PERNIX THERAPEUTICS HOLDINGS, INC.

Form 10-K March 28, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

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ldings, Inc.
33-0724736
(I.R.S. Employer Identification Number)
(800) 793-2145
(Telephone number, including area code)
ection 12(b) of the Act:
Name of each exchange on which registered
NASDAQ Global Market
issuer, as defined in Rule 405 of the Securities Act.

Act. Yes

o No b

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

b No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes

þ No o

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

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

Large accelerated filer	O	Accelerated filer	O
Non-accelerated filer	0	Smaller reporting	þ
		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

o No b

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2016 (the last business day of the registrant's most recently completed second quarter) was approximately \$38,304,000, based upon the \$4.50 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, 2017, the registrant had 10,015,641 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

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Unless the context indicates otherwise, references in the report to "Pernix®," "Company," "we," "us" and "our" and similar terms mean Pernix 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."

SPECIAL NOTE REGARDING CLASSIFICATION AS A SMALLER REPORTING COMPANY

Our Form 10-K for our fiscal year ended December 31, 2016 has been prepared following the Securities and Exchange Commission (SEC) guidelines for a smaller reporting company as defined by 229.10 (Item 10) of Regulation S-K. The rules and guidelines for a smaller reporting company allow a company to reduce the amount of historical disclosure required.

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.

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 and distribute our generic products through our wholly owned subsidiaries, Macoven Pharmaceuticals, LLC (Macoven) and Cypress Pharmaceuticals, Inc. [®] (Cypress).

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 the treatment of acute migraine;
- *Pain:* Zohydro® ER (hydrocodone bitartrate) with BeadTekTM, 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; and
- *Insomnia:* Silenor® (doxepin), the only non-narcotic, non-scheduled and non-addictive prescription sleep aid for the treatment of insomnia characterized by difficulty with sleep maintenance;

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
- Reviewing our strategic alternatives, including the restructuring of our outstanding debt and the potential sale of all or a portion of our company which may need to be effectuated through a filing under Chapter 11 of the Bankruptcy Code.

In 2016, we restructured our sales force and operations. The reorganization included (1) a reduction of 54 sales positions, primarily from our Neurology sales team; (2) prioritization and reorganization of sales territories to reduce the inefficient time that sales representatives spent driving long distances between customers; (3) improvement of our compensation plan to incentivize the field sales staff to increase the frequency of calls on the focused targets; and (4) consolidation of the Neurology and Pain sales forces under one sales management structure to eliminate redundancies. In addition, as part of this initiative, we reduced our administrative staff by 6 employees.

Our Products and Product Candidates

Pernix-Promoted Products

Treximet (sumatriptan/naproxen sodium)

Treximet is the only fixed dose combination product approved by the U.S. Food and Drug Administration (FDA) to treat acute migraines. 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 TechnologyTM. We believe 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 of Treximet has been shown to provide superior sustained pain relief compared to placebo and to both of the active ingredients alone. 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 alone.

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 U.S. 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 adolescents 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 and we began to market and sell Treximet for pediatric patients in October 2016.

We promote Treximet in the United States through our nationwide specialty sales force, which covers approximately 40 sales 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. In August 2014, we, through our wholly owned subsidiary, Pernix Ireland Limited (PIL) acquired the U.S. intellectual property rights to Treximet from GSK, as well as GSK's royalty obligation to POZEN. We currently have two qualified suppliers of Treximet. Treximet is covered by five patents in the U.S. Including six months of pediatric exclusivity, four of the patents expire on February 14, 2018, and one expires on April 2, 2026. Six companies filed abbreviated new drug applications (ANDAs) with the FDA seeking approval to market a generic version of Treximet, which resulted in three generics permitted to launch in 2018 and three other generics enjoined from launching until 2026. We also intend to launch our own authorized generic in early 2018. Net revenues of Treximet were \$67.0 million and \$101.8 million for the years ended December 31, 2016 and 2015, respectively. Net revenues of Treximet for the year ended December 31, 2016 were negatively impacted by \$15.3 million of

disputed rebate claims, which were recorded during the year ended December 31, 2016, for sales which occurred in prior periods (\$12.5 million and \$2.8 million for the years ended December 31, 2015 and 2014, respectively) related to the unfavorable arbitration ruling in our dispute with GSK.

The following table sets forth the impact of the GSK arbitration award on net revenues of Treximet (in thousands):

	Year Ended December 31,					
		2016		2015		2014
GAAP net revenues of Treximet	\$	66,961	\$	101,753	\$	54,775
GSK arbitration award adjustment		15,277		(12,484)		(2,793)
Adjusted net revenues of Treximet (1)	\$	82,238	\$	89,269	\$	51,982

(1) Adjusted net revenues of Treximet is a non-generally accepted accounting principles (GAAP) financial measure that adjusts GAAP net revenues of Treximet for the impact of the GSK arbitration award for the year ended December 31, 2016 and reclassifies it to the years ended December 31, 2015 and 2014 and, therefore, has not been calculated in accordance with GAAP. We believe that this non-GAAP financial measure provides meaningful supplemental information regarding our operating results because it reclassifies the gross-to-net adjustments that were the subject of the GSK arbitration award to the years (2015 and 2014) in which the sales directly related to the gross-to-net adjustments actually occurred. See further discussion under the heading "Non-GAAP Financial Measures" in Part II, Item 7 of this Annual Report on Form 10-K.

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 has six dosage 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 deter opioid abuse by immediately forming a viscous gel.

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 a good 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 85 territories. In April 2015, we acquired the Zohydro ER franchise from Zogenix, Inc. (Zogenix). Zohydro ER with BeadTek is manufactured by and licensed from Recro Pharma, Inc. (Recro). Prior to our

acquisition of the Zohydro ER franchise, Zogenix 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 supplier of the commercial product for distribution in the U.S. Zohydro ER with BeadTek is covered by 11 issued U.S. patents, which our subsidiary, Pernix Ireland Pain Limited (PIPL) either owns or has rights to. Two of these patents expire November 1, 2019, six expire July 25, 2033 and three expire September 12, 2034. Net revenues of Zohydro were \$24.7 million and \$16.5 million for the years ended December 31, 2016 and 2015, respectively.

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. Silenor, which uses doxepin at much lower dosages, does not exhibit the same pharmacological effects as high-dose doxepin.

In four separate Phase III clinical trials, Silenor demonstrated a favorable safety and tolerability profile, including a low dropout rate and an adverse event profile comparable to placebo. Silenor demonstrated no clinically meaningful next-day residual effects and no evidence of amnesia, complex sleep behaviors, hallucinations, tolerance or withdrawal effects. Silenor was approved by the FDA in March 2010 for the treatment of insomnia characterized by difficulty with sleep maintenance, and was launched commercially in the United States in September 2010 by Pernix Sleep, Inc. (f/k/a Somaxon Pharmaceuticals, Inc.) (Pernix Sleep). We acquired the Silenor product line as a result of our merger with Somaxon Pharmaceuticals, Inc. (Somaxon) on March 6, 2013, and we launched Silenor in the second quarter of 2013.

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

We believe that Silenor offers many benefits, including improved safety, tolerability and efficacy in the treatment of sleep maintenance. Unlike many of the other insomnia treatments currently available, Silenor is not designated as a controlled substance, and according to its FDA-approved labeling, Silenor does not appear to have any potential for dependency, addiction or abuse. Because Silenor is not a 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 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 Treximet and Zohydro ER with BeadTek nationwide specialty sales forces, which cover approximately 125 territories. 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 six issued U.S. patents, the latest expiring 2030, four of which are exclusively licensed from ProCom One, Inc. (ProCom). Four companies filed ANDAs with the FDA seeking approval to market a generic version of Silenor, which resulted in all four companies being permitted to launch in 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 Silenor. Net revenues of Silenor were \$16.9 million and \$20.9 million for the years ended December 31, 2016 and 2015, respectively.

Externally Promoted and Non-Promoted Products

We market and sell our non-core products, including generics, through our wholly owned subsidiaries, Cypress and Macoven. We market our non-promoted products through distributors and trade partners.

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Research and Development

Our development pipeline projects currently include line extensions and the generation of additional clinical data for existing products. 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 our pipeline.

We are currently exploring the following development programs in the pain area:

• Abuse-deterrent studies. We evaluated Zohydro ER with BeadTek for susceptibility to physical manipulation and chemical extraction of hydrocodone compared to the original formulation of Zohydro ER in a Category 1 study. The study demonstrated that injection by needles and syringes of various sizes is deterred in Zohydro ER with BeadTek, and that Zohydro ER with BeadTek deters abuse via common means such as crushing, grinding, and dissolving in commonly available and other aqueous and non-aqueous solvents. Further, all formulations studied were seen to decompose when heated, indicating abuse by inhalation of vapor will not be effective. In a separate, Category 3 intranasal Human Abuse Liability study, we assessed the abuse potential of crushed Zohydro ER with BeadTek capsules administered intranasally to nondependent, recreational opioid users with intranasal experience. The primary objective of the study was to assess the abuse potential of crushed Zohydro ER with BeadTek compared to the original formulation of Zohydro ER, with secondary objectives comparing Zohydro ER with BeadTek and the original formulation to hydrocodone active pharmaceutical ingredient (API) and placebo. The study demonstrated a statistically significant reduction in Drug Liking for Zohydro ER with BeadTek compared to the original formulation, thus meeting the primary objective of the study. However, the difference in Drug Liking compared to hydrocodone API was not statistically significant and the secondary endpoints did not demonstrate statistical significance.

While these results support the abuse-deterrent properties of Zohydro ER with BeadTek, we believe an opportunity exists to strengthen the properties of the product. As a result, we have prioritized the development of a next generation version of Zohydro ER with enhanced abuse-deterrent characteristics. The recent strengthening of our intellectual property portfolio for Zohydro ER through 2033 has allowed us to consider several options for our next generation product with enhanced abuse deterrent properties.

For the years ended December 31, 2016 and 2015, we recorded \$6.1 million and \$8.2 million, respectively, in research and development expenses. For 2017, our research and development expenses will be highly dependent upon our ability to acquire additional compounds or technologies during the year.

Sales and Marketing

On July 7, 2016, we announced a restructuring of our sales force and operations to drive top-line growth and increase efficiency. The reorganization plan included (1) a reduction of 54 sales positions, primarily from our Neurology sales team; (2) prioritization and reorganization of sales territories to reduce the inefficient time that sales representatives spent driving long distances between customers; (3) improvement of our compensation plan to incentivize the field sales staff to increase the frequency of calls on the focused targets; and (4) consolidation of the Neurology and Pain sales forces under one sales management structure to eliminate redundancies.

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 the Neurology and Pain sales forces, which consists of approximately 125 independent territories nationwide. Our teams of experienced sales professionals detail our products to prescribers 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 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 forces 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.

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GSK Arbitration, Restructuring and Business Development

GSK Arbitration Update

As previously disclosed we had been engaged in an arbitration proceeding with GSK relating to an alleged breach by us of Section 8.15 of the Asset Purchase and Sale Agreement (APSA) between the parties. GSK alleged approximately \$36 million in damages. We asserted a setoff under the APSA, as well as our own claims for GSK's alleged breach of a Supply Agreement between the parties, amounting to a combined damages request in excess of \$50 million. We and GSK subsequently entered into an Interim Settlement Agreement under which we paid GSK an amount equal to approximately \$10.3 million and deposited an additional amount of approximately \$6.2 million into an escrow account. The parties submitted their respective claims under both the APSA and the Supply Agreement to binding arbitration before the International Chamber of Commerce International Court of Arbitration. An arbitration hearing for the APSA claims was held in April 2016 and a second hearing for the Supply Agreement claims was held in October 2016. On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest. The tribunal also denied our claim that GSK breached its obligations under the supply agreement. We have already paid to GSK an aggregate amount of \$16.5 million, including \$6.2 million from the escrow account, which will offset the total award. Subsequent discussions with GSK resulted in an agreement on March 17, 2017, to amend the Interim Settlement Agreement with GSK whereby a payment schedule was established for satisfaction of the current balance of the award. Pursuant to the amendment, we have agreed that the current outstanding balance is approximately \$21.5 million and that we are obligated to pay the outstanding balance in quarterly installments in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. We have also agreed that for so long as the Interim Settlement Agreement is in effect, we will be subject to certain restrictions on non-ordinary course payments and transactions and GSK will have certain information rights. GSK has agreed that for so long as we comply with the payment schedule set forth in the Amendment, as well as other agreed-upon obligations, enforcement of the Award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the Award.

Reverse Stock Split

On October 13, 2016, we filed Articles of Amendment to our charter, with the State Department of Assessments and Taxation of Maryland to effect a one-for-ten reverse stock split of the outstanding shares of common stock, par value \$0.01 per share (the Reverse Stock Split). The purpose of the Reverse Stock Split was to raise the per share trading price of our common stock to regain compliance with the minimum \$1.00 continued listing requirement for the listing of our common stock on The NASDAQ Global Market. As of the date of this Report, we have regained compliance with NASDAQ Listing Rule 5450(a)(1).

Each stockholder's percentage ownership in us and proportional voting power remained unchanged immediately after the Reverse Stock Split, except for minor changes resulting from the rounding up of fractional shares. The rights and privileges of stockholders were also unaffected by the Reverse Stock Split. There was no change to the number of authorized shares of our common stock as a result of the Reverse Stock Split. Accordingly, all share and per share information in this Report has been restated to retroactively show the effect of the Reverse Stock Split.

Debt Restructuring

In August 2016, we announced the commencement of a formal process to pursue alternatives to improve financial flexibility, and we retained advisors to explore options to restructure our debt and assess other potential alternatives in order to maximize value for all stakeholders. As disclosed on Form 8-K filed on December 27, 2016, we were negotiating with a group of note holders (Treximet Noteholders) of the 12% Senior Secured Notes due 2020 (the Treximet Secured Notes) and a group of note holders (Convertible Noteholders, and together with the Treximet Noteholders, the Noteholders) of our 4.25% Convertible Senior Notes (the 4.25% Convertible Notes). We proposed an exchange of both the Treximet Secured Notes and the 4.25% Convertible Notes into a package of new securities,

including debt securities, preferred equity securities, common stock and warrants to purchase common stock.

Over the course of several months beginning in October 2016, the Treximet Noteholders and Convertible Noteholders, together with their respective advisors, engaged in negotiations with us and our advisors and with each other regarding a potential transaction. On October 24, 2016, meetings occurred among us, the Noteholders and their respective financial and legal advisors. On November 19, 2016, the Noteholders' advisors delivered to our Board of Directors a term sheet outlining the non-binding terms and conditions and proposed timeline of a potential transaction supported by the Noteholders (the Initial Noteholders' Proposal), as supplemented by a sale/restructuring process approach dated December 15, 2016. The Initial

Noteholders' Proposal contemplated, among other things, a sale and marketing process and/or an agreement to restructure our capital structure, in each case to be effected through an in-court process.

Following receipt of the Initial Noteholders' Proposal, we continued to negotiate with the Noteholders with respect to the treatment of various stakeholders in a potential Transaction. To that end, we and our advisors, on the one hand, and the Noteholders and their advisors, on the other hand, engaged in discussions outlining their respective considerations. After receiving a counterproposal from us, the Treximet Noteholders delivered a revised term sheet to us on December 22, 2016 (the Treximet Noteholders' Proposal, together with the Initial Noteholders' Proposal, the Noteholders' Proposals). We delivered our latest counterproposal to the Noteholders on December 26, 2016 (the Company Proposal).

Notwithstanding such negotiations, we and the Noteholders have been unable to reach an agreement on certain significant issues relating to a potential transaction. These significant issues include, among others, (i) treatment of notes held by the Noteholders, (ii) treatment of existing shareholders, (iii) the terms and procedures of the proposed sale process, and (iv) the Noteholders' involvement and consent rights in the decision to proceed with a sale or restructuring.

Accordingly, on December 26, 2016, we ceased discussions with the Noteholders regarding a concurrent exchange of the Treximet Secured Notes and the 4.25% Convertible Notes for a package of new securities. Since these discussion ceased, we have continued to work with the advisors of the Convertible Noteholders on structuring a potential alternative exchange transaction with respect to the 4.25% Convertible Note. In addition, we continue to analyze various strategic alternatives to proactively address our liquidity and capital structure in a constructive manner, including a range of potential strategic alternatives. These alternatives could include, among other things, the sale of part or all of the Company, a merger with another party or other strategic transaction, a restructuring or recapitalization, or continuing to execute on our long-term business plan. Our Board of Directors has not set a timetable for this process, nor has it made any decisions related to any strategic alternatives at this time. There can be no assurance that the exploration of strategic alternatives will result in the consummation of a transaction or other strategic alternative of any kind. We do not expect to make further public comment regarding these matters unless or until we determine that further disclosure is appropriate or necessary.

Acquisition of Zohydro ER with BeadTek

On April 24, 2015, through our wholly-owned subsidiary, PIPL, 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. 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, 168,209 shares of our Common Stock, \$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 the 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 we have also granted POZEN a warrant to purchase 50,000 shares of our common stock at an exercise price of \$42.80 per share (the closing price of our common stock on May 13, 2014 as reported on NASDAQ) (the Warrant). The Warrant was exercisable from the closing date of the acquisition (August 20, 2014) until February 28, 2018. In March 2015, an assignee of POZEN exercised the warrant on a cashless basis, resulting in the issuance of 31,584 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 us 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 was firm for the first year of the term. Thereafter, the price of Treximet is subject to increase based on the Pharmaceutical Preparation - Manufacturing Index for the twelve months immediately preceding additional years of the term. GSK is currently manufacturing Treximet for our adolescent sales and is no longer manufacturing Treximet for our adult sales. We have qualified and contracted with an additional manufacturing source to support current supply.

Financing Activities

Convertible Notes:

4.25% Convertible Notes

On April 22, 2015, we issued \$130.0 million aggregate principal amount in the 4.25% Convertible Notes. The 4.25% Convertible Notes mature on April 1, 2021, unless earlier converted, redeemed or repurchased. We 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 us. 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 our 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 us and the investors party thereto, and the related Indenture, dated February 21, 2014, by and between us 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 \$36.00 per share. We issued 1.8 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 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, 2016, the aggregate principal amount of the Treximet Secured Notes was approximately \$189.6 million.

Credit Facilities:

Wells Fargo

On August 21, 2015, we entered into a Credit Agreement with Wells Fargo National Association (Wells Fargo), 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, 2016, \$14.0 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 \$16.9 million as

of December 31, 2016. Availability of borrowings under the Wells Fargo Credit Facility varies from time to time and 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. Pursuant to the terms of the Wells Fargo Credit Facility, the Administrative Agent has the authority to impose reserves against our borrowing base under certain circumstances, in its sole discretion. We understand that the Administrative Agent is currently evaluating whether to impose such a reserve. If the Administrative Agent were to impose such a reserve, depending on our inventory levels and the size of the reserve, our excess availability under the Wells Fargo Credit Facility could fall below \$10.0 million, which, in turn, would trigger an obligation for us to meet a 1.0 to 1.0 fixed charge coverage ratio test. If we were unable to meet this fixed charge coverage ratio test, we would be in default under the terms of the Wells Fargo Credit Facility. If we were to be in default, we anticipate that we would consider entering into a forbearance agreement with the Administrative Agent or seeking an alternative funding source. There can be no assurance that we would be able enter into a forbearance agreement or find an alternative funding source on satisfactory terms, or at all.

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 the 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. On February 8, 2017, we agreed to provide Wells Fargo with 30 days' prior notice of any request for a borrowing under this facility until April 8, 2017.

MidCap Revolver Amendment

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 of our subsidiaries and repaid all outstanding loans thereunder (the MidCap Credit Facility).

See further discussion in Note 13, *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 value of 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 and Silenor in the U.S. market, and we intend to expand upon and leverage our early commercial success. We have also launched Pernix Prescriptions DirectTM, 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 Pernix 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 CNS indications, including neurology, pain and psychiatry.

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 was unable to supply our needs, we would have an alternative source available for those products.

We and all of our other manufacturers and suppliers are subject to the FDA's current Good Manufacturing Practices (cGMP), requirements. Certain of our manufacturers are also subject to the United States Drug Enforcement Administration (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 28 issued U.S. patents and 30 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.

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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) method of treatment, and bilayer tablet structure. 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 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 five licensed issued U.S. patents and six patents owned solely by PIPL. An additional four 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 Gainesville, LLC, broadly cover the multiparticulate modified release composition and are listed in the Orange Book. U.S. patent no.'s 9,132,096, 9,452,163 and 9,486,451 also in-licensed from Recro and also Orange Book listed, are directed to the abuse deterrent technology (BeadTek) and expire September 12, 2034. FDA Orange Book listed U.S. patent no.'s 9,265,760, 9,326,982, 9,333,201, 9,339,499, 9,421,200, 9,433,619, (all expire July 25, 2033) are 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.

Silenor benefits from six issued U.S. patents, all of which are listed in the Orange Book, with the latest expiring in September 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, 8,513,299, and 9,486,437, expiring May 1, 2028, September 7, 2030, and May 18, 2027 respectively, are directed to a method of treating sleep maintenance insomnia by administering doxepin to reduce fragmented sleep or early awakenings. Lastly, U.S. patent no. 9,532,971, expiring June 1, 2029, is directed to a pharmaceutical composition with doxepin and silicified microcrystalline cellulose. It is expected that all of these issued U.S. patents will likely cover the proposed over-the-counter (OTC) version. Further, we own or have rights to eleven pending U.S. patent applications that relate to Silenor.

In connection with the ASPA, GSK assigned to our wholly-owned subsidiary, PIL, all of its right, title and interest in and to that certain PDC Agreement. 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 PDC 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.

In a license agreement dated August 2003 and amended and restated in September 2010, Pernix Sleep acquired the exclusive, worldwide license from ProCom to certain patents to develop and commercialize low dosages of doxepin for the treatment of insomnia. Although patent protection for the current dosage form is limited to the United States, our license to these low-dose doxepin patents is a worldwide license. The term of the license extends until the last licensed patent expires, which is expected to occur no earlier than 2030. The license agreement is terminable at any time by us with 30 days' notice if we believe that the use of the product poses an unacceptable safety risk or if it fails to achieve a satisfactory level of efficacy. Either party may terminate the agreement with 30 days' notice if the other party commits a material breach of its obligations and fails to remedy the breach within 90 days, or upon the filing of

bankruptcy, reorganization, liquidation, or receivership proceedings relating to the other party. Under the terms of the agreement, we pay a royalty of five percent (5%) of net sales (as defined in the license agreement) to ProCom. Our predecessor-in-interest made upfront and milestone payments upon certain development milestones and regulatory approvals, all of which were satisfied prior to our acquisition of Somaxon.

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 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 goodwill and we continuously file new trademarks used to brand and market our products and services.

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.

Seasonality

We generally experience some effects of seasonality due to our patients resetting their deductible amounts in the beginning of the calendar year and reaching their deductible amounts during the year. Accordingly, sales of our products and associated revenue have generally decreased in the first quarter of each year and begin to increase during the remainder of the year. 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.

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% of gross product sales in each of 2016 and 2015, are all drug wholesalers. Each customer and its respective percentage of our gross product sales are listed by year below:

act Sales 2016		
36%	38%	
31%	27%	
26%	28%	
93%	93%	
	36% 31% 26%	

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 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.

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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 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;

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- 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

In the United States, the FDA regulates the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our drug products and product candidates under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations. Obtaining regulatory approvals and complying with applicable federal, state and local statutes and regulations require significant time and financial resources. Failure to comply with applicable FDA requirements during the development, approval or post-approval processes may subject an applicant to a range of judicial or administrative penalties, including the FDA's refusal to approve pending applications, withdrawal of an approval, clinical holds, warning letters, product recalls, product seizures, suspension of production or distribution, fines, refusals of contracts, restitution, disgorgement or civil or criminal sanctions.

Before a sponsor may market a drug in the U.S., the FDA requires a process that generally involves the following steps:

- performance of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice (GLP), regulations and the U.S. Department of Agriculture's Animal Welfare Act;
- submission of an investigational new drug application (IND), to the FDA, which must become effective before human clinical trials may commence;
- obtaining approval at each clinical trial site by an independent institutional review board (IRB) before each trial may begin;
- completion of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices (GCP), to establish the safety and efficacy of the proposed drug for its intended use;
- submission of a new drug application (NDA), to the FDA;
- adequate completion of an FDA advisory committee review, if applicable; and,
- FDA review and approval of the NDA.

Preclinical Studies

. Prior to full clinical studies, product candidates are evaluated in preclinical studies that may include 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. Unless the FDA raises concerns or questions related to proposed clinical trials (such as concerns that human research subjects will be exposed to unreasonable risks) and places the clinical trials on a clinical hold, an IND automatically becomes effective 30 days after receipt by the FDA and clinical trials may commence. If the FDA issues a clinical hold, the IND sponsor and the FDA must settle any pending concerns before the clinical trial can begin. In addition, the FDA can impose clinical holds at any time before or during trials due to safety concerns or non-compliance. Thus, submission of an IND does not guarantee that the FDA will allow the commencement or the completion of clinical trials.

Clinical Trials

. Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators. Clinical trials are subject to extensive regulation, including GCP requirements, which include, among other things, obtaining written informed consent from all study subjects, monitoring, and seeking review and approval by an IRB to conduct a clinical trial at each clinical study site.

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. 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 are generally conducted in three consecutive phases, which may coincide or be combined:

- Phase I: The investigational 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: The investigational product is administered to a limited patient population 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: The investigational product is administered to an expanded patient population 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.

An IND sponsor must submit reports to the FDA annually, or more frequently if the FDA requests, detailing among other things the results of the clinical trials and serious and unexpected adverse events. Phase I, II, and III trials may not be successfully completed within a specified period of time, or at all. Moreover, the FDA, an IRB, a Data Safety Monitoring Board or Data Monitoring Committee, or the sponsor may, at its discretion, suspend or terminate a clinical trial at any time on various grounds, including a finding that study subjects are being exposed to an unacceptable health risk.

NDA Approval

. If the required clinical testing is completed successfully, a sponsor may submit the results of the preclinical studies and clinical trials, along with detailed descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, 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. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the drug in relevant pediatric populations. At the request of an applicant or by its own initiative, the FDA may grant deferrals or 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.

The FDA must determine whether to accept a submitted NDA for filing within sixty days of receipt, based on the agency's threshold determination that the application is adequately complete to permit substantive review. Alternatively, the FDA may request additional information. In such an event, the NDA must be resubmitted with the additional information. Once the application 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.

As part of the approval process, The FDA also examines manufacturing facilities for the proposed product. 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 our interpretation of 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. The complete response letter may include recommended actions that the applicant could take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit the NDA upon 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 indications or 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, the FDA may require a risk evaluation and mitigation strategy (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 (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 studies 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 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 after initial approval has been granted.

Post-approval Requirements

. Drugs that receive FDA approval remain subject to continuing regulation by the FDA, including requirements to report adverse events, provide the FDA with updated safety and efficacy information, comply with advertising and promotion regulations, submit periodic reports and maintain records.

The FDA strictly regulates labeling, advertising and promotion of marketed drug products. Drugs may be promoted only for their approved indications. Improper promotion or advertising practices for prescriptions drugs may be subject to enforcement by the FDA and other federal and state agencies. The Federal Trade Commission regulates advertising for OTC drug products. Advertising for these products must be truthful, not misleading and supported by competent and reliable scientific evidence.

Additionally, drug manufacturers and other entities involved in the distribution and manufacturing of approved drugs must register with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP requirements. 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. Certain changes to the manufacturing process generally require prior FDA approval before implementation. Future FDA and state inspections may identify compliance issues at 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 approved application if we do not maintain compliance with regulatory requirements and standards or if problems arise after the product reaches the market. For example, the FDA may issue an approval letter for a drug that includes postmarket requirements (PMRs) or commitments (PMCs), including Phase IV clinical studies. The FDA may withdraw approval of a drug if it determines that the sponsor is not adequately completing its PMRs or PMCs. In addition, 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, failure to comply with regulatory requirements may result in administrative or judicial actions, such as product recalls 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; refusal 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.

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. Changes to the FDCA and other laws and regulations that affect the pharmaceutical industry remain possible and appear likely in the 115th United States Congress and under the Trump Administration. 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. During this period the FDA permitted thousands of drug products that were identical related or similar (IRS) to drugs (the active ingredients) covered by NDAs to be marketed on the grounds that they were generally recognized as safe and not new drugs. The agency contracted with the National Academy of Science/National Research Council (NAS/NRC), to make an initial evaluation of the effectiveness of drugs covered by NDSs at this time on an active drug ingredient basis and by regulation it applied the findings to all IRS drug products. The FDA's administrative implementation of the NAS/NRC reports was the Drug Efficacy Study Implementation (DESI Review). The DESI review involved a multistep notice, comment, opportunity for hearing, and appellate process that has vast administrative and legal complexities.

Although the DESI Review began in the late 1960's, it was never completed. In the ensuing 50 years, the FDA developed other regulatory priorities. Many IRS products remained in circulation, while newer IRS products entered the market with the FDA's tacit consent. The FDA developed a series of Compliance Policy Guides (CPGs) to prioritize its concerns. The FDA has periodically revised its regulatory priorities in this area, most recently in 2011 with the creation of a new guideline addressing these issues that remains in effect today.

We believe that several of our marketed pharmaceutical products are IRS to products that have existed on the market without an NDA or ANDA, and that may fall within the scope of the FDA's CPG. The regulatory status of each product is fact specific and we are exploring all the associated legal and regulatory issues. As all of these products are manufactured by subcontractors, we are monitoring their compliance with cGMPs in order to minimize product risk. 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

The FDA implemented a process of reviewing OTC drugs through rulemaking by therapeutic classes (e.g., antacids, antiperspirants, cold remedies). The FDA convenes an Advisory panel for each therapeutic class, and each advisory panel develops final monographs for the class to be published in the Federal Register. OTC monographs set forth permissible claims, labeling, and active ingredients for OTC drugs in a particular class. They also provide recipes 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 thus to be legally marketed without prior FDA approval. 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 plan to develop an OTC version of Silenor, which we expect to conform to an FDA OTC monograph.

We also market a number of dietary supplement and medical food products. As we have moved out of the DESI and OTC drug space, we have labeled these products in accord with the labeling requirements for dietary supplements and medical foods under the FDCA. There are no fixed lines of regulatory demarcation for these products. The labeling of each is intricate, and we have attempted to label our products in accord with the applicable statutory requirements. These products are not covered outpatient drugs. States and private payers have an array of options for the payment for non-covered drugs. These include the Children's Health Insurance Program (CHIP), as well as various state-specific programs.

The Hatch-Waxman Act

Abbreviated New Drug Applications

. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, created the ANDA pathway, which allows companies to seek approval for generic versions of brand-name drugs previously approved under an NDA. As part of the NDA approval process, applicants are required to list with the FDA each patent with claims that cover the applicant's product or an approved use of the product. Upon NDA approval, each of the patents listed in the application for the drug is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Potential generic manufacturers may reference certain drugs listed in the Orange Book as reference listed drugs (RLDs) as the basis of their ANDAs. Generally, an ANDA must contain data and information showing that the proposed generic product is the same as its RLD by demonstrating that the two products (1) have the same active ingredient in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. Certain ANDA approved drugs may be replaced by pharmacists under prescriptions written for the RLD.

An ANDA applicant must make one of the following certifications to the FDA for each patent listed for the RLD in the Orange Book:

- 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 (Paragraph IV certification).

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If the applicant does not challenge any of 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 if all patents have expired.

If an ANDA applicant makes a Paragraph IV certification, it must notify the NDA holder and patent owners and provide a comprehensive account of the factual and legal basis for the applicant's belief that the patents are invalid, unenforceable or not infringed. The ANDA applicant must provide this notification within 20 days after the FDA accepts the ANDA for filing. The NDA holder and patent owners may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. In general, the filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV notice prohibits the FDA from approving the ANDA for 30 months from the receipt of notice by the patent holder; however, the FDA may approve the proposed product before the expiration of this 30-month stay if a court deems the patent unenforceable, invalid or not infringed or if the court shortens the stay period because the parties have failed to cooperate in expediting the litigation. If an RLD has new chemical entity exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval.

The Hatch-Waxman Act also 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. "Authorized generics" are generic pharmaceutical products that are introduced by innovator companies, either directly or through partnering arrangements with other generic companies. Authorized generics are equivalent to the innovator companies' brand name drugs, but are sold at relatively lower prices than the brand name drugs. An authorized generic product may be marketed during the 180-day exclusivity period granted to the first manufacturer or manufacturers to submit an ANDA with a Paragraph IV certification for a generic version of the brand product.

Section 505(b)(2) New Drug Applications

. Another path to FDA approval, particularly for modifications to drug products previously approved by the FDA, is a Section 505(b)(2) NDA. The Hatch-Waxman Act created the Section 505(b)(2) pathway, which permits the submission of an NDA where 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 a previously approved product that the applicant references as the RLD. The FDA requires submission of information to support any changes relative to the RLD, 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 labeled indications for which the RLD product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

A Section 505(b)(2) application is subject to exclusivities for the reference product and is required to certify to the FDA regarding any patents listed for the RLD in the Orange Book as an ANDA applicant would. Therefore, approval of a Section 505(b)(2) NDA may be delayed until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity listed in the Orange Book for the RLD 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

. Certain 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 obtain approval of an NDA for a new chemical entity (NCE), which is an active pharmaceutical ingredient that the FDA has not previously approved. The Hatch-Waxman Act prohibits the approval 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 and sNDAs, if the sponsor conducts or sponsors new clinical investigations, other than bioavailability studies, and those investigations 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 indication, dosage, or strength associated with the new clinical investigations. Five-year and three-year exclusivity will not block the submission or approval of another "full" NDA submitted under section 505(b)(1) of the FDCA.

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 exclusivity 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 that fairly responds to 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 and certain other generic products are subject to the Controlled Substances Act, which imposes registration, recordkeeping, reporting, labeling, packaging, storage, distribution and other requirements administered by the DEA. The DEA regulates handlers of controlled substances, and 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, but not limited to, 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 currently accepted medical use in treatment in the U.S. Thus, a pharmaceutical product may be controlled in Schedule II, III, IV or V. Schedule II substances are considered to present a high potential for abuse and Schedule III through V substances are considered to pose relatively decreasing potential for abuse. All of our products containing hydrocodone, including Zohydro ER, 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, unless exempt from registration. The registration is specific to the particular location where controlled substances are handled, the activity engaged in, and the controlled substances utilized. For instance, the activities of importing and manufacturing require separate registrations, and each registration will indicate which schedules of controlled substances are authorized for use in the activity governed by the registration.

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 must be made to the DEA, including distribution, acquisition and inventory 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 significant losses of controlled substances. A manufacturer/distributor must also maintain a system to detect and report suspicious orders to DEA, which are defined as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A registrant must follow certain requirements when disposing of controlled substances, including using certain on-site destruction methods or transferring the substances to a person registered or authorized to accept controlled substances for the purposes of destruction. Additionally, particular authorization and notification requirements apply to imports and exports.

The DEA establishes annually an aggregate quota for how much certain controlled substances (including Schedule II controlled substances) may be produced in total in the United States, based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. Manufacturers must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

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.

Hazardous Materials

We 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 sales of currently marketed products and our ability to commercialize our products effectively depends substantially on the availability of sufficient coverage and reimbursement from third-party payors, including U.S. governmental payors such as the Medicare and Medicaid programs, MCOs and private insurers.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We expect to experience pricing pressure in the U.S. In connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals to curb healthcare costs and negative publicity regarding pricing and price increases generally, which could limit the prices that we charge for our products, limit our commercial opportunity and/or negatively impact revenues from sales of our products.

We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs, particularly given the current atmosphere of mounting criticism of prescription costs in the U.S. These cost containment measures include controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; pharmaceutical cost transparency bills that aim to require drug companies to justify their prices; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person and public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions. Any such changes could have a negative impact on revenues from sales of our products.

Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third-party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less effective, less safe or less cost-effective than other products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For example, third party payors have started to require discounts and/or exclusivity arrangements with some drug manufacturers in exchange for including a specific product on their formularies. Any such requirements could have a negative impact on revenues from sales of our products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. Both Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services (CMS). CMS surveys and publishes retail community pharmacy acquisition cost information in the

form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It is difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of average manufacturer price and the Medicaid rebate amount under Health Care Reform, discussed below, could affect our 340B ceiling price calculations and negatively impact our results of operations. In January 2016, CMS issued a final rule to implement the changes to the Medicaid rebate program under Health Care Reform, which became effective on April 1, 2016. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program, has and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final rule.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies, we participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies - the VA, U.S. Department of Defense (DoD), Public Health Service and U.S. Coast Guard - that is no higher than the statutory Federal Ceiling Price (FCP). The FCP is based on the non-federal average manufacturer price (Non-FAMP), which we calculate and report to the VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

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 (Affordable Care Act). On March 30, 2010, the President signed H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (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 intended to transform the delivery and payment for healthcare services in the U.S. The combination of these measures has expanded health coverage to an estimated 20 million individuals as of February 2016. In addition, there are significant health coverage reforms that have improved patients' ability to obtain and maintain health coverage. 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, Medicaid eligibility

expansion, tax penalties on individuals without health coverage and on certain employers who do not provide it, and tax credits to make health insurance more affordable. The expansion of healthcare coverage 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. Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. The legislation also expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid MCOs as well. Additionally, Health Care Reform increased the minimum Medicaid rebate, changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs, and expanded the list of covered entities eligible for 340B participation to include certain free-standing cancer

hospitals, critical access hospitals, rural referral centers and sole community hospitals. Finally, Health Care Reform also limited 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.

Health Care Reform also requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

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 until 2020. 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 Health Care Reform, including the constitutionality of its individual mandate that requires most Americans maintain health coverage starting in 2014. However, changes to Health Care Reform remain possible and appear likely in the 115th United States Congress and under the Trump Administration. There have also been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted, they could result in us owing additional rebates, which could have a negative impact on revenues from sales of our products.

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. Subsequent legislation extended the two-percent reduction to Medicare payments to healthcare providers through fiscal year 2025.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including rules and regulations that may be issued to implement or seek to roll back provisions of Health Care Reform or the outcome of any legal challenges to such legislation or regulations. We expect that Health Care Reform, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. 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 Laws and Regulations

Pharmaceutical companies participating in federal healthcare programs like Medicare or Medicaid are subject to various U.S. federal and state laws pertaining to healthcare "fraud and abuse", including anti-kickback and false claims laws. Violations of U.S. federal and state fraud and abuse laws may be punishable by criminal, civil and administrative sanctions, including fines, damages, imprisonment, civil monetary penalties and exclusion from federal

healthcare programs like 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, but are not limited to, the following:

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 the furnishing or arranging for the furnishing of 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 to include anything of value. Both the party offering or paying remuneration and the party receiving or

soliciting the remuneration are subject to liability under

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 induce referrals of federal health care program business, even if there are other legitimate reasons for the remuneration. The anti-kickback statute has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. There are narrow statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution for violations of the anti-kickback statute, but to qualify for a safe harbor an arrangement must precisely meet each of the requirements. Failure to meet all of the requirements of a particular statutory exemption or regulatory safe harbor does not make the conduct per se illegal under the anti-kickback statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. Moreover, there are no safe harbors for many common practices.

The Health Care Reform clarified that neither actual knowledge of the anti-kickback statute nor specific intent is required to show a violation of the anti-kickback statute. Additionally, Health Care Reform amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Federal False Claims Act

. The Federal False Claims Act imposes civil liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment of government funds; 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 and mandatory penalties of \$10,781 to \$21,563 per false claim or statement. In addition, the Federal False Claims Act permits a private individual acting 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 and share in any monetary 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 (HIPAA)

. 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.

In addition to HIPAA, numerous federal and state regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that negatively affect our business.

Other 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. The Open Payments program imposes annual reporting requirements on manufacturers of drugs, devices, or biologics for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, of certain payments and other transfers of value to physicians and teaching hospitals made during the preceding calendar year, and any ownership and investment interests held by physicians. 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. Manufacturers must submit reports by the 90th day of each calendar year.

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. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes that are consistent with the May 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, and/or the voluntary Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (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 limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals and entertainment, among other things.

The pharmaceutical industry is experiencing a high level of scrutiny and regulation by government authorities and has been the subject of numerous investigations related primarily to financial arrangements with health care providers, payors and customers, regulatory compliance, and product promotional practices. Government investigations into compliance with these laws typically require the expenditure of significant resources, divert the attention of company management from operating the business and generate negative publicity. Violations of these laws or other governmental regulations may subject us to significant civil, criminal and administrative penalties, imprisonment, damages, fines, exclusion from government funded health care programs such as Medicare and Medicaid, and the curtailment or restricting of business operations. Legislative changes to federal fraud and abuse laws are possible in the 115th United States Congress and under the Trump Administration, whether as part of changes to Health Care Reform or otherwise.

Employees

As of December 31, 2016, we had 185 full-time employees, including a field sales force that covers 125 territories nationwide. We have 52 employees engaged in management, finance, marketing, research, development, regulatory affairs, quality assurance, 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. (GTA), in November 1996. We are 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 Business

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

As of December 31, 2016, 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 \$14.0 million and an aggregate of \$189.6 million of Treximet Secured Notes, we had approximately \$333.6 million of debt principal outstanding and the ability to borrow approximately \$16.9 million under our credit agreement with Wells Fargo, subject to borrowing base capacity. We also owe an additional \$21.5 million to GSK pursuant to the arbitration decision. This significant indebtedness and other payment obligations 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;
- require us to seek Chapter 11 bankruptcy protection;
- 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:

- sell our business or all or substantially all of our assets to one or more third parties;
- seek Chapter 11 bankruptcy protection;
- 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.

Our board of directors has authorized us to explore alternatives to refinance or restructure our existing debt, but we can provide no assurances of the terms of any refinancing or restructuring or how it will impact our securityholders.

We are in the process of analyzing various strategic alternatives to address our liquidity and capital structure, including strategic and refinancing alternatives, assets sales, and mergers and acquisitions. We believe the consummation of a successful refinancing or restructuring of our existing debt is critical to our continued viability. We are currently in active dialogue with various parties with respect to these potential strategic alternatives. If we fail to successfully complete a restructuring or refinancing of all of our existing debt, all or certain of our indebtedness may be accelerated and we may not be able to otherwise source adequate liquidity to fund our operations, meet our obligations (including our debt payment obligations) and continue as a going concern. There can be no assurance that these efforts will result in any such agreement, that any refinancing or restructuring that we pursue will be successful, or what the terms thereof would be.

Any refinancing or restructuring will likely be subject to a number of conditions, many of which will be outside of our control. We can make no assurances that any refinancing or restructuring that we pursue will be successful, or what the terms thereof would be or what, if anything, our existing debt and equity holders would receive in any resulting transaction, which will depend on our enterprise value, although we believe that any refinancing or restructuring would be highly dilutive to our existing equity holders and certain debt holders. In addition, we can make no assurances with respect to what the value of our debt and equity will be following the consummation of any refinancing or restructuring. The issuance and sale of substantial amounts of common stock or the announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

If an agreement is reached and we pursue a restructuring, it may be necessary for us to file a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in order to implement this agreement through the confirmation and consummation of a plan of reorganization and/or one or more sale transactions approved by the bankruptcy court in the bankruptcy proceedings. We may also conclude that it is necessary to initiate Chapter 11 proceedings to implement a restructuring of our obligations even if we are unable to reach an agreement with our creditors and other relevant parties regarding the terms of a restructuring. If a plan of reorganization is implemented in a bankruptcy proceeding, it is likely that holders of claims and interests with respect to, or rights to acquire our equity securities, would likely be entitled to little or no recovery, and those claims and interests would likely be canceled for little or no consideration. If that were to occur, we anticipate that all, or substantially all, of the value of all investments in our common stock will be lost and that our equity holders would lose all or substantially all of their investment. It is also likely that our other stakeholders, including our secured and unsecured creditors, will receive substantially less than the amount of their claims. We have a significant amount of secured indebtedness that is senior to our unsecured indebtedness and a significant amount of total indebtedness that is senior to our existing common stock in our capital structure. As a result, we believe that seeking Bankruptcy Court protection under a Chapter 11 proceeding could result in a limited recovery for unsecured noteholders and debtholders and place equity holders at significant risk of losing all of their interests in us. The commencement of bankruptcy proceedings would also result in an event of default under the terms of our Treximet Secured Notes, the 4.25% Convertible Notes and the Wells Fargo Credit Facility, thereby resulting in such indebtedness becoming immediately due and payable.

Potential restructuring transactions may impact our business, financial condition and operations.

In connection with our exploration of alternatives to refinance or restructure our existing debt, we expect to incur expenses associated with identifying and evaluating our alternatives. The process of exploring refinancing or restructuring alternatives may be disruptive to our business operations. The inability to effectively manage the process and any resulting agreement or transaction could materially and adversely affect our business, financial condition or results of operations.

If we undertake a Chapter 11 proceeding, our senior management would be required to spend a significant amount of time and effort focusing on such proceedings. This diversion of attention from other matters may materially adversely

affect the conduct of our business, and, as a result, our financial condition and results of operations, particularly if the Chapter 11 proceedings are protracted. Bankruptcy Court protection also might make it more difficult to retain management and other key personnel necessary to the success and growth of our business. In addition, the longer a proceeding related to a Chapter 11 proceeding continues, the more likely it is that our customers and suppliers would lose confidence in our ability to reorganize our businesses successfully and would seek to establish alternative commercial relationships.

Recent changes in senior management and the reductions in workforce associated with our restructuring efforts could disrupt the operation of our business, distract our management from focusing on revenue-generating efforts, result in the erosion of employee morale, and impair our ability to respond rapidly to growth opportunities in the future.

We have experienced a number of recent changes in senior management and other key personnel, including the departure of our President and Chief Executive Officer, our Chief Financial Officer, our Chief Operating Officer, and our General Counsel. Our new Chief Executive Officer was appointed on a permanent basis in July 2016 after serving as interim Chief Executive Officer since May 2016 and our new President and Chief Financial Officer was appointed in July 2016, after serving as a senior advisor to the Board of Directors since May 2016. The recruitment and retention of a new senior management staff has created and could continue to create a number of transitional challenges for us. These transitional issues have caused, and may cause, disruptions to our business. We cannot be assured that a smooth transition of our senior management staff has occurred, or that we have taken the necessary steps to effect an orderly continuation of our operations during the transitional period. Further, the process of locating personnel with the combination of skills and attributes required to carry out our goals and integrating such personnel once they are recruited is often lengthy. We cannot be assured that the integration of our new senior management staff will occur in a timely manner, or that such integration will not present additional transitional challenges for us or adversely affect the operation of our business.

Moreover, we have implemented a number of recent restructuring plans, including the most recent restructuring activities in July 2016 that resulted in personnel reduction of approximately 23%, primarily through a reduction of sales positions. The employee reductions and changes in connection with our restructuring activities, as well as future changes in senior management and key personnel, could result in an erosion of morale, and affect the focus and productivity of our remaining employees, including those directly responsible for revenue generation and the management and administration of our finances, which in turn may adversely affect our revenue in the future or cause other administrative deficiencies. Additionally, employees directly affected by the reductions may seek future employment with our business partners, customers or competitors. We may face wrongful termination, discrimination, or other claims from employees affected by the reduction related to their employment and termination. We could incur substantial costs in defending ourselves or our employees against such claims, regardless of the merits of such actions. Furthermore, such matters could divert the attention of our employees, including management, away from our operations, harm productivity, harm our reputation and increase our expenses. We cannot assure you that our restructuring efforts will be successful, and we may need to take additional restructuring efforts, including additional personnel reduction, in the future.

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, 2016 and 2015 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 of our customers 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 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.

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, or seeking Chapter 11 Bankruptcy Court protection. 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, our 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 that exceed 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 and the terms of the Wells Fargo Credit Facility require us to maintain excess availability of not less than \$13.0 million in order to make additional borrowings under that facility. The Wells Fargo Credit Facility also requires us to maintain a fixed charge coverage ratio of at least 1 to 1 if our excess availability under the facility is less than \$10.0 million.

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 or an imposition of a reserve against our borrowing base, which Wells Fargo has the authority to do in its sole discretion,

could reduce our borrowing capacity under the credit agreement with Wells Fargo. We understand that Wells Fargo is currently evaluating whether to impose such a reserve. If Wells Fargo were to impose such a reserve, depending on our inventory levels and the size of the reserve, our excess availability under the Wells Fargo Credit Facility could fall below \$10.0 million, which, in turn, would trigger an obligation for us to meet a 1 to 1 fixed charge coverage ratio test. If we were unable to meet this fixed charge coverage ratio test, we would be in default under the terms of the Wells Fargo Credit Facility. If we were to be in default, we anticipate that we would consider entering into a forbearance agreement with Wells Fargo or seeking an alternative funding source. There can be no assurance that we would be able enter into a forbearance agreement or find an alternative funding source on satisfactory terms, or at all.

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. The loss of the services of any 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, imposes 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

When our patent rights expire, previously protected products may become subject to competition from generic versions, which may lower our net revenue.

We own, have applied for or hold licenses under a large number of patents in the United States. Our patent protection for our products extends for varying periods in accordance with the date of grant and the legal life of patents in the United States. The protection afforded is limited by the applicable terms of our patents and the availability of legal remedies in the United States. Following expiration of patents covering our products, other entities may be able to obtain approval to manufacture and market generic alternatives, which we expect would result in lower net revenue. For example, in August 2014, we, through our wholly owned subsidiary, PIL acquired the U.S. intellectual property rights to Treximet from GSK. Treximet is covered by five patents in the U.S. Including six months of pediatric exclusivity, four of the patents expire on February 14, 2018, and one expires on April 2, 2026. Six companies filed ANDAs with the FDA seeking approval to market a generic version of Treximet, which resulted in three generics permitted to launch in 2018 and three other generics enjoined from launching until 2026. Although we intend to launch our own authorized generic of Treximet in 2018, the addition of other generics into the market may have a significant adverse impact on our sales of Treximet and, ultimately, our results of operations.

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 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 (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 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 ANDAs for generic versions of innovator products and 505(b)(2) NDAs that rely, in part, on literature and clinical data not prepared for or by such manufacturers. A generic manufacturer may only be required to conduct a relatively inexpensive study to show that its proposed generic product has the same active pharmaceutical ingredient, dosage form, strength, route of administration and indication as, and is bioequivalent to, our brand-name product. The development costs for such generic products would be significantly less than those for our brand-name products and could lead to the emergence of multiple lower-priced competitor products, which would substantially limit our ability to obtain a return on the investments we have made in our brand-name products. Additionally, other innovator competitors may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, and they may obtain periods of exclusivity under applicable laws that may delay our own products' approval by the FDA.

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. Additionally, products we sell through our collaborative or co-promotion arrangements may also face competition in the marketplace.

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

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

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

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

on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors.

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

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

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

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

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 MCOs 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, and certain other generic products contain controlled substances, which are regulated by the DEA under the Controlled Substances Act. DEA quota requirements applicable to Schedule I and II controlled substances 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. 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, the FDA requires that the facilities in which the product will be manufactured be in compliance with cGMP requirements, which include, among other things, requirements relating to quality control and quality assurance, maintenance of records and documentation and utilization of qualified raw materials. To be successful, our products must be manufactured in compliance with cGMP during development and, following approval, in commercial quantities 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 must register our manufacturing facilities with the FDA, and our facilities are subject to FDA inspections confirming compliance with cGMP and other regulations. If we or our contract manufacturers fail to maintain regulatory compliance, the FDA may impose regulatory sanctions including, among other things, temporary or permanent 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 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 clinical 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 our patients resetting their deductible amounts in the beginning of the calendar year and reaching their deductible amounts during the year. Accordingly, sales of our products and associated revenue have generally decreased in the first quarter of each year and begin to increase during the remainder of the year. 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 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 NDA applications we submit. These cGMP requirements include, among other things, 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. 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, efficacy, or quantities of our drug products are 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 must approve these manufacturers' facilities and processes in advance, which would require new testing and compliance inspections. Moreover, new manufacturers may have to be trained 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, 2016, McKesson Corporation, Cardinal Health and AmerisourceBergen Drug Corporation accounted for 36%, 26% and 31%, respectively, of our total gross sales. 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.

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. We market certain branded and 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 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 rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators. 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 its investigational plan and approved clinical trial protocol. Moreover, the FDA requires us to comply with GCPs 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 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 may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and may 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. Current legal proceedings and disputes as well as those 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 Item 3, *Legal Proceedings* and Note 19, *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. 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 (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.

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 restructure our existing debt;
- 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 GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders' equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated charge backs, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. For new products, these sales adjustments may be estimated based on information available on any similar products in the marketplace or specific information provided by business partners or if management is not able to derive a reasonable estimate for the adjustments, gross revenue can be deferred and recognized as the product is prescribed.

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

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

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

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

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

- our operating results, including the amount and timing of sales of our products and our ability to successfully integrate the operations of newly acquired businesses or products;
- the availability and timely delivery of a sufficient supply of our products;
- the safety and quality of our products or those of our competitors;
- our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;
- the results of discoveries, preclinical studies and clinical trials by us or our competitors;
- the acquisition of technologies, product candidates or products by us or our competitors;
- \bullet 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, 2016 and 2015. 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, 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.

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 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 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 adequate and 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 with larger numbers of patients over longer periods of time 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 IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have difficulty complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

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- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective clinical research organizations (CROs) and trial sites, and the terms of those agreements may 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 development programs based upon negative or inconclusive results;
- 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 may have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or IRBs 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 our product candidates that are narrower than we had anticipated.

Our product development costs also will increase if we experience delays in testing or approvals. Significant clinical trial delays may also 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, if we fail to conduct a clinical trial in accordance with regulatory requirements or the clinical trial protocol, the FDA may exclude the data from consideration to support market approval.

Risks Related to Regulatory Matters

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 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 product candidates may not be effective, may be only moderately effective, or may 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 the regulatory review process for a product application may cause delays in the approval of, 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. The FDA may decline to approve one or more of our product candidates for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of a product candidate to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

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.

Even if our product candidates receive FDA approval, any approved product will be subject to continued requirements of and review by the FDA. 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 a product receives FDA approval, that approval may be subject to limitations on the indicated uses for which the product may be marketed, or to 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 administrative and judicial actions such as:

- withdrawal of the products from the market;
- restrictions on the marketing or distribution of such products;
- requirements to place additional warnings on the labels for such products;
- requirements to develop a REMS for such products or, if a REMS is already in place, to incorporate additional requirements under the REMS:
- requirements to conduct additional post-market studies;
- restrictions on the manufacturers or manufacturing processes;
- warning letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls;
- fines;
- $\bullet \ suspension \ or \ with drawal \ of \ regulatory \ approvals;$
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- private lawsuits alleging harm caused to subjects or patients.

In addition, the FDA strictly regulates labeling, advertising and promotion of marketed products. Drugs may only be promoted for FDA-approved indications and in accordance with the FDA-approved labeling. We may be subject to enforcement and other liability if we inappropriately promote our products.

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 and our ability to commercialize our products effectively depends substantially on the availability of sufficient coverage and reimbursement from third-party payors, including U.S. governmental payors such as the Medicare and Medicaid programs, MCOs and private insurers. 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.

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. Details of our reliance on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement are discussed in the Business section under the heading "Pharmaceutical Pricing and Reimbursement" in Part I, Item 1, of this Annual Report on Form 10-K.

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 (MMA), created a new Medicare benefit for prescription drugs. The Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. More recently, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. Legislative or administrative acts that reduce reimbursement or result in us owing additional rebates for our products could adversely impact our business.

On March 23, 2010, President Obama signed into law the Health Care Reform. Details of changes under Health Care Reform are discussed in the Business section under the heading "Effects of Legislation on the Pharmaceutical Industry" in Part I, Item 1, of this Annual Report on Form 10-K.

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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs.

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Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B (we currently do not market any Part B drugs). Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Health Care Reform made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid MCOs as well and changing the definition of average manufacturer price. Health Care Reform also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, Health Care Reform requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under Health Care Reform. These regulations became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. Health Care Reform expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under Health Care Reform and CMS's final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

Health Care Reform obligates the Secretary of the U.S. Department of Health and Human Services (HHS) to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration (HRSA), the federal agency that administers the 340B program, recently initiated the process of updating the agreement with participating manufacturers. Health Care Reform also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. HRSA has not yet released the guidance or regulation in final form. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The regulation was published on January 5, 2017, with an effective date of March 6, 2017, but the Trump Administration has temporarily delayed the effective date of regulations that were not yet in effect at the start of the Administration on January 20, 2017. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition,

legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties in the amount of \$178,156 per item of false information. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty of \$17,816 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS and the Office of the Inspector General have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies - the VA, the Department of Defense (DoD) the Public Health Service, and the Coast Guard - at pricing that is capped pursuant to a statutory federal ceiling price (FCP) formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP) which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$178,156 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer the same price to the Big 4 and other government agencies on our FSS contract.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

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, payors and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers exposes 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, any person or entity from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or arranging for or recommendation of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the anti-kickback statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate. 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 induce referrals of federal health care program business, even if there are other legitimate reasons for the remuneration. In addition, the government may assert that a claim including items or services resulting from a violation of the anti-kickback

statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The anti-kickback statute has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of the exception or safe harbor does not make the conduct per se illegal, but the legality of the arrangements will be evaluated based on the totality of the facts and circumstances. However, there are no safe harbors for many common practices, such as educational and research grants or product support and patient assistance programs. We seek to comply with the available statutory exceptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

- the federal civil False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent or knowingly making, or using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. In recent years, several pharmaceutical and other health care companies have faced enforcement actions under the False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectations that the customers will bill federal programs for the product. Federal enforcement agencies have also showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved and thus non-reimbursable uses. False Claims Act liability is potentially significant because the statute provides for treble damages and mandatory penalties of \$10,781 to \$21,563 per false claim or statement. Because of the potential for large monetary damages and penalties, pharmaceutical manufacturers often resolve allegations without admissions of liability for significant and material amounts. Companies may be required to enter into corporate integrity agreements with the government to avoid exclusion from federal health care programs. Corporate integrity agreements impose substantial costs on companies to ensure compliance. There are also federal criminal statutes that prohibit making or presenting a false or fictitious or fraudulent claim 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.
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- The Open Payments program imposes annual reporting requirements on manufacturers of drugs, devices, or biologics for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, of certain payments and other transfers of value to physicians and teaching hospitals made during the preceding calendar year, and any ownership and investment interests held by physicians. 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. Manufacturers must submit reports by the 90th day of each calendar year.
- 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. Several states require pharmaceutical companies to report
 expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts
 and payments to individual health care providers in those states. Some states also prohibit certain

marketing-related activities, including providing gifts, meals or other items to certain health care providers. Some states require pharmaceutical manufacturers to implement compliance programs or marketing codes that are consistent with the May 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, and/or the voluntary PhRMA Code.

We, as well as many other pharmaceutical companies, sponsor prescription drug coupons and other product support agreements to help ensure that financial need does not limit a patient's access to our products. Co-pay coupon programs and other product and patient assistance programs have received negative publicity related to their use to promote branded pharmaceutical products over less costly generics, and as a strategy to increase drug prices by shielding patients from those price increases. In recent years, other pharmaceutical manufacturers were named in class action lawsuits that challenged co-pay programs under a variety of federal and state laws including the Racketeer Influenced and Corrupt Organizations Act (RICO). The Office of Inspector General for the HHS has issued additional guidance related to co-pay and patient assistance programs,

and other government enforcement agencies have initiated investigations into and pursued enforcement actions related to other manufacturers' product and patient support programs. We cannot be certain whether our product and patient support programs will be named in any future similar lawsuits or become subject to government scrutiny.

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, imprisonment, fines, exclusion from federal health care 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.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA-other than potentially with respect to providing certain employee benefits-we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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 was due to expire 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 extended the original term of the lease to expire July 31, 2022.

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

We had been engaged in an arbitration proceeding with GSK relating to an alleged breach by us of Section 8.15 of the Asset Purchase and Sale Agreement (APSA) between the parties. GSK alleged approximately \$36 million in damages. We asserted a setoff under the APSA, as well as our own claims for GSK's alleged breach of a Supply Agreement between the parties, amounting to a combined damages request in excess of \$50 million. We and GSK subsequently entered into an Interim Settlement Agreement under which we paid GSK an amount equal to approximately \$10.3 million and deposited an additional amount of approximately \$6.2 million into an escrow account. The parties submitted their respective claims under both the APSA and the Supply Agreement to binding arbitration before the International Chamber of Commerce International Court of Arbitration. An arbitration hearing for the APSA claims was held in April 2016 and a second hearing for the Supply Agreement claims was held in October 2016. On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest (estimated to be approximately \$2 to \$5 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. We have already paid to GSK an aggregate amount of \$16.5 million, including \$6.2 million from the escrow account, which will offset the total award. Subsequent discussions with GSK resulted in an agreement on March 17, 2017, to amend the Interim Settlement Agreement whereby a payment schedule was established for satisfaction of the current balance of the award. Pursuant to the amendment, we have agreed that the current outstanding balance is approximately \$21.5 million and we are obligated to pay the outstanding balance in quarterly installments to GSK in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. We have also agreed that for so long as the Interim Settlement Agreement is in effect, we will be subject to certain restrictions on non-ordinary course payments and transactions and GSK will have certain information rights. GSK has agreed that for so long as we comply with the payment schedule set forth in the Amendment, as well as other agreed-upon obligations, enforcement of the Award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the Award.

Recro Gainesville LLC v. Actavis Laboratories FL, Inc.,

District of Delaware Case Nos. 14-1118, 15-413, and 15-1196; Recro Gainesville 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 FDA's Orange Book as covering Zohydro ER. Actavis and Alvogen each filed 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, On September 13, 2016, Recro and Actavis jointly filed a stipulation of dismissal of all claims and counterclaims relating to the '398 Patent, and that stipulation was entered by the Court on September 14, 2016. On September 29, 2016, Recro and Alvogen jointly filed a stipulation of dismissal of all claims and counterclaims then-pending, and that stipulation was entered by the Court on September 30, 2016, ending the case between Recro and Alvogen. Recro and Actavis participated in a bench trial in the United States District Court for the District of Delaware regarding the '742 and '096 Patents, which was completed on October 7, 2016. During the trial, Actavis declined to pursue its invalidity counterclaims as to both the '742 and '096 Patents. The parties' post-trial submissions regarding the remaining issues of infringement were filed on

November 7, 2016. On February 23, 2017 we received a favorable opinion for this litigation and the United States District Court for the District of Delaware concluded that Actavis' proposed generic version of Zohydro ER infringes U.S. Patent Nos. 9,132,096 and 6,902,742. The Judge has entered an order enjoining Actavis from engaging in the commercial manufacture, use, offer to sell, or sale in the United States, or importation into the United States of Actavis' ANDA product prior to expiration of the two patents. On March 17, 2017 Actavis filed a Notice of Appeal. We remain confident in Recro's legal position with respect to this matter.

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, U.S. Patent No. 9,326,982 (the '982 Patent), which issued on May 3, 2016, U.S. Patent No. 9,333,201 (the '201 Patent), which issued on May 10, 2016, and U.S. Patent No. 9,339,499 (the '499 Patent), which issued on May 17, 2016 (collectively, the Pernix Zohydro® ER Patents). The Pernix Zohydro® ER Patents are listed in the Orange Book as covering Zohydro® ER. Pernix Therapeutics, LLC (Pernix LLC) is the exclusive licensee of the Pernix Zohydro® ER Patents and is the sole distributor of Zohydro® ER in the United States. As discussed above, Actavis and Alvogen (Defendants) each filed 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 in Recro Gainesville LLC v. Actavis Laboratories FL, Inc., District of Delaware Case Nos. 14-1118, 15-413, 15-1196; and Recro Gainesville LLC v. Alvogen Malta Operations Ltd., District of Delaware Case No. 14-1364. Pernix LLC brought suit against Defendants in the District of Delaware on March 4, 2016, seeking declaratory judgment of infringement of the '760 Patent. The Complaints relating to the `760 Patent were served on March 7, 2016. Pernix LLC filed and served First and Second Amended Complaints on May 13, 2016 and May 31, 2016, against Alvogen and Actavis respectively, adding allegations of infringement with respect to the '982, '201, and '499 Patents. The defendants filed Motions to Dismiss the Complaints under Rule 12(b)(6), asserting that the claims of the Pernix Zohydro® ER Patents are invalid under 35 U.S.C. 101. Briefing regarding the Motion to Dismiss was completed on July 11, 2016. United States Patent Nos. 9,421,200 (the '200 Patent) and 9,433,619 (the '619 Patent) issued on August 23, 2016 and September 5, 2016, respectively. Pernix LLC filed and served Second and Third Amended Complaints, against Alvogen and Actavis respectively, on October 12, 2016, adding allegations of infringement with respect to the '200 and '619 Patents. Actavis and Alvogen filed their respective Answers on November 30, 2016, denying Pernix LLC's infringement allegations, and raising Counterclaims of noninfringement and invalidity as to each of the asserted Pernix LLC patents. Pernix LLC filed its Answers to Actavis and Alvogen's respective Counterclaims on December 23, 2016. Pursuant to the 30-month stay provision of the Hatch-Waxman Act, final approval of Actavis's ANDA is stayed until February 12, 2017, and final approval of Alvogen's ANDA is stayed until March 29, 2017. Trial in the case is scheduled for April 16, 2018.

Medicine to Go Pharmacies, Inc. v. Macoven Pharmaceuticals, LLC and Pernix Therapeutics Holdings, Inc., District Court of New Jersey Case No. 3:16-cv-07717

On October 23, 2016, Plaintiff filed an action against Macoven, Pernix and unidentified individuals seeking redress for the sending of unlawful advertisements to facsimile machines in violation of the Telephone Consumer Protection Act, 47 U.S.C. 227. On December 2, 2016, we filed our answers in defense of the allegations. The fax campaign that is the subject of this litigation was administered by a third party that is not presently a defendant in this litigation. We may not be able to secure indemnification from this third party for costs that it might incur relative to this matter and insurance defense and indemnity does not appear available to us. While certain cases of this nature have historically resolved for non-material amounts, it is difficult for us to quantify our potential liability, if any, at this time. Based upon known facts, we intend to vigorously defend ourselves in this litigation.

U.S. ex. Rel. Conrad v. Abbott Labs, Inc., et a. (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.

Although the motion was granted, no judgment was entered which would have triggered appeal rights. The joint defense group conferred and elected to wait for either the plaintiff or the court to take action in this regard. There has been no action impacting Cypress or Hawthorn since the dismissal.

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

On September 23, 2013, we were served as a defendant (along with our subsidiaries, Cypress and Hawthorn and its predecessor-in-interest, Zyber Pharmaceuticals) in this suit by the State of Louisiana against over 50 defendants with allegations under Louisiana state law regarding false submissions of unapproved drugs. We and our 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, which validated that, the Louisiana Department of Health and Hospitals ("DHH") is deemed to be the proper party plaintiff for the suit. The State appealed this ruling and the First Circuit Court of Appeal issued a decision affirming in part and reversing in part the District Court's opinion. Specifically, the First Circuit affirmed the District Court's decision that there is no right of action to the State's claims for fraud, negligent misrepresentation, redhibition and unjust enrichment. Additionally, the First Circuit reversed and remanded the District Court's judgment on the Exception of No Right of Action by the State with respect to the claims asserted under the Louisiana Unfair Trade Practices Act (LUTPA) and the Medicare Assistance Programs Integrity Law (MAPIL). The joint defendants requested a rehearing, which was denied by the First Circuit in December 2016. Both the State and the joint defendants applied for writs of certiorari to the Louisiana Supreme Court. On March 13, 2017, the Louisiana Supreme Court denied the writ applications of the parties and remanded the matter to the District court. The joint defendants plan to pursue their already filed Exception of No Cause of Action motion seeking dismissal of both the LUTPA and MAPIL claims.

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, we received approval from the NASDAQ Stock Market to transfer our common stock listing from the NYSE MKT LLC to the NASDAQ Global Market effective January 28, 2013. Our common stock is currently listed on the NASDAQ Global Market under the symbol "PTX."

On October 13, 2016, we filed Articles of Amendment to our charter (the Articles of Amendment), with the State Department of Assessments and Taxation of Maryland to effect a one-for-ten reverse stock split of our outstanding shares of common stock, par value \$0.01 per share (the Reverse Stock Split). The Reverse Stock Split was duly approved by our Board of Directors without stockholder approval in accordance with the authority conferred by Section 2-309(e)(2) of the Maryland General Corporation Law and Article IV, Section 6 of our charter. Pursuant to the Articles of Amendment, effective as of the close of business on October 13, 2016, each outstanding share of our common stock, par value \$0.01 per share, was automatically combined into 1/10th of share of common stock, par value \$0.01 per share. Fractional share holdings were rounded up to the nearest whole number. As a result of the Reverse Stock Split, the number of outstanding shares of our common stock was reduced to approximately 9.5 million shares.

Each stockholder's percentage ownership in us and proportional voting power remained unchanged immediately after the Reverse Stock Split, except for minor changes resulting from the rounding up of fractional shares. The rights and privileges of stockholders were also unaffected by the Reverse Stock Split. There was no change to the number of our authorized shares of common stock as a result of the Reverse Stock Split. Accordingly, all share and per share information in this Report has been restated to retroactively show the effect of the Reverse Stock Split.

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.

	High		Low	
2015				
First Quarter	\$ 118.90	\$	76.40	
Second Quarter	105.80		53.00	
Third Quarter	61.90		29.90	
Fourth Quarter	40.60		24.30	
2016				
First Quarter	\$ 29.00	\$	9.00	
Second Quarter	11.00		4.00	
Third Quarter	8.70		4.40	
Fourth Quarter	6.20		1.94	
Holders				

As of March 21, 2017, there were approximately 118 holders of record of our common stock.

Dividends

We have not declared or paid any cash dividends for the years ended December 31, 2016 and 2015. We intend to retain any future earnings to finance growth and development and therefore do not anticipate paying cash dividends in the foreseeable future.

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, 2016, \$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 of Directors at any time. We did not repurchase any of our shares of common stock during the fourth quarter of 2016.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 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, 2016.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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," "intend," "may," "plan," "potential," "project," "predict," "should," "target," "will," "would," "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 our ability to restructure our existing debt; our ability to comply with the covenants under our existing indebtedness; 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
- reviewing our strategic alternatives, including the restructuring of our outstanding debt and the potential sale of all or a portion of our company.

We target underserved segments, such as CNS indications, including neurology, pain and psychiatry. We promote our core branded products to physicians through our sales forces. 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, and Silenor, a non-controlled substance and approved medication indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. 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 since the beginning of 2016:

- On July 7, 2016, we announced a restructuring of our sales force and operations. The reorganization plan included (1) a reduction of 54 sales positions, primarily from our Neurology sales team; (2) prioritization and reorganization of sales territories to reduce the inefficient time that sales representatives spent driving long distances between customers; (3) improvement of our compensation plan to incentivize the field sales staff to increase the frequency of calls on the focused targets; and (4) consolidation of the Neurology and Pain sales forces under one sales management structure to eliminate redundancies. In addition, as part of this initiative, we reduced our administrative staff by 6 employees.
- On July 26, 2016, we announced a reorganization of our senior management team intended to improve our efficiency, drive profitability and position us for future growth. As part of the management change, John Sedor assumed the role of Chief Executive Officer on a permanent basis and pharmaceutical industry veteran, Dr. Graham Miao, who previously served as a senior advisor to our Board of Directors since May 2016, was appointed as President and Chief Financial Officer. Dr. Miao reports directly to Mr. Sedor and has responsibility for all functions related to finance, operations, regulatory and scientific affairs. In addition, Sanjay Patel, Chief Financial Officer, Terence Novak, Chief Operating Officer, and Barry Siegel, Senior Vice President and General Counsel are no longer employed by us.
- On August 11, 2016, we announced that we are discontinuing the development of a new formulation of Treximet that we had intended to launch prior to generic entry in early 2018. We recently experienced a delay related to the manufacturing of our proposed new formulation, and based on the revised development timeline, we do not believe the required spending on this program can achieve an acceptable return on investment. While we expect to realize near-term cost savings, we still believe that Treximet and our authorized generic will be important components of our product portfolio.
- On August 11, 2016, we announced the commencement of a formal process to pursue alternatives to improve financial flexibility, and we have retained advisors to explore options to restructure our debt and assess other potential alternatives in order to maximize value for all stakeholders. We were negotiating with a group of holders of the Treximet Secured Notes and a group of holders of the 4.25% Convertible Notes. We proposed an exchange of both the Treximet Secured Notes and the 4.25% Convertible Notes into a package of new securities, including debt securities, preferred equity securities, common stock and warrants to purchase common stock. However, we and the Noteholders were unable to reach an agreement with respect to certain material issues relating to such a transaction. Accordingly, on December 26, 2016, we ceased discussions with the Noteholders regarding a concurrent exchange of the Treximet Secured Notes and the 4.25% Convertible Notes for a package of new securities. Since these discussions ceased, we have continued to work with the advisers of the Convertible Noteholders on structuring a potential alternative exchange transaction with respect to the 4.25% Convertible Notes. In addition, we continue to analyze various strategic alternatives to proactively address our liquidity and capital structure in a constructive manner, including a range of potential strategic alternatives. These alternatives could include, among other things, the sale of part or all of the Company, a merger with another party or other strategic transaction, a restructuring or recapitalization, or continuing to execute on our long-term business plan. Our Board of Directors has not set a timetable for this process, nor has it made any decisions related to any strategic alternatives at this time. There can be no assurance that the exploration of strategic alternatives will result in the consummation of a transaction or other strategic alternative of any kind. We do not expect to make further public comment regarding these matters unless or until we determine that further disclosure is appropriate or necessary.
- On October 13, 2016, we filed Articles of Amendment to our charter, with the State Department of Assessments and Taxation of Maryland to effect a one-for-ten reverse stock split of the outstanding shares of common stock, par value \$0.01 per share. The purpose of the Reverse Stock Split was to raise the per share trading price of our common stock to regain compliance with the minimum \$1.00 continued listing requirement for the listing of our common stock on The NASDAQ Global Market. As of the date of this Report, we have regained compliance with NASDAQ Listing Rule 5450(a)(1).
- On November 1, 2016, we made the decision that we would not be exercising our option to obtain an exclusive, royalty-bearing license to the Altus Technology and the Altus Product Technology, as defined in the Development and Option Agreement dated November 1, 2013 between Zogenix, Inc. and Altus Formulation, Inc. The decision was made based on a careful evaluation of the Development and Option Agreement and the potential alternative technologies available to us. We remain committed to continuing to improve the abuse-deterrent properties of Zohydro ER by investing in innovative technologies for future development of the product, including a reformulation of Zohydro ER with BeadTek and/or the license, development and commercialization of other abuse-deterrent technologies.

- On November 3, 2016, we entered into employment agreements with each of John A. Sedor, our Chief Executive Officer and Dr. Miao, our President and Chief Financial Officer.
- On November 4, 2016, our Board of Directors increased its size to five members and appointed Graham Miao and Dennis Langer as members of the Board of the Directors. On November 21, 2016, our Board of Directors increased its size to six members and appointed Gabriel Leung as a member of the Board of Directors. On November 28, 2016, Steven A. Elms resigned from our Board of Directors.
- On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest (estimated to be approximately \$2 to \$5 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. We have already paid to GSK an aggregate amount of \$16.5 million, including \$6.2 million from the escrow account, which will offset the total award. On February 28, 2017, we entered into a stay agreement with GSK, whereby, GSK agreed to stay the enforcement of the arbitration award until July 3, 2017, subject to us releasing the escrow amount of \$6.2 million and paying \$250,000 to GSK. On March 17, 2017, we amended the Interim Settlement Agreement with GSK whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award. Pursuant to the amendment we have agreed that the current outstanding balance is approximately \$21.5 million to GSK and we have agreed to make quarterly installments in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. We also agreed that for so long as the Interim Settlement Agreement is in effect, we will be subject to certain restrictions on non-ordinary course payments and transactions and GSK will have certain information rights. GSK has agreed that for so long as we comply with the payment schedule set forth in the Amendment, as well as other agreed-upon obligations, enforcement of the Award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the Award. We recorded the fair value of this settlement in the amount of approximately \$18.5 million in our financial statements at December 31, 2016 and have recorded \$15.3 million as a reduction to net revenues, \$1.0 million to selling, general and administrative expense and \$2.2 million to interest expense in the year ended December 31, 2016.

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, 2016 and 2015 (in thousands):

Voor Ended December 21

		Year Ended December 3			
		2016	2015		
Net revenues	\$	140,856 \$	175,850		
Operating expenses					
Cost of product sales		43,320	51,408		
Selling, general and administrative expense		98,834	97,421		
Research and development expense		6,079	8,229		
Loss from disposal of assets, impairments of					
intangibles and goodwill		56,178	24,352		
Depreciation and amortization expense		86,138	94,695		
Change in fair value of contingent consideration		(11,652)	(138)		
Restructuring costs		2,287	1,137		
Other income (expense):					
Interest income		-	157		
Cost of inducement		-	(19,500)		
Loss on extinguishment of debt		-	(1,112)		
Foreign currency transaction gain (loss)		99	(582)		
Change in fair value of derivative liability		8,935	19,315		
Interest expense		(37,857)	(38,277)		
Income tax expense (benefit)		439	7,062		
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Comparison of the Year Ended December 31, 2016 and 2015

Net Revenues

Net revenues consist of net product sales and revenue from co-promotion and other revenue sharing agreements. 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, 2016 and 2015 (in thousands):

	Year ended December 31,			
		2016		2015
Treximet	\$	66,961	\$	101,753
Zohydro		24,713		16,545
Silenor		16,926		20,913
Other		31,790		32,047
Net product revenues		140,390		171,258
Co-promotion and other revenue		466		4,592
Total net revenues	\$	140,856	\$	175,850

Net revenues decreased by \$35.0 million or 20% during the year ended December 31, 2016 compared to the year ended December 31, 2015.

Treximet net revenues decreased by \$34.8 million, or 34% during the year ended December 31, 2016 compared to the year ended December 31, 2015. This decrease was primarily related to the impact of \$15.3 million of disputed rebate claims, which were recorded during the year ended December 31, 2016, for sales which occurred in prior periods, \$12.5 million and \$2.8 million for the years ended December 31, 2015 and 2014, respectively, for the unfavorable arbitration ruling with GSK which was announced in February 2017. Net revenues also decreased due to a decrease in demand and other factors.

The following table sets forth the impact of the GSK arbitration award on net revenues of Treximet (in thousands):

	Year Ended December 31,								
	2016 2015	2014							
GAAP net revenues of Treximet \$	66,961 \$ 101,753	\$ 54,775							
GSK arbitration award adjustment	15,277 (12,484)	(2,793)							
Adjusted net revenues of Treximet (1)	82,238 89,269	\$ 51,982							
Zohydro	24,713 16,545								
Silenor 16,926 20,913 Other 31,790 32,047	Adjusted net product revenues 155,667	158,774 Co-promotion and other							
revenue 466 4,592 Total adjusted net revenues	\$ 156,133 \$ 163,366								

(1) Adjusted net revenues of Treximet is a non-GAAP financial measure that adjusts GAAP net revenues of Treximet for the impact of the GSK arbitration award for the year ended December 31, 2016 and reclassifies it to the years ended December 31, 2015 and 2014 and, therefore, has not been calculated in accordance with GAAP. We believe that this non-GAAP financial measure provides meaningful supplemental information regarding our operating results because it reclassifies the gross-to-net adjustments that were the subject of the GSK arbitration award to the years (2015 and 2014) in which the sales directly related to the gross-to-net

adjustment actually occurred. See further discussion under the heading "Non-GAAP Financial Measures" in Part II, Item 7 of this Annual Report on Form 10-K

Zohydro ER was acquired in April 2015 with the first sale occurring on May 4, 2015. Zohydro ER net revenues increased by \$8.2 million during the year ended December 31, 2016 compared to the prior period, which consisted of eight months of sales.

Silenor net revenues decreased by \$4.0 million, or 19%, during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease in sales of Silenor was primarily driven by inventory changes at the wholesaler level.

Net product revenues - other decreased by \$257,000, during the year ended December 31, 2016 compared to the year ended December 31, 2015. Declining net product revenues - 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.

Co-promotion and other revenue decreased by \$4.1 million during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease in co-promotion and other revenue was primarily attributable to the termination of a co-promotion agreement during 2015, which released the remaining deferred revenue from our consolidated balance sheet.

Cost of Product Sales

Cost of product sales decreased by \$8.1 million, or 16%, during the year ended December 31, 2016, compared to the year ended December 31, 2015. The decrease in cost of product sales is primarily due to lower royalty expenses related to the impact of reducing net revenues for Treximet as a result of the unfavorable arbitration ruling with GSK and also due to decreased net revenue as discussed above.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by \$1.4 million, during the year ended December 31, 2016 compared to the year ended December 31, 2015. The increase was driven by legal fees associated with the GSK arbitration. The increase was partially offset by a decrease in selling and marketing costs for Treximet and Silenor.

Research and Development Expense

Research and Development expense decreased by \$2.2 million, or 26%, during the year ended December 31, 2016 compared to the year ended December 31, 2015, primarily due to the timing of work for Treximet and Zohydro.

Depreciation and Amortization Expense

Depreciation and amortization expense decreased by \$8.6 million, or 9%, during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease was primarily related to intangible asset impairments during the year ended December 31, 2016 and 2015 and the extension of the patent life of Zohydro ER developed technology in the first quarter of 2016. These decreases were partially offset by the amortization of Treximet pediatrics developed technology, which began in May 2015.

Change in Fair Value of Contingent Consideration

For the acquisition of Zohydro ER, we recorded \$14.2 million of contingent consideration. The fair value of the contingent consideration linked to FDA approval was \$2.7 million and the fair value of the contingent consideration linked to achievement of the net sales target was \$11.5 million. As of December 31, 2016, the total current fair value of the contingent consideration is approximately \$2.4 million. We recorded a benefit of \$11.7 million and \$138,000 as change in fair value of contingent consideration in the years ended December 31, 2016 and 2015, respectively. 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.

Loss from Disposal of Assets, Impairments of Intangibles and Goodwill

Loss from disposal of assets, impairments of intangibles was \$56.2 million for the year ended December 31, 2016 compared to \$24.4 million for the year ended December 31, 2015. The increase was attributable to our routine testing

for impairment for all of our intangibles. We have recorded impairment charges of \$11.3 million for Silenor, \$7.9 million for Treximet pediatrics, \$8.0 million for non-core branded products and \$4.2 million for the termination of our agreement with Altus and \$1.0 million for fixed assets during the year ended December 31, 2016. We have also tested our goodwill and have recorded a \$23.8 million impairment charge during the year ended December 31, 2016. During the year ended December 31, 2015, we launched an initiative to focus on our primary branded products, Treximet, Zohydro and Silenor and discontinued the promotion of our non-core products and recorded impairment charges of \$24.4 million.

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Restructuring Costs

Restructuring costs were \$2.3 million and \$1.1 million during the years ended December 31, 2016 and 2015, respectively. Restructuring costs during the year ended December 31, 2016 were related to the initiative to restructure our sales force and operations as discussed above. Restructuring costs during the year ended December 31, 2015 were related to the initiative to restructure operations and shut down the Charleston, South Carolina site in 2015.

Interest Expense

Interest expense decreased \$420,000, or 1%, during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease was primarily due to reduced interest expense on our Treximet Secured Notes due to the lower principal balance which was partially offset by interest expense associated with the GSK arbitration award.

Change in Fair Value of Derivative Liability

We are required to separate the conversion option in the 4.25% Convertible Notes under ASC 815, Derivatives and Hedging. We recorded the bifurcated conversion option valued at \$28.5 million at issuance, as a derivative liability, which creates additional 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. We recorded benefits of \$8.9 million and \$19.3 million as change in fair value of derivative liability in other income (expense) in the years ended December 31, 2016 and 2015, respectively. For further discussion, see Note 13, *Debt and Lines of Credit*, to our consolidated financial statements included in this Annual Report on Form 10-K.

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 233,813 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 13, *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.

Income Tax Provision

During 2016, we recognized an income tax expense of \$439,000. Our 2016 effective rate from continuing operations was (0.3%). This tax expense included a current income tax provision of approximately \$639,000 and a deferred tax benefit of approximately \$200,000. During 2015, we recognized an income tax expense of \$7.1 million. Our 2015 effective rate from continuing operations rate was (5.0%). The change in the 2016 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.

Non-GAAP Financial Measures

To supplement our financial results determined by GAAP, we have also disclosed in this Annual Report on Form 10-K and the tables below the following non-GAAP information: adjusted net revenues of Treximet and adjusted

earnings before interest, taxes, depreciation and amortization (EBITDA).

Adjusted net revenues of Treximet is a non-GAAP financial measure that adjusts GAAP net revenues of Treximet for the impact of the GSK arbitration award for the year ended December 31, 2016 and reclassifies it to the years ended December 31, 2015 and 2014 and, therefore, has not been calculated in accordance with GAAP. We believe that this non-GAAP financial measure provides meaningful supplemental information regarding our Treximet net revenues results because it reclassifies the gross-to-net adjustments that were the subject of the GSK arbitration award to the years (2015 and 2014) in which the sales directly related to the gross-to-net adjustments actually occurred. We believe that inclusion of this non-GAAP financial measure provides consistency and comparability with past reports of financial results and provides consistency in calculations by outside analysts reviewing our results. Accordingly, we believe this non-GAAP financial measure is useful to investors in allowing for greater transparency of supplemental information used by management.

Adjusted EBITDA is a non-GAAP financial measure that excludes the impact of certain items and, therefore, has not been calculated in accordance with GAAP. This non-GAAP financial measure excludes from net loss net interest, depreciation and amortization, taxes, net revenue adjustments, deal expenses, share-based compensation expense, amortization of inventory step-up included in cost of product sales, royalty expense adjustments, severance expenses, non-recurring arbitration and litigation expenses, certain research and development expenses, cost of inducement, change in fair value of contingent consideration and derivative liabilities, disposal of assets and impairments of intangibles and goodwill, foreign currency transactions, extinguishment of debt and restructuring costs. In addition, from time to time in the future there may be other items that we may exclude for the purposes of our use of adjusted EBITDA; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of adjusted EBITDA. We believe that adjusted EBITDA provides meaningful supplemental information regarding our operating results because it excludes or adjusts 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 adjusted EBITDA provides consistency and comparability with past reports of financial results and provides consistency in calculations by outside analysts reviewing our results. Accordingly, we believe that adjusted EBITDA is useful to investors in allowing for greater transparency of supplemental information used by management.

We believe that these non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, but 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 a supplement to GAAP financial measures and by reconciling the non-GAAP financial measure to its most comparable GAAP financial measure. Investors are encouraged to review the reconciliations of the non-GAAP financial measure to its most comparable GAAP financial measure that is included below in this Annual Report on Form 10-K.

Reconciliation of GAAP reported net revenues of Treximet to adjusted net revenues of Treximet is as follows (in thousands):

Voor Ended December 21

	Year Ended December 31,						
		2016		2015		2014	
GAAP net revenues of Treximet	\$	66,961	\$	101,753	\$	54,775	
GSK arbitration award adjustment		15,277		(12,484)		(2,793)	
Adjusted net revenues of Treximet	\$	82,238	\$	89,269	\$	51,982	

Reconciliation of GAAP reported net loss to adjusted EBITDA is as follows (in thousands):

	Year Ended December 31,				
		2016		2015	
GAAP net loss	\$	(169,590)	\$	(148, 315)	
Adjustments:					
Interest expense, net		37,857		38,120	
Depreciation and amortization		86,215		94,695	
Income tax expense (benefit)		439		7,062	
EBITDA		(45,079)		(8,438)	
Net revenue adjustments (1)		15,277		(12,181)	
Cost of product sales adjustments (2)		(2,521)		2,115	
Selling, general and administrative adjustments (3)		9,513		11,518	
Research and development adjustments (4)		-		500	
Cost of inducement		-		19,500	
Change in fair value of contingent consideration		(11,652)		(138)	
Change in fair value of derivative liability		(8,935)		(19,315)	
Loss from disposal of assets, impairments of					
intangibles and goodwill		56,178		24,352	
Foreign currency transaction (gain) loss		(99)		582	
Loss on extinguishment of debt		-		1,112	
Restructuring costs (5)		2,287		1,137	
Adjusted EBITDA	\$	14,969	\$	20,744	

- (1) Adjusts for the impact of GSK arbitration award of \$15.3 million for revenue deductions related to prior period sales for the year ended December 31, 2016 by excluding the full \$15.3 million from the year ended December 31, 2016 and including \$12.5 million for the year ended December 31, 2015. This line item also excludes the impact on returns from FDA reclass of Hydrocodone products from C3 to C2 classification of \$303,000 for the year ended December 31, 2015.
- (2) Adjusts for the royalty credit related to the adjusting of net revenues of Treximet for the GSK arbitration award of \$2.5 million related to prior period revenues for the year ended December 31, 2016 and including the \$2.0 million for the year ended December 31, 2015. This line item also excludes the amortization of inventory step-up from acquisitions for the year ended December 31, 2015.
- (3) Excludes deal expenses of \$2.8 million and \$4.3 million; stock compensation expense of \$2.7 million and \$5.3 million; severance expense of \$1.9 million and \$0 and non-recurring arbitration and litigation expenses of \$2.1 million and \$1.9 million for the years ended December 31, 2016 and 2015, respectively.
- (4) Excludes expense associated with contractual milestone assumed as part of the Zohydro ER acquisition for the year ended December 31, 2015.
- (5) Excludes expense related to the initiative to restructure our sales force and operations in 2016 and the restructure of our operations and the shut down of our Charleston, South Carolina site in 2015.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources (amounts in thousands):

	December 31,			
		2016		2015
Cash and cash equivalents	\$	36,375	\$	56,135
Total current assets		108,910		155,690
Current debt (1)		11,103		13,335
Arbitration award (2)		17,522		-
Non-current debt (1)		290,321		303,491
Stockholders' (deficit) equity	\$	(114,063)	\$	33,097

(1) The term "Current Debt" consists the line item "Treximet Secured Notes - current" in our Consolidated Balance Sheets included in this Form 10-K. The term "Non-current debt" consists of the sum of the line items "Convertible notes - long term", "Treximet Secured Notes - long term" and "Credit facilities - long term" in our Consolidated Balance Sheets included in this Form 10-K. Our debt includes, among other things, borrowings under the Wells Fargo Credit Facility (as defined below). During August 2015, we entered into the Wells Fargo 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. As of December 31, 2016, we had borrowings of \$14.0 million, and the ability to borrow approximately \$16.9 million under this facility. 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. Pursuant to the terms of the Wells Fargo Credit Facility, the Administrative Agent has the authority to impose reserves against our borrowing base under certain circumstances in its sole discretion. We understand that the Administrative Agent is currently evaluating whether to impose such a reserve. For more information, see "Risk Factors-Risks Related to our Business-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."

As of December 31, 2016, our debt also included \$189.6 million aggregate principal amount of our 12.0% Treximet Secured Notes issued August 19, 2014 and due August 1, 2020 and \$130.0 million aggregate principal amount of our 4.25% Convertible Notes, issued April 22, 2015 and due April 1, 2021, unless earlier converted. On each Payment Date, as defined in the Treximet Secured Note Indenture, 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, we have recorded \$176.8 million of the Treximet Secured Notes as long-term debt and \$12.8 million as short-term debt as of December 31, 2016.

The obligations of Wells Fargo Credit Facility, the Treximet Secured Notes and the 4.25% Convertible Notes place a substantial financial burden on us, and we have been in active discussions to refinance or otherwise restructure our existing debt. If we are unable to meet our obligations under these instruments, we may be required to sell our business or all or substantially all of our assets or seek Chapter 11 bankruptcy protection, among other possible outcomes. The inability to enter into a strategic transaction to refinance or otherwise restructure our debt, or a

transaction that is not successful or on attractive terms, could accelerate our need for cash and make securing funding on reasonable terms more difficult. For additional information, see "Risk Factors-Risks Related to our Business-Our business operations and financial position could be adversely affected as a result of our substantial indebtedness" and "-Our board of directors has authorized us to explore alternatives to refinance or restructure our existing debt, but we can provide no assurances of the terms of any refinancing or restructuring or how it will impact our securityholders."

(2) Relates to obligations associated with our arbitration proceeding with GSK. We had been engaged in an arbitration proceeding with GSK relating to an alleged breach by us of a covenant contained in the Asset Purchase and Sale Agreement by and among GSK and its affiliates and us pertaining to a pre-existing customer agreement. The parties entered into an Interim Settlement Agreement in July 2015 under which we paid approximately \$10.3 million to GSK and escrowed an additional amount of approximately \$6.2 million. On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest (estimated to be approximately \$2 to \$5 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. We have already paid to GSK an aggregate of \$16.5 million, consisting of \$10.3 million in 2015 pursuant to the Interim Settlement Agreement and \$6.2 million from the escrow account originally created pursuant to the Interim Settlement Agreement, which will offset the total award. On March 17, 2017, we amended the Interim Settlement Agreement with GSK whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award. Pursuant to the amendment, we have agreed that the current outstanding balance is approximately \$21.5 million and that we are obligated to pay the outstanding balance in quarterly installments in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. We have agreed that for so long as the Interim Settlement Agreement, as amended, is in effect, we will be subject to certain restrictions on non-ordinary course payments and transactions and GSK will have certain information rights. GSK has agreed that for so long as we comply with the payment schedule set forth in the Interim Settlement Agreement, as amended, as well as other agreed-upon obligations, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award.

During 2016 and 2015 we utilized cash from operations of \$16.5 million and \$14.7 million, respectively. On April 24, 2015, we, through our wholly owned subsidiary 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 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 our common stock, \$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. We have sold 3,859,903 shares of common stock under this controlled equity program for net proceeds of \$19.7 million during the year ended December 31, 2016. Our ability to access the capital markets may be affected by our ongoing exploration of alternatives to refinance or restructure our existing debt. For additional information, see "Risk Factors-Risks Related to our Business-Our business operations and financial position could be adversely affected as a result of our substantial indebtedness" and "-Our board of directors has authorized us to explore alternatives to refinance or restructure our existing debt, but we can provide no assurances of the terms of any refinancing or restructuring or how it will impact our securityholders."

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 1.2 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. However, as noted above, our ability to effectively access the capital markets may be affected by our ongoing exploration of alternatives to refinance or restructure our existing debt. For additional information, "Risk Factors-Risks Related to our Business-Our business operations and financial position could be adversely affected as a result of our substantial indebtedness" and "-Our board of directors has authorized us to explore alternatives to refinance or restructure our existing debt, but we can provide no assurances of the terms of any refinancing or restructuring or how it will impact our securityholders."

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

- our ability to restructure our existing debt;
- the level of product sales of 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 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;
- the costs of and any judgments resulting from legal proceedings;
- the principal and interest payments due under the Treximet Secured Notes and our 4.25% Convertible Notes, as applicable; 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.

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. To improve financial flexibility, we have retained advisors to explore options to restructure our debt and assess other potential alternatives in order to maximize value for all stakeholders. 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. There can be no assurance that the exploration of options will result in the identification or consummation of any transaction.

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Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2016 and 2015 (in thousands).

	2016	2015
Cash (used in) provided by		
Operating activities	\$ (16,501)	\$ (14,749)
Investing activities	(1,567)	(84,348)
Financing activities	(1,692)	120,377
Net (decrease) increase in cash and cash equivalents	\$ (19,760)	\$ 21,280
Net cash used in operating activities		

Net cash used in operating activities during 2016 and 2015 was \$16.5 million and \$14.7 million, respectively. The \$16.5 million used in operating activities during 2016 was primarily driven by: net loss of \$169.6 million, adjusted by non-cash expenses totaling \$130.3 million and \$22.8 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities. 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.

Net cash used in investing activities

Net cash used in investing activities during 2016 and 2015 was \$1.6 million and \$84.3 million, respectively. The \$1.6 million used in investing activities during 2016 was primarily due to purchases of fixed assets. 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.

Net cash (used in) provided by financing activities

Net cash used in financing activities during 2016 was \$1.7 million. Net cash provided by financing activities during 2015 was \$120.4 million. Cash used in financing activities for the year ended December 31, 2016 was primarily for principal payments on our Treximet Secured Notes of \$20.4 million, which were partially offset by the sales of common stock of \$19.8 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.

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 judgments 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 judgments 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 judgments 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.

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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, 2016 and 2015:

		Government						
	Product			Program	Price			
		Returns		Rebates		djustments		
Balance at December 31, 2014	\$	9,691	\$	9,968	\$	32,945		
Allowances for certain co-agreements(1)		326		194		-		
Provision		17,807		6,166		138,306		
Payments and credits		(15,928)		(9,646)		(127,151)		
Balance at December 31, 2015		11,896		6,682		44,100		
Allowances for certain co-agreements(1)		-		91		362		
Provision		8,377		13,459		170,133		
Payments and credits		(1,959)		(12,819)		(179,361)		
Balance at December 31, 2016	\$	18,314	\$	7,413	\$	35,234		

(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 than 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.

Inventory Valuation

Inventory primarily consists of finished goods, which include pharmaceutical products ready for commercial sale. 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 fair value of our restricted stock units is equal to the market price of our stock at the date of grant. 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 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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Pernix Therapeutics Holdings, Inc. and Subsidiaries Table of Contents

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Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-K 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, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2016. We have also audited the accompanying consolidated financial statement schedule for each of the two years in the period ended December 31, 2016 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016 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 two years in the period ended December 31, 2016, 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.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

March 28, 2017

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

December 31, 2016 and 2015

(in thousands, except share and per share data)

	2016			2015
Assets				
Current assets:	_		_	
Cash and cash equivalents	\$	36,375	\$	56,135
Restricted cash				10,002
Accounts receivable, net		50,729		61,209
Inventory, net		7,775		10,035
Prepaid expenses and other current assets		12,617		11,574
Income tax receivable		1,414		6,735
Total current assets		108,910		155,690
Property and equipment, net		1,103		2,346
Goodwill		30,600		54,865
Intangible assets, net		169,571		285,943
Other		257		347
Total assets	\$	310,441	\$	499,191
Liabilities and Stockholders' (Deficit) Equity				
Current liabilities:				
Accounts payable	\$	7,275	\$	14,081
Accrued personnel expense		5,357		4,336
Accrued allowances		60,961		62,678
Other accrued expenses		8,711		9,355
Interest payable		10,897		11,903
Treximet Secured Notes - current		11,103		13,335
Restricted cash payable				10,002
Other liabilities - current		5,224		6,753
Total current liabilities		109,528		132,443
Convertible notes - long-term		104,071		99,776
Derivative liability		230		9,165
Contingent consideration		2,403		14,055
Treximet Secured Notes - long-term		172,250		188,715
Credit facilities - long-term		14,000		15,000
Deferred income tax liability - long-term		-		202
Arbitration award		17,522		-
Other liabilities		4,500		6,738
Total liabilities		424,504		466,094
Commitments and contingencies (notes 1, 3, 10, 12, 13, 19 and 20) Stockholders' (deficit) 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 shares authorized, 10,015,641 and 6,387,455 issued and 10,015,641 and 6,111,253 outstanding				
at December 31, 2016 and 2015, respectively		100		61
Additional paid-in capital		244,309		227,387
Treasury stock, at cost, 0 and 2,762,022 shares held at December 31, 2016		,		.,
and 2015, respectively, see Note 14		-		(5,548)
Accumulated other compreshensive loss		(79)		-
Accumulated deficit		(358,393)		(188,803)
Total stockholders' (deficit) equity		(114,063)		33,097
Total liabilities and stockholders' (deficit) equity	\$	310,441	\$	499,191
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PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS Years ended December 31, 2016 and 2015

(in thousands, except per share data)

		2016		2015
Net revenues	\$	140,856	\$	175,850
Costs and operating expenses:				
Cost of product sales		43,320		51,408
Selling, general and administrative expense		98,834		97,421
Research and development expense		6,079		8,229
Depreciation and amortization expense		86,138		94,695
Change in fair value of contingent consideration		(11,652)		(138)
Loss from disposal of assets, impairments of intangibles and goodwill		56,178		24,352
Restructuring costs		2,287		1,137
Total costs and operating expenses		281,184		277,104
Loss from operations		(140,328)		(101,254)
Other income (expense):				
Interest income		-		157
Interest expense		(37,857)		(38,277)
Change in fair value of derivative liability		8,935		19,315
Foreign currency transaction gain (loss)		99		(582)
Cost of inducement		-		(19,500)
Loss on extinguishment of debt		-		(1,112)
Other expense, net		(28,823)		(39,999)
Loss before income tax expense		(169,151)		(141,253)
Income tax expense		439		7,062
Net loss		(169,590)		(148,315)
Other comprehensive loss				
Unrealized loss during period, net of tax of \$0, and \$0, respectively		(79)		-
Comprehensive loss	\$	(169,669)	\$	(148,315)
Net loss per common and potential common share				
Basic	\$	(21.67)	\$	(27.81)
Diluted	\$	(21.67)	\$	(27.81)
Weighted-average common and potential common				
shares outstanding:		7.027		£ 222
Basic		7,827		5,333
Diluted	1' 1 4	7,827	. 1	5,333

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY Years ended December 31, 2016 and 2015

(in thousands)

	Preferi Shares	red Stock Amount	Comm Shares	non Stock Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings (Deficit)	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at December 31,									
2014	-	\$ -	3,835	\$ 38	\$ 129,473	\$ (5,431)	\$ (40,488)	\$ -	\$ 83,592
Net proceeds from issuance									
of restricted stock	-	-	5	-	-	(117)	-	-	(117)
Compensation expense on									
share-based awards	-	-	-	-	5,944	-	-	-	5,944
Net proceeds from sale of									
shares	-	-	65	1	394	-	-	-	395
Conversion of 8.0%									
convertible notes	-	-	1,805	18	60,154	-	-	-	60,172
Issuance of stock for									
inducement	-	-	233	2	19,498	-	-	-	19,500
Stock issued in connection									
with the			4.60		44.004				44.00
purchase of Zohydro ER	-	-	168	2	11,924	-	-	-	11,926
Net loss	-	-	-	-	-	-	(148,315)	-	(148,315)
Balance at December 31,			C 111		227 207	(5.540)	(100.002)		22.007
2015	-	-	6,111	61	227,387	(5,548)	(188,803)	-	33,097
Net proceeds from issuance			4			(22)			(22)
of restricted stock	-	-	4	-	-	(23)	-	-	(23)
Reclassification of treasury					(5.571)	5 571			
stock	-	-	-	-	(5,571)	5,571	-	-	-
Compensation expense on share-based awards					2.710				2,718
Net proceeds from sale of	-	-	-	-	2,718	-	-	-	2,/18
shares			3,901	39	19,775				19,814
	-	-	3,901	39	19,773	-	-	(79)	*
Other comprehensive loss Net loss	-	-	-	-	-	-	(169,590)	(79)	(79) (169,590)
Balance at December 31,	-	\$ -	10.016	\$ 100	\$ 244,309	\$ -	\$ (358,393)		\$ (114,063)
2016	-	р -	10,016	э 100	φ 244,309	φ -	φ (336,393)	\$ (79)	φ (114,003)
2010									

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2016 and 2015

(in thousands)

	2016	2015
Cash flows from operating activities:		
Net loss	\$ (169,590)	\$ (148,315)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	704	361
Amortization of intangibles	85,511	94,334
Amortization of deferred financing costs	2,440	2,730
Accretion of debt discount	3,590	2,286
Interest accretion of notes receivable	-	(127)
Deferred income tax expense (benefit)	(202)	6,746
Loss on disposal of fixed assets	35	19
Loss on extinguishment of debt	-	1,112
Stock compensation expense	2,718	5,944
Fair market value change in derivative liability	(8,935)	(19,315)
Fair market value change in contingent consideration	(11,652)	(138)
Issuance of stock for inducement		19,500
Loss on impairment	56,143	24,352
Decrease (increase) in operating assets (excluding effect of acquisitions):		
Accounts receivable	11,009	(17,082)
Income taxes	5,321	(4,145)
Inventory	2,260	444
Prepaid expenses and other assets	(533)	2,471
Increase (decrease) in operating liabilities (excluding effect of acquisitions):	(5.050)	
Accounts payable and accrued expenses	(7,958)	6,682
Accrued allowances	(1,717)	10,074
Arbitration award	17,522	2 201
Interest payable	(1,006)	2,291
Other liabilities	(2,161)	(4,973)
Net cash used in operating activities	(16,501)	(14,749)
Cash flows from investing activities:		
Acquisitions	(583)	(87,986)
Payments received on notes receivable	-	4,850
Purchase of software and equipment	(984)	(1,212)
Net cash used in investing activities	(1,567)	(84,348)
Cash flows from financing activities:		
Proceeds from issuance of Convertible Notes	_	130,000
Payments on Treximet Secured Notes	(20,406)	(10,013)
Net drawdowns (payments) on credit facilities	(1,000)	7,655
Payments for financing costs	-	(5,349)
Payment of consent fee	_	(2,150)
Payments on mortgages and capital leases	(77)	(44)
Proceeds from issuance of common stock, net of tax and costs	19,814	395
Shares withheld for the payment of taxes	(23)	(117)
Net cash (used in) provided by financing activities	(1,692)	120,377
Net (decrease) increase in cash and cash equivalents	(19,760)	21,280
Cash and cash equivalents, beginning of period	56,135	34,855
Cash and cash equivalents, end of period	\$ 36,375	\$ 56,135
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PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS December 31, 2016 and 2015

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. 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.

Subsequent Events

The Company has evaluated all events and transactions since December 31, 2016. The Company did not have any non-recognized subsequent events, but had the following recognized subsequent event:

On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest (estimated to be approximately \$2 to \$5 million). The tribunal also denied the Company's claim that GSK breached its obligations under the supply agreement. Subsequent discussions with GSK resulted in an agreement on March 17, 2017, to amend the Interim Settlement Agreement. A payment schedule was established for satisfaction of the current balance of the award. Pursuant to the amendment, we have agreed that the current outstanding balance is approximately \$21.5 million and we have agreed to make quarterly installments to GSK in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. Pernix has also agreed that for so long as the Interim Settlement Agreement is in effect, Pernix will be subject to certain restrictions on non-ordinary course payments and transactions and GSK will have certain information rights. GSK has agreed that for so long as Pernix complies with the payment schedule set forth in the Amendment, as well as other agreed-upon obligations, enforcement of the Award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the Award. The Company recorded the fair value of this settlement in the amount of approximately \$18.5 million in its financial statements at December 31, 2016 and has recorded \$15.3 million as a reduction to net revenues, \$1.0 million to selling, general and administrative expense and \$2.2 million to interest expense in the year ended December 31, 2016.

Reverse Stock Split

On October 13, 2016, the Company filed Articles of Amendment to its charter (the Articles of Amendment), with the State Department of Assessments and Taxation of Maryland to effect a one-for-ten reverse stock split of the outstanding shares of common stock, par value \$0.01 per share, of the Company (the Reverse Stock Split). The Reverse Stock Split was duly approved by the Board of Directors of the Company without stockholder approval in accordance with the authority conferred by Section 2-309(e)(2) of the Maryland General Corporation Law and Article IV, Section 6 of the Company's charter. Pursuant to the Articles of Amendment, effective as of the close of business on October 13, 2016, each outstanding share of the Company's common stock, par value \$0.01 per share, was automatically combined into 1/10th of share of common stock, par value \$0.01 per share. Fractional share holdings were rounded up to the nearest whole number. As a result of the Reverse Stock Split, the number of outstanding shares of common stock of the Company was reduced to approximately 9.5 million shares.

Each stockholder's percentage ownership in the Company and proportional voting power remained unchanged immediately after the Reverse Stock Split, except for minor changes resulting from the rounding up of fractional shares. The rights and privileges of stockholders were also unaffected by the Reverse Stock Split. There was no change to the number of authorized shares of the Company's common stock as a result of the Reverse Stock Split. Accordingly, all share and per share information in this Annual Report on Form 10-K has been restated to retroactively show the effect of the Reverse Stock Split.

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.

Reclassifications

Certain comparative figures have been reclassified to conform to the current year presentation. In accordance with Accounting Standards Update (ASU) 2015-03, Simplifying the Presentation of Debt Issuance Costs, (ASU 2015-03), the Company reclassified \$1.7 million from Prepaid expenses and other current assets to Treximet Secured Notes - current, \$4.0 million from Other assets to Convertible notes - long-term and \$6.2 million from Other assets to Treximet Secured Notes - long-term on the consolidated balance sheet at December 31, 2015.

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 and for determining the Company's liquidity and going concern analysis; 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.

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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 consisted of amounts escrowed for the purchase of Zohydro ER with BeadTek. In accordance with the asset purchase agreement, the Company had 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 was 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 was 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. The conditions for the release of this escrow had been satisfied during the year ended December 31, 2016 and therefore the restricted cash has been released to Zogenix. 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 2016 and 2015. See Note 15, *Concentrations*, for additional information. At December 31, 2016 and 2015, the allowance for doubtful accounts was approximately \$500,000 and \$15,000, 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, 2016, approximately 42% of the inventory purchases, were from three primary suppliers - Recro Gainesville, LLC, Aphena Pharma Solutions and Belcher Pharmaceuticals, LLC, allocated 16%, 14% and 12%, respectively. For the year ended December 31, 2015, approximately 25% of the inventory purchases were from two primary suppliers - GSK and Aphena Pharma Solutions, allocated 15% and 10%, respectively. 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.

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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 eight years. Leasehold improvements are amortized over the shorter of the non-cancelable 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, the Company reports 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. During the testing of goodwill for impairment during the year ended December 31, 2016, it was noted that the Company's carrying value exceeded its fair value and therefore the Company failed Step 1 and performed Step 2 of the goodwill impairment test. Step 2 of the impairment test determined a \$23.8 million impairment charge for goodwill. See Note 9, *Goodwill and Intangible Assets*, for further information.

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 18 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, 2016 and 2015, the Company recorded impairment charges of \$31.4 million and \$24.4 million, respectively. See Note 9, *Goodwill and Intangible Assets*, for further information.

Impairment of Long-lived Assets

The Company reviews long-lived assets, such as property and equipment and finite lived intangibles, 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.

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Deferred Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization, and are recorded as a reduction of the debt outstanding in current or long-term debt, unless there is no current portion for the period presented, in which case, the deferred financing cost will be recorded in prepaid expenses. Amortization expense is included in interest expense. Deferred financing costs amortized during years ended December 31, 2016 and 2015 were \$2.4 million and \$2.7 million, respectively. Unamortized deferred financing costs were \$10.4 million and \$12.8 million as of December 31, 2016 and 2015, respectively.

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 the Company's 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 the Company's 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, the Company's expectations regarding future utilization rates for these programs and channel inventory data.

Co-promotion, Royalties and Other Product Related Revenues

The Company receives royalties from third parties based on sales of the Company's products under licensing and distribution arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes revenues based on estimates of royalties earned during the applicable period, and adjusts for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been significant.

The Company's contract revenues consist of fees and milestone payments. Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. In situations where the Company has continuing performance obligations, non- refundable fees are deferred and are recognized ratably over the Company's projected performance period. Sales-based milestone payments are typically payments made to the Company 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. The Company recognizes sales-based milestone payments from a collaborator when the event that triggers the obligation of payment has occurred, there is no further obligation on the Company's 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, 2016 and 2015 included \$0 and \$97,000, respectively of inventory costs associated with the increase in the basis of the inventory that was amortized as the inventory was subsequently sold. The remaining balance of the increase in the basis of the inventory acquired was \$0 as of December 31, 2016.

Research and Development

Research and development costs in connection with the Company's internal programs for the development of products are expensed as incurred. Pernix either expenses research and development costs as incurred or will advance third parties a research and development fee, which is amortized over the term of the related agreement.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred in SG&A. Advertising expenses for 2016 and 2015 were \$12.6 million and \$18.3 million, respectively. The decrease is due to advertising programs for Silenor and Treximet that were decreased during 2016.

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.

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 operations and comprehensive 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

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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. The Company considers many factors when evaluating and estimating the Company's 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 2013 through 2016.

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 19, *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	mber 31,	
			2016		2015
Numerator:					
Net loss		\$	(169,590)	\$	(148,315)
Denominator:					
Weighted-average common shares, basic			7,827		5,333
Dilutive effective of stock options			-		-
Weighted-average common shares, diluted			7,827		5,333
Net loss per share, basic and diluted		\$	(21.67)	\$	(27.81)
Tee 1055 per share, busic and direct	83	Ψ	(21.07)	Ψ	(27.01)
	63				

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 De	cember 31,
	2016	2015
4.25% Convertible Notes	1,133	789
Stock options and restricted stock	774	395
Warrants	33	47
Total potential dilutive effect	1,940	1,231
Recent Accounting Pronouncements		

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows (Topic 230)* (ASU 2016-15) which provides updated guidance on eight classification issues related to the statement of cash flows: debt prepayments and extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interests in securitization transactions and separately identifiable cash flows and application of the predominance principle. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently assessing the potential impact of adopting ASU 2016-15 on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, (ASU 2016-09). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company does expect adoption of ASU No. 2016-09 to have a material impact on its consolidated financial statements.

In February 2016, the FASB issued 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 19, *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 the Company's 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 Company will adopt this standard during the first quarter of 2017. The adoption of this standard is not expected to have a material impact on the Company's 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 became effective for annual reporting periods ending after December 15, 2016 and interim periods with years beginning after December 15, 2016. The Company adopted this standard during the fourth quarter of 2016. The adoption of this standard did not have a material impact on the Company's financial position or results of operations.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU No. 2015-14 "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date" (ASU 2015- 14), which defers the effective date of ASU 2014-09 by one year to fiscal years and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted for fiscal years and interim periods within those years, beginning after December 15, 2016. Accordingly, the standard is effective for the Company on January 1, 2018 using either a full retrospective or a modified retrospective approach. The Company anticipates adopting the standard using the modified retrospective method. There may be differences in timing of revenue recognition under the new standard compared to recognition under ASC 605, *Revenue Recognition*.

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, 2016 and December 31, 2015 (in thousands):

	As of December 31, 2016									
		Level 1		Level 2		Level 3			Total	
Money market fund and trust cash sweep investments ⁽¹⁾	\$. \$	-	\$		-	\$	-	
Total assets	\$		\$	-	\$		-	\$	-	
				As of Dece	mber	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	

(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, 2016 or December 31, 2015.

As of December 31, 2016 and December 31, 2015, the Company did not have any investments in Level 2 or Level 3 securities.

There were no transfers of assets or liabilities between Level 1 and Level 2 during the years ended December 31, 2016 and 2015.

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):

		As of Decei	31, 2016	As of Decei	er 31, 2015				
		Fair Value		Carrying Value		Fair Value		Carrying Value	
4.25% Convertible Notes	\$	32,595	\$	104,071	\$	68,637	\$	99,776	
Derivative liability		230		230		9,165		9,165	
Contingent consideration		2,403		2,403		14,055		14,055	
Treximet Secured Notes		147,551		183,353		179,518		202,050	
Total	\$	182,779	\$	290,057	\$	271,375	\$	325,046	
Convertible Notes									

The fair values of the convertible notes were estimated using the following significant observable inputs: (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. Significant

increases (decreases) in these observable inputs in isolation would likely result in a significantly (lower) higher fair value measurement.

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. Significant increases (decreases) in these observable inputs in isolation would likely result in a significantly (lower) higher fair value measurement.

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 12% Senior Secured Notes due 2020 (Treximet Secured Notes) was estimated using a discounted cash flow model. Significant increases (decreases) in the expected future annual revenue streams and probability of achievement in isolation would likely result in a significantly (lower) higher fair value measurement.

Within the hierarchy of fair value measurements, the fair values of the convertible notes, derivative liability, Treximet Secured Notes and contingent consideration 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, 2016 and 2015 (in thousands).

		nber	iber 31,		
			2015		
Derivative liability:					
Balance at beginning of year	\$	9,165	\$	-	
Initial measurement of derivative liability		-		28,480	
Remeasurement adjustments - gains included in earnings		(8,935)		(19,315)	
Ending balance	\$	230	\$	9,165	
Contingent consideration:					
Balance at beginning of year	\$	14,055	\$	-	
Initial measurement of contingent consideration		-		14,193	
Remeasurement adjustments - gains included in earnings		(11,652)		(138)	

Ending balance \$ 2,403 \$ 14,055

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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 the Company, \$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 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 \$3.7 million. The net impact of these measurement period adjustments increased goodwill to \$6.6 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):

Purchase price:		s of April 24, 2015 As initially		Measurement Period Adjustments		As of April 24, 2015 As adjusted
Cash consideration paid to Zogenix	\$	reported 70,000	\$	Aujustinents	\$	70,000
1 0	Ф		Ф	-	Ф	,
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	\$	122,180	\$	(15,134)	\$	107,046
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		122,000		(17,858)		104,142
Liabilities assumed (6)		-		(3,726)		(3,726)
Amount attributable to net assets acquired		122,000		(21,584)		100,416
Goodwill(7)	\$	180	\$	6,450	\$	6,630

- (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 restricted cash payable are presented separately under current assets and current liabilities, respectively, in the consolidated balance sheets. The conditions for the release of this escrow had been satisfied during the year ended December 31, 2016 and therefore the restricted cash has been released to Zogenix.
- (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 \$118.90. Accordingly, Pernix issued 168,209 shares of common stock to Zogenix (\$20.0 million/\$118.90 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 \$70.90 and accordingly the fair value of common stock issued by the Company on the closing date was determined to be \$11.9 million. \$1,682 representing the par value of 168,209 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 at December 31, 2016 were \$0 and \$2.4 million, respectively and \$2.7 million and \$11.5 million, at December 31, 2015, respectively. The Company recorded \$11.7 million and \$138,000 as change in fair value of contingent consideration in the years ended December 31, 2016 and 2015, respectively. The total contingent consideration is classified in other long-term liabilities and is marked to its fair value of \$2.4 million and \$14.1 million as of December 31, 2016 and 2015, respectively. 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 at December 31, 2015. The core technology intangible assets represent developed technology of products approved for sales in the market, which the Company refers to as marketed products, and have finite useful lives. They are amortized on a straight-line basis over a period of 18.3 years. The IPR&D are considered indefinite-lived intangible assets until the completion or abandonment of the associated research and development efforts. Accordingly, during the development period, these assets are not amortized but subject to an annual impairment review. During year ended December 31, 2016, the Company abandoned the IPR&D intangibles discussed above and impaired the \$4.2 million.

- (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 related to supplier contracts assumed 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 year ended December 31, 2015, as though the Zohydro ER acquisition had been completed as of January 1, 2015. 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):

	I	December 31,
		2015
	(ı	inaudited)
Revenue	\$	180,856
Net loss	\$	(166,709)
Pro forma net loss per common share:		
Basic	\$	(31.26)
Diluted	\$	(31.26)

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 are 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 Pernix;
- 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 FDA-issued "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 received pediatric exclusivity and may seek 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 50,000 shares of the Company's common stock at an exercise price of \$42.80 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.

Note 5. Accounts Receivable

Accounts receivable consist of the following (in thousands):

	December 3				
		2016		2015	
Trade accounts receivable	\$	50,532	\$	60,564	
Less allowance for prompt pay discounts		(1,038)		(1,844)	
Less allowance for doubtful accounts		(500)		(15)	
Total trade receivables, net		48,994		58,705	
Receivables from third parties		1,200		1,594	
Other miscellaneous receivables		535		910	
Total accounts receivable, net	\$	50,729	\$	61,209	

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 6. 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 7. Inventory

Inventories consist of the following (in thousands):

	December 31,			
	2016	2015		
Raw materials	\$ 2,365 \$	2,047		
Work-in-process	-	1,425		
Finished goods	7,393	9,011		
Inventory, gross	9,758	12,483		
Reserve for obsolescence	(1,983)	(2,448)		
Inventory, net	\$ 7,775 \$	10,035		

Note 8. Property, Plant & Equipment

	Decemb					
	2016			2015		
Land	\$	-	\$	572		
Buildings and improvements		31		31		
Equipment		622		840		
Furniture and fixtures		701		713		
Computer software and website		447		657		
Total fixed assets		1,801		2,813		
Less: accumulated depreciation		(698)		(467)		
Total property and equipment	\$	1,103	\$	2,346		

Depreciation expense amounted to approximately \$704,000 and \$361,000 for the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, the Company has classified \$525,000 of land as held for sale, which is included in prepaid expenses and other current assets on the consolidated balance sheet. The carrying value reflects the estimated selling price based on market data, which is a Level 2 input. During the year ended December 31, 2016, the Company recorded an impairment loss of \$47,000, related to the write-down of land held for sale, as the book value of the property was in excess of its fair value less costs to sell. The Company is actively marketing the land held for sale as of December 31, 2016 and expects it to be sold within one year.

Note 9. Goodwill and Intangible Assets

Goodwill consists of the following (in thousands):

	Amount
Balance at December 31, 2014	\$ 44,900
Goodwill acquired - Zohydro	180
Measurement period adjustments - Zohydro	6,949
Measurement period adjustments - Treximet	2,836
Balance at December 31, 2015	54,865
Goodwill impairment	(23,766)
Measurement period adjustments - Zohydro	(499)
Balance at December 31, 2016	\$ 30,600

During the Company's annual impairment test it was noted that the Company's carrying value exceeded its fair value and therefore the Company failed Step 1 and performed Step 2 of the goodwill impairment test. Step 2 of the impairment test determined a \$23.8 million impairment charge for goodwill.

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

Total intangible assets

	As of December 31, 2016											
	Weighted Carrying Accumula		6		, ,		Carrying		Accumulated nt Amortization		I	Net Carrying Amount
Unamortized intangible assets:												
In-process research and development	Indefinite	\$	26,500	\$	(15,500)	\$	-	\$	11,000			
Total unamortized intangible assets			26,500		(15,500)		-		11,000			
Amortized intangible assets:												
Brand	0.0 years		3,887		(891)		(2,996)		-			
Product licenses	8.4 years		2,846		-		(1,232)		1,614			
Supplier contracts	5.0 years		583		-		(78)		505			
Acquired developed technologies	7.7 years		379,737		(15,052)		(208,233)		156,452			
Total amortized intangible assets	Ž		387,053		(15,943)		(212,539)		158,571			

413.553 \$

(31.443) \$

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

As of December 31, 2016, the weighted average life for the Company's definite-lived intangible assets in total was approximately 7.7 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 18.3 years. During the year ended December 31, 2016, the Company abandoned the IPR&D intangibles and impaired the \$4.2 million.

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 2016, the Company determined that the carrying value of certain of its intangible assets were not recoverable based upon the existence of one or more of the indicators of impairment. The Company measured these impairments based on a

169,571

(212,539) \$

probability weighted projected discounted cash flow method using a discount rate determined to be commensurate with the risk inherent in the Company's current business model and therefore, recorded impairment charges of approximately \$15.5 million against IPR&D (including the \$4.2 million in the preceding paragraph), \$891,000 against brands, and \$15.1 million against acquired developed technologies.

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.

Estimated amortization expense related to intangible assets with definite lives for each of the five succeeding years and thereafter is as follows (in thousands):

	Amount
2017	\$ 72,940
2018	13,961
2019	5,507
2020	5,420
2021	5,325
Thereafter	55,418
Total	\$ 158,571

Amortization expense was \$85.5 million, of which, \$78,000 is included in the cost of product sales and \$94.3 million for the years ended December 31, 2016 and 2015, respectively.

Note 10. Accrued Allowances

Accrued allowances consist of the following (in thousands):

	December 31,		
	2016		2015
Accrued returns allowance	\$ 18,314	\$	11,896
Accrued price adjustments	35,234		44,100
Accrued government program rebates	7,413		6,682
Total	\$ 60,961	\$	62,678

Note 11. Accrued Expenses

Accrued expenses consist of the following (in thousands):

		December 31,			
			2016		2015
Due to third parties (revenue sharing arrangements)		\$	5,402	\$	6,995
Other accrued expenses			3,309		2,360
Total		\$	8,711	\$	9,355
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Note 12. Other Liabilities

Other liabilities consist of the following (in thousands):

	December 31,			
		2016		2015
Settlement obligations (see Note 19)	\$	7,783	\$	12,955
Deferred revenue		283		314
Other		1,658		222
Total contracts payable and other obligations		9,724		13,491
Less current portion		(5,224)		(6,753)
Other liabilitites - long-term	\$	4,500	\$	6,738

Note 13. Debt and Lines of Credit

Debt consists of the following (in thousands):

	December 31,			
		2016		2015
Wells Fargo Credit Facility	\$	14,000	\$	15,000
4.25% Convertible Notes		104,071		99,776
Treximet Secured Notes		183,353		202,050
Total outstanding debt		301,424		316,826
Less current portion		11,103		13,335
Long term debt outstanding	\$	290,321	\$	303,491

The following table represents, by year, the future maturity schedule of the outstanding debt and line of credit as of December 31, 2016 (in thousands):

	Amount
2017	\$ 12,812
2018	14,000
2019	-
2020	176,769
2021	130,000
Thereafter	-
Total maturities	333,581
Less: note discount and deferred financing costs	(32,157)
Total outstanding debt	\$ 301,424

Interest expense amounted to \$37.9 million and \$38.3 million for the years ended December 31, 2016 and 2015, 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, 2016, \$14.0 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 \$16.9 million as of December 31, 2016. Pursuant to the terms of the Wells Fargo Credit Facility, the Administrative Agent has the authority to impose reserves against our borrowing base under certain circumstances in its sole discretion. We understand that the Administrative Agent is currently evaluating whether to impose such a reserve. If the Administrative Agent were to impose such a reserve, depending on the Company's inventory levels and the size of the reserve, the Company's excess availability under the Wells Fargo Credit Facility could fall below \$10.0 million, which, in turn, would trigger an obligation for the Company to meet a 1 to 1 fixed charge coverage ratio test. If the Company were unable to meet this fixed charge coverage ratio test, the Company would be in default under the terms of the Wells Fargo Credit Facility. If the Company were to be in default, the Company anticipate that it would consider entering into a forbearance agreement with the Administrative Agent or seeking an alternative funding source. There can be no assurance that the Company would be able enter into a forbearance agreement or find an alternative funding source on satisfactory terms, or at all.

MidCap Funding V, LLC

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 \$107.4 million and \$103.8 million is recorded as long-term debt on the consolidated balance sheet as of December 31, 2016 and 2015, respectively.

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. Effective upon the Reverse Stock Split, the conversion rate decreased from 87.2030 shares of the Company's common stock for each \$1,000 principal amount of the 4.25% Convertible Notes to 8.7237 shares of the Company's common stock for each \$1,000 principal amount of the 4.25% Convertible Notes, which represents a conversion price of approximately \$114.63 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 \$230,000 and \$9.2 million as of December 31, 2016 and 2015, respectively. 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 \$9.1 million and \$6.1 million for the years ended December 31, 2016 and 2015, respectively, related to the 4.25% Convertible Notes. Change in fair value of derivative liability was income of \$8.9 million and \$19.3 million for the years ended December 31, 2016 and 2015, respectively. Accrued interest on the 4.25% Convertible Notes was approximately \$1.4 million as of December 31, 2016 and December 31, 2015, respectively. As of December 31, 2016 and December 31, 2015, the Company had outstanding borrowings of \$130.0 million related to the 4.25% Convertible Notes.

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 233,813 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 the Company's 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 such shares of the Company's common stock. In addition, such holders are permitted to dispose of up to 80 percent of such shares of the Company's 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 \$36.00 per share. The Company issued 1.8 million shares pursuant to this conversion and retired the \$65.0 million of the outstanding 8.00% Convertible Notes.

Interest expense was \$0 and \$1.6 million for the years ended December 31, 2016 and 2015, respectively related to the 8.00% Convertible Notes. As of December 31, 2016 and 2015, the Company had outstanding borrowings of \$0 related to the 8.00% Convertible Notes, respectively. Accrued interest on the 8.00% Convertible Notes was \$0 as of December 31, 2016 and 2015, 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

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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 remaining balance outstanding on the Treximet Secured Notes will be due on the maturity date, which is August 1, 2020. As of December 31, 2016 and 2015, the Company classified \$12.8 million and \$15.0 million, 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 occurred on or after August 1, 2015 and prior to August 1, 2016, the redemption price would have been equal to 106% of the outstanding principal amount of Treximet Secured Notes being redeemed plus accrued and unpaid interest thereon, or occurs (i) on or after August 1, 2016 and prior to August 1, 2017, the redemption price will equal 103% of the outstanding principal amount of the Treximet Secured Notes being redeemed plus accrued and unpaid interest thereon and (ii) 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 and (ii) 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 and (ii) 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 \$23.3 million and \$25.9 million, for the years ended December 31, 2016 and 2015, respectively. Accrued interest on the Treximet Secured Notes was approximately \$9.5 million and \$10.5 million as of December 31, 2016 and 2015, respectively. The Company recorded debt issuance costs of \$7.8 million, which are being amortized using the effective interest method. As of December 31, 2016, \$1.3 million and \$3.4 million are recorded on the consolidated balance sheet in Treximet Secured Notes - current and Treximet Secured Notes long-term, respectively. As of December 31, 2015, \$1.3 million and \$4.7 million are recorded on the consolidated balance sheet in Treximet Secured Notes long-term, 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 August 2014 Indenture, 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 \$403,000 and \$1.1 million is recorded in Treximet Secured Notes - current and Treximet Secured Notes - long term on the consolidated balance sheet at December 31, 2016, respectively and \$403,000 and \$1.5 million is recorded in Treximet Secured Notes - long term on the consolidated balance sheet at December 31, 2015, respectively and are being amortized using the straight-line method, which approximates the effective interest method.

Note 14. Stockholders' Equity

Reverse Stock Split

On October 13, 2016, the Company effectuated a reverse stock split of its outstanding shares of common stock at a ratio of 1 to 10. Upon the effectiveness of the Reverse Stock Split, which occurred on October 13, 2016, the Company's issued and outstanding shares of common stock was decreased from 94,961,549 to 9,499,812 shares, all with a par value of \$0.01. Accordingly, all share and per share information has been restated to retroactively show the effect of the Reverse Stock Split.

Capital Stock

In July 2015, the Company filed an Articles of Amendment of the Amended and Restated Articles of Incorporation of the Company (the Articles of Amendment) with the State Department of Assessment and Taxation of Maryland. The Articles of Amendment amended the Company's Amended and Restated Articles 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 168,207 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 233,813 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 1,805,556 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 13, *Debt and Lines of Credit*.

Controlled Equity Offering

On November 7, 2014, the Company entered into a controlled equity offering sales agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) pursuant to which the Company could issue and sell shares of its common stock having an aggregate offering price of up to one hundred million dollars, pursuant to an effective registration statement on Form S-3 (No. 333-200005), from time to time through Cantor, acting as agent. The Company will pay Cantor a commission rate of 3.0% of the gross sales price per share of the common stock sold through Cantor as agent under the Sales Agreement.

During the year ended December 31, 2016, the Company sold 3,859,903 shares of common stock under the Sales Agreement at an average price of approximately \$5.28 per share for gross proceeds of \$20.4 million and net proceeds of \$19.8 million, after deducting Cantor's commission. As of December 31, 2016, approximately \$79.6 million of common stock remained available to be sold under this facility.

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Warrants Issued in Acquisition of Somaxon

In connection with the acquisition of Somaxon in March 2013, the Company assumed approximately 46,900 outstanding warrants in the acquisition of Somaxon. These warrants have exercise prices ranging from \$77.03 to \$907.21 and expiration dates ranging from July 2016 through December 2021. As of December 31, 2016, the Company has 32,992 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 50,000 shares of the Company's common stock at an exercise price of \$42.80 per share (equal to the closing price of the Company's 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. 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 50,000 of their warrants in a cashless exercise for which 31,584 shares were issued.

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

The Company issued to Frontline Pharmaceuticals LLC warrants to purchase 50,000 shares of Pernix common stock at an exercise price of \$36.00 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 22,264 and 27,737, respectively, of their warrants in cashless exercises for which 21,757 shares were issued. There are no warrants remaining for Frontline.

Treasury Shares

The Company reclassified the \$5.6 million of outstanding treasury stock from Treasury stock to Common stock and Additional paid-in capital at December 31, 2016 and the 278,239 shares were permanently retired.

Note 15. 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, 2016 and 2015, 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, 2016 and 2015:

Gross Product Sales	2016	2015
McKesson Corporation	36%	38%
AmerisourceBergen Drug Corporation	31%	27%
Cardinal Health, Inc.	26%	28%
Total	93%	93%
Accounts Receivable	2016	2015

McKesson Corporation	36%	34%
AmerisourceBergen Drug Corporation	28%	30%
Cardinal Health, Inc.	28%	28%
Total	92%	92%

Note 16. 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, 2016 and 2015, the Company recognized approximately \$18.2 million and \$25.4 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 \$466,000 and \$4.6 million for the years ended December 31, 2016 and 2015, respectively.

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. The Company 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 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% of net sales. See Note 4, *Business Combinations and Other Acquisitions*, for additional information.

Note 17. 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, 2016 and 2015, 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. Effective January 1, 2016, all eligible employees are automatically enrolled in the plan, unless the employee elects to not participate in the plan. Employees are 100 percent

vested in employee and employer contributions once they are eligible to participate. Contribution expense was approximately \$950,000 and \$519,000 for the years ended December 31, 2016 and 2015, 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 700,000. 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.

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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 775,000. 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 70,000 shares of common stock, have been terminated. As of December 31, 2016, the 2007 Plan had 4,200 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 period.

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 values using the Black-Scholes option pricing model were as follows:

Year ended December 31, 2016 2015

Weighted average expected stock price volatility 77.9 % 72.3 % Estimated dividend yield - % - % Risk-free interest rate 1.4 % 1.7 % Expected life of option (in years) 6.1 6.3 Weighted average grant date fair value per option \$ 7.63 \$ 42.30

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 \$2.7 million and \$5.9 million for the years ended December 31, 2016 and 2015, 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, 2016, approximately 650,000 options are outstanding that have been issued to current officers and employees under the 2007 Plan, the 2009 Plan and the 2015 Plan. As of December 31, 2016, there was approximately \$5.7 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 2.4 years.

During the year ended December 31, 2015, the Company's Board of Directors awarded a total of 48,500 options (Performance Options) to certain of the Company's former executive officers. Due to the corporate restructuring that was announced in July 2016 and the associated departures of Company's former executive officers, all outstanding Performance Options have been canceled and none of these Performance Options have vested.

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 years ended December 31, 2016 and 2015, the Company recorded \$35,000 and \$42,000, respectively, of share-based compensation expense related to these options.

The following table shows the stock option activity, described above, during the year ended December 31, 2016 (share and intrinsic values in thousands):

	Shares		Average Exercise Price	Weighted Average Remaining Contractual Life		Aggregate Intrinsic Value
Options Outstanding at December 31, 2015	703	\$	55.42	(years)		value
Granted	632	φ	11.73			
Exercised	032		11.73		\$	
Cancelled	(685)		43.15		Φ	-
	(063)		43.13			
Expired	-					
Options outstanding at December 31, 2016	650	\$	25.85	9.0	\$	-
Options vested and expected to						
vest as of December 31, 2016	491	\$	30.80	8.9	\$	-
Options vested and exercisable as of December 31,						
2016	79	\$	70.34	6.9	\$	-

The total intrinsic value of options exercised during the years ended December 31, 2016 and 2015 were \$0 and \$211,000, respectively.

Options issued subsequent to January 2014 have a graded vesting schedule over either three or 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, 2016 (share and intrinsic values in thousands):

		Weighted Average Grant Date	Aggregate
	Shares	Fair Value	Intrinsic Value
Non-vested restricted stock outstanding at December 31, 2015	6	\$ 30.00	
Granted	197	3.36	
Vested	(6)	30.00	\$ 63
Forfeited	-	-	
Non-vested restricted stock outstanding at December 31, 2016	197	\$ 3.36	

The total intrinsic value of restricted stock vested during the years ended December 31, 2016 and 2015 was \$63,000 and \$562,000, respectively.

Restricted stock issued subsequent to January 2014 have a graded vesting schedule over either three or four years.

As of December 31, 2016, there was approximately \$619,000 of total unrecognized compensation cost related to non-vested restricted stock issued to employees and directors of the Company.

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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 100,000 shares are available for purchase under this plan of which 61,698 have been issued. Compensation expense related to the Employee Stock Purchase Plan was \$29,000 and \$134,000 for the years ended December 31, 2016 and 2015, respectively. Effective December 31, 2016, the Company's board of directors suspended the Employee Stock Purchase Plan and directed the Company to return all funds in each participant's deposit account to such participant as soon as possible.

Note 18. 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, 2016 and 2015 (in thousands):

	Year Ended December 31,			
		2016		2015
Current:				
Federal	\$	455	\$	6,923
State		356		508
Foreign		(172)		207
Total current provision		639		7,638
Deferred Provision:				
Federal		(189)		(1,329)
State		(11)		(551)
Foreign		-		1,304
Total deferred provision (benefit)		(200)		(576)
Total	\$	439	\$	7,062

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 31,			
		2016		2015
Deferred tax assets:				
Accruals and other reserves	\$	36,052	\$	24,205
Intangibles		4,414		-
Inventory		1,157		985
Stock awards		4,532		3,757
Net operating loss carryovers		33,241		8,038
Gross deferred tax assets		79,396		36,985
Valuation allowance		(79,373)		(31,453)
Net deferred tax asset		23		5,532
Deferred tax liabilities:				
Fixed Assets		(23)		(1,021)
Intangibles		_		(4,713)
Gross deferred tax liability		(23)		(5,734)
Net deferred tax asset/(liability)		-		(202)
Included in consolidated balance sheet:				
Deferred income tax assets/(liabilities) - current		_		_
Deferred income tax assets/(liabilities) - long-term		_		(202)
Net deferred tax asset/(liability)	\$	-	\$	(202)

Somaxon has federal net operating loss carryforwards (NOL's) of approximately \$250.2 million at December 31, 2016 ranging in expiration from 2023 to 2033. However, based on the change in ownership provision of IRC Section 382, \$22.4 million of those NOL are expected to be available for utilization.

The Company has federal NOL's of approximately \$62.1 million at December 31, 2016 ranging in expiration from 2035 to 2036. Included in the \$62.1 million are \$798,000 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, 2016 ranging in expiration from 2021 to 2029. However, based on the change in ownership provisions of IRC Section 382, approximately \$519,000 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, 2016. However, based on the change in ownership provision of IRC Section 382, approximately \$263,000 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's NOLs noted above).

The effective income tax rate from continuing operations is different from the federal statutory rate for the years ended December 31, 2016 and 2015 for the following reasons:

	Year Ended De	ecember 31,
	2016	2015
Expected taxes at statutory rates	35.0 %	35.0 %
State taxes, net of federal tax benefit	(0.1)%	-
Foreign income tax rate differential	(10.0)%	(13.6)%
Amortization and impairment of goodwill	(8.7)%	(2.0)%
Mark to market adjustment	4.3 %	-
Deductible inducement payment	3.3 %	2.0 %
Change in valuation allowance	(25.2)%	(21.7)%
Change in liability for uncertain tax positions	-	(4.8)%
Permanent differences and other	1.1 %	0.1 %
	(0.3)%	(5.0)%

Changes in tax laws or in their application or interpretation, such as to the transfer pricing between the Company's non-U.S. operations and the U.S., could increase the Company's effective tax rate and negatively affect the Company's results of operations.

Approximately \$0 and \$500,000 of the deferred tax liability at December 31, 2016 and 2015, respectively, relates to the difference between the financial statement and tax basis of the intangibles acquired in the Cypress acquisition.

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

	Year Ended December 31,			
		2016		2015
Balance at beginning of year	\$	7,410	\$	-
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	\$	7,410	\$	7,410

As of December 31, 2016 and 2015, the total amount of gross unrecognized tax benefits was \$7.4 million. Of these amounts as of December 31, 2016 and 2015, \$0, 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, 2016 and 2015, the amount of accrued interest or penalties related to unrecognized tax benefit totaled \$0 and \$0, respectively. For unrecognized tax benefits that existed at December 31, 2016, 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, 2016, the Company's 2014 Federal tax return is under examination by the Internal Revenue Service. Other years subject to potential examination include 2012, 2013 and 2015 in the United States.

Note 19. Commitments and Contingencies

Arbitration award

On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35 million, plus interest (estimated to be approximately \$2 to \$5 million). The tribunal also denied the Company's claim that GSK breached its obligations under the supply agreement. The Company has already paid to GSK an aggregate of \$16.5 million, including \$6.2 million from the escrow account, which will offset the total award. After discussions with GSK, an agreement was reached on March 17, 2017, to amend the Interim Settlement Agreement with GSK whereby the Company agreed to establish a payment schedule for satisfaction of the current balance of the award. Pursuant to the amendment the Company has agreed that the current outstanding balance is approximately \$21.5 million to GSK and the Company has agreed to make quarterly installments in amounts totaling \$1.0 million in 2017, \$3.5 million in 2018 and approximately \$17.0 million in 2019. The Company recorded the fair value of this settlement in the amount of approximately \$18.5 million in its financial statements at December 31, 2016 and has recorded \$15.3 million as a reduction to net revenues, \$1.0 million to selling, general and administrative expense and \$2.2 million to interest expense in the year ended December 31, 2016.

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. The Company's failure to satisfy minimum sales requirements under its co-promotion agreements generally allows the counterparty to terminate the agreement and/or results in a loss of the Company's exclusivity rights.

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 20, *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, 2016 (in thousands):

	Amount
2017	\$ 617
2018	628
2019	640
2020	518
2021	524
Thereafter	309
Total	\$ 3.236

Future minimum lease payments under non-cancelable operating subleases are as follows as of December 31, 2016 (in thousands):

	Amount	
2017	\$ 118	
2018	121	
2019	125	
2020	-	
2021	-	
Thereafter	-	
Total	\$ 364	

Total rent expense was approximately \$760,000 and \$653,000 for the years ended December 31, 2016 and 2015, respectively. Total sublease rental income was approximately \$115,000 and \$19,000 for the years ended December 31, 2016 and 2015, 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, 2016, remaining payment obligations owed under these settlement agreements are \$1.3 million, payable in equal annual installments of \$250,000 through 2019, and \$500,000, payable in 2017. These settlement agreements are recorded in other liabilities (both current and long-term) on the balance sheets as of December 31, 2016 and 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. 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 \$5.5 million and \$7.1 million as of December 31, 2016 and 2015 and is included in other liabilities (both current and long-term) on the consolidated balance sheets.

Note 20. Restructuring

On July 7, 2016, the Company announced a restructuring of its sales force and operations. The reorganization plan included (1) a reduction of 54 sales positions, primarily from the Company's Neurology sales team; (2) prioritization and reorganization of sales territories to reduce the inefficient time that sales representatives spent driving long distances between customers; (3) improvement of the Company's compensation plan to incentivize the field sales staff to increase the frequency of calls on the focused targets; and (4) consolidation of the Neurology and Pain sales forces under one sales management structure to eliminate redundancies. In addition, as part of this initiative, the Company reduced its administrative staff by six employees. The Company incurred \$2.3 million during the year ended December 31, 2016 in severance and other related cash expenses. The charge during the year ended December 31, 2016 was comprised of \$1.3 million in severance related cash expenses, and \$1.0 million in other cash related expenses. Associated severance and other related payments are expected to be paid by December 31, 2017.

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 were 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, are as follows (in thousands):

	December 31, 2015	Charges	Cash	Non-cash	December 31, 2016
2016 restructuring costs	\$ -	\$ 2,287	\$ (1,669)	\$ -	\$ 618
2015 restructuring costs	104	-	(104)	-	-
Totals	\$ 104	\$ 2,287	\$ (1,773)	\$ -	\$ 618
	December 31,				December 31,
	2014	Charges	Cash	Non-cash	2015
2015 restructuring costs	\$ -	\$ 1,137	\$ (380)	\$ (653)	\$ 104

Note 21. Supplemental Cash Flow Information

	7	Years ended December 31,			
		2016		2015	
Supplemental disclosures of Cash Flow Information:					
Cash received for income taxes, net	\$	(4,780)	\$	(352)	
Cash paid for interest		30,165		30,207	
Supplemental disclosures of Non-cash Investing and Financing Activities:					
Reclassification of treasury stock		5,571		-	
Conversion of 8.00% Convertible notes		-		60,172	
Issuance of 168,209 shares to Zogenix for Zohydro acquisition		-		11,926	
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Note 22. Quarterly Financial Data (Unaudited)

Selected quarterly consolidated financial data are shown below (in thousands, except per share data, unaudited).

	Three Months Ended							
	N	March 31,		June 30,	Se	otember 30,	De	ecember 31,
2016								
Net revenues	\$	32,469	\$	36,746	\$	41,468	\$	30,173
Operating loss		(23,809)		(22,300)		(17,402)		(76,817)
Net loss		(25,936)		(31,139)		(26,438)		(86,077)
Basic loss per common share	\$	(4.24)	\$	(4.67)	\$	(2.99)	\$	(8.92)
Diluted loss per common								
and potential common share	\$	(4.24)	\$	(4.67)	\$	(2.99)	\$	(8.92)
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	\$	(6.16)	\$	(6.15)	\$	(1.76)	\$	(13.37)
Diluted loss per common								
and potential common share	\$	(6.16)	\$	(6.15)	\$	(1.76)	\$	(13.37)

Schedule II Pernix Therapeutics Holdings, Inc.

Valuation and Qualifying Accounts Years Ended December 31, 2016 and 2015

(in thousands)	beg	llance at inning of period	Additions charged to costs and expenses		Deductions		Balance at end of period	
For the year ended December 31, 2016								
Allowance for doubtful accounts (1)	\$	15	\$	618	\$	(133)	\$	500
Allowance for prompt pay discounts (1)		1,844		6,718		(7,524)		1,038
Inventory obsolescence allowance (2)		2,448		2,184		(2,649)		1,983
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

⁽¹⁾ Shown as a reduction of accounts receivable. Charges related to prompt pay discounts are reflected as a reduction of revenue.

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 (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, 2016.

⁽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.

(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, 2016. 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, 2016, our internal control over financial reporting is effective based on those criteria.

(c) Change in Internal Control over Financial Reporting

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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.

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 (the Definitive Proxy Statement), to be filed with the SEC in connection with our 2017 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, 2016, 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 Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and our principal accounting officer and every other director, officer and employee of Pernix. The Code of Business Conduct and Ethics is available on our Internet website at www.pernixtx.com. A copy of the Code of Business 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 Business 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 "Securities

Authorized for Issuance Under Equity Compensation Plans," "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

	Page
Report of Independent Registered Public Accounting Firm	72
Consolidated Balance Sheets as of December 31, 2016 and 2015	73
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016 and 2015	74
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016 and 2015	75
Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015	76
Notes to Consolidated Financial Statements 2. Financial Statement Schedules.	77

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.

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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 28, 2017	By:	/s/ John Sedor
John Sedor		
Chief Executive Officer and Chairman		
		act of 1934, this Annual Report on Form 10-K has been gistrant and in the capacities and on the dates indicated
Signature		
	Т	Title
	Γ	Date

/s/ John Sedor	
Chief Executive Officer and Chairman	
	March 28, 2017
John Sedor	
(Principal Executive Officer)	
/s/ Graham Miao	
President, Chief Financial Officer and Director	
	March 28, 2017
Graham Miao	
(Principal Financial Officer)	

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC Form 10-K
/s/ Michael J. Golembiewski
Vice President of Finance and Corporate Controller
March 28, 2017
Michael J. Golembiewski
(Principal Accounting Officer)
(Principal Accounting Officer)
/s/ Dennis Langer
Director

	Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC.	- Form 10-K
Dennis Langer		
/s/ Gabriel Leung		
Director		
	March 28, 2017	
Gabriel Leung		
Swerrer Zeung		

Director	
Tasos Konidaris	March 28, 2017
Tusos Itomauris	
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Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-K INDEX TO EXHIBITS

No. 2.1	Description Securities Purchase Agreement, dated as of November 13, 2012, by and among Pernix Therapeutics Holdings, Inc., Cypress Pharmaceuticals, Inc., all of the stockholders of Cypress Pharmaceuticals, Inc. and an	Filed or Furnished with this Form 10-K	Incorpora Refere Form 8-K	
2.2	individual as agent of all of the stockholders of Cypress Pharmaceuticals, Inc. First Amendment to Securities Purchase Agreement dated December 28, 2012 among Pernix Therapeutics Holdings, Inc., on the one hand, and Cypress Pharmaceuticals, Inc., a Mississippi corporation, all of the stockholders of Cypress, and for limited purposes set forth therein, an individual as agent of the Sellers, on the other hand.		8-K	1/4/2013
2.3	Agreement and Plan of Merger dated December 10, 2012 by and among Pernix Therapeutics Holdings, Inc., Pernix Acquisition Corp I. and Somaxon Pharmaceuticals, Inc.		8-K	12/12/2012
2.4	Asset Purchase Agreement by and among Breckenridge Pharmaceutical, Inc. (Breckenridge), on the one hand, and the Company and Cypress Pharmaceuticals, Inc. (Cypress), on the other hand, dated as of August 5, 2013		10-Q	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 Pernix Therapeutics Holdings, Inc.		8-K	5/16/2014
2.7	Letter Agreement dated August 14, 2014 among Pernix Therapeutics Holdings, Inc., Worrigan Limited, Glaxo Group, Limited, GlaxoSmithKline Intellectual Property Management Limited, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline, LLC		8-K	8/22/2014
2.8	Asset Purchase Agreement, dated as of March 10, 2015, between Zogenix Inc., Pernix Ireland Limited, and solely with respect to Sections 5.9.2, 10.2 and 10.14, Pernix Therapeutics Holdings Inc.		10-Q/A	8/19/2015
2.9	Amendment to Asset Purchase Agreement, dated as of April 23, 2015, between Zogenix Inc., Pernix Ireland Limited and Pernix Therapeutics Holdings Inc.		10-Q	<u>5/1/2015</u>
3.1	Articles of Incorporation of Pernix Therapeutics Holdings, Inc.		8-K	3/15/2010
3.2	Bylaws of Pernix Therapeutics Holdings, Inc.		8-K	3/15/2010
3.3	Articles of Amendment to the Articles of Incorporation of Pernix Therapeutics Holdings, Inc.		8-K	7/28/2015
3.4	Articles of Amendment to the Articles of Incorporation of Pernix Therapeutics Holdings, Inc.		8-K	10/13/2016
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3.5	First Amendment to the Bylaws of Pernix Therapeutics Holdings, Inc.	8-K	<u>10/13/2016</u>
4.1	Form of certificate representing shares of common stock of Pernix Therapeutics Holdings, Inc.	10-K	<u>3/29/2012</u>
4.2	Indenture, dated February 21, 2014, by and between Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association	8-K	<u>2/26/2014</u>
4.3	Common Stock Purchase Warrant dated May 13, 2014 issued to Pozen, Inc.	8-K	5/16/2014
4.4	Indenture, dated August 19, 2014, among Pernix Therapeutics Holdings, Inc., the Guarantors named therein and U.S. Bank National Association, as Trustee and as Collateral Agent	8-K	8/22/2014
4.5	Forms of 12% Senior Secured Notes due 2020 (included in Exhibit 4.6)	8-K	<u>8/22/2014</u>
4.6	First Supplemental Indenture, dated as of August 19, 2014, among Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	8/22/2014
4.7	Second Supplemental Indenture, dated as of August 19.	8-K	8/22/2014

as of August 19,

2014, among Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee. 4.8 Form of S-3/A Warrant to Purchase Common Stock, dated as of 1/30/2015 December 31, 2014, issued by Pernix Therapeutics Holdings, Inc. (No. 333-200011) 4.9 Third 8-K 4/24/2015 Supplemental Indenture, dated as of April 21, 2015, between Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee. 4/24/2015 4.1 First 8-K Supplemental Indenture, dated as of April 21, 2015, between Pernix Therapeutics Holdings, Inc. and U.S. Bank National Association, as Trustee. 4/24/2015 4.11 Indenture, dated 8-K April 22, 2015, between Pernix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee. Forms of 4.25% 4/24/2015 Convertible Senior Notes due 2021 (included in Exhibit 4.12) Amended and Restated 2009 Stock Incentive

Plan

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10.2* Amended and Restated 2010 Employee Stock Purchase Plan √ 10.3* Amended and Restated Golf Trust of America, Inc. 2007 Stock Option Plan √ 10.4 Form of Amended and Restated Merger Partner Stockholder Agreement 10.5 Amended and Restated License Agreement by and between Pernix Sleep, Inc. (formerly Somaxon 8-K <u>5/31/2011</u> 10-Q <u>11/12/2013</u> Pharmaceuticals, Inc.) and ProCom One, Inc. dated September 15, 2010. 10.6 Form of Securities Purchase Agreement, dated February 4, 2014. 10.7* Employment Agreement dated as of February 5, 2014 by and 8-K <u>2/7/2014</u> between Pernix Therapeutics Holdings, Inc. and Douglas Drysdale. 8-K <u>2/7/2014</u> 10.8 Form of Representation Agreement, dated February 21,2014, by and between Pernix Therapeutics Holdings, Inc. and the Investors party thereto 8-K <u>2/26/2014</u> Form of Registration Rights Agreement, dated February 21,2014, by and between Pernix Therapeutics Holdings, Inc. and the Investors party 8-K 2/26/2014

	_	-	
10.10*	Amendment No. 1 to the Pernix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan	10-K	3/17/2014
10.11*	Employment Agreement dated as of March 9, 2014 by and between Pernix Therapeutics Holdings, Inc. and Terence Novak	10-Q	5/12/2014
10.12*	Pernix Therapeutics Holdings, Inc. Amended and Restated 2009 Stock Incentive Plan	DEF 14A	4/28/2014
10.13*	Employment Offer Letter, dated June 20, 2014, by and between Pernix Therapeutics Holdings, Inc. and Sanjay S. Patel	8-K	6/25/2014
10.14	Controlled Equity Offering SM Sales Agreement, dated November 7, 2014, by and between Pernix Therapeutics Holdings, Inc. and Cantor Fitzgerald & Co.	S-3 (No. 333-200005)	11/7/2014
10.15	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
10.16	Inducement Agreement, dated as of April 16, 2015, by and among Pernix Therapeutics Holdings, Inc. and the investors listed on Schedule 1 thereto.	8-K	4/17/2015
10.17*	Amended and Restated Pernix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan	N	
10 10		0.77	0/00/0017

8-K <u>8/28/2015</u>

10.18

Credit Agreement by and among Wells Fargo Bank, National Association, as Administrative Agent, the Lenders that are parties thereto, as Lenders and Pernix Therapeutics Holdings, Inc., Pernix Therapeutics, LLC, Pernix Sleep, Inc., Cypress Pharmaceuticals, Inc., Macoven Pharmaceuticals, Inc., Gaine, Inc., Repicopea Inc. and Macoven Pharmaceuticals, L.L.C., as Borrowers dated as of August 21, 2015. 10.19* **Employment Offer** Letter, dated May 9, 2016, by and between 8/11/2016 Pernix TherapeuticsHoldings, Inc. and John Sedor 10-Q 10.20* Offer Letter, dated October 27, 2016, by and between Pernix 11/7/2016 Therapeutics Holdings,Inc. and Dennis H. Langer, 8-K M.D., J.D. 10.21* Employment Agreement, dated November 3, 2016, by 11/7/2016 and between Pernix Therapeutics Holdings, Inc. and John A. Sedor. 8-K 10.22* Nonqualified Stock Option Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2009 Stock 11/7/2016 Incentive Plan, dated November 3, 2016, by and between Pernix Therapeutics Holdings, Inc. and John A. Sedor. 8-K

10.23* Nonqualified Stock 8-K 11/7/2016 Option Agreement

Option Agreement under the Amended and Restated Pernix Therapeutics Holdings,

Inc. 2015 Omnibus Incentive Plan, dated November 3, 2016, by and between Pernix Therapeutics Holdings, Inc. and John A. Sedor.

10.24* Restricted Share Unit

Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2015 Omnibus Incentive

mnibus Incentive <u>11/7/2016</u>

Plan, dated November 3, 2016, by and between Pernix Therapeutics Holdings,

Inc. and John A. Sedor. 8-K

10.25* Employment

Agreement, dated November 3, 2016, by and between Pernix

and between Pernix 11/7/2016

Therapeutics Holdings, Inc. and Graham G.

Miao, Ph.D. 8-K

10.26* Nonqualified Stock

Option Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2009 Stock

Incentive Plan, dated 11/7/2016

November 3, 2016, by and between Pernix Therapeutics Holdings, Inc. and Graham G.

Miao, Ph.D. 8-K

10.27* Restricted Share Unit

Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan, dated November

mnibus incentive
an dated November

Plan, dated November 3, 2016, by and between Pernix Therapeutics Holdings, Inc. and Graham G.

Miao, Ph.D. 8-K

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10.28*	Resignation and Release Agreement, dated July 26, 2016, by and between Pernix Therapeutics Holdings, Inc. and Barry Siegel.		10-Q	11/10/2016
10.29*	Offer Letter, dated November 16, 2016, by and between Pernix Therapeutics Holdings, Inc. and Gabriel Leung.		8-K	11/22/2016
10.30*	Form of Indemnification Agreement between Pernix Therapeutics Holdings, Inc. and Certain Executive Officers and Directors.	Ŋ		
10.31*	Resignation and Release Agreement, dated December 21, 2016, by and between Pernix Therapeutics Holdings, Inc. and Terence Novak.		8-K	<u>12/28/2016</u>
10.32*	Offer Letter, dated December 16, 2016, by and between Pernix Therapeutics Holdings, Inc. and Kenneth R. Pina.	Ŋ		
10.33*	Form of Nonqualified Stock Option Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2009 Stock			

Incentive Plan.

10.34* Form of Nonqualified Stock Option Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan. 10.35* Restricted Share Unit Agreement under the Amended and Restated Pernix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan. 21.1 Subsidiaries of the Company 23.1 Consent of Cherry Bekaert 1 L.L.P. 31.1 Certification by John Sedor (Principal Executive Officer) pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley 1 Act of 2002. 31.2 Certification by Graham Miao (Principal Financial Officer) pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. 1 32.1 Certification by John Sedor and

Graham Miao 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