805") which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The Company believes that the estimates used were reasonable and the significant effects of the Zohydro ER acquisition were properly reflected.

After the June 30, 2015 condensed consolidated financial statements were filed, the Company updated certain estimates used in the purchase price allocation, primarily with respect to forecast of all expected cash flows due to more current information. The revisions were based on updated assumptions and information related to the facts and circumstances that existed as of the acquisition date. These revisions in the estimates increased the fair value of the developed technology intangible asset by \$31.4 million, decreased the fair value of IPR&D by \$50.4 million and decreased the fair value of contingent consideration by \$15.1 million. In addition, the Company also recognized an intangible asset from a supplier contract amounting to \$1.1 million and recognized liabilities assumed amounting to \$4.2 million. The net impact of these measurement period adjustments increased goodwill to \$7.1 million. These measurement period adjustments resulted in an increase of amortization expense of intangible assets of \$3.9 million and a decrease in gain from change in fair value of contingent consideration by \$11.5 million in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2015. The Company has finalized the purchase price allocation and these measurement period adjustments are recorded as current period adjustments in accordance with ASU 2015-16. There were no impacts of these measurement period adjustments in the comparative periods included in the financial statements.

The following table summarizes the consideration paid to acquire Zohydro ER and amounts recognized for assets acquired and liabilities assumed as of the acquisition date as well as adjustments made during the measurement period after the acquisition date to the amounts initially recorded on the acquisition date (in thousands):

	As of April 24, 2015 As initially reported	Measurement Period Adjustments	As of April 24, 2015 As adjusted
Purchase price:			
Cash consideration paid to Zogenix	\$ 70,000	\$ -	\$ 70,000
Escrow fund deposited at the time of closing ⁽¹⁾	10,000	-	10,000
Purchased product inventory ⁽²⁾	927	-	927
Common stock issued ⁽³⁾	11,926	-	11,926
Fair value of contingent consideration payable to Zogenix ⁽⁴⁾	29,327	(15,134)	14,193
Total purchase price	<u>\$ 122,180</u>	<u>\$ (15,134)</u>	<u>\$ 107,046</u>
Estimated fair value of net assets acquired:			
Intangible assets ⁽⁵⁾ :			
Developed technologies	\$ 67,400	\$ 31,400	\$ 98,800
In-process research and development	54,600	(50,400)	4,200
Supplier Contract ⁽⁶⁾	-	1,142	1,142
Assets acquired	<u>122,000</u>	<u>(17,858)</u>	<u>104,142</u>
Liabilities assumed ⁽⁶⁾	-	(4,226)	(4,226)
Amount attributable to net assets acquired	<u>122,000</u>	<u>(22,084)</u>	<u>99,916</u>
Goodwill ⁽⁷⁾	<u>\$ 180</u>	<u>\$ 6,950</u>	<u>\$ 7,130</u>

1. In accordance with the asset purchase agreement, the Company has deposited \$10.0 million in an escrow fund to be held for a period of 12 months from the closing date as a security to pay, or be applied against, any losses incurred by the Company that are subject to the general representations, warranties and indemnification obligations of Zogenix. The Company is considered to be the legal and tax owner of the fund until the expiration of the escrow period of 12 months. Accordingly, the amount of \$10.0 million in the escrow fund is recognized as restricted cash and consideration payable to Zogenix. Restricted cash and the restricted cash payable are presented separately under current assets and current liabilities, respectively, in the consolidated balance sheets.

2. Under the asset purchase agreement, the Company purchased a specified quantity of Generation 1 version of Zohydro ER product line from Zogenix on the closing date for \$927,000. Shortly before the closing date, the Generation 2 version of Zohydro ER with BeadTek was approved by the FDA and was announced by the Company to be launched in the immediate future. This announcement for the launch of Zohydro ER with BeadTek made the Generation 1 version of Zohydro ER obsolete and unsellable in the market. As a result, the fair value of the Generation 1 product inventory acquired from Zogenix has been estimated to be de-minimis on the closing date.
3. Under the asset purchase agreement, the number of common shares issued to Zogenix equaled \$20.0 million divided by the closing price of the common stock on a trading day immediately preceding the purchase agreement date. The closing price of the common stock of Pernix on March 9, 2015 (i.e. trading day immediately preceding the purchase agreement date) was \$11.89. Accordingly, Pernix issued 1,682,086 shares of common stock to Zogenix (\$20.0 million/\$11.89 per share).

The common stock issued by the Company is measured at fair value at the closing date (i.e. April 24, 2015) in accordance with the measurement guidance in ASC 805. The closing price of common stock of the Company on the closing date was \$7.09 and accordingly the fair value of common stock issued by the Company on the closing date was determined to be \$11.9 million. \$16,820 representing the par value of 1,682,086 shares at \$0.01 per share was recorded in common stock and the remaining amount of \$11.9 million was recorded in Additional paid-in capital.

4. Contingent consideration includes (a) \$12.5 million milestone payment payable upon approval of ZX007 abuse-deterrent extended-release hydrocodone tablet, and (b) up to \$271 million payable if the Zohydro ER product line achieves certain agreed-upon net sales targets. Each type of contingent consideration has been recognized as a separate unit of account. In accordance with the provisions of ASC 805-30-25-5, each unit of contingent consideration is recognized at the acquisition date fair value. The acquisition date fair value of the contingent consideration linked to FDA approval is \$10.3 million and the fair value of the contingent consideration linked to achievement of net sales target is \$19.0 million. During the year ended December 31, 2015, the Company recorded measurement period adjustments of \$15.1 million, which adjusted the carrying value to \$14.2 million. The adjusted values of the contingent consideration linked to FDA approval and net sales targets were \$2.7 million and \$11.5 million, respectively. The Company recorded \$138,000 as change in fair value of contingent consideration in the year ended December 31, 2015. The total contingent consideration of \$14.2 million is classified in other long-term liabilities and is marked to its current fair value of \$14.1 million as of December 31, 2015. Such fair values are determined based on a probabilistic model with weights assigned on the likelihood of the Company achieving the sales target in the future. Each unit of contingent consideration is classified as a liability in the consolidated balance sheets and will be subsequently measured at fair value on each reporting date. Any change in fair values between the reporting dates will be recognized in the consolidated statements of operations.
5. As of the effective date of the 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 these consolidated financial statements, it is assumed 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 synergies will be achieved.

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 financial statements include estimated identifiable intangible assets representing core technology intangibles valued at \$98.8 million, and in-process research and development ("IPR&D") intangibles valued at \$4.2 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 finite useful lives. They are amortized on a straight-line basis over a period of 4.6 years. 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.

6. The measurement period adjustments for intangible assets represent recognition of intangible assets related to a favorable supplier contract. The Company assumed the supplier contract from the seller that had favorable terms for the supply of the product. The intangible assets recognized are amortized over the life of the supplier contract. The measurement period adjustments for liabilities assumed represents the amount owed by the Company to Zogenix for the difference between the

notional net selling price stipulated in the Asset Purchase Agreement and the discounted price as stipulated in the supplier contract with respect to a particular product. The measurement period adjustment for liabilities consists of \$2.4 million and \$500,000 related to supplier and research and development contracts assumed, respectively and \$1.3 million related to inventory obsolescence.

7. Goodwill is calculated as the difference between the acquisition date fair value of the consideration expected to be transferred and the fair values assigned to the net 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, 2015 and 2014, as though the Zohydro ER acquisition had been completed as of January 1, 2014. 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 Zohydro ER acquisition or any estimated costs that will be incurred to integrate the Zohydro ER 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 for per share data):

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
	<u>(unaudited)</u>	<u>(unaudited)</u>
Revenue	\$ 180,856	\$ 133,331
Net loss	\$ (166,709)	\$ (128,935)
Pro forma net loss per common share:		
Basic	\$ (3.13)	\$ (3.40)
Diluted	\$ (3.13)	\$ (3.40)

The Company's historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the Zohydro ER 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 incremental interest expense and amortization of debt issuance costs 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 Pemix;
- Adjustment to recognize pro forma income tax based on income tax benefit on the amortization of intangible assets 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%).

For the year ended December 31, 2015, the Company has recognized revenue for Zohydro ER subsequent to the closing of April 24, 2015 in the amount of \$16.5 million and pre-tax net loss of \$14.6 million. Non-recurring transaction costs of \$2.9 million related to the acquisition for the year ended December 31, 2015 are included in the consolidated statements of operations in selling, general and administrative expense. These non-recurring transaction costs have been excluded from the pro forma results in the above table.

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. Since the date of acquisition, the Company finalized the purchase price allocation and recorded measurement period adjustments related to the recognition of a product liability return due to the seller, which has increased goodwill by \$2.8 million. There is no impact of the measurement period adjustment in the consolidated statement of operations and comprehensive loss for the years ended December 31, 2015 and 2014. This measurement period adjustment is recorded as a current period adjustment in accordance with ASU 2015-16.

The following table summarizes the consideration paid to acquire Treximet and amounts recognized for assets acquired and liabilities assumed as of the acquisition date as well as adjustments made during the measurement period after the acquisition date to the amounts initially recorded on the acquisition date (in thousands):

	August 20, 2014	Measurement Period	August 20, 2014
	As initially reported	Adjustments	As adjusted
Purchase price:			
Cash consideration paid to GSK	\$ 250,000	\$ -	\$ 250,000
Fair value of contingent consideration payable to GSK (1)	1,950	-	1,950
Cash paid to CPPIB (2)	3,000	-	3,000
Fair value of Warrant issued to Pozen (2)	2,359	-	2,359
Total purchase price	<u>\$ 257,309</u>	<u>\$ -</u>	<u>\$ 257,309</u>
Estimated fair value of assets acquired:			
Intangible assets(3):			
Developed technologies	\$ 230,000	\$ -	\$ 230,000
In-process research and development	23,000	-	23,000
Liabilities assumed (4)	<u>-</u>	<u>(2,836)</u>	<u>(2,836)</u>
Amount attributable to assets acquired	<u>253,000</u>	<u>(2,836)</u>	<u>250,164</u>
Goodwill (5)	<u>\$ 4,309</u>	<u>\$ 2,836</u>	<u>\$ 7,145</u>

1. 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.
2. 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 million fair value of the warrants was calculated using a Black-Scholes valuation model with assumptions for the following variables: price of Pemix 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.

3. 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. 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.

4. The measurement period adjustments for liabilities assumed represents the amount owed by the Company to customers for product returns beginning November 2014 as stipulated in the Asset Purchase Agreement.
5. 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.

Somaxon Acquisition

On March 6, 2013, the Company completed an acquisition of Somaxon pursuant to an agreement and plan of merger dated December 10, 2012. The Company acquired all of the outstanding common stock of Somaxon pursuant to an agreement and plan of merger. As a result of merger, the Company issued an aggregate of approximately 3,665,689 shares of its common stock to the former stockholder of Somaxon. The Company subsequently changed the name of Somaxon to Pernix Sleep, Inc. The Company acquired the Silenor product line in this acquisition.

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. This acquisition is reflected in the Company's consolidated financial statements for the year ended December 31, 2013 and 2014.

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 31,	
	2015	2014
Trade accounts receivable	\$ 60,564	\$ 42,565
Less allowance for prompt pay discounts	(1,844)	(893)
Less allowance for doubtful accounts	(15)	(228)
Total trade receivables, net	58,705	41,444
Receivables from third parties	1,594	2,601
Other miscellaneous receivables	910	82
Total accounts receivable, net	\$ 61,209	\$ 44,127

The Company typically requires customers to remit payments within the first 30 days for brand purchases and 60 to 75 days for generic purchases (depending on the customer and the products purchased). The Company offers wholesale distributors a prompt payment discount, which is typically between two and three 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 matured 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 matured and was paid in full on September 11, 2015.

Note 9. Inventory

Inventories consist of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	\$ 2,047	\$ 499
Work-in-process	1,425	-
Finished goods	9,011	12,200
Inventory, gross	12,483	12,699
Reserve for obsolescence	(2,448)	(2,220)
Inventory, net	\$ 10,035	\$ 10,479

An increase in the basis of inventory related to the acquisitions of Cypress and Somaxon is included in the balance above as of December 31, 2014. The increase included in raw materials from the Somaxon acquisition was approximately \$97,000 as of December 31, 2014. The Company reclassified \$883,000 of product samples from inventory, net to prepaid expenses and other current assets as of December 31, 2014.

Note 10. Property, Plant & Equipment

	December 31,	
	2015	2014
Land	\$ 572	\$ 572
Buildings and improvements	31	12
Equipment	840	253
Furniture and fixtures	713	339
Computer software and website	657	517
Total fixed assets	2,813	1,693
Less: accumulated depreciation	(467)	(179)
Total property and equipment	\$ 2,346	\$ 1,514

Depreciation expense amounted to approximately \$361,000, \$331,000 and \$672,000 for the years ended December 31, 2015, 2014 and 2013, 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 its 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. Goodwill and Intangible Assets

Goodwill consists of the following (in thousands):

	<u>Amount</u>
Balance at December 31, 2013	\$ 42,497
Goodwill acquired - Treximet	4,309
Goodwill impairment - PML	(916)
Measurement period adjustments	<u>(990)</u>
Balance at December 31, 2014	44,900
Goodwill acquired - Zohydro	180
Measurement period adjustments - Zohydro	6,949
Measurement period adjustments - Treximet	<u>2,836</u>
Balance at December 31, 2015	<u>\$ 54,865</u>

Intangible assets consist of the following (dollars in thousands):

		<u>As of December 31, 2015</u>			
		<u>Gross Carrying</u>		<u>Accumulated</u>	<u>Net Carrying</u>
		<u>Weighted Average Life</u>	<u>Amount</u>	<u>Impairment</u>	<u>Amortization</u>
Unamortized intangible assets:					
Trademark rights	Indefinite	\$ 400	\$ (400)	\$ -	\$ -
In-process research and development	Indefinite	<u>29,500</u>	<u>(3,000)</u>	-	<u>26,500</u>
Total unamortized intangible assets		<u>29,900</u>	<u>(3,400)</u>	-	<u>26,500</u>
Amortized intangible assets:					
Patents	11.0 years	500	(106)	(394)	-
Brand	8.0 years	3,887	-	(2,794)	1,093
Product licenses	10.5 years	17,581	(10,059)	(5,542)	1,980
Non-compete and supplier contracts	5.6 years	6,337	-	(6,337)	-
Acquired developed technologies	4.1 years	<u>391,624</u>	<u>(10,787)</u>	<u>(124,467)</u>	<u>256,370</u>
Total amortized intangible assets		<u>419,929</u>	<u>(20,952)</u>	<u>(139,534)</u>	<u>259,443</u>
Total intangible assets		<u>\$ 449,829</u>	<u>\$ (24,352)</u>	<u>\$ (139,534)</u>	<u>\$ 285,943</u>

	Weighted Average Life	As of December 31, 2014		
		Gross Carrying	Accumulated	Net Carrying
		Amount	Amortization	Amount
Unamortized intangible assets:				
Trademark rights	Indefinite	\$ 400	\$ -	\$ 400
In-process research and development	Indefinite	48,300	-	48,300
Total unamortized intangible assets		<u>48,700</u>	<u>-</u>	<u>48,700</u>
Amortized 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 amortized intangible assets		<u>296,988</u>	<u>(45,199)</u>	<u>251,789</u>
Total intangible assets		<u>\$ 345,688</u>	<u>\$ (45,199)</u>	<u>\$ 300,489</u>

As of December 31, 2015, the weighted average life for our definite-lived intangible assets in total was approximately 4.50 years.

In connection with the acquisition of the Zohydro ER acquisition (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 \$98.8 million and IPR&D intangibles valued at \$4.2 million. Intellectual property will be amortized on a straight-line basis over 4.6 years. IPR&D will be amortized on a straight-line basis over its useful life once the receipt of regulatory approval is obtained.

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. During the year ended December 31, 2015, the Company reclassified \$23.0 million from IPR&D intangibles to Acquired developed technologies due to the approval of the Treximet pediatric indication. Intellectual property will be amortized on a straight-line basis over 3.5 years.

During 2015, the Company recorded impairment charges of approximately \$400,000 against trademark rights, \$3.0 million against IPR&D, \$106,000 against patents, \$10.1 million against product licenses and \$10.8 million against acquired developed technologies. The Company decided during the year ended December 31, 2015 to focus its efforts on certain core products and no longer promote certain other products which are not aligned with this business strategy or due to the termination of certain contractual agreements.

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 consists of \$8.9 million related to projects the Company acquired in the acquisition of Cypress that it has 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):

	<u>Amount</u>
2016	\$ 99,817
2017	98,151
2018	32,560
2019	21,364
2020	1,588
Thereafter	<u>5,963</u>
Total	<u>\$ 259,443</u>

Amortization expense was \$94.3 million, \$32.7 million and \$7.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Note 13. Accrued Allowances

Accrued allowances consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Accrued returns allowance	\$ 11,896	\$ 9,691
Accrued price adjustments	44,100	32,945
Accrued government program rebates	<u>6,682</u>	<u>9,968</u>
Total	<u>\$ 62,678</u>	<u>\$ 52,604</u>

Note 14. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Due to third parties (revenue sharing arrangements)	\$ 6,995	\$ 9,153
Accrued legal reserve	-	3,500
Other accrued expenses	<u>2,360</u>	<u>2,680</u>
Total	<u>\$ 9,355</u>	<u>\$ 15,333</u>

Note 15. Other Liabilities

Other liabilities consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Settlement obligations (see note 22)	\$ 12,955	\$ 11,229
Deferred revenue	314	3,743
Other	<u>222</u>	<u>47</u>
Total contracts payable and other obligations	13,491	15,019
Less current portion	<u>(6,753)</u>	<u>(3,264)</u>
Other liabilities - long-term	<u>\$ 6,738</u>	<u>\$ 11,755</u>

Note 16. Debt and Lines of Credit

Debt consists of the following (in thousands):

	December 31,	
	2015	2014
Wells Fargo Credit Facility	\$ 15,000	\$ -
Midcap Credit Facility	-	7,345
8.00% Convertible Notes	-	65,000
4.25% Convertible Notes	103,806	-
Treximet Secured Notes	<u>209,987</u>	<u>220,000</u>
Total outstanding debt	328,793	292,345
Less current portion	15,044	7,345
Long term debt outstanding	<u>\$ 313,749</u>	<u>\$ 285,000</u>

The following table represents, by year, the future maturity schedule of the outstanding debt and line of credit as of December 31, 2015 (in thousands):

	Amount
2016	\$ 15,044
2017	-
2018	15,000
2019	-
2020	194,943
Thereafter	<u>130,000</u>
Total maturities	354,987
Less: note discount	<u>(26,194)</u>
Total outstanding debt	\$ 328,793

Interest expense amounted to \$38.3 million, \$19.2 million and \$4.2 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Credit Facilities:

Wells Fargo

On August 21, 2015, the Company entered into a Credit Agreement with Wells Fargo, National Association, as Administrative Agent and the lenders party thereto for a \$50.0 million, three-year senior secured revolving credit facility (the "Wells Fargo Credit Facility"), which may be increased by an additional \$20.0 million in the lenders' discretion.

The Company's obligations under the Wells Fargo Credit Facility are secured by, among other things, the Company's and certain subsidiaries' inventory and accounts receivable, and are guaranteed by certain of the Company's subsidiaries. As of December 31, 2015, \$15.0 million is outstanding under the Wells Fargo Credit Facility and classified as Credit facilities - long-term on the consolidated balance sheets. Availability of borrowings under the Wells Fargo Credit Facility from time to time is subject to a borrowing base calculation based upon a valuation of the Company's eligible inventories and eligible accounts receivable, each multiplied by an applicable advance rate. Borrowing availability under the Wells Fargo Credit Facility was \$15.3 million as of December 31, 2015. Borrowings under the Wells Fargo Credit Facility will bear interest at the rate of LIBOR plus 1.5% to LIBOR plus 2.0%. The applicable interest rate margin percentage will be determined by the average daily availability of borrowings under the Wells Fargo Credit Facility. In addition, the Company is required to pay a commitment fee on the undrawn commitments under the Wells Fargo Credit Facility from time to time at an applicable rate of 0.25% per annum according to the average daily balance of borrowings under the Wells Fargo Credit Facility during any month. The Wells Fargo Credit Facility contains representations and warranties, affirmative, restrictive and financial covenants, and events of default (applicable to the Company and certain of its subsidiaries) which are customary for credit facilities of this type. The effective interest rate was 5.2% at December 31, 2015.

On August 21, 2015, the Company terminated the Amended and Restated Credit Agreement, dated as of May 8, 2013, as amended, by and among MidCap Funding IV, LLC, and certain subsidiaries of the Company and repaid all outstanding loans thereunder (the "MidCap Credit Facility"). The MidCap Credit Facility provided for a \$20.0 million revolving loan commitment and a \$20 million uncommitted accordion feature. The obligations under the MidCap Credit Facility were secured by a first priority security interest in the Company's accounts, inventory, deposit accounts, securities accounts, securities entitlements, permits and cash and bore 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. The MidCap Credit Facility has been closed and has been replaced with the Wells Fargo Credit Facility.

Convertible Notes:

4.25% Convertible Notes

On April 22, 2015, the Company issued \$130.0 million aggregate principal amount 4.25% Convertible Senior Notes (the "4.25% Convertible Notes"). The 4.25% Convertible Notes mature on April 1, 2021, unless earlier converted, redeemed or repurchased. The Company received net proceeds from the sale of the 4.25% Convertible Notes of \$125.0 million, after deducting placement agent fees and commissions and offering expenses payable by the Company. Interest on the 4.25% Convertible Notes is payable on April 1 and October 1 of each year, beginning October 1, 2015. The discounted note balance of \$103.8 million is recorded as long-term debt on the consolidated balance sheet as of December 31, 2015.

The 4.25% Convertible Notes are governed by the terms of an indenture (the "Indenture"), between the Company and Wilmington Trust, National Association (the "Trustee"), each of which were entered into on April 22, 2015.

The Company may not redeem the 4.25% Convertible Notes prior to April 6, 2019. However, the holders may convert their 4.25% Convertible Notes at any time prior to the close of business on the business day immediately preceding January 1, 2021 only under certain circumstances. 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 87.2030 shares of the Company's common stock for each \$1,000 principal amount of the 4.25% Convertible Notes, which represents an initial conversion price of approximately \$11.47 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 4.25% Convertible Notes in connection with such a corporate transaction. In addition to the holder option to convert, the 4.25% Convertible Notes may be redeemed upon the occurrence of certain events. The Company incurred debt issuance costs of approximately \$5.0 million, which have been deferred and which are being amortized over a six-year period, unless earlier converted, in which case the unamortized costs would be recorded in additional paid-in capital. The effective interest rate on the 4.25% Convertible Notes, including debt issuance costs and bifurcated conversion option derivative (discussed below), is 9.7%.

The Company is required to separate the conversion option in the 4.25% Convertible Notes under ASC 815, *Derivatives and Hedging*. On April 1, 2015, the Company recorded the bifurcated conversion option valued at \$28.5 million as a derivative liability, which creates a discount on the debt. The derivative liability is marked to market through the other income (expense) section on the consolidated statements of operations for each reporting period, while the discount created on the 4.25% Convertible Notes is accreted as interest expense over the life of the debt. The derivative liability is valued at \$9.2 million as of December 31, 2015. If the Company obtains shareholder approval to remove the contractual limit on the number of shares that may be delivered to settle the conversion of the 4.25% Convertible Notes, the conversion feature may meet an exception from derivative accounting and no longer require separate accounting as a bifurcated derivative. As the conversion feature is accounted for as a bifurcated derivative liability, the Company was not required to consider whether the cash conversion or beneficial conversion guidance contained in ASC 470-20, *Debt with Conversion and Other Options*, is applicable to the 4.25% Convertible Notes.

In addition to the bifurcated conversion feature, there are two other features that require bifurcation but contain de minimis value. Although the probability was considered remote, at the time of the transaction, that (1) additional interest would be incurred for failure to file financial statements timely or (2) the 4.25% Convertible Notes would be redeemed by the Company following the failure of the Zohydro ER acquisition to close prior to July 8, 2015. The Company will continue to monitor the timely filing of its financial statements for any additional interest that could be incurred.

Interest expense was \$6.1 million for the year ended December 31, 2015 related to the 4.25% Convertible Notes. Change in fair value of derivative liability was income of \$19.3 million for the year ended December 31, 2015. Accrued interest on the 4.25% Convertible Notes was approximately \$1.4 million and \$0 as of December 31, 2015 and December 31, 2014, respectively. As of December 31, 2015 and December 31, 2014, the Company had outstanding borrowings of \$130.0 million and \$0 related to the 4.25% Convertible Notes, respectively.

8.00% Convertible Notes

On April 16, 2015, the Company entered into an agreement (the "Inducement Agreement") with all of the holders of its 8.00% Convertible Senior Notes due 2019 (the "8.00% Convertible Notes") representing \$65.0 million aggregate principal amount, pursuant to which such holders agreed to the removal of substantially all of the material restrictive covenants in the indenture governing the 8.00% Convertible Notes and to convert their notes in accordance with the provisions of such indenture in exchange for an aggregate of 2,338,129 shares of the Company's common stock (the "Inducement Shares"). The Company recorded \$19.5 million as cost of inducement expense in the year ended December 31, 2015. The issuance of the Inducement Shares was made pursuant to an exemption from the registration requirements of the Securities Act contained in Section 4(a)(2). Each of the holders entering into the Inducement Agreement agreed not to sell the shares of our common stock to be issued to it upon conversion of the 8.00% Convertible Notes for 145 days (the "lock-up period") subject to exceptions, including in connection with settling existing short positions with respect to the 8.00% Convertible Notes and underwritten public offerings pursuant to existing registration rights with respect to such shares of our common stock. In addition, such holders are permitted to dispose of up to 80 percent of such shares of our common stock remaining after settling existing short positions prior to the end of the lock-up period in specified intervals.

During the year ended December 31, 2015, the holders of the 8.00% Convertible Notes converted the outstanding notes at a conversion price of \$3.60 per share. The Company issued 18.1 million shares pursuant to this conversion and retired the \$65.0 million of the outstanding 8.00% Convertible Notes.

Interest expense was \$1.6 million and \$4.5 million for the years ended December 31, 2015 and 2014, respectively related to the 8.00% Convertible Notes. As of December 31, 2015 and 2014, the Company had outstanding borrowings of \$0 and \$65.0 million related to the 8.00% Convertible Notes, respectively. Accrued interest on the 8.00% Convertible Notes was approximately \$0 and \$231,000 as of December 31, 2015 and 2014, respectively. Interest expense of \$547,000 that accrued during the year ended December 31, 2015 was forfeited and recorded in additional paid-in capital. During the year ended December 31, 2015, the Company recorded the remaining \$5.4 million unamortized deferred financing costs related to the 8.00% Convertible Notes in additional paid-in capital.

Secured Notes:

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 Secured 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 Secured 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, the Company will pay an installment of principal of the Treximet Secured 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 Secured Notes on such Payment Date). 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 Secured 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 Secured Notes, or the full amount of the \$210 million remaining principal due of the notes will be due on the maturity date of the Treximet Secured Notes which is August 1, 2020. As of December 31, 2015 and 2014, the Company classified \$15.0 million and \$0, respectively, of the Treximet Secured Notes as a current liability.

The Treximet Secured Notes are unconditionally guaranteed, jointly and severally, by the Guarantors. The Treximet Secured 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 Secured 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 was prior to August 1, 2015, the redemption price would have been equal to the greater of (i) the principal amount of the Treximet Secured Notes being redeemed and (ii) the present value, discounted at the applicable treasury rate of the principal amount of the Treximet Secured 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 Secured Notes being redeemed assuming the principal balances were 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 August 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 August 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 Secured 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 Secured 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 Secured 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 Secured 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 Secured 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 Secured Notes; and (i) certain changes in control of a Guarantor.

Interest expense related to the Treximet Secured Notes was \$25.9 million and \$9.8 million, for the years ended December 31, 2015 and 2014, respectively. Accrued interest on the Treximet Secured Notes was approximately \$10.5 million and \$9.8 million as of December 31, 2015 and 2014, respectively. The Company recorded debt issuance costs of \$7.8 million, which are being amortized using the effective interest method. As of December 31, 2015, \$1.3 million and \$4.7 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Other long-term assets, respectively.

On April 13, 2015, the Company furnished to the holders of the Treximet Secured Notes a Consent Solicitation Statement (the "Consent Solicitation"). The Consent Solicitation sought the consent of the holders of a majority of the principal amount of the Treximet Secured Notes to amend the Indenture, dated August 19, 2014 (the "Indenture"), among the Company, certain subsidiaries of the Company, as guarantors, and U.S. Bank National Association, that governs the Treximet Secured Notes to allow the Company to, among other things, incur up to \$42.2 million of additional debt (the "Indenture Amendments") in exchange for a consent fee in cash equal to 1% of the principal amount of consenting Treximet Secured Notes (the "Consent Fees"). Through April 28, 2015, the Company received consent to the Indenture Amendments from holders representing approximately 98% of the principal amount of the Notes, and subsequently paid the holders approximately \$2.2 million during the year ended December 31, 2015. The cost of inducement of \$2.2 million is recorded in prepaid expenses and other current assets and other long term assets on the consolidated balance sheet at December 31, 2015 and are being amortized using the effective interest method.

Note 17. Stockholders' Equity

Capital Stock

In July 2015, the Company filed a Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Company (the "Certificate of Amendment") with the Secretary of State of the State of Maryland. The Certificate of Amendment amended the Company's Amended and Restated Certificate of Incorporation by increasing the number of authorized shares of the Company's common stock from 90,000,000 shares to 140,000,000 shares and the attendant increase in capital stock of all classes from 100,000,000 to 150,000,000, consisting of 140,000,000 shares of common stock and 10,000,000 shares of preferred stock, which shall include 1,000,000 shares of Series B junior participating stock. The Company did not change the authorized number of shares of preferred stock.

In April 2015, the Company issued 1,682,086 shares of common stock for approximately \$11.9 million in connection with the acquisition of Zohydro ER, see Note 4, *Business Combination and Other Acquisitions*.

In April 2015, the Company issued 2,338,129 shares of Common stock for approximately \$19.5 million for the inducement, which was recorded as an expense in the year ended December 31, 2015, and 18,055,556 shares for \$60.2 million, net of deferred financing costs and accrued interest forfeited of \$4.8 million in connection with the conversion of the outstanding 8.00% Convertible Notes, see Note 16, *Debt and Lines of Credit*.

Controlled Equity Offering

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 the Company's 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 the Company's common stock that may be issued and sold under the Controlled Equity Offering Sales Agreement, dated November 7, 2014, between the Company and Cantor as agent. This program will provide the Company with financial flexibility and the ability to opportunistically access the capital markets.

Also in November 2014, the Company filed an acquisition shelf registration statement on Form S-4 with the SEC, which will enable the Company 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.

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. As of December 31, 2015, the Company has approximately 469,000 outstanding warrants in connection with these warrants.

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, 2015. In March 2015, Pozen exercised all 500,000 of their warrants in a cashless exercise for which 315,835 shares were issued. See Note 4, *Business Combinations and Other Acquisitions*, for further information.

Warrants Issued in connection with Issuance of the 8.00% Convertible Notes

The Company 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 to the Company in connection with the sale of the 8.0% Convertible Notes and in connection with the settlement of a lawsuit instituted by Frontline against the Company in October 2014. The exercise price of the warrant equals the conversion price of the convertible notes. The warrants were recorded at a fair value of \$841,000 to stockholders' equity as additional paid in capital. In February 2015 and July 2015, Frontline exercised 222,631 and 277,369, respectively, of their warrants in cashless exercises for which 217,562 shares were issued. There are no warrants remaining for Frontline.

Treasury Shares

Treasury shares increased by 297,715 and 335,357 shares from restricted share awards that vested during the years ended December 31, 2015 and 2014, respectively, that were forfeited to cover personal income tax liabilities as a result of the vesting.

Note 18. 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, 2015, 2014 and 2013, 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, 2015 and 2014:

Gross Product Sales	2015	2014	2013
McKesson Corporation	38%	37%	35%
AmerisourceBergen Drug Corporation	27%	31%	20%
Cardinal Health, Inc.	28%	23%	24%
Total	93%	91%	79%

Accounts Receivable	2015	2014
McKesson Corporation	34%	29%
AmerisourceBergen Drug Corporation	30%	42%
Cardinal Health, Inc.	28%	18%
Total	92%	89%

Note 19. 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, 2015, 2014 and 2013, we recognized approximately \$25.4 million, \$18.5 million and \$6.9 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 \$4.6 million, \$2.7 million and \$4.3 million for the years ended December 31, 2015, 2014, and 2013.

In September 2013, the Company amended the terms of its 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 were being recognized on a straight-line basis over the term of the agreement. On November 16, 2015, the Company terminated this agreement and recognized the remaining deferred revenue of \$3.0 million during the year ended December 31, 2015. There were additional milestones at the first and second anniversary dates of the execution of the agreement totaling \$4.0 million in the aggregate. These milestones were not met and have been canceled. Royalty payments ranging from 15% to 20% were based on tiered levels of gross profits and 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 Omeclamox-Pak. The aforementioned royalty period ended September 2015 and the license and supply agreement was terminated on November 18, 2015 with no future liability to Permex.

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.

In connection with the acquisition of Zohydro, the Company is responsible for the payment of royalties to Recro of 6%. 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. 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 \$4.0 million 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 20. Stock Benefit Plans and Stock-Based Compensation Plans

The Company maintains a tax-qualified employee savings and retirement plan (401(k) Plan) covering all of the Company's full-time employees in the United States. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation up to the maximum percent allowable, not to exceed the limits of the code section 401(k), 403(b), 404 and 415, of eligible compensation or the prescribed IRS annual limit and have the amount of such reduction contributed to the 401(k) Plan. The 401(k) Plan permits, but does not require, additional matching contributions to the 401(k) Plan by the Company on behalf of all participants. During the years ended December 31, 2015, 2014 and 2013, the Company matched 100% of employee contributions up to 3% of employee pre-tax contributions and 50% of employee contribution over 3% up to 5% of employee pre-tax contributions. The 401(k) Plan currently meets the minimum requirements of a Safe Harbor 401(k) plan. As of December 31, 2015, 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 \$519,000, \$361,000 and \$450,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

In June 2015, the Company's shareholders approved the 2015 Omnibus Incentive Plan (the "2015 Plan"). The maximum number of shares that can be offered under this plan is 7.0 million. Incentives may be granted under the 2015 Plan to eligible participants in the form of (a) incentive stock options, (b) non-qualified stock options, (c) restricted shares, (d) restricted stock units, (e) share appreciation rights and (f) other share-based awards. Incentive grants under the 2015 Plan generally vest based on four years of continuous service and have 10-year contractual terms.

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 the Company's shareholders 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, 2015, the 2007 Plan had 44,000 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 share-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 model were as follows:

	Year ended December 31,		
	2015	2014	2013
Weighted average expected stock price volatility	72.3 %	74.7 %	66.8 %
Estimated dividend yield	- %	- %	- %
Risk-free interest rate	1.7 %	1.9 %	1.0 %
Expected life of option (in years)	6.3	6.2	6.0
Weighted average grant date fair value per option	\$ 4.23	\$ 3.44	\$ 4.64

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-based compensation expense was \$5.9 million, \$4.7 million and \$2.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. Stock-based compensation expense for the periods presented is included within the selling, general and administrative expense in the consolidated statements of operations.

Stock Options

As of December 31, 2015, approximately 7.0 million options are outstanding that have been issued to current officers and employees under the Company's 2007 Stock Option Plan, the 2009 Plan and the 2015 Plan. As of December 31, 2015, there was approximately \$14.3 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 2.9 years.

Performance Options

During the year ended December 31, 2015, the Company's Board of Directors awarded a total of 485,000 options ("Performance Options") to certain of the Company's executive officers. A determination of whether and how many of the Performance Options vest and become exercisable will be made on August 14, 2018 (the "Measuring Date") (the date that is three-years from the grant date) based upon the average closing bid price of the Company's Common Stock for the twenty trading days ending on the Measuring Date. If the average closing bid price of the Company's Common Stock for the twenty trading days immediately ending on the Measuring Date is (i) less than \$20 per share, no Performance Options vest, (ii) \$20 per share or more and less than \$25 per share, then 50% of the Performance Options vest, (iii) \$25 per share or more and less than \$30 per share, then 75% of the Performance Options vest, (iii) \$30 per share or more and less than \$35 per share, then 100% of the Performance Options vest, and (iv) \$35 per share or more, then 150% of the Performance Options vest. 50% of any such vested options shall be exercisable on the Measuring Date and the remaining 50% of such vested options shall be exercisable one year after the Measuring Date. Upon a change of control of the Company after the Measuring Date, any vested but un-exercisable Performance Options shall become exercisable. Upon a change of control prior to the Measuring Date, the Measuring Date shall become the effective date of the change of control and the amount of Performance Options that vest, if any, shall be based upon the common stock price as of the effective date of the change of control. For example, if a change of control occurs prior to August 14, 2018 and the price of the Company's Common Stock for the twenty trading days prior to the effective date of the change of control is \$24 per share then each named executive officer would vest in 50% of the Performance Options.

The Company utilized a Monte Carlo simulation to determine the grant date fair value of the awards. Compensation expense is recognized over the performance period of each tranche in accordance with ASC 718, *Compensation - Stock Compensation*. For the year ended December 31, 2015, the Company recorded \$42,000 of share-based compensation expense related to these options.

The following table shows the option activity, described above, during the year ended December 31, 2015 (share and intrinsic values in thousands):

	Average	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
	Exercise Price		
	Shares		
Options Outstanding at December 31, 2014	4,551	\$ 5.35	
Granted	2,849	6.15	
Exercised	(39)	3.92	\$ 211
Cancelled	(331)	8.34	
Expired	-	-	
Options outstanding at December 31, 2015	<u>7,030</u>	\$ 5.54	8.7 \$ 1,129
Options vested and expected to vest as of December 31, 2015	6,223	\$ 5.50	8.7 \$ 1,035
Options vested and exercisable as of December 31, 2015	1,461	\$ 5.08	7.8 \$ 430

The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 were \$211,000, \$2.9 million and \$132,000, 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.

Restricted Stock

The following table shows the Company's non-vested restricted stock activity during the year ended December 31, 2015 (share and intrinsic values in thousands):

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>	<u>Aggregate Intrinsic Value</u>
Non-vested restricted stock outstanding at December 31, 2014	140	\$ 4.52	
Granted	-	-	
Vested	(64)	6.25	\$ 562
Forfeited	(20)	3.18	
Non-vested restricted stock outstanding at December 31, 2015	<u>56</u>	<u>3.00</u>	

The total intrinsic value of restricted stock vested during the years ended December 31, 2015, 2014 and 2013 were \$562,000, \$2.9 million and \$795,000, respectively.

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, 2015, there was approximately \$0 of total unrecognized compensation cost related to non-vested restricted stock issued to employees and directors of the Company.

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 annual 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 244,899 have been issued. Compensation expense related to the Employee Stock Purchase Plan was \$253,000, \$124,000 and \$71,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

Note 21. Income Taxes

During the year ended December 31, 2015, the Company established a valuation allowance against its deferred tax assets. A valuation allowance, if needed, reduces deferred tax assets to the amount expected to be realized. In assessing the need for a valuation allowance, the Company considered both positive and negative evidence related to the likelihood of realization of the deferred tax assets. This evidence includes, but is not limited to, assessing changing business model(s) and market conditions, current and prior earnings history, expected future earnings, carry-back and carry-forward periods, and the feasibility of ongoing tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset. The weight given to the positive and negative evidence is commensurate with the extent the evidence may be objectively verified. As such, the Company concluded that there was not sufficient positive evidence to outweigh the objective negative evidence of recent financial reporting losses and expected future losses resulting from its new business model.

The components of the provision (benefit) for income taxes are as follows for the years ending December 31, 2015, 2014 and 2013 (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Current:			
Federal	\$ 6,923	\$ (1,817)	\$ 1,176
State	508	232	583
Foreign	207	(387)	-
Total current provision (benefit)	<u>7,638</u>	<u>(1,972)</u>	<u>1,759</u>
Deferred Provision:			
Federal	(1,329)	(9,497)	(18,985)
State	(551)	(952)	(3,531)
Foreign	1,304	(1,304)	-
Total deferred provision (benefit)	<u>(576)</u>	<u>(11,753)</u>	<u>(22,516)</u>
Total	<u>\$ 7,062</u>	<u>\$ (13,725)</u>	<u>\$ (20,757)</u>

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 (in thousands):

	Year Ended December	
	2015	2014
Deferred tax assets:		
Accruals and other reserves	\$ 24,205	\$ 19,215
Differences in carrying value of property and equipment	-	93
Inventory	985	958
Stock awards	3,757	2,060
Net operating loss carryovers	<u>8,038</u>	<u>9,045</u>
Gross deferred tax assets	36,985	31,371
Valuation allowance	<u>(31,453)</u>	-
Net deferred tax asset	5,532	31,371
Deferred tax liabilities:		
Fixed Assets	(1,021)	-
Other	-	(497)
Intangibles	(4,713)	(22,577)
Installment sale	-	(1,753)
Gross deferred tax liability	<u>(5,734)</u>	<u>(24,827)</u>
Net deferred tax asset/(liability)	<u>(202)</u>	<u>6,544</u>
Included in consolidated balance sheet:		
Deferred income tax assets/(liabilities) - current	-	6,544
Deferred income tax assets/(liabilities) - long-term	<u>(202)</u>	-
Net deferred tax asset/(liability)	<u>\$ (202)</u>	<u>\$ 6,544</u>

Somaxon has federal net operating loss carryforwards (NOL's) of approximately \$250.2 million at December 31, 2015 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 \$9.8 million at December 31, 2015 ranging in expiration from 2023 to 2032. Included in the \$9.8 million are \$1.2 million of NOLs which have not been recognized for financial reporting purposes due to unrecognized tax benefits and excess tax benefits related to stock-based compensation. Excess tax benefits related to option exercises cannot be recognized until realized through a reduction of current taxes payable.

GTA has federal NOL's of approximately \$85.3 million at December 31, 2015 ranging in expiration from 2024 to 2033. However, based on the change in ownership provisions of IRC Section 382, approximately \$500,000 of those NOL are expected to be available for utilization.

Somaxon has federal research and development credit carryovers of approximately \$4.5 million at December 31, 2015. However, based on the change in ownership provision of IRC Section 382, approximately \$300,000 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).

The effective income tax rate from continuing operations is different from the federal statutory rate for the years ended December 31, 2015, 2014 and 2013 for the following reasons:

	Year Ended December 31,		
	2015	2014	2013
Expected taxes at statutory rates	35.0 %	35.0 %	35.0 %
State taxes, net of federal tax benefit	-	1.0 %	4.1 %
Foreign income tax rate differential	(13.6)%	(7.5)%	-
Amortization and impairment of goodwill	(2.0)%	-	-
Cypress put option - change in value and contingent gain	-	-	6.0 %
Deductible inducement payment	2.0 %	-	-
Change in valuation allowance	(21.7)%	-	-
Change in liability for uncertain tax positions	(4.8)%	-	-
Permanent differences and other	0.1 %	(0.5)%	(0.4)%
	<u>(5.0)%</u>	<u>28.0 %</u>	<u>44.7 %</u>

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 \$500,000 and \$11.1 million of the deferred tax liability at December 31, 2015 and 2014, 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.

The following summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	Year Ended December	
	2015	2014
Balance at beginning of year	\$ -	\$ -
Tax positions taken in prior periods	-	-
Tax positions taken in current year	7,410	-
Accrual of interest related to tax positions taken	-	-
Settlements	-	-
Foreign currency translation	-	-
Balance at end of year	<u>\$ 7,410</u>	<u>\$ -</u>

As of December 31, 2015, 2014 and 2013, the total amount of gross unrecognized tax benefits was \$7.4 million, \$0, and \$0, respectively. Of these amounts as of December 31, 2015, 2014 and 2013, \$0, \$0 and \$0, respectively would impact the effective tax rate if recognized as the unrecognized tax benefits are associated with deferred tax assets subject to a full valuation allowance.

It is the Company's policy to classify accrued interest and penalties as part of the accrued unrecognized tax benefits liability and record the expense in the provision for income taxes. For the years ended December 31, 2015, 2014 and 2013, the amount of accrued interest or penalties related to unrecognized tax benefit totaled \$0, \$0, and \$0, respectively. For unrecognized tax benefits that existed at December 31, 2015, the Company does not anticipate any significant changes within the next twelve months.

The Company files income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. As of December 31, 2015, the 2012 through 2014 tax years are open and may be subject to potential examinations in the United States.

Note 22. 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 \$6.7 million.

Leases

The Company leases facilities space and equipment under operating lease arrangements that have terms expiring at various dates through 2022. 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. In January 2015, the Company amended its lease in Morristown, NJ to add 9,562 square feet of office space for a total of 15,990 square feet for approximately \$40,000 per month, which is subject to certain annual escalators and extend the original term of the lease to expire July 31, 2022. The total lease obligation is approximately \$3.7 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 were based. In conjunction with the restructuring discussed in Note 23, *Restructuring*, the Company shut down this office and relocated all remaining positions to the Company's Morristown, NJ office as of September 30, 2015. Effective October 1, 2015, the Company subleased this office space to a third party for the remainder of the lease term. The term of this lease is 62 months and the total financial obligation under this lease is approximately \$593,000.

Future minimum lease payments under non-cancelable operating leases are as follows as of December 31, 2015 (in thousands):

	<u>Amount</u>
2016	\$ 677
2017	617
2018	628
2019	640
2020	518
Thereafter	833
Total	<u>\$ 3,913</u>

Future minimum lease payments under non-cancelable operating subleases are as follows as of December 31, 2015 (in thousands):

	<u>Amount</u>
2016	\$ 116
2017	118
2018	121
2019	125
2020	-
Thereafter	-
Total	<u>\$ 480</u>

Total rent expense was approximately \$653,000, \$553,000 and \$730,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Total sublease rental income was approximately \$19,000, 0 and 0 for the years ended December 31, 2015, 2014 and 2013, respectively and was recorded as a reduction to rent expense.

Other Commitments

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, 2015, remaining payment obligations owed under these settlement agreements are \$1.0 million, payable in equal annual installments of \$250,000 through 2019, and \$1.0 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, 2015.

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 the Company 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 its financial statements at December 31, 2013 and recorded as an expense during the year 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 \$7.1 million and \$8.2 million as of December 31, 2015 and 2014 and is included in other liabilities (both current and long-term) on the consolidated balance sheet.

Note 23. Restructuring

On March 16, 2015, the Company decided to institute an initiative to restructure operations and shut down the Charleston, South Carolina site. This step was done to consolidate operations within the Company's headquarters located in Morristown, New Jersey.

During the year ended December 31, 2015, the Company incurred a charge of \$1.1 million related to the restructuring. The charge during the year ended December 31, 2015 was comprised of \$485,000 in severance related cash expenses, and \$653,000 for the modification and accelerated vesting of options and awards under existing employee agreements. Associated severance payments are anticipated to be paid by May 31, 2016.

A summary of accrued restructuring costs, included as a component of accounts payable and accrued expenses on the consolidated balance sheets, is as follows (in thousands):

	<u>December 31,</u> <u>2014</u>	<u>Charges</u>	<u>Cash</u>	<u>Non-cash</u>	<u>December 31,</u> <u>2015</u>
Restructuring Costs	\$ -	\$ 1,137	\$ (380)	\$ (653)	\$ 104

Note 24. Supplemental Cash Flow Information

	<u>Years ended December 31,</u>		
	<u>2015</u>	<u>2014</u>	<u>2013</u>
<i>Supplemental disclosures of Cash Flow Information:</i>			
Cash (received) paid for income taxes, net	\$ (352)	\$ 4,217	\$ 1,265
Cash paid for interest	30,207	6,451	2,733
<i>Supplemental disclosures of Non-cash Investing and Financing Activities:</i>			
Conversion of 8.00% Convertible notes	60,172	-	-
Issuance of 1,682,086 shares to Zogenix for Zohydro acquisition	11,926	-	-
Acquisition of TREXIMET® - warrants issued to Pozen	-	2,359	-
Accrued severance paid in restricted common stock	-	-	142
Acquisition of Cypress and Somaxon - Purchase price adjustment	-	(990)	5,412
Acquisition of Somaxon - Fair value of common stock	-	-	24,840
Warrants issued to Frontline in connection with the issuance of the			
8% Convertible Notes	-	841	-
Acquisition of license - contract payable	-	-	500

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,	June 30,	September 30,	December 31,
2015				
Net revenues	\$ 33,889	\$ 46,977	\$ 48,615	\$ 46,369
Operating loss	(18,905)	(15,362)	(16,153)	(50,834)
Net loss	(23,674)	(32,235)	(10,740)	(81,666)
Basic loss per common share	\$ (0.62)	\$ (0.62)	\$ (0.18)	\$ (1.34)
Diluted loss per common and potential common share	\$ (0.62)	\$ (0.62)	\$ (0.18)	\$ (1.34)
2014				
Net revenues	\$ 19,052	\$ 17,382	\$ 31,479	\$ 53,834
Operating loss	(14,143)	(7,749)	(5,702)	(2,620)
Net loss	(9,542)	(6,233)	(11,692)	(7,819)
Basic loss per common share	\$ (0.26)	\$ (0.16)	\$ (0.31)	\$ (0.20)
Diluted loss per common and potential common share	\$ (0.26)	\$ (0.16)	\$ (0.31)	\$ (0.20)

Schedule II
Pernix Therapeutics Holdings, Inc.
Valuation and Qualifying Accounts
Years Ended December 31, 2015, 2014 and 2013

(in thousands)	<u>Balance at beginning of period</u>	<u>Additions charged to costs and expenses</u>	<u>Deductions</u>	<u>Balance at end of period</u>
For the year ended December 31, 2015				
Allowance for doubtful accounts (1)	\$ 228	\$ -	\$ (213)	\$ 15
Allowance for prompt pay discounts (1)	893	6,949	(5,998)	1,844
Inventory obsolescence allowance (2)	2,220	960	(732)	2,448
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

(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 operations and comprehensive loss.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures, or Disclosure Controls, are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms. Our Disclosure Controls include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on the controls evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the date of their evaluation, our disclosure controls and procedures were effective as of December 31, 2015.

(b) Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide our management and board of directors reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2015. 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 we believe that, as of December 31, 2015, our internal control over financial reporting is effective based on those criteria.

Cherry Bekaert LLP, our independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting as of December 31, 2015. This report appears on page 74 of this report.

(c) Change in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, due to the restructuring and the subsequent consolidation of offices to New Jersey, we have reviewed all of our internal controls over financial reporting in an effort to maximize the value of existing internal controls. Additionally, we have hired several new accounting personnel in our New Jersey office that are responsible for internal controls over financial reporting beginning in the second quarter of 2015.

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 2016 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, 2015, 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 Pemix. 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*

	<u>Page</u>
Reports of Independent Registered Public Accounting Firm	74
Consolidated Balance Sheets as of December 31, 2015 and 2014	76
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013	77
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013	78
Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	79
Notes to Consolidated Financial Statements	80

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 10, 2016

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Douglas Drysdale</u> Douglas Drysdale	President, Chief Executive Officer and Chairman (Principal Executive Officer)	March 10, 2016
<u>/s/ Sanjay S. Patel</u> Sanjay S. Patel	Chief Financial Officer (Principal Financial Officer)	March 10, 2016
<u>/s/ Michael J. Golembiewski</u> Michael J. Golembiewski	Vice President of Finance and Corporate Controller (Principal Accounting Officer)	March 10, 2016
<u>/s/ Steven A. Elms</u> Steven A. Elms	Director	March 10, 2016
<u>/s/ John Sedor</u> John Sedor	Director	March 10, 2016
<u>/s/ Tasos Konidaris</u> Tasos Konidaris	Director	March 10, 2016

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 Pemix 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 Pemix 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	1/4/2013
2.3	Agreement and Plan of Merger dated December 10, 2012 by and among Pemix Therapeutics Holdings, Inc., Pemix 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	8/9/2013
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	9/17/2013
2.6	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 Pemix Therapeutics Holdings, Inc.		8-K	5/16/2014
2.7	Letter Agreement dated August 14, 2014 among Pemix Therapeutics Holdings, Inc., Worrigan Limited, Glaxo Group, Limited, GlaxoSmithKline Intellectual Property Management Limited, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline, LLC		8-K	8/22/2014
2.8	Asset Purchase Agreement, dated as of March 10, 2015, between Zogenix Inc., Pemix Ireland Limited, and solely with respect to Sections 5.9.2, 10.2 and 10.14, Pemix Therapeutics Holding Inc.		10-Q/A	8/19/2015
2.9	Amendment to Asset Purchase Agreement, dated as of April 23, 2015, between Zogenix Inc., Pemix Ireland Limited and Pemix Therapeutics Holding Inc.		10-Q	5/1/2015
3.1	Articles of Incorporation of Pemix Therapeutics Holdings, Inc.		8-K	3/15/2010
3.2	Bylaws of Pemix Therapeutics Holdings, Inc.		8-K	3/15/2010
3.3	Articles of Amendment to the Articles of Incorporation of Pemix Therapeutics Holdings, Inc.		8-K	7/28/2015
4.1	Form of certificate representing shares of common stock of Pemix Therapeutics Holdings, Inc.		10-K	3/29/2012

4.2	Indenture, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association	8-K	2/26/2014
4.3	Form of 8.00% Convertible Senior Note due 2019 (included in Exhibit 4.2)	8-K	2/26/2014
4.4	Common Stock Purchase Warrant dated May 13, 2014 issued to Pozen, Inc.	8-K	5/16/2014
4.5	Indenture, dated August 19, 2014, among Pemix Therapeutics Holdings, Inc., the Guarantors named therein and U.S. Bank National Association, as Trustee and as Collateral Agent	8-K	8/22/2014
4.6	Forms of 12% Senior Secured Notes due 2020 (included in Exhibit 4.6)	8-K	8/22/2014
4.7	First Supplemental Indenture, dated as of August 19, 2014, among Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	8/22/2014
4.8	Second Supplemental Indenture, dated as of August 19, 2014, among Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	8/22/2014
4.9	Form of Warrant to Purchase Common Stock, dated as of December 31, 2014, issued by Pemix Therapeutics Holdings, Inc.	S-3/A (No. 333-200011)	1/30/2015
4.10	Third Supplemental Indenture, dated as of April 21, 2015, between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	4/24/2015
4.11	First Supplemental Indenture, dated as of April 21, 2015, between Pemix Therapeutics Holdings, Inc. and U.S. Bank National Association, as Trustee.	8-K	4/24/2015
4.12	Indenture, dated April 22, 2015, between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	4/24/2015
4.13	Forms of 4.25% Convertible Senior Notes due 2021 (included in Exhibit 4.12)	8-K	4/24/2015
10.1*	2009 Stock Incentive Plan	8-K	3/15/2010
10.2*	2010 Employee Stock Purchase Plan	8-K	8/16/2010
10.3*	Golf Trust of America, Inc. 2007 Stock Option Plan	S-8	6/4/2010
10.4*	2007 Stock Option Plan	DEF14A	11/16/2007
10.5*	Employment and Non-Compete Agreement, dated December 31, 2008, by and between Pemix Therapeutics, Inc. and Michael Venters	8-K	3/15/2010
10.6*	Employment Offer Letter, dated May 10, 2013, by and between Pemix Therapeutics, Inc. and Cooper Collins	10-Q	8/9/2013
10.7*	Amended and Restated Employment and Non-Compete Agreement, dated March 14, 2011, by and among Pemix Therapeutics Holdings, Inc., Macoven Pharmaceuticals, LLC. and John McMahon	10-K	3/30/2011
10.8*	Amendment No. 1 to Amended and Restated Employment and Non-Compete Agreement, dated March 23, 2012, by and among Pemix Therapeutics Holdings, Inc., Macoven Pharmaceuticals, LLC. and John McMahon	10-K	3/29/2012
10.9*	Employment Offer Letter, dated May 10, 2013, by and between Pemix Therapeutics Holdings, Inc., and Michael Pearce	10-Q	8/9/2013

10.10	Form of Amended and Restated Merger Partner Stockholder Agreement	8-K	5/31/2011
10.11	Amended and Restated Credit Agreement dated as of May 8, 2013 by and among Pemix 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	5/13/2013
10.12*	Severance Letter, dated July 19, 2013, by and between Pemix Therapeutics Holdings, Inc. and Tracy S. Clifford	10-Q	8/9/2013
10.13*	Employment Offer Letter, dated April 19, 2013, by and between Pemix Therapeutics Holdings, Inc. and Brian T. Dorsey	8-K	4/25/2013
10.14	Amended and Restated License Agreement by and between Pemix 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	2/7/2014
10.16*	Employment Agreement dated as of February 5, 2014 by and between Pemix Therapeutics Holdings, Inc. and Douglas Drysdale.	8-K	2/7/2014
10.17	Amendment No. 1 to the Amended and Restated Credit Agreement, dated February 21, 2014, between Pemix 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	2/26/2014
10.18	Amended and Restated Security and Pledge Agreement, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and MidCap Funding IV, LLC, as Agent.	8-K	2/26/2014
10.19	Form of Representation Agreement, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and the Investors party thereto	8-K	2/26/2014
10.20	Form of Registration Rights Agreement, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and the Investors party thereto	8-K	2/26/2014
10.21*	Amendment No. 1 to the Pemix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan	10-K	3/17/2014
10.22	Employment Agreement dated as of March 9, 2014 by and between Pemix Therapeutics Holdings, Inc. and Terence Novak	10-Q	5/12/2014
10.23	Pemix Therapeutics Holdings, Inc. Amended and Restated 2009 Stock Incentive Plan	DEF 14A	4/28/2014
10.24	Amendment No. 2 to the Amended and Restated Credit Agreement, dated April 23, 2014, between Pemix 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	5/12/2014
10.25	Employment Offer Letter, dated June 20, 2014, by and between Pemix Therapeutics Holdings, Inc. and Sanjay S. Patel	8-K	6/25/2014
10.26	Amendment No. 3 to the Amended and Restated Credit Agreement, dated as of August 19, 2014, among MidCap Funding IV, LLC, as Agent, Pemix Therapeutics Holdings, Inc. and the subsidiary guarantors identified therein.	8-K	8/22/2014
10.27	Controlled Equity OfferingSM Sales Agreement, dated November 7, 2014, by and between Pemix Therapeutics Holdings, Inc. and Cantor Fitzgerald & Co.	S-3 (No. 333-200005)	11/7/2014

10.28	Consent Solicitation Support Agreement, dated as of April 13, 2015, between the Company and each of the Noteholders party thereto.	8-K	4/16/2015
10.29	Inducement Agreement, dated as of April 16, 2015, by and among Permex Therapeutics Holdings, Inc. and the investors listed on Schedule 1 thereto.	8-K	4/17/2015
10.30*	Permex Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan	DEF 14A	5/8/2015
10.31	Credit Agreement by and among Wells Fargo Bank, National Association, as Administrative Agent, the Lenders that are parties thereto, as Lenders and Permex Therapeutics Holdings, Inc., Permex Therapeutics, LLC, Permex Sleep, Inc., Cypress Pharmaceuticals, Inc., Macoven Pharmaceuticals, Inc., Gain, Inc., Repicopea Inc. and Macoven Pharmaceuticals, L.L.C., as Borrowers dated as of August 21, 2015.	8-K	8/28/2015
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

LIST OF SUBSIDIARIES

Name	Jurisdiction
Macoven Pharmaceuticals, LLC	Louisiana
Pemix Manufacturing, LLC	Texas
Pemix Ireland Limited	Ireland
Pemix Therapeutics, LLC	Louisiana
Pemix Sleep, Inc.	Delaware
Cypress Pharmaceuticals, Inc.	Mississippi
Gain, Inc.	Delaware
Respicopea, Inc.	Delaware
Hawthorn Pharmaceuticals, Inc.	Mississippi
Pemix Ireland Pain Limited	Ireland

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-168877, No. 333-167327, No. 333-166062, No. 333-175992, and No. 333-204997), Form S-4 (No. 333-200042) and Forms S-3 (No. 333-186048, No. 333-174629, No. 333-200005, and No. 333-200011) of Pernix Therapeutics Holdings, Inc. of our reports dated March 10, 2016 relating to the consolidated balance sheets of the Company as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows and the related consolidated statement schedule for each of the three years in the period ending December 31, 2015, and the effectiveness of internal control over financial reporting for the Company as of December 31, 2015.

/s/ Cherry Bekaert LLP

Atlanta, Georgia
March 10, 2016

CERTIFICATION

I, Douglas L. Drysdale, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pemix Therapeutics Holdings, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the Registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an Annual Report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

March 10, 2016

/s/ DOUGLAS L. DRYSDALE

Douglas L. Drysdale

*Chairman and Chief Executive Officer and
President and Director
(Principal Executive Officer)*

CERTIFICATION

I, Sanjay S. Patel, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pemix Therapeutics Holdings, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the Registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an Annual Report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

March 10, 2016

/s/ SANJAY S. PATEL

Sanjay S. Patel

*Chief Financial Officer
(Principal Financial Officer)*

**CERTIFICATION UNDER SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned certifies that this annual report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and that information contained in this annual report fairly presents, in all material respects, the financial condition and results of operations of Pemix Therapeutics Holdings, Inc. for the periods covered by this annual report.

Date: March 10, 2016

/s/ DOUGLAS L. DRYSDALE

Douglas L. Drysdale
*Chairman and Chief Executive Officer and
President and Director
(Principal Executive Officer)*

Date: March 10, 2016

/s/ SANJAY S. PATEL

Sanjay S. Patel
*Chief Financial Officer
(Principal Financial Officer)*
