

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2017**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-14494



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

**Maryland**

(State or Other Jurisdiction of Incorporation)

**33-0724736**

(I.R.S. Employer Identification Number)

**10 North Park Place, Suite 201  
Morristown, NJ 07960**

(Address of principal executive offices) (Zip Code)

**(800) 793-2145**

(Telephone number, including area code)

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

**Title of each class**

Common Stock, par value \$0.01 per share

**Name of each exchange on which registered**

NASDAQ Global Market

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

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

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

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company  Emerging growth company   
(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2017 (the last business day of the registrant's most recently completed second quarter) was approximately \$40,263,000, based upon the \$4.02 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 1, 2018, the registrant had 11,872,758 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 2018 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2017.

---

### PERNIX THERAPEUTICS HOLDINGS, INC. Annual Report on Form 10-K for the Year Ended December 31, 2017 TABLE OF CONTENTS

	<b><u>Page</u></b>
<b>PART I</b>	
<a href="#">Item 1.</a> Business	3
<a href="#">Item 1A.</a> Risk Factors	27
<a href="#">Item 1B.</a> Unresolved Staff Comments	52
<a href="#">Item 2.</a> Properties	52
<a href="#">Item 3.</a> Legal Proceedings	52
<a href="#">Item 4.</a> Mine Safety Disclosures	54
<b>PART II</b>	
<a href="#">Item 5.</a> Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	55
<a href="#">Item 6.</a> Selected Financial Data	56
<a href="#">Item 7.</a> Management's Discussion and Analysis of Financial Condition and Results of Operations	56
<a href="#">Item 7A.</a> Quantitative and Qualitative Disclosures About Market Risk	75
<a href="#">Item 8.</a> Financial Statements and Supplementary Data	76
<a href="#">Item 9.</a> Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	118
<a href="#">Item 9A.</a> Controls and Procedures	119
<a href="#">Item 9B.</a> Other Information	118
<b>PART III</b>	
<a href="#">Item 10.</a> Directors, Executive Officers and Corporate Governance	119
<a href="#">Item 11.</a> Executive Compensation	119
<a href="#">Item 12.</a> Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	120
<a href="#">Item 13.</a> Certain Relationships and Related Transactions, Director Independence	120
<a href="#">Item 14.</a> Principal Accounting Fees and Services	120
<b>PART IV</b>	
<a href="#">Item 15.</a> Exhibits, Financial Statement Schedules	120
<a href="#">Item 16.</a> Form 10-K Summary	124

---

## PART I

Unless the context indicates otherwise, references in the report to "Permixon<sup>®</sup>," "Company," "we," "us" and "our" and similar terms mean Permixon 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, 2017 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 pain, neurology, and psychiatry, as well as other specialty therapeutic areas. We promote our core branded products to physicians through our sales force of 74 Sales Specialists 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:

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

Our strategy is to continue to create shareholder value by:

- Growing or maintaining sales of the existing products in our portfolio in various ways, including identifying new growth opportunities; and
- Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure.

On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to our Treximet<sup>®</sup> fixed dose combination product. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees (representing approximately 22% of our workforce), the majority of which were associated with our sales force and commercial infrastructure. In connection with this commercial reorganization, we expect to realize annualized cost savings of \$7.0 million - \$8.0 million beginning in the first quarter of 2018. We anticipate recording a one-time charge of approximately \$1.0 million during the first quarter of 2018 as a result of this realignment.

## **Our Products and Product Candidates**

### ***Pernix-Promoted Products***

#### **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 U.S. Food and Drug Administration (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, a viscous gel forms when the inactive beads are crushed and dissolved in liquids or solvents.

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 74 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 13 issued U.S. patents, which our subsidiary, Pernix Ireland Pain Designated Activity Company (PIP DAC) (formerly known as Pernix Ireland Pain Ltd. (PIPL)) either owns or has rights to. Two of these patents expire November 1, 2019, seven expire July 25, 2033 and four expire September 12, 2034. Net revenues of Zohydro were \$24.0 million and \$24.7 million for the years ended December 31, 2017 and 2016, respectively.

In May 2017, we announced that, due to a manufacturing issue with our supplier, we expect that the 20mg strength of Zohydro ER with BeadTek will be on back order until at least the first quarter of 2018. During this time, we have continued to market and distribute other strengths of Zohydro ER with BeadTek, including the 10 mg, 15 mg, 30 mg, 40 mg and 50 mg strengths. While utilization of the 10mg, 15mg and 30mg strengths have increased, we believe that the temporary stock out of the 20 mg strength has impacted the overall prescription volume for Zohydro ER with BeadTek, resulting in a loss of revenue and adverse effect on our financial condition.

#### **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 Pemix Sleep, Inc. (f/k/a Somaxon Pharmaceuticals, Inc.) (Pemix 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<sup>®</sup>); zolpidem tartrate extended-release tablets (Ambien CR<sup>®</sup>), a controlled-release formulation of Ambien; eszopiclone (Lunesta<sup>®</sup>); and zalepon (Sonata<sup>®</sup>) and Belsomra<sup>®</sup> (suvorexant), an orexin receptor antagonist. In addition, melatonin agonists such as ramelteon (Rozerem<sup>®</sup>), hypnotic benzodiazepines, such as temazepam (Restoril<sup>®</sup>) and flurazepam (Dalmane<sup>®</sup>), and sedating antidepressants such as trazodone (Desyrel<sup>®</sup>) 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. In addition, for these reasons, we believe Silenor is an attractive candidate for the over-the-counter (OTC) market. We are engaged in life-cycle management activities relating to Silenor, including the assessment of OTC opportunities such as potential out-licensing transactions. We also continue to review and assess options for internal development.

We promote Silenor in the United States through a nationwide specialty sales force, which covers 74 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 eight issued U.S. patents, the latest expiring 2030, five of which are exclusively licensed from ProCom One, Inc. (ProCom). Four companies filed abbreviated new drug applications (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<sup>®</sup>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. Net revenues of Silenor were \$22.3 million and \$16.9 million for the years ended December 31, 2017 and 2016, respectively.

#### **Treximet (sumatriptan/naproxen sodium)**

Treximet is the only fixed dose combination product approved by the 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 the patented formulation technology owned by Aralez Pharmaceuticals, Inc. (formerly POZEN Inc.) (Aralez) and the RT Technology<sup>™</sup> of GlaxoSmithKline's (GSK). 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.

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 medical providers and patients have limited options 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 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.

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 Aralez. Treximet is exclusively licensed to us by GSK for U.S. marketing, sales and distribution. We originally promoted Treximet in the United States through our nationwide specialty sales force. After the sales force restructure on January 4, 2018, we are no longer promoting Treximet with a sales force. 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 expired 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, three of which are permitted to launch in 2018 and three other generics enjoined from launching until 2026.

On February 14, 2018, four patents covering Treximet expired, enabling up to three generic competitors to enter the market. As of February 28, 2018, one of these competitors entered the market and we are expecting the other two competitors to enter later in 2018. Concurrent with the launch of generics by third parties, we launched an authorized generic version of Treximet. We will also continue to distribute the branded versions of Treximet. We have one additional patent that covers Treximet that will expire in 2026 that we expect to prevent additional generic competitors from entering the market until that time. We expect that generic competition for Treximet will negatively impact our net revenues for the fiscal year ending December 31, 2018.

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. There was no impact on 2017 net revenues as a result of this ruling.

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

	<b>Year Ended December 31,</b>			
	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
GAAP net revenues of Treximet	\$ 68,405	\$ 66,961	\$ 101,753	\$ 54,775
GSK arbitration award adjustment	-	15,277	(12,484)	(2,793)
Adjusted net revenues of Treximet (1)	<u>\$ 68,405</u>	<u>\$ 82,238</u>	<u>\$ 89,269</u>	<u>\$ 51,982</u>

- (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.

### ***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 also market our non-promoted products through distributors and trade partners.

Through our Macoven entity, we had distributed a combination product called isometheptene mucate, dichlorphenazone, and acetaminophen, or IDA, which was originally approved in 1948 by the FDA, for safety only. The product's efficacy as an adjunct treatment for peptic ulcer disease, as well as other medical conditions, such as migraine headaches, was reviewed under the FDA's Drug Efficacy Study Implementation process, DESI notice 3265.

We received a letter from the FDA dated October 19, 2017, asserting that IDA was subject to DESI 3265 and that any drug products identified in DESI 3265, including IDA, require an approved new drug application (NDA) or an abbreviated new drug application (ANDA) in order for them to continue to be distributed. Since we have not obtained an NDA or ANDA for IDA, the FDA directed that we should immediately cease distribution of IDA. While IDA has a long history of safe use, we complied with the FDA's request and confirmed with the FDA within its requested time frame that we ceased distribution of the product. For the year ended December 31, 2017, our net revenues from the sale of IDA were \$14.9 million. As we will not have further revenues from the product in 2018, the discontinuance of the product will impact net revenues for the fiscal year ending December 31, 2018.

### **Research and Development**

Our current development projects include potential line extensions. 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 reviewing alternatives for a Prescription -to-Over-The-Counter (OTC) switch for Silenor. We held a pre-IND meeting with the FDA in June 2015, during which we received clarity from the FDA on the development activities that would be required to seek approval to market Silenor in the U.S. OTC market. Specifically, the FDA advised us that the results of preclinical studies to assess the abuse potential of Silenor, a label comprehension study, a driving study, a self-selection study and an actual use trial, among other things, would be needed as part of an NDA submission. Based upon our interactions with clinical research organizations (CROs) and potential out-licensing partners, we believe that it could take approximately four to five years to complete the development work needed to file an NDA and seek approval to market Silenor as an over-the counter (OTC) product.

For the years ended December 31, 2017 and 2016, we recorded \$787,000 and \$6.1 million, respectively, in research and development expenses.

### **Sales and Marketing**

On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to our Treximet® fixed dose combination product. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees (representing approximately 22% of our workforce), the majority of which were associated with our sales force and commercial infrastructure.

Our commercial activities in the United States are dedicated to our marketed products Zohydro ER with BeadTek and Silenor. Our commercial team also provides support for sales of certain of our other products from time to time. We currently sell our products through our nationwide sales force, which consists of approximately 74 territories. Our teams of experienced sales professionals discuss our products with Healthcare Providers (HCPs), such as 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.

## **GSK Arbitration, Restructuring and Business Development**

### ***GSK Arbitration Update***

We were involved in an arbitration proceeding with Glaxo Group Limited, GlaxoSmithKline LLC, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline Intellectual Property Management Limited (collectively, GSK). GSK claimed that we owed GSK damages relating to an alleged breach by us of a covenant contained in the Asset Purchase and Sale Agreement (APSA), dated as of May 13, 2014 by and among GSK and us pertaining to a pre-existing customer agreement. We asserted counterclaims and defenses under the APSA and also asserted claims against GSK related to breaches of a supply agreement between the parties. We and GSK entered into an interim settlement agreement (the Interim Settlement Agreement) under which we agreed to make payments to GSK and escrow additional funds. Additionally, the parties agreed to submit the matter to binding arbitration.

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 had 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 we agreed to establish a payment schedule for satisfaction of the current balance of the award. Pursuant to the amendment, we agreed that the outstanding balance as of the date of the amendment was approximately \$21.5 million to GSK and we 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 recorded the fair value of this settlement in the amount of approximately \$18.5 million in our financial statements at December 31, 2016 and 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.

On July 20, 2017, we and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 supersedes Amendment No. 1 and permitted payment by us to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, we were obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, we agreed that if on or before September 30, 2019, we (x) redeem or repurchase our 4.25% Convertible Notes (as defined below) for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchange such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, we shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as we comply with the payment terms set forth in the Amendment No. 2, enforcement of the Award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award granted to GSK, and that the outstanding balance of such award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. We have recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in Arbitration Award on our consolidated balance sheet at December 31, 2017. Also, we recorded \$10.5 million as gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

### ***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 affect 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 Annual Report on Form 10-K 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.

On July 20, 2017, we entered into several refinancing transactions (collectively, the Transactions) with certain holders (the Holders) of our outstanding 4.25% Convertible Senior Notes Due 2021 (the 4.25% Convertible Notes). The Transactions closed on July 21, 2017, and included:

1. A new five-year \$40.0 million asset-based revolving credit facility (the ABL Credit Agreement) by and among us and certain of our subsidiaries as borrowers and guarantors (the ABL Borrowers) and Pernix Ireland Pain DAC (PIP DAC), Pernix Ireland Limited, Pernix Holdco 1, LLC, Pernix Holdco 2, LLC and Pernix Holdco 3, LLC as additional guarantors (the ABL Guarantors), Cantor Fitzgerald Securities, as agent, and the Holders, as lenders. The ABL Credit Agreement replaced our asset-based revolving credit agreement, dated as of August 21, 2015, by and among the ABL Borrowers, Wells Fargo Bank, National Association, as administrative agent, and the lenders party thereto, as amended (the Old ABL Facility); We have drawn \$14.2 million under this facility at December 31, 2017;
2. A new five-year \$45.0 million delayed draw term loan facility (the Delayed Draw Term Loan or DDTL) among PIP DAC, Cantor Fitzgerald Securities, as agent, and the Holders, as lenders. We drew \$30.0 million of the proceeds under this facility upon closing of the Transactions;
3. The issuance of (a) \$36.2 million aggregate principal amount of PIP DAC's 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes) and (b) 1,100,498 shares of Pernix's common stock (the Exchange Shares), in exchange for the tender to PIP DAC of \$51.8 million aggregate principal amount of Convertible Notes held by the Holders (the Exchange). The Exchangeable Notes are governed by a new indenture under which PIP DAC is the issuer and Pernix and its other subsidiaries are the guarantors (the Exchangeable Notes Guarantors), with Wilmington Trust, National Association, as trustee (the Exchangeable Notes Trustee). Concurrent with the Transactions, we entered into a registration rights agreement among Pernix, PIP DAC and the Holders that provides for the registration under the Securities Act of 1933, as amended, for the offer and sale of the Exchange Shares and the Underlying Shares (the Registration Rights Agreement). The Exchangeable Notes will be exchangeable for our common stock. After giving effect to the Exchange, approximately \$78.2 million principal amount of the 4.25% Convertible Notes remain outstanding.

These transactions are discussed in further detail below.

## ***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. \$51.8 million of these notes were tendered in consideration for the issuance of (a) \$36.2 million aggregate principal amount of PIP DAC's 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes) and (b) 1,100,498 shares of Pernix's common stock (the Exchange Shares) discussed above.

### ***Secured Notes:***

#### ***Treximet Secured Notes***

On August 19, 2014, we issued \$220.0 million aggregate principal amount of our 12% Senior Secured Notes due 2020 (the Treximet Secured Notes) pursuant to an Indenture (the Treximet Notes Indenture), dated as of August 19, 2014, among us, certain of our subsidiaries (the Treximet 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, 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, 2017, the aggregate principal amount of the Treximet Secured Notes was approximately \$172.1 million.

### ***Third Supplemental Indenture***

On December 29, 2017, we and U.S. Bank National Association, as trustee, entered into a third supplemental indenture (the "Third Supplemental Indenture") to the Treximet Notes Indenture with the consent of the holders of a majority in aggregate principal amount of our Treximet Secured Notes. The Third Supplemental Indenture amends the Treximet Notes Indenture to clarify the definition of "Net Sales", as such term is defined in the Treximet Notes Indenture and resulted in the deferral of \$3.2 million of principal payments until maturity.

### ***Credit Facilities:***

#### ***Cantor Fitzgerald***

On July 21, 2017, we entered into a new five-year \$40.0 million asset-based revolving credit facility (the ABL Credit Agreement) by and among Pemix and certain subsidiaries of Pemix as borrowers and guarantors (the ABL Borrowers) and Pemix Ireland Pain Designated Activity Company (PIP DAC), Pemix Ireland Limited, Pemix Holdco 1, LLC, Pemix Holdco 2, LLC and Pemix Holdco 3, LLC as additional guarantors (the ABL Guarantors), Cantor Fitzgerald Securities, as agent, and the Holders, as lenders. The ABL Credit Agreement replaced our asset-based revolving credit agreement, dated as of August 21, 2015, by and among the ABL Borrowers, Wells Fargo Bank, National Association, as administrative agent, and the lenders party thereto, as amended (the Old ABL Facility). As of December 31, 2017, the aggregate principal amount of the ABL Credit Agreement was approximately \$14.2 million.

Our obligations under the ABL Credit Agreement are secured by, among other things, our and certain of our subsidiaries' inventory and accounts receivable and were guaranteed by certain of our subsidiaries. Borrowings under the ABL Credit Agreement will bear interest at our election at (i) the rate of LIBOR plus 7.5% (ii) the Base Rate (as defined in the ABL Credit Agreement) plus 6.5%. In addition, we are required to pay a commitment fee on the undrawn commitments under the ABL Credit Agreement from time to time at an applicable rate of 0.25% per annum according to the average daily balance of borrowings under the ABL Credit Agreement during any month.

#### ***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 have been increased by an additional \$20.0 million in the lenders' discretion.

Our obligations under the Wells Fargo Credit Facility were secured by, among other things, our and certain of our subsidiaries' inventory and accounts receivable and were guaranteed by certain of our subsidiaries. The outstanding balances on this facility as of December 31, 2017 and 2016, were \$0 and \$14.0 million, respectively.

Borrowings under the Wells Fargo Credit Facility accrued 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 were 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. 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.

As discussed earlier, the ABL Credit Facility entered into on July 21, 2017 replaced the Wells Fargo Credit Facility and the Company used the proceeds from the ABL Credit Facility to repay the outstanding obligation of the Wells Fargo Credit Facility.

## ***Term Facility***

### ***Cantor Fitzgerald***

On July 21, 2017, we entered into a \$45.0 million term loan credit agreement (the Delayed Draw Term Loan or DDTL) with Cantor Fitzgerald Securities, as agent (the Term Agent) and the lenders party thereto to obtain the DDTL. \$30 million under the DDTL was drawn on the date of closing of the Transactions, and the remaining \$15.0 million will be available for subsequent draws for certain specified purposes, including to finance certain acquisitions, subject to conditions set forth in the DDTL Credit Agreement. The DDTL includes an incremental feature that allows PIP DAC, with the consent of the requisite lenders under the Term Facility, to obtain up to an additional \$20.0 million in term loan commitments from new or existing lenders under the Term Facility that agree to provide such commitments. Interest on the loans will accrue either in cash or a combination of cash and in-kind interest, at PIP DAC's election. Cash interest will accrue at a rate of 7.50% per annum, while the combination of cash and in-kind interest will accrue at a rate of 8.50% per annum, with up to 4.00% per annum added to the principal amount of loans and the balance paid in cash. The DDTL will contain representations and warranties, affirmative and negative covenants, and events of default applicable to PIP DAC and its subsidiaries (if any) that are customary for credit facilities of this type. The DDTL will mature on July 21, 2022. As of December 31, 2017, the aggregate principal amount outstanding of the DDTL was \$30.0 million.

### ***Exchangeable Notes***

#### ***Wilmington Trust***

On July 21, 2017, PIP DAC, the Exchangeable Notes Guarantors, and Wilmington Trust, National Association, as Trustee, entered into a \$36.2 million New Exchangeable Notes Indenture. The Exchangeable Notes issued under the New Notes Indenture will be guaranteed by Pernix and each other subsidiary thereof. The Exchangeable Notes are senior, unsecured obligations of PIP DAC. Interest on the Exchangeable Notes will be paid in cash or a combination of cash and in-kind interest at PIP DAC's election. Interest paid in cash (the "All Cash Method") will accrue at a rate of 4.25% per annum, while interest paid in a combination of cash and in-kind will accrue at a rate of 5.25% per annum, with 2.25% per annum of interest (plus additional interest, if any) capitalized to the principal amount of the Exchangeable Notes, and the balance paid in cash. The maturity date of the Exchangeable Notes Indenture is July 15, 2022.

The Exchangeable Notes initially are exchangeable into shares of our common stock at an exchange price per share of \$5.50 (the "Exchange Price"). The Exchange Price will be subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, the payment of cash dividends and certain Company tender or exchange offers. As of December 31, 2017, the aggregate principal amount outstanding of the Exchange Note was \$35.7 million.

Holders will exchange all or a portion of their Exchangeable Notes at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity dates. See further discussion under the heading "Liquidity and Capital Resources" in Part II, Item 7 of this Annual Report on Form 10-K.

See further discussion in Note 12, *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.

#### ***Acquisition of Zohydro ER with BeadTek***

On April 24, 2015, through our wholly-owned subsidiary, PIP DAC, formerly known as Pernix Ireland Pain Limited and Ferrimill Limited, we completed the acquisition of the pharmaceutical product line, Zohydro ER, including an abuse-deterrent pipeline and rights to all related intellectual property, a supplier contract and an associated liability payable and a specified quantity of inventory associated therewith, from Zogenix. 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 \$130.0 million aggregate principal amount of the 4.25% Convertible Notes.

### ***Acquisition of Treximet***

On August 20, 2014, we, through our wholly owned subsidiary Pemix Ireland Limited (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 Aralez. 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 Aralez 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 Aralez 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 Aralez under the PDC Agreement, equal to 18% of net sales or lower under certain circumstances, 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 was obligated to 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 manufactured 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.

### **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 Silenor in the U.S. market. We intend to expand upon and leverage our commercial successes and have launched an authorized generic version of Treximet. We have also launched Pemix Prescriptions Direct<sup>®</sup>, 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 Pemix Prescriptions Direct program offers patients and healthcare professionals improved convenience 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 pain, neurology, and psychiatry, though we will consider other indications opportunistically.

### **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. 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 44 issued U.S. patents and 21 pending U.S. Patent Applications relating to our products and technology. Further detail with respect to our patents pertaining to Treximet, Zohydro ER with BeadTek and Silenor are described below.

Our Treximet patent portfolio broadly covers the pharmaceutical formulation, including the proprietary combination of a 5-HT agonist (i.e. sumatriptan) and a long-acting NSAID (i.e. naproxen), 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 Aralez.

Zohydro ER with BeadTek is covered by 13 Orange Book listed patents, 6 of the 13 are in-licensed and the other 7 are solely owned by PIP DAC. Six additional 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. U.S. patent nos. 9,132,096, 9,452,163, 9,486,451 and 9,713,611, also in-licensed from Recro, are directed to the abuse deterrent technology (BeadTek) and expire September 12, 2034. U.S. patent nos. 9,265,760, 9,326,982, 9,333,201, 9,339,499, 9,421,200, 9,433,619 and 9,610,286 (all expire July 25, 2033) are solely owned by PIP DAC and are directed to methods of dosing patients with mild or moderate hepatic impairment where no adjustment in start dose is required relative to patients without hepatic impairment.

In a license agreement dated August 2003 and amended and restated in September 2010, Permex Sleep, Inc. acquired the exclusive, worldwide license from ProCom One, Inc. to certain patents to develop and commercialize low dosages of doxepin for the treatment of insomnia. Silenor benefits from eight 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 nos. 7,915,307 and 9,572,814 are directed to methods of providing sleep therapy by administering doxepin several hours after a meal and expire August 24, 2027. U.S. patent nos. 9,107,898 and 8,513,299, expiring May 1, 2028 and September 7, 2030, respectively, and 9,486,437 and 9,861,607, expiring May 18, 2027, are directed to methods 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 anticipated that all of these issued U.S. patents will cover the proposed over-the-counter (OTC) version. Further, we own or have rights to 11 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 Aralez patents and other technology. 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), which amount may be reduced under certain circumstances. 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.

### Trademarks and Trade Secrets

We own trademark interests in most of our current products and believe that having distinguishing marks is an important factor in marketing these products. We currently own or have rights to approximately 25 trademarks registered with the United States Patent and Trademark Office, including PERNIX, SILENOR, TREXIMET, ZOHYDRO, ZOHYDRO ER, BEADTEK and many more. The trademark registrations we own or hold rights to include registrations covering our 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. In some circumstances, we may depend on trade secrets to aid in protecting our technology.

### ***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, specialty pharmacies, 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 88% and 93% of gross product sales in each of 2017 and 2016, are all drug wholesalers. Each customer and its respective percentage of our gross product sales are listed by year below:

<b>Gross Product Sales</b>	<b><u>2017</u></b>	<b><u>2016</u></b>
McKesson Corporation	34%	36%
AmerisourceBergen Drug Corporation	30%	31%
Cardinal Health, Inc.	<u>24%</u>	<u>26%</u>
Total	<u>88%</u>	<u>93%</u>

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

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

- ensuring product stocking in major channels in the geographic areas where we do business;
- continually following up with accounts and monitoring product performance;
- developing successful product launch strategies; and
- partnering with customers on other value-added programs.

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

#### ***Reimbursement***

In the U.S. market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care organizations, or MCOs, and private insurance plans. Most of our products are generally covered by managed care and private insurance plans. The status or tier within each plan varies, but coverage for our products is similar to other products within the same class of drugs. We also participate in the Medicaid Drug Rebate Program with the Centers for Medicare & Medicaid Services and submit all of our covered 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 pain, 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, Collegium, Egalet 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 some states in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

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

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

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

## Government Regulation

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

## ***FDA Regulation of Drug Products***

In the United States, the FDA regulates the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, marketing, advertising and promotion of our drug products and product candidates under the Federal Food, Drug, and Cosmetic Act, or 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, 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 Practices, or GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act;
- submission of an investigational new drug application, or 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, or IRB, before each trial may begin;
- completion of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;
- submission of a new drug application, or NDA, to the FDA;
- adequate completion of an FDA advisory committee review, if applicable; 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 can be 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, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Once adopted, REMS are subject to periodic assessment and modification. In addition, the FDA may require Phase IV 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 prescription 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 must 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, or PMRs, or commitments, or 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. 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.

### ***Products Subject to Ongoing DESI Proceedings***

The FDCA, enacted in 1938, was the first statute requiring premarket approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the FDCA to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. These amendments also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted with the National Academy of Science/National Research Council, or NAS/NRC, to evaluate the effectiveness of drugs covered by NDAs at that time on an active drug ingredient basis and by regulation it applied the findings to all identical, related or similar, or IRS, drug products. The FDA's administrative implementation of the NAS/NRC reports was the Drug Efficacy Study Implementation, or DESI Review. The DESI review involved a multistep notice, comment, opportunity for hearing, and appellate process that has had vast administrative and legal complexities.

Although the DESI Review began in the late 1960s, it was never completed. In the ensuing 50 years, the FDA developed other regulatory priorities, thus some unapproved products are subject to DESI proceedings in which a final determination regarding efficacy has not yet been made. In 2011, FDA published a Compliance Policy Guide, or CPG, that clarified how the FDA intends to exercise enforcement discretion with respect to drugs that are marketed without FDA approval.

We believe that a small number of our marketed pharmaceutical products are IRS to products with a pre-1962 NDA or ANDA that are subject to an ongoing DESI proceeding, 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 monitor their compliance with cGMPs in order to minimize product risk.

### ***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 specify 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, or 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 also market a number of dietary supplement and medical food products. While FDCA regulatory guidance relative to the labeling requirements for dietary supplements and medical foods products is general and the labeling for each of our products is intricate, we believe that we have labeled our products in accordance with applicable statutory requirements. While these products are not covered outpatient drugs, some options for the payment for non-covered drugs do exist, including the Children's Health Insurance Program, or 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 abbreviated new drug application, or 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, or 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 (i) have the same active ingredient in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. Under certain state laws, certain ANDA approved drugs may be (and in some cases, must 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).

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 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 submit an ANDA with a paragraph IV certification for a generic version of 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 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, or 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 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, 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, as well as 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 and our third-party manufacturers 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. Zohydro ER with BeadTek is classified as a Schedule II substance.

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, Managed Care Organizations (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 the impact of 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. These and other factors 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 is prescribed; 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 for the purpose of providing 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 (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. 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 (as defined below) 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 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 required 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, which became effective on April 1, 2016. The issuance of the final regulations, 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.

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.

Health Care Reform also made changes to the 340B program by expanding 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. Health Care Reform obligates the Secretary of the U.S. Department of Health and Human Services, (HHS), to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, the U.S. Health Resources and Services Administration (HRSA), an agency of the HHS 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 effective date of the regulation has been delayed until July 1, 2018. 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 that we cannot presently 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.

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 covered drugs (innovators and biologics) 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 (PHS) 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, or 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, the Patient Protection and Affordable Care Act, or Affordable Care Act was signed into law. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010, or Reconciliation Act, which included a package of corrective changes to the Affordable Care Act as well as additional elements to reform healthcare in the United States, was also signed into law. We refer to the Affordable Care Act and the Reconciliation Act as Health Care Reform.

The passage of Health Care Reform was intended to transform the delivery and payment for healthcare services in the U.S. The combination of these measures expanded health coverage and also provided for significant health coverage reforms that were intended to improve the ability of patients to obtain and maintain health coverage. Such measures included, 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. Health Care Reform provided 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.

A number of provisions contained in Health Care Reform could 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 choosing not to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Health Care Reform also expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid MCOs and 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 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 required pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government and also created an Independent Payment Advisory Board, (IPAB), 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.

Certain legislative changes to and regulatory changes under Health Care Reform have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. In addition, the Bipartisan Budget Act of 2018 increased the Affordable Care Act required manufacturer point-of-sale discount from 50% to 70% off the negotiated price for Medicare Part D beneficiaries during their coverage gap period beginning in 2019. Additional legislative changes to and regulatory changes under Health Care Reform remain possible. 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.

*U.S. Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the EU General Data Protection Regulation (GDPR).* 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.

Also, the European Parliament has adopted the General Data Protection Regulation (GDPR), which will become effective on May 25, 2018. This regulation replaces the EU's 1995 data protection directive and shall be the single EU standard across all member states. The GDPR takes a broad view of the types of information that are deemed covered as personal identification information and contains provisions that require businesses to protect such personal data and the privacy of EU citizens for transactions that occur within EU member states. The GDPR also regulates the exportation of personal data outside of the EU. Non-compliance with the GDPR could result in significant penalties. Many companies, including our company, are assessing the requirements of the GDPR against current business practices and preparing for compliance with this regulation once it becomes effective.

*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 90<sup>th</sup> 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. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Other states and cities require identification or licensing of state representatives. 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, or the 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, 2017, we had 171 full-time employees, including a field sales force that covered 122 territories nationwide, and 49 employees engaged in management, finance, marketing, research, development, regulatory affairs, quality assurance, supply chain and administration. On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to our Treximet® fixed dose combination product. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees (representing approximately 22% of our workforce), the majority of which were associated with our sales force and commercial infrastructure. As a result of this restructuring we now cover 74 territories. Currently, none of our employees are subject to a collective bargaining agreement. We consider our employee relations to be good.

### **About Pernix Therapeutics Holdings, Inc.**

We were incorporated in Maryland as Golf Trust of America, Inc., or GTA, in November 1996. 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](http://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.pemixtx.com](http://www.pemixtx.com). Information is also available through the Securities and Exchange Commission's website at [www.sec.gov](http://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, 2017, we had approximately \$330.2 million aggregate principal amount of debt outstanding, consisting of approximately \$35.7 million aggregate principal amount of our 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes), issued pursuant to a new indenture, under which Pernix Ireland Pain Designated Activity Company, or PIP DAC, formerly known as Pernix Ireland Pain Limited (PIPL), is the issuer and we and our other subsidiaries are the guarantors with Wilmington Trust, National Association, as trustee, of approximately \$78.2 million aggregate principal amount of our 4.25% Convertible Notes due 2021 (the Convertible Notes), approximately \$172.1 million aggregate principal amount of our 12% Senior Secured Notes due 2020 (the Treximet Secured Notes), approximately \$14.2 million outstanding under our five-year \$40 million asset-based revolving credit facility (the New ABL Facility), and approximately \$30 million aggregate principal amount outstanding under PIP DAC's new term loan credit agreement with Cantor Fitzgerald Securities, as agent and the lenders party thereto (the Term Credit Agreement), and together with the New ABL Facility, the Credit Facilities. In addition, we have the ability to borrow up to an additional \$15.0 million under the Term Credit Agreement for certain specified purposes, including future acquisitions, subject to conditions set forth in the Term Credit Agreement, and up to an additional approximately \$26 million under the New ABL Facility, subject to borrowing base capacity and the conditions set forth in the New ABL Facility. In addition, the Term Credit Agreement includes an incremental feature that allows us, with the consent of the requisite lenders under the Term Credit Agreement, to obtain up to an additional \$20 million in term loan commitments from new or existing lenders under the Term Credit Agreement that agree to provide such commitments. We owed approximately \$6.7 million to GSK pursuant to the Interim Settlement Agreement between us and GSK, as amended by Amendment No. 2 to the Interim Settlement Agreement, which was paid in full at the end of 2017. Our significant indebtedness and other payment obligations could have important consequences. For example, it could:

- make it difficult for us to satisfy our obligations under our outstanding notes 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 covenants in the agreements governing our credit facilities, 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. 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.

***Recent reductions in workforce associated with our realignment plan 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 recently completed a realignment plan in January 2018 that resulted in personnel reduction of approximately 22% of our workforce, primarily through a reduction of sales and commercial infrastructure positions. The employee reductions 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 realignment plan will be successful, and we may need to take additional realignment efforts, including additional personnel reduction, in the future.

***We may not be able to grow through acquisitions of businesses and assets, the formation of collaborations or other strategic alliances or the in-licensing of products or product candidates.***

We have sought growth largely through acquisitions, including the acquisitions of the Zohydro ER product line in 2015, the rights to Treximet intellectual property in 2014, Pemix Sleep in 2013 and Cypress in 2012. As part of our strategy, we plan to pursue acquisitions of assets, businesses or strategic alliances and collaborations (including the in-licensing of products or product-candidates), to expand our existing technologies and operations. However, the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes, and the agreements governing our credit facilities 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. For additional information see the notes to our audited consolidated financial statements for the years ended December 31, 2017 and 2016 contained in Part II, Item 8 of this Annual Report on Form 10-K. Moreover, we cannot assure you that acquisitions will be available on terms attractive to us or that such acquisitions will be permissible under the indentures governing our outstanding notes and the covenants in the agreements governing our credit facilities 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 or other collaborations or strategic alliances.***

Management has in the past devoted, and will in the future devote, significant attention and resources to integrating newly acquired businesses and assets and/or establishing functioning collaborations that leverage our capabilities in pursuit of developing and commercializing our products and product candidates. 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 deciding not to do business with us following the acquisition of a business or asset;
- 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.
- our collaborative partners may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborative partners may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborative partners may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborative partners may terminate our relationship.

With respect to potential collaborations or strategic alliances, our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to reduce or delay our development or commercialization programs or initiatives.

For all these reasons, you should be aware that it is possible that integrating a newly acquired business or asset and/or the establishment of collaborations or other strategic alliances 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 agreements governing our credit facilities and the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured 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. Among other things, we have the ability to borrow up to an additional \$15.0 million under the Term Credit Agreement for certain specified purposes, including future acquisitions, subject to conditions set forth in the Term Credit Agreement, and approximately \$26 million of additional funds under the New ABL Facility, subject to borrowing base capacity and the conditions set forth in the New ABL Facility. In addition, the Term Credit Agreement includes an incremental feature that allows us, with the consent of the requisite lenders under the Term Credit Agreement, to obtain up to an additional \$20 million in term loan commitments from new or existing lenders under the Term Credit Agreement that agree to provide such commitments. 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 high 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 and in our other filings with the SEC. 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 affected 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 facilities 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 the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes and the covenants in the agreements governing our credit facilities 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 the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes and the agreements governing our credit facilities 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 New ABL Facility require us to maintain unrestricted minimum liquidity of \$7.5 million at all times. In order to maintain minimum liquidity, we must maintain cash or the availability to borrow cash under the New ABL Facility in a combined amount of no less than the minimum liquidity set forth in the Treximet Secured Notes indenture and the New ABL Facility.

Upon the occurrence of a fundamental change, as described in the indenture governing the Convertible Notes, holders of the Convertible Notes may require us to repurchase for cash all or part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest. If a holder elects to convert its Convertible Notes for shares in excess of the conversion cap, as described in the indenture governing the 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

Convertible Notes surrendered therefor in connection with a fundamental change or payments of cash on Convertible Notes converted in excess of the conversion cap. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 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 Convertible Notes or make cash payments upon conversions as required by the indenture.

Upon the occurrence of a fundamental change, as described in the indenture governing the Exchangeable Notes, holders of the Exchangeable Notes may require us to repurchase for cash all or part of Exchangeable Notes at a repurchase price equal to 100% of the capitalized principal amount of the Exchangeable Notes to be repurchased, plus accrued and unpaid interest. 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 Exchangeable Notes surrendered therefor in connection with a fundamental change. In addition, our ability to repurchase the Exchangeable Notes or to pay cash upon conversions of the Exchangeable Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the Exchangeable Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Exchangeable 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 Exchangeable 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 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 including transactions, collaborations or other commercial transactions or to engage in other business activities that would be in our interest.

Our ability to borrow under the New ABL Facility 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 Cantor Fitzgerald Securities has the authority to do in its sole discretion, could reduce our borrowing capacity under the New ABL Facility.

***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 requires 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;
- 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; and
- we may be restricted from licensing or otherwise acquiring suitable products due to restrictions contained in the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes and the restrictions contained in the covenants in the agreements governing our credit facilities.

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 licensing or 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, in-licensed 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 or in-licenses 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 or in-license 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 to patents. Our patent protection for our products extends for varying periods in accordance with the legal life of patents. 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, through our wholly owned subsidiary, Pernix Ireland Limited (PIL), we 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 expired on February 14, 2018, and one expires on April 2, 2026. Six companies filed Abbreviated

New Drug Applications, or ANDAs, with the U.S. Food and Drug Administration, or FDA, seeking approval to market a generic version of Treximet. Three of the ANDA filers are enjoined from engaging in the commercial manufacture, use, offer to sell, or sale in or importation into the United States of the proposed ANDA products prior to April 2, 2026. One of the two ANDA filers that were legally able to launch their generic versions of Treximet on February 15, 2018 did enter the market. The one ANDA filer that could have launched as early as January 3, 2018 has not yet entered the market. While we launched our own generic version of Treximet on February 15, 2018, the entry of generics into the market will likely 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 Industry in which we operate is highly competitive. Our competitors include large and small pharmaceutical companies, and other private and public research organizations. We face significant competition for our currently marketed products, including significant price competition from products for the same therapeutic categories. Some of our currently marketed products do not have patent protection and face or could face generic competition.

Some or all of our products 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. As a result, our commercial opportunities 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 our products.

Our patent rights may not adequately protect our products or product candidates if competitors develop products that compete with us without legally infringing our patent rights. Further, our patent rights may be subject to challenge by branded and generic competition.

The FDCA and FDA regulations and policies provide certain exclusivity incentives to manufacturers to develop generic versions of innovator products and 505(b)(2) New Drug Applications. A generic manufacturer may only be required 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 branded 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. 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 may face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, our revenue and profit from existing products and anticipated revenue and profit from product candidates. If our products or product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those products or product candidates.

***If four competitors sell 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 the revenues that we might receive from sales of products that are the subject to commercial partnerships could largely depend upon the efforts our partners. The efforts of partners, in many instances, could likely be outside our control. If we are unable to maintain commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected. In addition, despite arrangements with 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.

From time to time, we compliment the efforts of our sales force with on-line and other non-personal promotional initiatives that target both physicians and patients. We also focus upon ensuring broad patient access to our products by negotiating agreements with leading commercial managed care organizations, or 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.***

Our product, Zohydro ER with BeadTek, contains a controlled substance that is 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 such product 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 product, our reputation and our brands could be harmed and physicians may be less likely to prescribe such product 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 Good Manufacturing Practices, or 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 the manufacturing facilities used to manufacture and package our products 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 to confirm continuing 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 product, Zohydro ER with BeadTek, the DEA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of such product from the market or other penalties.***

We, our third-party manufacturers and our Zohydro with BeadTek product, are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we must adhere to a number of requirements, 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.

***Changes in laws, regulations and policies applicable to the market for opioid products, litigation and government investigations may adversely affect our business, financial condition and results of operations.***

The manufacture, marketing, sale, promotion and distribution of Zohydro ER are subject to comprehensive government regulations. Changes in laws and regulations applicable to the market for opioid products, including Zohydro ER with BeadTek, could potentially affect our business. For instance, federal, state and local governments have recently given increased attention to the public health issue of opioid abuse.

At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, the DEA, and other agencies to address this issue. The FDA recently requested that Endo International plc, or Endo, withdraw Opana® ER, one of its opioid pain medications, from the market due to the public health consequences of abuse (even when taken at recommended doses) associated with the use of Endo's product. Endo voluntarily complied with the FDA's removal request. In publicly announcing the request, the FDA noted that it would take similar regulatory action with regard to other opioid products if the risks for abuse outweighed the product's potential benefits. The FDA also recently revised the "black-box" warnings required in the labeling of opioid pain medications, including Zohydro ER with BeadTek, that highlight the risk of misuse, abuse, addiction, overdose and death. The DEA continues its efforts to hold manufacturers, distributors, prescribers and pharmacies accountable through various enforcement actions, as well as the implementation of compliance practices for controlled substances. In addition, the Centers for Disease Control and Prevention (CDC), issued national, non-binding guidelines in 2016 relative to the prescribing of opioids. These guidelines included recommended considerations for primary care provider use when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents. Certain payors are, or are considering, adopting these CDC guidelines, as well as putting other restrictions on the prescribing of opioid pain medications. Additionally, the Trump administration and certain members of Congress have called for the DEA to restrict the quantity of opioids that can be manufactured in the United States.

Recent federal activity includes the issuance of a Presidential commission's final recommendations on combating opioid abuse; the federal Department of Health and Human Services declaring the opioid crisis a national public health emergency; President Trump's establishing a commission to make recommendations regarding new laws and policies to combat opioid addiction and abuse; Mallinckrodt's \$35.0 million settlement with the Justice Department regarding allegations that the company failed to report signs that large quantities of its highly addictive oxycodone pills were diverted to the black market in Florida; and the FDA's announced intention to extend to immediate-release opioids the Risk Evaluation and Mitigation Strategy, or REMS, currently imposed on extended-release opioids, such as Zohydro ER. At the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that manufacture opioid pain medications.

These initiatives and other changes and potential changes in laws, regulations and policies, including those that have the effect of reducing the overall market for opioids or reducing the prescribing of opioids, could adversely affect our business, financial condition and results of operations.

***Our ceasing the distribution of our combination drug product IDA will impact our net revenues. In the future, FDA could also request that we no longer market and distribute certain of our other DESI, OTC, medical foods and dietary supplement products.***

Through our Macoven entity, Pemix distributed a combination product called isometheptene mucate, dichlorphenazone, and acetaminophen, or IDA, which was originally approved by the US Food and Drug Administration, or FDA, in 1948 for safety only. The product's efficacy as an adjunct treatment for peptic ulcer disease, as well as other medical conditions, such as migraine headaches, was reviewed under the FDA's Drug Efficacy Study Implementation process, DESI notice 3265.

On October 20, 2017, we received a letter dated October 19, 2017 from the FDA asserting that IDA was subject to DESI 3265 and that any drug products identified in DESI 3265, including IDA, require an approved NDA or ANDA in order for them to continue to be distributed. Since we have not obtained an NDA or ANDA for IDA, the FDA directed that we should immediately cease distribution of IDA. While IDA has a long history of safe use, we complied with the FDA's request and confirmed with the FDA within the requested time frame that we ceased distribution of the product. For the year ended December 31, 2017, our net revenues from the sale of IDA were \$14.9 million. As we will not have further revenues from the product in 2018, the discontinuance of the product will impact net revenues for the fiscal year ending December 31, 2018.

Additionally, it is possible that the FDA could in the future request that we no longer distribute certain of our DESI, OTC, medical foods and dietary supplement products, which could adversely affect our net revenues.

***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. For example, at the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that manufacture opioid pain medications. While we are not a party to these actions, it is possible that we could be included in them in the future.

If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could 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 might incur. Further, there may be instances where our existing insurance coverage will not respond to or cover a claimed liability or where our insurers may dispute whether their insurance contracts must legally respond to such claimed liabilities. In such instances, we may not have insurance funds available to cover such liabilities, as well as the legal defense costs that would have to be incurred, which could have a material adverse effect on our business financial condition and results of operations. Finally, 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**

***We may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues 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 do not manufacture our marketed products, and we do not currently plan to develop any capacity to do so. We rely on third parties to manufacture 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.

For example, we recently announced that, due to a manufacturing issue with our supplier, we expect that the 20 mg. strength of Zohydro ER with BeadTek will be on back order until at least the first quarter of 2018. During this time, we will continue to market and distribute other strengths of Zohydro ER with BeadTek, including the 10 mg., 15 mg., 30 mg., 40 mg. and 50 mg. strengths. While utilization of the 10 mg., 15 mg. and 30 mg. strengths are expected to increase in order to fulfill patient needs, the temporary stock-out of the 20 mg. strength has and will continue to impact the overall prescription volume for Zohydro ER with BeadTek, which may result in a continued loss of revenue and have an adverse effect on our financial condition.

In addition, in connection with our acquisition of the rights to Treximet intellectual property in August 2014, we discovered short-term supply constraints for the product. While we believe that we have addressed this issue by securing another manufacturer, 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 the FDA's current 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 NDAs we submit to the FDA. 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, 2017, McKesson Corporation, Cardinal Health and AmerisourceBergen Drug Corporation accounted for 34%, 24% and 30%, respectively, of our total gross sales. 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.

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. In the future, we might market certain branded and generic products in the U.S. pursuant to collaboration arrangements. The success of such collaboration arrangements may 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 collaboration arrangements regarding clinical development and commercialization matters can lead to delays in the development process or commercialization of applicable product candidates 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.

***To the extent that we conduct clinical trials, we plan to rely on third parties to conduct these trials and such third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.***

We do not plan to independently conduct clinical trials for product candidates that we might acquire in the future and, instead, would rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators. Reliance on these third parties for clinical development activities would reduce our control over these activities, although we would remain responsible for ensuring that clinical trials performed at our direction are conducted in accordance with approved investigational plans and approved clinical trial protocols. Moreover, the FDA requires compliance with good clinical practices for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights and confidentiality of trial participants are protected. Reliance on third parties does not relieve a sponsor of these responsibilities and requirements. Furthermore, these third parties could 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 might not be able to obtain, or may be delayed in obtaining, regulatory approvals for future product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize such 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 some or all of which may not be covered by our existing insurance coverage or might result in the granting of 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 18, *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 products, the value of our 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 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 products.



We may not be able to obtain additional patent rights relating to our products and pending patent applications to which we have rights may not issue as patents or may not issue in a form that will be advantageous to us. Further, our patents could be challenged, narrowed, invalidated, or held to be unenforceable, which could limit our ability to stop third party competitors from marketing competing products. Moreover, some physicians may prescribe a competitive or similar product that is not approved by the FDA to treat patients with insomnia in lieu of prescribing Silenor and we cannot guarantee that our intellectual property will prevent or deter such "off-label" use.

Our patent rights also may not afford us protection against all competitors. In September 2011, the Leahy-Smith America Invents Act, or 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. If a third party has also filed a U.S. patent application covering 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. Further, our patents may be challenged by one or more post-grant proceedings. The cost of any type of patent proceeding could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of patent protection. In addition, patents generally expire, regardless of the date of issue, 20 years from the earliest non-provisional effective U.S. filing date, thus loss of patent protection may occur from patent terms expiring.

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 our marketed, branded products and believe that having distinctive marks is an important factor in marketing those products and maintaining good will. Distinctive marks may also be important for any additional products that we successfully develop and/or commercially market. However, even though we register, maintain, monitor and defend our trademarks as necessary, we generally do not rely on our marks to provide a meaningful competitive advantage over other products. We believe that efficacy, safety, convenience, price, the level of competition and the availability of reimbursement from government and other third-party payors are likely to continue to be more important factors in the commercial success of our products.

***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 similar 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 license agreement. Even if we contest any such termination or claim and are ultimately successful, our business could suffer. In addition, upon any termination of a license agreement, our market position could be impacted if we were legally required to provide a licensor with a license to use 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 patents and trademarks, we rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our relevant persons, such as employees, consultants and other third parties, including vendors (when appropriate), to execute confidentiality and assignment-of-inventions agreements with us.

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 pending patent application which we do not hold a license or other rights. Third parties may own or control these patents or patent applications and 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 commercializing a product, or maybe required to obtain licenses from the patent owners of each such patent, or to redesign our products, and could be liable for 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. An adverse determination in a judicial or administrative proceeding, failure to redesign, or failure to obtain necessary licenses could prevent us or our future collaborators from manufacturing and selling our products and would have a material adverse effect on our business.

There has been substantial litigation and other proceedings regarding patents 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 and/or in-licensed products or product candidates into our product portfolio;
- our ability to successfully establish and maintain collaborations or other strategic alliances;
- 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 that 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. 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. 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 we may have to grant licenses on terms that are not favorable to us.

If efforts to raise additional funds 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 agree to accept or we may have to 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 might 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 upon 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.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

As of December 31, 2017, we had net operating losses ("NOLs") of approximately \$396.5 million for federal income tax purposes. Subject to applicable limitations, these NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce our future federal income taxes otherwise payable.

Under Section 382 of the Internal Revenue Code (the "Code"), if a corporation undergoes an "ownership change" as defined in that section, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may become subject to significant limitations. In general terms, an ownership change occurs if there is a greater than 50 percentage point increase in the amount of the corporation's stock owned by certain stockholders during a three year testing period. An ownership change may be triggered by the purchase and sale, redemption, or new issuance of stock. \$366.5 million of our NOLs are already subject to limitation under Section 382 of the Code. We may experience an ownership change in the future as a result of shifts in our stock ownership, which may result from, among other things, issuances of common stock, including upon the exercise by the holders of our existing convertible debt securities and any convertible debt securities we may offer in the future of the conversion rights under such instruments, and upon the exercise of stock options and other equity compensation awards. If a future ownership change were to be triggered, our ability to use some or all of our remaining NOLs could be significantly limited. Further, depending on the level of our taxable income, all or a portion of our NOLs may expire unutilized, which could prevent us from offsetting future taxable income by the entire amount of our current and future NOLs.

Additionally, on December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act contains significant changes to corporate taxation and modifies several existing laws around NOLs, including a limitation on the deduction for NOLs to 80 percent of current year taxable income as well as an indefinite carryover period for NOLs. Both provisions are applicable for losses arising in tax years beginning after December 31, 2017. For these reasons, even if we generate taxable income in the future, our ability to utilize our NOLs may be limited, potentially significantly so.

***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 an over-the-counter market, such as the OTCQX, OTCQB or the OTC Pink. Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest and confidence in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5.00 per share, our shares could be subject to Rule 15c-9 under the Exchange Act which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital.

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

The market price of our common stock may be subject to substantial volatility as a result of announcements by us or other companies in our industry, including our collaborators. Announcements that may subject the price of our common stock to substantial volatility include but are not limited to announcements regarding:

- our operating results, including the amount and timing of sales of our products and our ability to successfully integrate the operations of newly acquired businesses or products;
- the availability and timely delivery of a sufficient supply of our products;
- the safety and quality of our products or those of our competitors;
- our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;
- the results of discoveries, preclinical studies and clinical trials by us or our competitors;
- the acquisition of technologies, product candidates or products by us or our competitors;
- the development of new technologies, product candidates or products by us or our competitors;
- regulatory actions with respect to our product candidates or products or those of our competitors; and
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

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

We did not make any distributions for the years ended December 31, 2017 and 2016. We are currently investing in our promoted products lines 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 the agreements governing our credit facilities and the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured 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.

***Exchange of the Exchangeable Notes and conversion of the Convertible Notes may dilute the ownership interest of existing stockholders.***

Subject to certain contractual restrictions, holders of the Exchangeable Notes and the Convertible Notes are entitled to exchange or convert, respectively, the Exchangeable Notes or the Convertible Notes for shares of our common stock at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date of the Exchangeable Notes or the Convertible Notes, respectively. The exchange of some or all of the Exchangeable Notes or the conversion of some or all of the Convertible Notes will dilute the ownership interests of existing stockholders. If holders of the Exchangeable Notes were to exchange all of the outstanding Exchangeable Notes (not taking into account the potential for capitalization of interest or additional interest or changes to the exchange price), we would need to deliver approximately 6,498,273 shares of our common stock to settle the exchange, which would result in significant dilution to existing stockholders. If holders of the Convertible Notes were to exchange all of the outstanding Convertible Notes, we would need to deliver approximately 682,413 shares of our common stock to settle the conversion, which would result in additional dilution to existing stockholders. Any sales in the public market of any shares of our common stock issuable upon such exchange or conversion could adversely affect prevailing market prices 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 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.***

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. Should we acquire or develop a product candidate, the failure to obtain regulatory approval would 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. Additionally, it is possible that future 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 ultimately obtained may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***Any pharmaceutical product for which we currently have 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.***

Any FDA approved products are 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 after 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;

- suspension or withdrawal 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. A pharmaceutical product that receives FDA approval 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 (CMS) and submit all of our covered products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, our covered products are made available under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. 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. Details of the 340B program, 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, or 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.

Details of changes under Health Care Reform, as well as current uncertainties arising as a result of Trump administration and Congressional initiatives, 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 acquire and market 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.

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 the 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, which 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 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.

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 HHS, to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HHS 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 effective date of the regulation has been delayed until July 1, 2018. 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. Our failure to submit the required price data on a timely basis could also result in a civil monetary penalty 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, or DoD, the Public Health Service (PHS), 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, or 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. In 2017, the civil monetary penalties for the knowing provision of false information in connection with a Non-FAMP filing was \$181,071 for each item of false information. This penalty amount has not yet been updated for 2018.

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 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 uses. False Claims Act liability is potentially significant because the statute provides for treble damages and mandatory penalties of \$11,181 to \$22,363 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.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. 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 \$1.0 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 90<sup>th</sup> 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 restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Other states and cities require identification or licensing of state representatives. 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. 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.

We attempt to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations, utilizing the expertise of outside experts. However, it is possible that governmental authorities might conclude that our business practices do 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, would be 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 and remain subject to change. This increases the risk of potential violations. 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.

Also, the European Parliament has adopted the General Data Protection Regulation (GDPR), which will become effective on May 25, 2018. This regulation replaces the EU's 1995 data protection directive and shall be the single EU standard across all member states. The GDPR takes a broad view of the types of information that are deemed covered as personal identification information and contains provisions that require businesses to protect such personal data and the privacy of EU citizens for transactions that occur within EU member states. The GDPR also regulates the exportation of personal data outside of the EU. Non-compliance with the GDPR could result in significant penalties. Many companies, including our company, are assessing the requirements of the GDPR against current business practices and preparing for compliance with this regulation once it becomes effective.

#### **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. We are currently trying to sell this property and as of December 31, 2017 has classified \$500,000 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.

#### **ITEM 3. LEGAL PROCEEDINGS**

##### ***GlaxoSmithKline (GSK) Arbitration***

We were involved in an arbitration proceeding with GSK. GSK claimed damages relating to an alleged breach by us of a covenant pertaining to a pre-existing customer agreement contained in the Asset Purchase and Sale Agreement (ASPA) relative to Treximet. We asserted counterclaims and defenses under the APSA and also asserted claims against GSK related to breaches of a supply agreement between the parties. We and GSK entered into the Interim Settlement Agreement under which we agreed to make payments to GSK and escrow additional funds. Additionally, the parties agreed to submit the matter to binding arbitration.

On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35.0 million, plus interest (estimated to be approximately \$2.0 to \$5.0 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. After discussions with GSK, an agreement was reached on March 17, 2017, to amend the Interim Settlement Agreement (Amendment No. 1) whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award. We had already paid to GSK an aggregate of \$16.5 million, including \$6.2 million from the escrow account, which was to be applied as an offset to the total award. Pursuant to the amendment, we agreed that the outstanding balance owing to GSK as of the date of the amendment was approximately \$21.5 million and we further 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 recorded the fair value of this settlement in the amount of approximately \$18.5 million in our financial statements at December 31, 2016 and 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.

On July 20, 2017, we and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 superseded Amendment No. 1 and permitted payment by us to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, we were obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, we agreed that if on or before September 30, 2019,

we (x) redeem or repurchase our 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchanges such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, we shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as we comply with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of December 31, 2017, the Company has recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in Arbitration Award on the Company's consolidated balance sheet at December 31, 2017. Also, the Company recorded \$10.5 million as Gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

**Recro Gainesville LLC v. Actavis Laboratories FL, Inc., District of Delaware Case Nos. 14-1118, 15-413, 15-1196, and 17-cv-01535; 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 Orange Book as covering Zohydro ER with BeadTek. Actavis and Alvogen each filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval of proposed generic versions of Zohydro ER with BeadTek 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. The 30-month stay for Actavis expired on February 12, 2017 and on February 22, 2017, the United States District Court for the District of Delaware concluded that Actavis Laboratories FL, Inc.'s proposed generic versions of Zohydro ER with BeadTek infringe U.S. Patent Nos. 9,132,096 (which expires on September 12, 2034) and 6,902,742 (which expires on November 1, 2019). Further, the Court 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 these two patents. On March 22, 2017 Actavis filed an appeal, which was fully briefed as of September 13, 2017. Oral argument in the appeal has not yet been scheduled. On October 30, 2017, Recro brought suit against Actavis for infringement of U.S. Patent No. 9,713,611 ("the '611 Patent"), a continuation of the '096 Patent that issued on July 25, 2017 and was listed in the Orange Book as covering Zohydro ER with BeadTek. Pernix and Actavis entered into a settlement agreement on January 29, 2018 (discussed further in the litigation described immediately below). That settlement agreement resolved the pending disputes between Recro and Actavis.

**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 with BeadTek. Pernix Therapeutics, LLC is the exclusive licensee of the Pernix Zohydro ER Patents and is the sole distributor of Zohydro ER with BeadTek 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 with BeadTek 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 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 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. 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 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's infringement allegations, and raising Counterclaims of non-infringement and invalidity as to each of the asserted Pernix patents. Pernix and Actavis entered into a settlement agreement on January 29, 2018. Under the terms of the agreement, Pernix will grant Actavis a license to begin selling a generic version of Zohydro ER with BeadTek on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER with BeadTek. Trial related to the suit against Alvogen is scheduled for June 11, 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, Medicine to Go Pharmacies, Inc. (the Macoven 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 an answer in defense of the allegations. The fax campaign that is the subject of this litigation was administered by a third party, Odyssey Services (Odyssey), that was not initially named as a defendant in this litigation. On June 22, 2017, we filed a third-party complaint against Odyssey, seeking indemnity and contribution for any amounts that we may be liable to pay to the Plaintiff. Odyssey has since filed a motion for summary judgment, seeking to dismiss the third-party claims against it. That motion is currently pending before the Court. We therefore may not be able to secure indemnification from Odyssey for costs that we might incur relative to this matter and insurance defense and indemnity do not appear available to us. We are still in discovery on this matter and are unable to predict probable outcomes at this time. We continue to dispute plaintiffs' claims and, based upon known facts, intend to vigorously defend ourselves against the claims in this litigation.

**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 affect 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.

	<u>High</u>	<u>Low</u>
<b>2016</b>		
First Quarter	\$ 29.00	\$ 9.00
Second Quarter	11.00	4.00
Third Quarter	8.70	4.40
Fourth Quarter	6.20	1.94
<b>2017</b>		
First Quarter	\$ 4.17	\$ 2.10
Second Quarter	6.84	3.30
Third Quarter	4.82	2.47
Fourth Quarter	3.16	2.30

#### Holders

As of March 1, 2018, there were approximately 119 holders of record of our common stock.

#### Dividends

We have not declared or paid any cash dividends for the years ended December 31, 2017 and 2016. 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

There were no repurchases of equity securities in the fiscal year ended 2017.

## 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, 2017.

## Recent Sales of Unregistered Securities

All information regarding the issuance of our securities during the year ended December 31, 2017 have been previously disclosed in current reports we have filed on Form 8-K or in quarterly reports we have filed on Form 10-Q. We did not issue any unregistered equity securities during the quarter ended December 31, 2017.

## 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 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 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; and
- Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure;
- Developing and marketing an authorized generic version of Treximet once the product no longer benefits from patent exclusivity.
- Engaging in life-cycle management activities relating to Silenor, including the assessment of OTC opportunities (such as potential out-licensing transactions), as well as options for internal development.

We target underserved segments, such as CNS indications, including pain, neurology, 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 Zohydro ER with BeadTek, an extended-release opioid agonist indicated for the management of pain, Silenor, a non-controlled substance and approved medication indicated for the treatment of insomnia characterized by difficulty with sleep maintenance and Treximet, a medication indicated for the acute treatment of migraine attacks, with or without aura, in adults. See Part I, Item 1 - Business included in this Annual Report on Form 10-K for additional information regarding our products.

## Annual Update

The following significant transactions and/or events occurred since the beginning of 2017:

- As previously disclosed, we were involved in an arbitration proceeding with GSK. GSK claimed damages relating to an alleged breach by us of a covenant pertaining to a pre-existing customer agreement contained in the Asset Purchase and Sale Agreement (APSA) relative to Treximet. We asserted counterclaims and defenses under the APSA and also asserted claims against GSK related to breaches of a supply agreement between the parties. We and GSK entered into the Interim Settlement Agreement under which we agreed to make payments to GSK and escrow additional funds. Additionally, the parties agreed to submit the matter to binding arbitration.

On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35.0 million, plus interest (estimated to be approximately \$2.0 to \$5.0 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. After discussions with GSK, an agreement was reached on March 17, 2017, to amend the Interim Settlement Agreement (Amendment No. 1) whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award. We had already paid to GSK an aggregate of \$16.5 million, including \$6.2 million from the escrow account, which was to be applied as an offset to the total award. Pursuant to the amendment, we agreed that the outstanding balance owing to GSK as of the date of the amendment was approximately \$21.5 million and we further 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 recorded the fair value of this settlement in the amount of approximately \$18.5 million in our financial statements at December 31, 2016 and 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.

On July 20, 2017, we and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 superseded Amendment No. 1 and permitted payment by us to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, we were obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, we agreed that if on or before September 30, 2019, we (x) redeem or repurchase our 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchanges such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, we shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as we comply with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the

outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of December 31, 2017, the Company has recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in Arbitration Award on the Company's consolidated balance sheet. Also, the Company recorded \$10.5 million as Gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

- On July 20, 2017, we announced that we used the proceeds from the New ABL Facility, discussed below, to repay the outstanding obligation of the Wells Fargo Credit Facility.
- Exchange Agreement

On July 20, 2017, we entered into an Exchange Agreement (the Exchange Agreement) with certain holders of our outstanding 4.25% Convertible Notes. The Exchange Agreement governed our entry into the Transactions. The Transactions closed on July 21, 2017, and include:

- a. The New ABL Credit Agreement by and among the ABL Borrowers and PIP DAC the ABL Guarantors, Cantor Fitzgerald Securities, as agent, and the Holders, as lenders. The ABL Credit Agreement replaced the Old ABL Facility;
- b. A new five-year \$45.0 million Delayed Draw Term Loan among PIP DAC, Cantor Fitzgerald Securities, as agent, and the Holders, as lenders;
- c. A new indenture providing for 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes Indenture) under which PIP DAC is the issuer and Pemix and its other subsidiaries are the guarantors (the Guarantors), with Wilmington Trust, National Association, as trustee (the Trustee);
- d. The issuance to the Holders of (a) \$36.2 million aggregate principal amount of PIP DAC's 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes) pursuant to the New Notes Indenture and (b) 1,100,498 shares of Pemix's common stock (the Exchange Shares), in exchange for the tender to PIP DAC of \$51.8 million aggregate principal amount of Convertible Notes held by the Holders (the Exchange). The Exchangeable Notes will be exchangeable for Pemix's common stock. After giving effect to the Exchange, approximately \$78.2 million principal amount of the 4.25% Convertible Notes will remain outstanding; and
- e. A registration rights agreement among Pemix, PIP DAC and the Holders that provides for the registration under the Securities Act of 1933, as amended, the offer and sale of the Exchange Shares and the Underlying Shares (the Registration Rights Agreement).

The parties to the Exchange Agreement made certain customary representations and warranties. Under the Exchange Agreement, Pemix and each of its subsidiaries party thereto agreed to indemnify each Holder (or certain funds and/or accounts for which a Holder or any of its affiliates acts as investment advisor), its affiliates and the directors, officers, employees and agents of such Holder and each person who controls such Holder for certain losses arising out of the Exchange Agreement or the "transactions," as defined therein. Pemix also agreed to conduct a search for up to three new directors and to use its reasonable best efforts to facilitate the selection and appointment of such directors to Pemix's board of directors within ninety days following the closing of the Transactions.

#### *Cantor ABL Facility*

The ABL Borrowers entered into an asset-based revolving credit agreement (the ABL Credit Agreement) with Cantor Fitzgerald Securities, as agent (the ABL Agent) and the lenders party thereto to obtain the ABL Credit Agreement.

The ABL Borrowers' obligations under the New ABL Facility are guaranteed by the ABL Borrowers and the ABL Guarantors and are secured by, among other things, the ABL Borrowers' cash, inventory and accounts, in each case pursuant to a guaranty and security agreement between the ABL Borrowers, ABL Guarantors and Cantor Fitzgerald Securities as agent. Availability of borrowings under the ABL Credit Agreement from time to time will be subject to a borrowing base calculation based upon a valuation of the ABL Borrowers' eligible inventories and eligible accounts receivable, each multiplied by an

applicable advance rate, subject to adjustments in accordance with the ABL Credit Agreement. Borrowings under the ABL Credit Agreement will bear interest at the rate of LIBOR plus 7.50%. In addition, the ABL Borrowers will be required to pay a commitment fee on the undrawn commitments under the ABL Credit Agreement from time to time at a rate per annum of 0.25% on the unused commitments under the ABL Credit Agreement, payable monthly. The ABL Credit Agreement contains representations and warranties, affirmative and negative covenants, and events of default applicable to us, the other ABL Borrowers, the ABL Guarantors and their respective subsidiaries that are customary for credit facilities of this type. The ABL Credit Agreement will mature on July 21, 2022.

#### *Term Facility*

PIP DAC entered into the DDTL with the Term Agent and the lenders party thereto to obtain the DDTL. \$30.0 million under the DDTL was drawn on the date of closing of the Transactions, and the remaining \$15.0 million will be available for subsequent draws for certain specified purposes, including to finance certain acquisitions, subject to conditions set forth in the DDTL Credit Agreement. The DDTL includes an incremental feature that allows PIP DAC, with the consent of the requisite lenders under the Term Facility, to obtain up to an additional \$20.0 million in term loan commitments from new or existing lenders under the Term Facility that agree to provide such commitments. Interest on the loans will accrue either in cash or a combination of cash and in-kind interest, at PIP DAC's election. Cash interest will accrue at a rate of 7.50% per annum, while the combination of cash and in-kind interest will accrue at a rate of 8.50% per annum, with up to 4.00% per annum added to the principal amount of loans and the balance paid in cash. The DDTL will contain representations and warranties, affirmative and negative covenants, and events of default applicable to PIP DAC and its subsidiaries (if any) that are customary for credit facilities of this type. The DDTL will mature on July 21, 2022.

PIP DAC also entered into a mortgage debenture with Cantor Fitzgerald Securities as agent, pursuant to which PIP DAC's obligations under the DDTL will be secured by substantially all of the assets of PIP DAC and its future-acquired subsidiaries.

Upon the closing of the Transactions, the DDTL provided us with \$30.0 million of liquidity immediately and, subject to conditions set forth in the DDTL Credit Agreement, \$15.0 million of additional liquidity for certain specified purposes in the future, as well as the potential for an additional \$20.0 million in commitments subject to lender consent.

#### *Exchangeable Notes*

PIP DAC, the Exchangeable Notes Guarantors, and Wilmington Trust, National Association, as Trustee, entered into the New Exchangeable Notes Indenture. The Exchangeable Notes issued under the New Notes Indenture will be guaranteed by Permex and each other subsidiary thereof. The Exchangeable Notes are senior, unsecured obligations of PIP DAC. Interest on the Exchangeable Notes will be paid in cash or a combination of cash and in-kind interest at PIP DAC's election. Interest paid in cash (the "All Cash Method") will accrue at a rate of 4.25% per annum, while interest paid in a combination of cash and in-kind will accrue at a rate of 5.25% per annum, with 2.25% per annum of interest (plus additional interest, if any) capitalized to the principal amount of the Exchangeable Notes, and the balance paid in cash. The maturity date of the Exchangeable Notes Indenture is July 15, 2022.

The Exchangeable Notes initially are exchangeable into shares of our common stock at an exchange price per share of \$5.50 (the "Exchange Price"). The Exchange Price will be subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, the payment of cash dividends and certain Company tender or exchange offers.

Holders will exchange all or a portion of their Exchangeable Notes at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date.

Upon not less than 30 nor more than 45 trading days' notice, if the daily VWAP (as defined in the Exchangeable Notes Indenture) of our common stock has been at least 120% of the Exchange Price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which such notice of redemption is provided (the "Provisional Redemption", and such date of a Provisional Redemption, the "Redemption Date"), we will have the right to redeem any or all of the Exchangeable Notes at a price equal to 100% of the principal amount thereof (including any interest capitalized thereto) plus accrued interest that has not been paid or capitalized to, but excluding, the date on which the Exchangeable Notes are to be redeemed. The redemption price will be paid in cash.

No "sinking fund" will be provided for the Exchangeable Notes, which means that PIP DAC will not be required to periodically redeem or retire the Exchangeable Notes. If PIP DAC or we undergo a Fundamental Change (as defined below), subject to certain conditions, holders of the Exchangeable Notes may require PIP DAC to repurchase for cash all or part of their Exchangeable Notes. The fundamental change repurchase price will be equal to 100% of the principal amount (including any interest capitalized thereto) of the Exchangeable Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the date, chosen by PIP DAC, that is not less than 20 business days or more than 35 business days following the date on which notice of the Fundamental Change was provided by PIP DAC.

Under the Exchangeable Notes Indenture, a "Fundamental Change" will be deemed to have occurred if, among other events, any of the following occurs: (i) any "group" or "person," within the meaning of Section 13(d) of the Securities Exchange Act of 1934 (as amended, the "Exchange Act"), other than a permitted holder under the Exchangeable Notes Indenture, becomes the direct or indirect "beneficial owner," as defined in Rule 13d-3 under the Exchange Act, of our common stock representing more than 50% of our voting power; (ii) we consummate any recapitalization, reclassification or change of our common stock, subject to certain exceptions as contained in the Exchangeable Notes Indenture; (iii) we effect any share exchange, consolidation or merger pursuant to which our common stock will be converted into cash, securities or other property or assets; (iv) we effect any sale, lease or other transfer in one transaction or a series of transactions of all or substantially all of our consolidated assets to a person or entity other than a permitted holder under the Exchangeable Notes Indenture; (v) our stockholders approve a plan or proposal for our liquidation or dissolution or the liquidation or dissolution of PIP DAC; and (vi) our common stock ceases to be listed on The New York Stock Exchange, The Nasdaq Global Select Market or The Nasdaq Global Market (or any of their respective successors).

Holders of the Exchangeable Notes are entitled to receive, in certain circumstances, additional shares of our common stock upon exchanges of Exchangeable Notes in connection with a Provisional Redemption or certain Fundamental Changes.

Subject to certain limited exceptions, the Exchangeable Notes contain covenants which prohibit or limit the ability of PIP DAC and the Exchangeable Notes Guarantors to, among other things: (i) pay cash dividends or make distributions on our capital stock or redeem or repurchase our capital stock; (ii) create, assume or suffer to exist at any time any lien upon any of our properties or assets; (iii) incur any debt other than debt permitted under the terms of the Exchangeable Notes Indenture; (iv) enter into transactions with affiliates other than on terms and conditions that, taken as a whole, would be obtained in an arm's-length transaction with non-affiliates; and (v) make any sale of our assets and the assets of our subsidiaries except in accordance with the terms of the Exchangeable Notes Indenture.

The Exchangeable Notes Indenture also provides for customary events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving PIP DAC) occurs and is continuing, the Trustee by notice to PIP DAC, or the holders of at least 25% in principal amount of the then outstanding Exchangeable Notes by written notice to PIP DAC and the Trustee, may declare 100% of the accreted principal of and accrued and unpaid interest, if any, on all of the Exchangeable Notes to be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving PIP DAC, 100% of the principal of and accrued and unpaid interest, if any, on all of the Exchangeable Notes will become due and payable automatically, including a make-whole premium in an amount equal to the present value of the interest that would accrue on such Exchangeable Notes (assuming the All Cash Method) from, and including, such date of acceleration until the maturity date of the Exchangeable Notes, with such present value computed using a discount rate equal to the sum of (i) the yield to maturity of United States Treasury securities with remaining maturity equal to that of the Exchangeable Notes (as determined in a commercially reasonable manner by PIP DAC) on such date of acceleration and (ii) 50 basis points. Notwithstanding the foregoing, for up to 270 days after the occurrence of an event of default, PIP DAC may elect to have the sole remedy for an event of default relating to certain of PIP DAC's failures to comply with certain reporting covenants in the Exchangeable Notes Indenture consist exclusively of the right to receive additional interest on the Exchangeable Notes.

Holders of Exchangeable Notes will not be entitled to receive shares of our common stock upon exchange of any Exchangeable Notes to the extent such holder (or group of which such holder is a part) would beneficially own more than 9.99% of the outstanding shares of our common stock. Subject to such limitation, at the initial Exchange Price, the Exchangeable Notes will be exchangeable into approximately 40% of our outstanding common stock as of the date hereof (after giving effect to the issuance of the Exchange Shares and the common stock underlying the Exchangeable Notes).

The Exchange allowed us to reduce the principal amount of its outstanding indebtedness through the exchange of the Holders' 4.25% Convertible Notes for a smaller principal amount of the Exchangeable Notes. The principal amount of the Exchangeable Notes may be reduced if the holders thereof exchange their Exchangeable Notes for shares of our common stock. The Exchangeable Notes Indenture will provide capacity to refinance up to an additional \$25.0 million principal amount of the 4.25% Convertible Notes, which refinancing could also provide an opportunity to further reduce the principal amount of our outstanding indebtedness.

#### *Second Supplemental Indenture*

In connection with the Transactions, we and certain of our wholly owned subsidiaries, Pemix Holdco 1, LLC, Pemix Holdco 2, LLC and Pemix Holdco 3, LLC (each, a "New Guarantor", and collectively, the "New Guarantors") and U.S. Bank, National Association, as trustee, entered into a second supplemental indenture (the "Second Supplemental Indenture") to the Treximet Notes Indenture. Pursuant to the Second Supplemental Indenture, the New Guarantors provided guarantees of our obligations with respect to the Treximet Secured Notes issued under the Treximet Notes Indenture.

#### *Third Supplemental Indenture*

On December 29, 2017, we and the Treximet Notes Trustee, entered into a third supplemental indenture (the "Third Supplemental Indenture") to the Treximet Notes Indenture with the consent of the holders of a majority in aggregate principal amount of our Treximet Secured Notes. The Third Supplemental Indenture amends the Treximet Notes Indenture to clarify the definition of "Net Sales", as such term is defined in the Treximet Indenture and resulted in the deferral of \$3.2 million of principal payments until August 2020.

- *Isometheptene Mucate, Dichlorphenazone (IDA) Discontinuance*

Through our Macoven entity, Pemix has distributed a combination product called isometheptene mucate, dichlorphenazone, and acetaminophen ("IDA"). IDA was originally approved in 1948 for safety only. The product's efficacy as an adjunct to peptic ulcer treatment and for other indications, including the treatment of migraine headaches was reviewed under the Drug Efficacy Study Implementation process, DESI notice 3265. In January 2014, the FDA announced that all outstanding hearings requests for DESI 3265 were withdrawn. On October 20, 2017, we received a letter dated October 19, 2017 from the FDA asserting that IDA is subject to DESI 3265 and that since the outstanding requests for hearings in that matter were withdrawn, any drug products that are identified in DESI 3265, including IDA, require an approved NDA or ANDA in order for them to be distributed. Since we had not obtained an NDA or ANDA for IDA, the FDA stated in its letter that we should immediately cease distribution of IDA. While IDA has a long history of safe use, we complied with the FDA's request and confirmed to the Agency within the requested time frame that we ceased distribution of the product. For the year ended December 31, 2017 and 2016, our net revenues from the sale of IDA were \$14.9 million and \$13.4 million, respectively. Since we will not have further revenues from the product in 2018, we anticipate that the discontinuance of the product will impact net revenues beginning January 1, 2018.

- *Zohydro ER with BeadTek, 20 mg*

In May 2017, we announced that, due to a manufacturing issue with our supplier, we expect that the 20 mg. strength of Zohydro ER with BeadTek will be on back order until at least the first quarter of 2018. During this time, we have continued to market and distribute other strengths of Zohydro ER with BeadTek, including the 10 mg., 15 mg., 30 mg., 40 mg. and 50 mg. strengths. While utilization of the 10 mg., 15 mg. and 30. mg strengths have increased, we believe that the temporary stock-out of the 20 mg. strength has impacted the overall prescription volume for Zohydro ER with BeadTek, resulting in a loss of revenue and adverse effect on our financial condition.

- *Resignations*

On October 12, 2017, Graham G. Miao, our former President and Chief Financial Officer, notified the Chairman of our Board of Directors that the decision not to re-nominate him for re-election as a member of the Board at our 2017 Annual Meeting of Stockholders, held on November 15, 2017, created a "Good Reason" basis for resignation pursuant to the terms of his Employment Agreement dated November 3, 2016. Dr. Miao subsequently informed us of his decision to pursue other professional opportunities and offered his resignation effective December 31, 2017. Dr. Miao's employment with us ended on December 31, 2017, at which time he became eligible, pursuant to his employment agreement, to receive separation benefits. Dr. Miao's resignation did not reflect any disagreement with our financial results or strategy for growth.

On November 3, 2017, Michael J. Golembiewski resigned as our Vice President of Finance, Principal Accounting Officer and Corporate Controller, effective as of November 24, 2017. Mr. Golembiewski resigned in order to pursue other professional opportunities and his resignation did not reflect any disagreement with our financial results or strategy for growth.

- *Divestiture of Cedax*

On November 6, 2017, we announced the sale of a non-core product, Cedax® (ceftibuten capsules and ceftibuten for oral suspension), a third-generation cephalosporin antibiotic for the treatment of acute bacterial exacerbations of chronic bronchitis and middle ear infection, to SI Pharmaceuticals, LLC, for \$2.0 million in gross cash proceeds. Cedax® was discontinued by Pemix in 2016 and we did not generate any sales from this product in 2017. Pursuant to the terms of the Exchangeable Notes Indenture, \$0.5 million of the proceeds from this acquisition were used to prepay amounts outstanding under the Exchangeable Notes.

- *Workforce Realignment*

On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to our Treximet® fixed dose combination product. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees (representing approximately 22% of our workforce), the majority of which were associated with our sales force and commercial infrastructure. In connection with this commercial reorganization, we expect to realize annualized cost savings of \$7.0 million-\$8.0 million beginning in the first quarter of 2018. We anticipate recording a one-time charge of approximately \$1.0 million during the first quarter of 2018 as a result of this realignment.

- *IP Litigation Settlement*

We announced on January 29, 2018 that we entered into a settlement agreement with Actavis resolving patent litigation related to Zohydro ER with BeadTek. Under the terms of the agreement, we granted Actavis a license to begin selling a generic version of Zohydro ER with BeadTek on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER with BeadTek. The settlement agreement also resolves a pending appeal related to a patent litigation between Recro Gainesville LLC and Actavis, which also relates to Actavis's proposed generic version of Zohydro ER with BeadTek. As required by law, the parties will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. A patent litigation brought by us against Alvogen Malta Operations Ltd. related to Alvogen's proposed generic version of Zohydro ER with BeadTek remains pending in the U.S. District Court for the District of Delaware.

- *Treximet - Entry of Generic Competitors*

On February 14, 2018, four patents covering Treximet expired, enabling up to three generic competitors to enter the market. As of February 28, 2018, one of these competitors entered the market and we are expecting the other two competitors to enter later in 2018. Concurrent with the launch of generics by third parties, we launched an authorized generic version of Treximet. We will also continue to distribute the branded versions of Treximet. We have one additional patent that covers Treximet that will expire in 2026 that we expect to prevent additional generic competitors from entering the market until that time. We expect that generic competition for Treximet will negatively impact our net revenues for the fiscal year ending December 31, 2018

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, 2017 and 2016 (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Net revenues	\$ 146,068	\$ 140,856
Operating expenses		
Cost of product sales	44,631	43,320
Selling, general and administrative expense	76,801	98,834
Research and development expense	787	6,079
Loss from impairments of intangibles, goodwill and other assets	18,525	56,178
Gain from legal settlement	(10,476)	-
Depreciation and amortization expense	73,216	86,138
Change in fair value of contingent consideration	(1,045)	(11,652)
Restructuring costs	88	2,287
Other income (expense):		
Gain from exchange of debt	14,650	-
Foreign currency transaction gain (loss)	(49)	99
Change in fair value of derivative liability	47	8,935
Interest expense	(36,957)	(37,857)
Income tax expense	373	439

### Comparison of the Year Ended December 31, 2017 and 2016

#### *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, service 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, 2017 and 2016 (in thousands):

	<b>Year Ended December 31,</b>		<b>Increase/ Decrease</b>	<b>Percent</b>
	<b>2017</b>	<b>2016</b>		
Treximet	\$ 68,405	\$ 66,961	\$ 1,444	2%
Zohydro	24,007	24,713	(706)	-3%
Silenor	22,298	16,926	5,372	32%
Other	31,037	31,790	(753)	-2%
Net product revenues	145,747	140,390	5,357	4%
Co-promotion and other revenue	321	466	(145)	-31%
Total net revenues	\$ 146,068	\$ 140,856	\$ 5,212	4%

Overall, net revenues increased by \$5.2 million or 4% during the year ended December 31, 2017 compared to the year ended December 31, 2016, as follows:

Treximet net revenues increased by \$1.4 million, or 2% during the year ended December 31, 2017, compared to the year ended December 31, 2016. Treximet 2016 net revenues included 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.

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

	<b>Year Ended December 31,</b>			
	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
GAAP net revenues of Treximet	\$ 68,405	\$ 66,961	\$ 101,753	\$ 54,775
GSK arbitration award adjustment	-	15,277	(12,484)	(2,793)
Adjusted net revenues of Treximet (1)	<u>\$ 68,405</u>	<u>\$ 82,238</u>	<u>\$ 89,269</u>	<u>\$ 51,982</u>

(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.

Adjusted net revenues of Treximet declined \$13.8 million or 17% during the year ended December 31, 2017, compared to the year ended December 31, 2016. The decrease was due primarily to a decline in sales volumes partially offset by higher net price.

Zohydro ER net revenues decreased by \$706,000, or 3%, during the year ended December 31, 2017, compared to the year ended December 31, 2016. The reduction in revenue was due to a decrease in net price driven by lower gross-to-net rates.

Silenor net revenues increased by \$5.4 million, or 32%, during the year ended December 31, 2017, compared to the year ended December 31, 2016, reflecting an increase in both net price and sales volume.

Net product revenues - other decreased by \$753,000 or 2% during the year ended December 31, 2017, compared to the year ended December 31, 2016. The decrease was due primarily to discontinuation of products no longer sold.

Co-promotion and other revenue decreased by \$145,000 during the year ended December 31, 2017, compared to the year ended December 31, 2016, which was attributable primarily to product discontinuation.

#### *Cost of Product Sales*

Cost of product sales increased by \$1.3 million, or 3%, during the year ended December 31, 2017, compared to the year ended December 31, 2016. The increase in cost of product sales was due primarily to non-recurrence of \$2.5 million of lower royalty expenses in 2016 related to the impact of reducing net revenues of Treximet as a result of the unfavorable arbitration ruling with GSK for the year ended December 31, 2016 partially offset by higher net sales of generic products that require royalty payments and the write off of inventory related to the discontinuation of IDA.

#### *Selling, General and Administrative Expense*

Selling, general and administrative expense decreased by \$22.0 million, or 22%, during the year ended December 31, 2017, compared to the year ended December 31, 2016. The decrease was driven by lower sales force related expenses stemming from the sales force restructuring during the year ended December 31, 2016, lower legal fees as well as a conscious effort to reduce spending across the organization.



#### *Research and Development Expense*

Research and Development expense decreased by \$5.3 million, or 87%, during the year ended December 31, 2017, compared to the year ended December 31, 2016, due primarily to the timing of work for Zohydro and Treximet.

#### *Depreciation and Amortization Expense*

Depreciation and amortization expense decreased by \$12.9 million, or 15%, during the year ended December 31, 2017, compared to the year ended December 31, 2016. The decrease was related primarily to lower amortization of developed technology intangible assets as a result of asset impairments during the year ended December 31, 2016 and the extension of the patent life of Zohydro ER developed technology in the first quarter of 2016.

#### *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, 2017, the total current fair value of the contingent consideration is approximately \$1.4 million. We recorded a benefit of \$1.0 million and \$11.7 million as change in fair value of contingent consideration in the years ended December 31, 2017 and 2016, respectively.

#### *Loss from Disposal of Assets, Impairments of Intangibles and Goodwill*

Loss from disposal of assets and impairments of intangibles, excluding goodwill, was \$0 million for the year ended December 31, 2017 compared to \$56.2 million for the year ended December 31, 2016. 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 impairment charges of \$18.5 million and \$23.8 million, during the years ended December 31, 2017 and 2016, respectively.

#### *Gain from legal settlement*

We recorded a gain of \$10.5 million and \$0 during the years ended December 31, 2017 and 2016, respectively, as a result of concluding Amendment No. 2 with GSK as previously discussed.

#### *Restructuring Costs*

Restructuring costs were \$88,000 and \$2.3 million during the years ended December 31, 2017 and 2016, respectively. Restructuring costs during the year ended December 31, 2016 were related to the initiative to restructure our sales force and operations.

#### *Interest Expense*

Interest expense decreased \$900,000, or 2%, during the year ended December 31, 2017 compared to the year ended December 31, 2016. The decrease was due primarily to reduced interest expense on our Treximet Secured Notes due to the lower principal balance.

#### *Gain on sale of assets*

On November 6, 2017 the Company announced the sale of a non-core product, Cedax® (ceftibuten capsules and ceftibuten for oral suspension), a third-generation cephalosporin antibiotic for the treatment of acute bacterial exacerbations of chronic bronchitis and middle ear infection, to SI Pharmaceuticals, LLC, for \$2.0 million in gross cash proceeds. Cedax® was discontinued by Pemix in 2016 and the Company has not generated any sales from this product in 2017. This was recorded in the gain on sale of assets line on the consolidated statement of operations and comprehensive loss. There were no such sales in 2016.

### *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 \$47,000 and \$8.9 million as change in fair value of derivative liability in other income (expense) in the years ended December 31, 2017 and 2016, respectively. For further discussion, see Note 12, *Debt and Lines of Credit*, to our consolidated financial statements included in this Annual Report on Form 10-K.

### *Gain from exchange of debt*

We recorded a gain of \$14.7 million and \$0 during the years ended December 31, 2017 and 2016, respectively, related to the Exchange Agreement. In July 2017, certain holders of the 4.25% Convertible Notes exchanged \$51.8 million in principal notes for \$36.2 million in Exchangeable Notes.

### *Income Tax Provision*

During 2017, we recognized an income tax expense of \$0.4 million. Our 2017 effective rate from continuing operations was (0.5%). This tax expense included a current income tax provision of approximately \$0.6 million and a deferred tax benefit of approximately (\$0.2) million. During 2016, we recognized an income tax expense of \$0.4 million. Our 2016 effective rate from continuing operations rate was (0.3%). The change in the 2017 effective tax rate relates mainly to the tax effect of permanent differences and other items on our pre-tax loss and foreign income tax rate differential.

### **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; cost of product sales adjustments; selling, general and administrative adjustments; change in fair value of contingent consideration; gain from disposal of asset; disposal of assets and impairments of assets; non-recurring arbitration and litigation expenses; change in fair value of derivative liability; restructuring costs; extinguishment of debt; and foreign currency transactions. 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):

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
GAAP net revenues of Treximet	\$ 68,405	\$ 66,961	\$ 101,753
GSK arbitration award adjustment	-	15,277	(12,484)
Adjusted net revenues of Treximet	<u>\$ 68,405</u>	<u>\$ 82,238</u>	<u>\$ 89,269</u>

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

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
GAAP net loss	\$ (77,141)	\$ (169,590)
Adjustments:		
Interest expense	36,957	37,857
Depreciation and amortization expense	73,335	86,215
Income tax expense	373	439
EBITDA	<u>33,524</u>	<u>(45,079)</u>
Net revenue adjustments (1)	-	15,277
Cost of product sales adjustments (2)	1,083	(2,521)
Selling, general and administrative adjustments (3)	4,192	9,513
Change in fair value of contingent consideration (4)	(1,045)	(11,652)
Gain from disposal of asset (5)	(2,000)	-
Loss from impairment of intangibles, goodwill and other assets (6)	18,525	56,178
Gain from legal settlement (7)	(10,476)	-
Change in fair value of derivative liability (8)	(47)	(8,935)
Restructuring costs (9)	88	2,287
Gain from exchange of debt (10)	(14,650)	-
Foreign currency transaction (gain) loss	49	(99)
Adjusted EBITDA	<u>\$ 29,243</u>	<u>\$ 14,969</u>

- (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.
- (2) Excludes inventory write-offs of \$1.1 million for the year ended December 31, 2017, related to cessation of distribution of IDA. 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.
- (3) Excludes purchase price adjustment of \$0.9 million for the year ended December 31, 2017. Excludes stock compensation expense of \$2.5 million and \$2.7 million; deal expenses of \$1.5 million and \$2.8 million; severance expense of \$1.1 million and \$1.9 million; and non-recurring arbitration and litigation expenses of \$0 and \$2.1 million for the years ended December 31, 2017 and 2016, respectively.
- (4) Excludes gain from change in fair value of contingent consideration related to the 2015 acquisition of Zohydro ER and is linked to the achievement of certain net sales targets. Any change in fair values between the reporting dates is recognized in the consolidated statements of operations.

- (5) Excludes gain from the sale of a non-core product, Cedax® (ceftibuten capsules and ceftibuten for oral suspension) that was discontinued by Pemix in 2016.
- (6) Excludes loss from impairment of intangibles, goodwill and other assets. We 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 tested our goodwill and recorded a \$18.5 million and \$23.8 million impairment charge during the years ended December 31, 2017 and 2016, respectively.
- (7) Excludes \$10.5 million gain from Pemix and GSK amended settlement agreement resulting from Amendment NO. 2 to the Interim Settlement Agreement with GSK under which Pemix will pay approximately \$6.7 million to GSK (potentially up to \$8.7 million), which is a reduction of up to approximately \$14.5 million from the initial settlement agreement.
- (8) Excludes (gain) loss from change in fair value of derivative liability consideration. 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.
- (9) Excludes expense related to the initiative to restructure our sales force and operations in 2016.
- (10) Excludes gain related to the July 2017 financing transactions in which certain holders of the 4.25% Convertible Notes exchanged \$51.8 million in principal notes for \$36.2 million in Exchangeable Notes.

### Liquidity and Capital Resources

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

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Cash and cash equivalents	\$ 32,820	\$ 36,375
Total current assets	93,771	108,910
Current debt (1)	3,664	11,103
Arbitration award (2)	2,000	17,522
Non-current debt (1)	279,976	290,321
Stockholders' (deficit) equity	\$ (174,257)	\$ (114,063)

- (1) The Table below lists the Total Borrowing, the Note Discount, the Deferred Financing Costs that when combined equal the components of Current and Non-current Book Value of the debt listed on our Consolidated Balance Sheets at December 31, 2017 and 2016, respectively; See Note 12, *Debt and Lines of Credit* of Item 8 of this Form 10K for the terms of each debt instrument:

	<b>Total Borrowings</b>	<b>Note Discount</b>	<b>Deferred Financing Costs</b>	<b>Book Value</b>
4.25% Convertible Notes	\$ 78,225	\$ (11,060)	\$ (1,433)	\$ 65,732
Exchangeable Notes	35,743	(24,363)	(3,105)	8,275
Delayed Draw Term Loan	30,000	-	(2,103)	27,897
Treximet Secured Notes - Long Term	166,697	-	(2,810)	163,887
Treximet Secured Notes - Short Term	5,373	-	(1,709)	3,664
ABL Credit Agreement	14,185	-	-	14,185
Balance at December 31, 2017	<u>\$ 330,223</u>	<u>\$ (35,423)</u>	<u>\$ (11,160)</u>	<u>\$ 283,640</u>

	<b>Total Borrowings</b>	<b>Note Discount</b>	<b>Deferred Financing Costs</b>	<b>Book Value</b>
4.25% Convertible Notes	\$ 130,000	\$ (22,604)	\$ (3,325)	\$ 104,071
Exchangeable Notes	-	-	-	-
Delayed Draw Term Loan	-	-	-	-
Treximet Secured Notes - Long Term	176,769	-	(4,519)	172,250
Treximet Secured Notes - Short Term	12,812	-	(1,709)	11,103
Wells Fargo Credit Facility	14,000	-	-	14,000
Balance at December 31, 2016	<u>\$ 333,581</u>	<u>\$ (22,604)</u>	<u>\$ (9,553)</u>	<u>\$ 301,424</u>

## (2) GlaxoSmithKline (GSK) Arbitration

We were involved in an arbitration proceeding with GSK. GSK claimed damages relating to an alleged breach by us of a covenant pertaining to a pre-existing customer agreement contained in the Asset Purchase and Sale Agreement (ASPA) relative to Treximet. We asserted counterclaims and defenses under the ASPA and also asserted claims against GSK related to breaches of a supply agreement between the parties. We and GSK entered into the Interim Settlement Agreement under which we agreed to make payments to GSK and escrow additional funds. Additionally, the parties agreed to submit the matter to binding arbitration. On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35.0 million, plus interest (estimated to be approximately \$2.0 to \$5.0 million). The tribunal also denied our claim that GSK breached its obligations under the supply agreement. After discussions with GSK, an agreement was reached on March 17, 2017, to amend the Interim Settlement Agreement (Amendment No. 1) whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award. We had already paid to GSK an aggregate of \$16.5 million, including \$6.2 million from the escrow account, which was to be applied as an offset to the total award. Pursuant to the amendment, we agreed that the outstanding balance owing to GSK as of the date of the amendment was approximately \$21.5 million and we further 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 recorded the fair value of this settlement in the amount of approximately \$18.5 million in our financial statements at December 31, 2016 and 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.

On July 20, 2017, we and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 superseded Amendment No. 1 and permitted payment by us to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, we were obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, we agreed that if on or before September 30, 2019, we (x) redeem or repurchase our 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchanges such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, we shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as we comply with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of December 31, 2017, the Company has recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in other liabilities - long term on the Company's consolidated balance sheet at December 31, 2017. Also, the Company recorded \$10.5 million as Gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

During 2017 and 2016 we utilized cash from operations of \$5.9 million and \$16.5 million, respectively.

As of December 31, 2017, we had cash and cash equivalents of \$32.8 million and borrowing availability of \$24.8 million under our \$40.0 million ABL Credit Agreement.

We have an effective shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to \$150.0 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 \$10.0 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 680,926 and 3,859,903 shares of common stock under this controlled equity program in the years ended December 31, 2017 and 2016, respectively, for net proceeds of \$2.0 million and \$19.7 million for the years ended December 31, 2017 and 2016, respectively. 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."

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

- 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 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, 4.25% Convertible Notes and Exchangeable Notes as applicable;
- our ability to draw down on our ABL Credit Agreement and DDTL
- our obligations to make cash payments under our indebtedness; 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.

We believe that our existing cash balance, cash from operations, funding from the Transactions, and availability of offerings under our shelf registration will be sufficient to fund our existing level of operating expenses, current development activities, non-operating payments of debt, interest and general capital expenditure requirements through at least the next twelve months.

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 may in the future retain 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 might pursue could materially affect our liquidity and capital resources and could 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.

## Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2016 (in thousands).

	<u>2017</u>	<u>2016</u>
Cash (used in) provided by		
Operating activities	\$ (5,939)	\$ (16,501)
Investing activities	1,982	(1,567)
Financing activities	402	(1,692)
Net decrease in cash and cash equivalents	<u>\$ (3,555)</u>	<u>\$ (19,760)</u>

### *Net cash used in operating activities*

Net cash used in operating activities during 2017 and 2016 was \$5.9 million and \$16.5 million, respectively. The \$5.9 million used in operating activities during 2017 was driven primarily by: net loss of \$77.1 million, adjusted by non-cash expenses totaling \$74.9 million and \$3.7 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities. 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 \$130.8 million and \$22.3 million in net changes in accounts receivable, inventories, accounts payable, accrued expenses and other operating assets and liabilities.

### *Net cash provided by (used in) investing activities*

Net cash provided by investing activities during 2017 was \$2.0 million. Net cash used in investing activities in 2016 was \$1.6 million. The \$2.0 million provided by investing activities during 2017 was due primarily to the sale of non-core assets. The \$1.6 million used in investing activities during 2016 was primarily due to purchases of fixed assets.

### *Net cash provided by (used in) financing activities*

Net cash provided by financing activities during 2017 was \$402,000. Net cash used in financing activities during 2016 was \$1.7 million. Cash provided by financing activities for the year ended December 31, 2017 was as a result of net proceeds from the Delayed Draw Term Loan, the sales of common stock of \$2.0 million and \$185,000 from net drawdowns on credit facilities which were partially offset by principal payments on our Treximet Secured Notes of \$17.5 million, \$13.6 million related to financing costs paid as a result of the various debt restructuring and principal payments on our Exchangeable Notes. 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, net payments on credit facilities of \$1.0 million which were partially offset by the sales of common stock of \$19.8 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.

## 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, 2017 and 2016:

	<u>Product Returns</u>	<u>Government Program Rebates</u>	<u>Price Adjustments</u>	<u>Managed Care Rebates</u>	<u>Total</u>
Balance at January 1, 2016	\$ 11,896	\$ 6,682	\$ 19,547	\$ 24,553	\$ 62,678
Allowances for certain co-agreements(1)	-	91		362	453
Provision	8,377	13,459	70,923	99,211	191,970
Payments and credits	<u>(1,959)</u>	<u>(12,819)</u>	<u>(76,610)</u>	<u>(102,752)</u>	<u>(194,140)</u>
Balance at December 31, 2016	18,314	7,413	13,860	21,374	60,961
Allowances for certain co-agreements(1)	-	35	-	-	35
Provision	10,058	13,469	68,004	90,248	181,779
Payments and credits	<u>(6,691)</u>	<u>(14,276)</u>	<u>(71,098)</u>	<u>(94,401)</u>	<u>(186,466)</u>
Balance at December 31, 2017	<u>\$ 21,681</u>	<u>\$ 6,641</u>	<u>\$ 10,766</u>	<u>\$ 17,221</u>	<u>\$ 56,309</u>

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

*Product Returns.* Consistent with industry practice, we offer contractual return rights that allow our customers to return short-dated or expiring products within an 18-month period, commencing from six months prior to and up to twelve months subsequent to the product expiration date. Our products have expiration periods ranging from 15 to 42 months after the date of manufacture. We account for product returns as a reduction in net revenue at the time of sale. Product returns are 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 within the distribution channel, the shelf life of shipped product, 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 is reviewed quarterly and adjusted as warranted. 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 organizations and other indirect customers at contractual prices that are lower than the list prices that we charge to 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 that 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 that 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 that 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**

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	77
Consolidated Balance Sheets	78
Consolidated Statements of Operations and Comprehensive Loss	79
Consolidated Statements of Stockholders' Deficit	80
Consolidated Statements of Cash Flows	81
Notes to Consolidated Financial Statements	82
Schedule II - Valuation and Qualifying Accounts	118

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pernix Therapeutics Holdings, Inc. and subsidiaries (collectively, the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes and schedules (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of the internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2008.

Atlanta, Georgia  
March 8, 2018

**PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

**December 31, 2017 and 2016**

(in thousands, except share and per share data)

	<b>2017</b>	<b>2016</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 32,820	\$ 36,375
Accounts receivable, net	45,317	50,729
Inventory, net	5,396	7,775
Prepaid expenses and other current assets	10,115	12,617
Income tax receivable	123	1,414
<b>Total current assets</b>	<b>93,771</b>	<b>108,910</b>
Property and equipment, net	752	1,103
Goodwill	12,100	30,600
Intangible assets, net	96,606	169,571
Other	2,263	257
<b>Total assets</b>	<b>\$ 205,492</b>	<b>\$ 310,441</b>
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 7,911	\$ 7,275
Accrued personnel expense	5,748	5,357
Accrued allowances	56,309	60,961
Other accrued expenses	6,909	8,711
Interest payable	10,612	10,897
Treximet Secured Notes - current, net	3,664	11,103
Other liabilities - current	2,648	5,224
<b>Total current liabilities</b>	<b>93,801</b>	<b>109,528</b>
Convertible notes - long-term, net	65,732	104,071
Exchangeable notes - long-term, net	8,275	-
Delayed draw term loan - long-term, net	27,897	-
Derivative liability	93	230
Contingent consideration	1,358	2,403
Treximet Secured Notes - long-term, net	163,887	172,250
Credit facilities - long-term	14,185	14,000
Arbitration award	2,000	17,522
Other liabilities	2,521	4,500
<b>Total liabilities</b>	<b>379,749</b>	<b>424,504</b>
Commitments and contingencies (note 18)		
<b>Stockholders' (deficit) equity:</b>		
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, 11,841,173 and 10,015,641 issued and outstanding at December 31, 2017 and 2016, respectively	119	100
Additional paid-in capital	261,158	244,309
Accumulated other comprehensive loss	-	(79)
Accumulated deficit	(435,534)	(358,393)
<b>Total stockholders' deficit</b>	<b>(174,257)</b>	<b>(114,063)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 205,492</b>	<b>\$ 310,441</b>

*See accompanying notes to consolidated financial statements*

**PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**Years ended December 31, 2017 and 2016**

(in thousands, except per share data)

	<b>2017</b>	<b>2016</b>
<b>Net revenues</b>	\$ 146,068	\$ 140,856
<b>Costs and operating expenses:</b>		
Cost of product sales	44,631	43,320
Selling, general and administrative expense	76,801	98,834
Research and development expense	787	6,079
Depreciation and amortization expense	73,216	86,138
Change in fair value of contingent consideration	(1,045)	(11,652)
Loss from impairments of intangibles, goodwill and other assets	18,525	56,178
Gain from legal settlement	(10,476)	-
Restructuring costs	88	2,287
<b>Total costs and operating expenses</b>	<b>202,527</b>	<b>281,184</b>
<b>Loss from operations</b>	<b>(56,459)</b>	<b>(140,328)</b>
<b>Other income (expense):</b>		
Interest expense	(36,957)	(37,857)
Gain on sale of assets	2,000	-
Change in fair value of derivative liability	47	8,935
Gain from exchange of debt	14,650	-
Foreign currency transaction gain (loss)	(49)	99
<b>Total other expense, net</b>	<b>(20,309)</b>	<b>(28,823)</b>
<b>Loss before income tax expense</b>	<b>(76,768)</b>	<b>(169,151)</b>
Income tax expense	373	439
<b>Net loss</b>	<b>(77,141)</b>	<b>(169,590)</b>
<b>Other comprehensive loss</b>		
Unrealized gain/(loss) during period, net of tax of \$0, and \$0, respectively	79	(79)
<b>Comprehensive loss</b>	<b>\$ (77,062)</b>	<b>\$ (169,669)</b>
<b>Net loss per common and potential common share</b>		
Basic	\$ (7.21)	\$ (21.67)
Diluted	\$ (7.21)	\$ (21.67)
<b>Weighted-average common and potential common shares outstanding:</b>		
Basic	10,706	7,827
Diluted	10,706	7,827

*See accompanying notes to consolidated financial statements*

**PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**  
**Years ended December 31, 2017 and 2016**  
(in thousands)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Treasury Stock</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Total Stockholders' Deficit</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balance at January 1, 2016	-	\$ -	6,111	\$ 61	\$ 227,387	\$ (5,548)	\$ (188,803)	\$ -	\$ 33,097
Conversion of restricted stock units	-	-	4	-	-	(23)	-	-	(23)
Reclassification of treasury stock	-	-	-	-	(5,571)	5,571	-	-	-
Compensation expense on share-based awards	-	-	-	-	2,718	-	-	-	2,718
Net proceeds from sale of shares	-	-	3,901	39	19,775	-	-	-	19,814
Other comprehensive loss	-	-	-	-	-	-	-	(79)	(79)
Net loss	-	-	-	-	-	-	(169,590)	-	(169,590)
Balance at December 31, 2016	-	-	10,016	100	244,309	-	(358,393)	(79)	(114,063)
Conversion of restricted stock units	-	-	44	1	(113)	-	-	-	(112)
Issuance of Convertible Debt	-	-	1,100	11	12,499	-	-	-	12,510
Compensation expense on share-based awards	-	-	-	-	2,491	-	-	-	2,491
Net proceeds from sale of shares	-	-	681	7	1,972	-	-	-	1,979
Other comprehensive income	-	-	-	-	-	-	-	79	79
Net loss	-	-	-	-	-	-	(77,141)	-	(77,141)
Balance at December 31, 2017	-	\$ -	11,841	\$ 119	\$ 261,158	\$ -	\$ (435,534)	\$ -	\$ (174,257)

*See accompanying notes to consolidated financial statements*



**PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years ended December 31, 2017 and 2016**  
(in thousands)

	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (77,141)	\$ (169,590)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	370	704
Amortization of intangibles	72,965	85,511
Amortization of deferred financing costs	3,296	2,440
Accretion expense	5,279	4,057
PIK interest payable	233	-
Deferred income tax benefit	(238)	(200)
Loss on disposal of fixed assets	-	35
Stock compensation expense	2,491	2,718
Fair market value change in derivative liability	(47)	(8,935)
Fair market value change in contingent consideration	(1,045)	(11,652)
Gain from legal settlement	(10,476)	-
Gain from exchange of debt	(14,650)	-
Gain from sale of non-core assets	(2,000)	-
Impairment of fixed assets and intangibles	18,525	56,143
Decrease (increase) in operating assets (excluding effect of acquisitions):		
Accounts receivable	5,412	11,009
Income taxes	1,291	5,321
Inventory	2,379	2,260
Prepaid expenses and other assets	3,830	(533)
Increase (decrease) in operating liabilities (excluding effect of acquisitions):		
Accounts payable and accrued expenses	(2,115)	(7,960)
Accrued allowances	(4,652)	(1,717)
Arbitration award	(6,900)	17,522
Interest payable	(518)	(1,006)
Other liabilities	(2,228)	(2,628)
<b>Net cash used in operating activities</b>	<b>(5,939)</b>	<b>(16,501)</b>
<b>Cash flows from investing activities:</b>		
Acquisitions	-	(583)
Proceeds from sale of non-core assets	2,000	-
Purchase of software and equipment	(18)	(984)
<b>Net cash (used in) provided by investing activities</b>	<b>1,982</b>	<b>(1,567)</b>
<b>Cash flows from financing activities:</b>		
Payments on Treximet Secured Notes	(17,511)	(20,406)
Net proceeds from Delayed Draw Term Loan	30,000	-
Payments for financing costs	(13,587)	-
Payments on Exchangeable Notes	(500)	-
Net drawdowns (payments) on credit facilities	185	(1,000)
Payments on mortgages and capital leases	(52)	(77)
Proceeds from issuance of common stock, net of tax and costs	1,979	19,814
Shares withheld for the payment of taxes	(112)	(23)
<b>Net cash provided by (used in) financing activities</b>	<b>402</b>	<b>(1,692)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(3,555)</b>	<b>(19,760)</b>
Cash and cash equivalents, beginning of period	36,375	56,135
<b>Cash and cash equivalents, end of period</b>	<b>\$ 32,820</b>	<b>\$ 36,375</b>

*See accompanying notes to consolidated financial statements*

**PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2017 and 2016**

**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 therapeutic areas such as central nervous system (CNS), including pain, psychiatry and neurology. 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 Zohydro ER with BeadTek, an extended-release opioid agonist indicated for the management of pain, Silenor, a non-controlled substance and approved medication for the treatment of insomnia characterized by difficulty with sleep and Treximet, a medication indicated for the acute treatment of migraine pain and inflammation.

*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 affect 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.

**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.

*Reclassifications*

On its 2016 Consolidated Statement of Cash Flows, the Company reclassified \$467,000 of accretion expense related to the Texas Medicaid settlement from Other Liabilities to Accretion expense.

*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 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.

#### *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 may include certain money-market funds with maturities of three months or less when purchased.

#### *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 may from time to time invest its excess cash in high quality, money market instruments. The Company maintains the majority of its cash and cash equivalents with one major financial institutions. 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 its products to three major customers in 2017 and 2016. See Note 14, *Concentrations*, for additional information. At December 31, 2017 and 2016, the allowance for doubtful accounts was approximately \$15,000 and \$500,000, 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, 2017, approximately 65% of the inventory purchases, were from three primary suppliers - Recro Gainesville, LLC, Contract Pharmacal Corporation and Belcher Pharmaceuticals, LLC, allocated 27%, 24% and 14%, respectively. 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. The Company believes that it has good relationships with its current suppliers, and could secure the services of alternative suppliers if necessary or required.

#### *Inventories*

Inventory is valued at the lower of cost or market, with cost determined by using the specific identification method. Allowances for slow-moving, obsolete, and/or declines in the value of inventory are determined based on management's assessments. Sample inventory is included in prepaid expenses and other current assets on the consolidated balance sheets and are expensed to selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss when the sample units are distributed to the Company's sales representatives.

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

#### *Property, Equipment and Depreciation*

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which ranges from three to seven years. Leasehold improvements are amortized over the shorter of the 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.

In January 2017, the FASB issued Accounting Standards Update 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-04"), which simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test which previously required measurement of any goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill.

Under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying value and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; without exceeding the total amount of goodwill allocated to that reporting unit. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company has elected to early adopt this guidance as of January 1, 2017 and is applying it on a prospective basis. The adoption did not have a material impact on its consolidated financial statements.

During the Company's annual impairment test, it was noted that the carrying value of the reporting unit exceeded its fair value by \$18.5 million for the year ended December 31, 2017. A \$23.8 million impairment charge for goodwill was recorded for the year ended December 31, 2016. See Note 8, *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, 2017 and 2016, the Company recorded impairment charges of \$0 and \$31.4 million, respectively. See Note 8, *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.

#### *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, 2017 and 2016 were \$3.3 million and \$2.4 million, respectively. Unamortized deferred financing costs were \$15.3 million and \$10.4 million as of December 31, 2017 and 2016, 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 upon 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.

#### *Research and Development*

Research and development costs in connection with the Company's internal programs for the development of products are expensed as incurred. The Company 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 selling general and administrative expenses. Advertising expenses for 2017 and 2016 were \$10.4 million and \$12.6 million, respectively.

#### *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 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 2014 through 2017.

## 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 incurred 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 18, *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):

	<u>Year ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
Numerator:		
Net loss	\$ <u>(77,141)</u>	\$ <u>(169,590)</u>
Denominator:		
Weighted-average common shares, basic	10,706	7,827
Dilutive effective of stock options	<u>-</u>	<u>-</u>
Weighted-average common shares, diluted	<u>10,706</u>	<u>7,827</u>
Net loss per share, basic and diluted	\$ (7.21)	\$ (21.67)

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):

	<b>Year ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
4.25% Convertible Notes	931	1,133
Exchangeable Notes	2,949	-
Stock options and restricted stock units	1,091	774
Warrants	33	33
Total potential dilutive effect	<u>5,004</u>	<u>1,940</u>

#### *Recent Accounting Pronouncements*

In February 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220), Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, (ASU 2018-02). The amendments in this Update allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act (H.R. 1) (the Act). Consequently, the amendments eliminate the stranded tax effects resulting from the Act and will improve the usefulness of information reported to financial statement users. However, because the amendments only relate to the reclassification of the income tax effects of the Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. The amendments in this Update also require certain disclosures about stranded tax effects. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2018-02 on its financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, (ASU 2017-09). ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The adoption of this ASU is not expected to have a material impact on the Company's financial position or results of operations.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-01, *Business Combination (Topic 805)* (ASU 2017-01) which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluation whether transactions should be accounted for as acquisitions (or disposals) of a business. The amendments in this update provide a screen to determine when an asset is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early application of the amendments in this update is allowed as follows:



1. For transactions for which the acquisition date occurs before the issuance date or effective date of the amendments, only when the transaction has not been reported in financial statements that have been issued or made available for issuance
2. For transactions in which a subsidiary is deconsolidated or a group of assets is derecognized that occur before the issuance date or effective date of the amendments, only when the transaction has not been reported in financial statements that have been issued or made available for issuance.

The adoption of this ASU is not expected to have a material impact on the Company's financial position or results of operations.

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 anticipates some changes to the presentation of its consolidated statements of cash flows upon adoption of this standard.

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 18, *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 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 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 will adopt the standard using the modified retrospective method.

The Company has completed an analysis of existing contracts with its customers and assessed the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards. Based on its review of current customer contracts, the Company does not expect the implementation of ASU 2014-09 to have a material quantitative impact on its consolidated financial statements as the timing of revenue recognition for product sales is not expected to significantly change. Adoption of the new standard will also result in additional revenue-related disclosures in the footnotes to the Company's consolidated financial statements.

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***

As of December 31, 2017 and December 31, 2016, the Company did not have any investments in Level 1, 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, 2017 and 2016.

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 4.25% Convertible Notes, Exchangeable Notes, Delayed Draw Term Loan and the Treximet Secured Notes (each, as defined below in Note 12, *Debt and Lines of Credit*) are recorded at carrying value. The derivative liability and contingent consideration are recorded at fair value. Within the hierarchy of fair value measurements, the derivative liability and contingent consideration are Level 3 fair values. The fair and carrying value of the Company's debt instruments are detailed as follows (in thousands):

	As of December 31, 2017		As of December 31, 2016	
	Fair Value	Carrying Value	Fair Value	Carrying Value
4.25% Convertible Notes	\$ 36,208	\$ 65,732	\$ 32,595	\$ 104,071
Exchangeable Notes	21,375	8,275	-	-
Delayed draw term loan	30,300	27,897	-	-
Derivative liability	93	93	230	230
Contingent consideration	1,358	1,358	2,403	2,403
Treximet Secured Notes	139,201	167,551	147,551	183,353
Total	<u>\$ 228,535</u>	<u>\$ 270,906</u>	<u>\$ 182,779</u>	<u>\$ 290,057</u>

*Convertible Notes, Exchangeable Notes and Delayed Draw Term Loan*

The fair values of the 4.25% Convertible Notes, the Exchangeable Notes and the Delayed Draw Term Loan (as defined below in Note 12, *Debt and Lines of Credit*) were estimated using the (i) terms of the agreements; (ii) rights, preferences, privileges, and restrictions of the underlying security; (iii) time until any restriction(s) are released; (iv) fundamental financial and other characteristics of the Company; (v) trading characteristics of the underlying security (exchange, volume, price, and volatility); (vi) valuation of derivative liability; and (vii) precedent sale transactions.

*Derivative Liability*

The fair value of the derivative liability was determined using a "with and without" conversion scenario. Under this methodology, valuations are performed on the 4.25% Convertible Notes inclusive of all terms as well as for a convertible note that has identical terms and features but excluding the conversion option. The difference between the two valuations is equal to the fair value of the conversion option. Significant increases or decreases in these inputs would result in a significant change in the fair value of the derivative liability.

*Contingent Consideration*

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

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

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

*Treximet Secured Notes*

The fair value of the Company's 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 higher (lower) fair value measurement.

Within the hierarchy of fair value measurements, the fair values of the convertible notes, Exchangeable Notes and Delayed Draw Term Loan, 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, 2017 and 2016 (in thousands).

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Derivative liability:		
Balance at beginning of year	\$ 230	\$ 9,165
Partial conversion	(90)	-
Remeasurement adjustments - loss (gains) included in earnings	(47)	(8,935)
Ending balance	<u>\$ 93</u>	<u>\$ 230</u>
Contingent consideration:		
Balance at beginning of year	\$ 2,403	\$ 14,055
Remeasurement adjustments - loss (gains) included in earnings	(1,045)	(11,652)
Ending balance	<u>\$ 1,358</u>	<u>\$ 2,403</u>

#### **Note 4. Business Combinations/ Divestitures and Other Acquisitions**

##### *Sale of Non-Core Assets*

On November 6, 2017 the Company announced the sale of a non-core product, Cedax (ceftibuten capsules and ceftibuten for oral suspension), a third-generation cephalosporin antibiotic for the treatment of acute bacterial exacerbations of chronic bronchitis and middle ear infection, to SI Pharmaceuticals, LLC, for \$2.0 million in gross cash proceeds. Cedax was discontinued by Permex in 2016 and the Company has not generated any sales from this product in 2017. This was recorded in the gain on sale of assets line on the consolidated statement of operations and comprehensive loss.

##### *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.

##### *Treximet Acquisition*

On August 20, 2014, the Company, through a wholly owned subsidiary PIL, formerly known as Worriqan 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.

Treximet is a medication indicated for the acute treatment of migraine pain and inflammation. In June 2003, POZEN Inc. (now Aralez Pharmaceuticals, Inc. (Aralez)), 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, Aralez sold most of the future royalty and milestone payments covering Treximet sales in the U.S. to CPPIB Credit Investments Inc. ("CPPIB"). Treximet was covered by three patents in the U.S. which expired August 14, 2017. In addition, the Company received pediatric exclusivity which provided an additional six months of market exclusivity in the U.S.

In connection with the transaction, GSK assigned to PIL the Product Development and Commercialization Agreement, (the PDC Agreement) between GSK and Aralez. 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 Aralez 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 was 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 Aralez 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):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Trade accounts receivable	\$ 45,752	\$ 50,532
Less allowance for prompt pay discounts	(846)	(1,038)
Less allowance for doubtful accounts	(15)	(500)
Total trade receivables, net	<u>44,891</u>	<u>48,994</u>
Receivables from third parties	118	1,200
Other miscellaneous receivables	308	535
Total accounts receivable, net	<u>\$ 45,317</u>	<u>\$ 50,729</u>

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. Inventory**

Inventories consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Raw materials	\$ 727	\$ 2,365
Work-in-process	238	-
Finished goods	5,889	7,393
Inventory, gross	6,854	9,758
Reserve for obsolescence	(1,458)	(1,983)
Inventory, net	<u>\$ 5,396</u>	<u>\$ 7,775</u>

**Note 7. Property, Plant & Equipment**

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Buildings and improvements	\$ 31	\$ 31
Equipment	495	622
Furniture and fixtures	701	701
Computer software and website	435	447
Total fixed assets	1,662	1,801
Less: accumulated depreciation	(910)	(698)
Total property and equipment	<u>\$ 752</u>	<u>\$ 1,103</u>

Depreciation expense amounted to approximately \$370,000 and \$704,000 for the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017 and December 31, 2016 the Company has classified \$500,000 and \$525,000, respectively, of land as held for sale, which is included in prepaid expenses and other current assets on the consolidated balance sheets. The carrying value reflects the estimated selling price based on market data, which is a Level 2 input. During the years ended December 31, 2017 and December 31, 2016, the Company recorded an impairment loss of \$25,000 and \$47,000, respectively, 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, 2017 and expects it to be sold within one year.

#### Note 8. Goodwill and Intangible Assets

Goodwill consists of the following (in thousands):

	<u>Amount</u>
Balance at December 31, 2015	\$ 54,865
Measurement period adjustments - Zohydro ER	(499)
Goodwill impairment	<u>(23,766)</u>
Balance at December 31, 2016	30,600
Goodwill impairment	<u>(18,500)</u>
Balance at December 31, 2017	<u>\$ 12,100</u>

The Company performs an impairment test of goodwill annually in the fourth quarter. In the fourth quarter of 2017, the Company early adopted ASU 2017-04. See Note 2, *Summary of Significant Accounting Policies and Recent Accounting Pronouncements*, for additional information.

The Company estimates the fair values of its reporting unit using a discounted cash flow model. The discounted cash flow model relies on assumptions regarding revenue growth rates, cost of goods sold, gross margin, projected working capital needs, selling, general and administrative expenses, research and development expenses, capital expenditures, income tax rates, discount rates and terminal growth rates. To estimate fair value, the Company discounts the expected cash flows of its reporting unit. The discount rate the Company uses represents the estimated weighted average cost of capital, which reflects the overall level of inherent risk involved in its reporting unit operations and the rate of return a market participant would expect to earn. To estimate cash flows beyond the final year of its model, the Company estimates a terminal value by applying an in-perpetuity growth assumption and discount factor to determine the reporting unit's terminal value.

The Company forecasted cash flows for its reporting unit and took into consideration economic conditions and trends, estimated future operating results, management's and a market participant's view of growth rates and product lives, and anticipated future economic conditions. Revenue growth rates inherent in these forecasts were based on input from internal and external market research that compare factors such as industry trends and product life-cycles.

The fair value of a reporting unit derived using the above methodology was compared with the carrying value and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value.

During the Company's annual impairment test, carrying value of the reporting unit exceeded its fair value by \$18.5 million for the year ended December 31, 2017 and accordingly an impairment charge of \$18.5 million was recorded. The decline in the estimated fair value of the reporting unit resulted from management's review of its then-current forecast. As a result of this review, management lowered its forecast for Zohydro ER. The lower projected operating results reflected changes in assumptions related to revenue, market trends, cost structure, and other expectations about the anticipated short-term and long-term operating results of the business.

During the year ended December 31, 2016, \$23.8 million impairment charge for goodwill was recorded. The decline in the estimated fair value of the reporting unit resulted from management's review of its then-current forecast. As a result of this review, management lowered its forecast for Zohydro ER. Additionally, forecast for Treximet was lowered resulting from anticipated patent expiration. The lower projected operating results reflected changes in assumptions related to revenue, market trends, cost structure, and other expectations about the anticipated short-term and long-term operating results of the business.

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

<b>As of December 31, 2017</b>					
	<b>Weighted Average Life Remaining</b>	<b>Gross Carrying</b>		<b>Accumulated</b>	<b>Net Carrying</b>
		<b>Amount</b>	<b>Impairment</b>	<b>Amortization</b>	<b>Amount</b>
Unamortized intangible assets:					
In-process research and development	Indefinite	\$ 11,000	\$ -	\$ -	\$ 11,000
Total unamortized intangible assets		<u>11,000</u>	<u>-</u>	<u>-</u>	<u>11,000</u>
Amortized intangible assets:					
Product licenses	5.4 years	2,846	-	(1,623)	1,223
Supplier contracts	3.3 years	583	-	(194)	389
Acquired developed technologies	13.7 years	364,686	-	(280,692)	83,994
Total amortized intangible assets		<u>368,115</u>	<u>-</u>	<u>(282,509)</u>	<u>85,606</u>
Total intangible assets		<u>\$ 379,115</u>	<u>\$ -</u>	<u>\$ (282,509)</u>	<u>\$ 96,606</u>

<b>As of December 31, 2016</b>					
	<b>Weighted Average Life Remaining</b>	<b>Gross Carrying</b>		<b>Accumulated</b>	<b>Net Carrying</b>
		<b>Amount</b>	<b>Impairment</b>	<b>Amortization</b>	<b>Amount</b>
Unamortized intangible assets:					
In-process research and development	Indefinite	\$ 26,500	\$ (15,500)	\$ -	\$ 11,000
Total unamortized intangible assets		<u>26,500</u>	<u>(15,500)</u>	<u>-</u>	<u>11,000</u>
Amortized intangible assets:					
Brand	0.0 years	3,887	(891)	(2,996)	-
Product licenses	5.9 years	2,846	-	(1,232)	1,614
Supplier contracts	4.3 years	583	-	(78)	505
Acquired developed technologies	8.9 years	379,737	(15,052)	(208,233)	156,452
Total amortized intangible assets		<u>387,053</u>	<u>(15,943)</u>	<u>(212,539)</u>	<u>158,571</u>
Total intangible assets		<u>\$ 413,553</u>	<u>\$ (31,443)</u>	<u>\$ (212,539)</u>	<u>\$ 169,571</u>

As of December 31, 2017, the weighted average life for the Company's definite-lived intangible assets in total was approximately 12 years.

In connection with the acquisition of the Zohydro ER acquisition, 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.

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 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 related to Zohydro), \$891,000 against brands, and \$15.1 million against acquired developed technologies. The Company determined that there was no impairment of its intangible assets in 2017.

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

	<u>Amount</u>
2018	\$ 13,936
2019	5,507
2020	5,420
2021	5,325
2022	5,286
Thereafter	<u>50,132</u>
Total	<u>\$ 85,606</u>

Amortization expense was \$73.0 million for the year ended December 31, 2017, of which, \$119,000, is included in the cost of product sales. Amortization expense was \$85.5 million for the year ended December 31, 2016 of which, \$77,000 is included in the cost of product sales.

**Note 9. Accrued Allowances**

Accrued allowances consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Accrued returns allowance	\$ 21,681	\$ 18,314
Accrued managed care rebates	17,221	21,374
Accrued price adjustments	10,766	13,860
Accrued government program rebates	6,641	7,413
Total	<u>\$ 56,309</u>	<u>\$ 60,961</u>

**Note 10. Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Due to third parties (revenue sharing arrangements)	\$ 5,812	\$ 5,402
Other accrued expenses	1,097	3,309
Total	<u>\$ 6,909</u>	<u>\$ 8,711</u>

**Note 11. Other Liabilities**

Other liabilities consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Settlement obligations (see Note 18)	\$ 4,335	\$ 7,783
Deferred revenue	252	283
Other	582	1,658
Total contracts payable and other obligations	<u>5,169</u>	<u>9,724</u>
Less current portion	<u>(2,648)</u>	<u>(5,224)</u>
Other liabilities - long-term	<u>\$ 2,521</u>	<u>\$ 4,500</u>



## Note 12. Debt and Lines of Credit

Debt consists of the following, net of discounts and deferred financing costs (in thousands):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
4.25% Convertible Notes	\$ 65,732	\$ 104,071
Exchangeable Notes	8,275	-
Delayed Draw Term Loan	27,897	-
Treximet Secured Notes	167,551	183,353
Wells Fargo Credit Facility	-	14,000
ABL Credit Agreement	14,185	-
Total outstanding debt	<u>283,640</u>	<u>301,424</u>
Less current portion	<u>3,664</u>	<u>11,103</u>
Long term debt outstanding	<u>\$ 279,976</u>	<u>\$ 290,321</u>

The following table represents, by year, the future maturity schedule of the outstanding debt and line of credit as of December 31, 2017 (in thousands):

	<b>Amount</b>
2018	\$ 5,373
2019	-
2020	166,697
2021	78,225
2022	79,928
Thereafter	-
Total maturities	<u>330,223</u>
Less:	
Note discount	(35,423)
Deferred financing costs	(11,160)
Total outstanding debt	<u>\$ 283,640</u>

Interest expense amounted to \$37.0 million and \$37.9 million for the years ended December 31, 2017 and 2016, respectively.

### **Convertible Notes:**

#### *4.25% Convertible Notes*

On April 22, 2015, the Company issued \$130.0 million aggregate principal amount 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 4.25% Convertible Notes are governed by the terms of an indenture (the 4.25% Convertible Notes Indenture), between the Company and Wilmington Trust, National Association (the 4.25% Convertible Notes 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 1-for-10 reverse stock split effected on October 13, 2016, 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 Accounting Standards Codification (ASC) 815, Derivatives and Hedging. During April 2015, the Company recorded the bifurcated conversion option valued at \$28.5 million as a derivative liability, which created 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 \$93,000 and \$230,000 as of December 31, 2017 and 2016, 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 \$7.9 million and \$9.1 million for the years ended December 31, 2017 and 2016, respectively, related to the 4.25% Convertible Notes. Change in fair value of derivative liability was income of \$47,000 and \$8.9 million for the years ended December 31, 2017 and 2016, respectively. Accrued interest on the 4.25% Convertible Notes was approximately \$831,000 and \$1.4 million for the years ended December 31, 2017 and 2016, respectively. The Company initially recorded debt issuance costs of \$5.0 million, which were being amortized using the effective interest method. As a result of the debt restructure in July 2017, \$1.4 million of these debt issuance costs were extinguished and the remaining amortizable debt issuance costs as of July 21, 2017 were reduced to \$2.2 million and are being amortized using the effective interest method. As of December 31, 2017, \$538,000 and \$1.4 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Convertible Notes - long-term, respectively. As of December 31, 2016, \$705,000 and \$3.3 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Convertible Notes - long-term, respectively. As of December 31, 2017 and 2016, the Company had outstanding borrowings of \$78.2 million and \$130.0 million, respectively, related to the 4.25% Convertible Notes.

The Company recorded \$14.7 million as gain from exchange of debt for the year ended December 31, 2017 (See table below).

4.25% Convertible Notes:

Principal	\$	51,775
Deferred financing costs		(1,452)
Debt discount		(8,146)
Derivative liability		90
Exchangeable Notes:		
Principal		(36,243)
Debt discount		25,091
Fair value of conversion option		(12,690)
Issuance of 1.1 million shares		(3,775)
Net Gain on Extinguishment	\$	<u>14,650</u>

## *Exchangeable Notes*

On July 20, 2017, the Company entered into an exchange agreement (the Exchange Agreement) with certain holders of its 4.25% Convertible Notes pursuant to which \$51.8 million of aggregate principal amount of its 4.25% Convertible Notes held by such holders were exchanged for (i) \$36.2 million aggregate principal amount of 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes), issued by PIP DAC (formerly Pemix Ireland Pain Limited, or PIPL), a wholly-owned subsidiary of the Company, pursuant to an Indenture, dated July 21, 2017 (the New Notes Indenture), among PIP DAC, the guarantors party thereto (the Guarantors), and Wilmington Trust, National Association, as Trustee and (ii) 1,100,498 shares of the Company's common stock.

The Exchangeable Notes issued under the New Notes Indenture are guaranteed by the Company and each other subsidiary thereof. The Exchangeable Notes are senior, unsecured obligations of PIP DAC. Interest on the Exchangeable Notes will be paid in cash or a combination of cash and in-kind interest at PIP DAC's election. Interest paid in cash (the "All Cash Method") will accrue at a rate of 4.25% per annum, while interest paid in a combination of cash and in-kind will accrue at a rate of 5.25% per annum, with 2.25% per annum (plus additional interest, if any) capitalized to the principal amount of the Exchangeable Notes, and the balance paid in cash. The maturity date of the Exchangeable Notes Indenture is July 15, 2022.

The Exchangeable Notes initially are exchangeable into shares of the Company's common stock at an exchange price per share of \$5.50 (the Exchange Price). The Exchange Price will be subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of certain stock dividends on the Company's common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, the payment of cash dividends and certain Company tender or exchange offers.

Holders will exchange all or a portion of their Exchangeable Notes at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date.

Upon not less than 30 nor more than 45 trading days' notice, if the daily Volume Weighted Average Price (VWAP) (as defined in the Exchangeable Notes Indenture) of the Company's common stock has been at least 120% of the Exchange Price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which such notice of redemption is provided (the "Provisional Redemption", and such date of a Provisional Redemption, the "Redemption Date"), the Company will have the right to redeem any or all of the Exchangeable Notes at a price equal to 100% of the principal amount thereof (including any interest capitalized thereto) plus accrued interest that has not been paid or capitalized to, but excluding, the date on which the Exchangeable Notes are to be redeemed. The redemption price will be paid in cash.

No "sinking fund" will be provided for the Exchangeable Notes, which means that PIP DAC will not be required to periodically redeem or retire the Exchangeable Notes. If PIP DAC or the Company undergoes a Fundamental Change (as defined below), subject to certain conditions, holders of the Exchangeable Notes may require PIP DAC to repurchase for cash all or part of their Exchangeable Notes. The fundamental change repurchase price will be equal to 100% of the principal amount (including any interest capitalized thereto) of the Exchangeable Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the date, chosen by PIP DAC, that is not less than 20 business days or more than 35 business days following the date on which notice of the Fundamental Change was provided by PIP DAC.

Under the Exchangeable Notes Indenture, a "Fundamental Change" will be deemed to have occurred if, among other events, any of the following occurs: (i) any "group" or "person," within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), other than a permitted holder under the Exchangeable Notes Indenture, becomes the direct or indirect "beneficial owner," as defined in Rule 13d-3 under the Exchange Act, of the Company's common stock representing more than 50% of the Company's voting power; (ii) the Company consummates any recapitalization, reclassification or change of the Company's common stock, subject to certain exceptions as contained in the Exchangeable Notes Indenture; (iii) the Company effects any share exchange, consolidation or merger pursuant to which the Company's common stock will be converted into cash, securities or other property or assets; (iv) the Company effects any sale, lease or other transfer in one transaction or a series of transactions of all or substantially all of the Company's consolidated assets to a person or entity other than a permitted holder under the Exchangeable Notes Indenture; (v) the Company's stockholders approve a plan or proposal for the Company's liquidation or dissolution or the liquidation or dissolution of PIP DAC; and (vi) the Company's common stock ceases to be listed on The New York Stock Exchange, The Nasdaq Global Select Market or The Nasdaq Global Market (or any of their respective successors).

Holders of the Exchangeable Notes are entitled to receive, in certain circumstances, additional shares of the Company's common stock upon exchanges of Exchangeable Notes in connection with a Provisional Redemption or certain Fundamental Changes.

Subject to certain limited exceptions, the Exchangeable Notes contain covenants which prohibit or limit the ability of PIP DAC and the Guarantors to, among other things: (i) pay cash dividends or making distributions on the Company's capital stock or redeem or repurchase the Company's capital stock; (ii) create, assume or suffer to exist at any time any lien upon any of the Company's properties or assets; (iii) incur any debt other than debt permitted under the terms of the Exchangeable Notes Indenture; (iv) enter into transactions with affiliates other than on terms and conditions that, taken as a whole, would be obtained in an arm's-length transaction with non-affiliates; and (v) make any sale of the Company's assets and the assets of the Company's subsidiaries except in accordance with the terms of the Exchangeable Notes Indenture.

The Exchangeable Notes Indenture provides for customary events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving PIP DAC) occurs and is continuing, the Trustee by notice to PIP DAC, or the holders of at least 25% in principal amount of the then outstanding Exchangeable Notes by written notice to PIP DAC and the Trustee, may declare 100% of the accreted principal of and accrued and unpaid interest, if any, on all of the Exchangeable Notes to be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving PIP DAC, 100% of the principal of and accrued and unpaid interest, if any, on all of the Exchangeable Notes will become due and payable automatically, including a make-whole premium in an amount equal to the present value of the interest that would accrue on such Exchangeable Notes (assuming the All Cash Method) from, and including, such date of acceleration until the maturity date of the Exchangeable Notes, with such present value computed using a discount rate equal to the sum of (i) the yield to maturity of United States Treasury securities with remaining maturity equal to that of the Exchangeable Notes (as determined in a commercially reasonable manner by PIP DAC) on such date of acceleration and (ii) 50 basis points. Notwithstanding the foregoing, for up to 270 days after the occurrence of an event of default, PIP DAC may elect to have the sole remedy for an event of default relating to certain of PIP DAC's failures to comply with certain reporting covenants in the Exchangeable Notes Indenture consist exclusively of the right to receive additional interest on the Exchangeable Notes.

Holders of Exchangeable Notes will not be entitled to receive shares of the Company's common stock upon exchange of any Exchangeable Notes to the extent such holder (or group of which such holder is a part) would beneficially own more than 9.99% of the outstanding shares of the Company's common stock. Subject to such limitation, at the initial Exchange Price, the Exchangeable Notes will be exchangeable into approximately 40% of the Company's outstanding common stock as of the date hereof (after giving effect to the issuance of the Exchange Shares and the common stock underlying the Exchangeable Notes).

The Exchange allowed the Company to reduce the principal amount of its outstanding indebtedness through the exchange of the Holders' 4.25% Convertible Notes for a smaller principal amount of the Exchangeable Notes. The principal amount of the Exchangeable Notes may be reduced if the holders thereof exchange their Exchangeable Notes for shares of the Company's common stock. The Exchangeable Notes Indenture will provide capacity to refinance up to an additional \$25.0 million principal amount of the 4.25% Convertible Notes, which refinancing could also provide an opportunity to further reduce the principal amount of the Company's outstanding indebtedness.

The outstanding borrowings of the Exchangeable Notes were paid down by \$500,000 in November 2017 with a portion of the proceeds from the sale of non-core assets (see Note 4, *Business Combinations/Divestitures and Other Acquisitions*). Interest expense was \$1.4 million and \$0 for the years ended December 31, 2017 and 2016, respectively, related to the Exchangeable Notes. Accrued interest on the Exchangeable Notes was approximately \$675,000 and \$0 as of December 31, 2017 and 2016, respectively. The Company recorded debt issuance costs of \$3.5 million, which are being amortized using the effective interest method. As of December 31, 2017, \$300,000 and \$3.1 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Exchangeable Notes - long-term, respectively. As of December 31, 2017 and December 31, 2016, the Company had outstanding borrowings of \$35.7 million and \$0, related to the Exchangeable Notes, respectively.

**Term Facility:**

PIP DAC entered into a term loan credit agreement (the Delayed Draw Term Loan or DDTL) with Cantor Fitzgerald Securities, as agent (the Term Agent) and the lenders party thereto to obtain the DDTL. \$30.0 million under the DDTL was drawn on the date of closing of the Transactions, and the remaining \$15.0 million will be available for subsequent draws for certain specified purposes, including to finance certain acquisitions, subject to conditions set forth in the Term Credit Agreement. The DDTL includes an incremental feature that allows PIP DAC, with the consent of the requisite lenders under the Term Facility, to obtain up to an additional \$20.0 million in term loan commitments from new or existing lenders under the DDTL that agree to provide such commitments. Interest on the loans will accrue either in cash or a combination of cash and

in kind interest, at PIP DAC's election. Cash interest will accrue at a rate of 7.50% per annum, while the combination of cash and in-kind interest will accrue at a rate of 8.50% per annum, with up to 4.00% per annum added to the principal amount of loans and the balance paid in cash. The DDTL contains representations and warranties, affirmative and negative covenants, and events of default applicable to PIP DAC and its subsidiaries (if any) that are customary for credit facilities of this type. The DDTL will mature on July 21, 2022.

PIP DAC also entered into a mortgage debenture with Cantor Fitzgerald Securities as agent, pursuant to which PIP DAC's obligations under the DDTL will be secured by substantially all of the assets of PIP DAC and its future-acquired subsidiaries.

Interest expense was \$1.1 million and \$0 for the years ended December 31, 2017 and 2016, respectively, related to the DDTL. Accrued interest on the DDTL was \$484,000 and \$0, for the years ended December 31, 2017 and December 31, 2016, respectively. The Company recorded debt issuance costs of \$3.0 million, which are being amortized using the effective interest method. As of December 31, 2017, \$649,000 and \$2.1 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Delayed draw term loan - long-term, net, respectively. As of December 31, 2017 and 2016, the Company had outstanding borrowings of \$30.0 million and \$0, respectively, related to the DDTL.

#### **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 "Treximet 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 began paying installments of principal of the Treximet Secured Notes in an amount equal to 50% of net sales of Treximet for the two consecutive fiscal quarters immediately preceding such Payment Date (less the amount of interest paid on the Treximet Secured Notes on such Payment Date). At each month-end beginning with January 2015, the net sales of Treximet will be calculated, the monthly interest accrual amount will then be deducted from the net sales and this resulting amount will be recorded as the current portion of the Treximet Secured Notes. If the Treximet net sales less the interest due at each month-end of each six-month period does not result in any excess over the interest due, no principal payment must be paid at that time. The remaining balance outstanding on the Treximet Secured Notes will be due on the maturity date, which is August 1, 2020. As of December 31, 2017 and 2016, the Company had current outstanding borrowings of \$5.4 million and \$12.8 million, respectively, of the Treximet Secured Notes and \$166.7 million and \$176.8 million as non-current outstanding borrowings, respectively.

The Treximet Secured Notes are unconditionally guaranteed, jointly and severally, by the Treximet Guarantors. The Treximet Secured Notes and the guarantees of the Treximet Guarantors are secured by a continuing first-priority security interest in substantially all of the assets of the Company and the Treximet 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 would have been equal to 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.

The August 2014 Indenture contains covenants that limit the ability of the Company and the Treximet 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 Treximet 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 Treximet 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 Treximet 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 Treximet 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 Treximet 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 Treximet Guarantor disaffirms its obligations under its guarantee of the Treximet Secured Notes; and (i) certain changes in control of a Treximet Guarantor.

Interest expense related to the Treximet Secured Notes was \$21.1 million and \$23.3 million for the years ending December 31, 2017 and 2016, respectively. Accrued interest on the Treximet Secured Notes was approximately \$8.6 million and \$9.5 million as of December 31, 2017 and 2016, respectively. The Company recorded debt issuance costs of \$7.8 million, which are being amortized using the effective interest method. As of December 31, 2017, \$1.3 million and \$2.1 million are recorded on the consolidated balance sheet in Treximet Secured Notes - current and Treximet Secured Notes - long-term, respectively. 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.

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 remaining unamortized cost of inducement of \$403,000 and \$672,000 is recorded Treximet Secured Notes - current and Treximet Secured Notes - long term on the consolidated balance sheet at December 31, 2017, respectively and \$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 are being amortized using the straight-line method, which approximates the effective interest method.

#### *Third Supplemental Indenture*

On December 29, 2017, "the Company and U.S. Bank National Association, as trustee, entered into a third supplemental indenture (the Third Supplemental Indenture) to that certain indenture dated as of August 19, 2014, as amended and supplemented from time to time (the "Senior Secured Notes Indenture") with the consent of the holders of a majority in aggregate principal amount of its outstanding 12.0% Senior Secured Notes due 2020 issued under the Senior Secured Notes Indenture. The Third Supplemental Indenture amends the Senior Secured Notes Indenture to clarify the definition of "Net Sales", as such term is defined in the Senior Secured Notes Indenture and resulted in the deferral of \$3.2 million of principal payments until maturity of the notes.

***Credit Facility:***

*Cantor Fitzgerald*

On July 21, 2017, Pemix and certain subsidiaries of Pemix as borrowers and guarantors (the "ABL Borrowers") and PIP DAC, PIL Pemix Holdco 1, LLC, Pemix Holdco 2, LLC and Pemix Holdco 3, LLC as additional guarantors (the ABL Guarantors), entered into an asset-based revolving credit agreement (the ABL Credit Agreement) with Cantor Fitzgerald Securities, as agent (the ABL Agent) and the lenders party thereto to obtain the ABL Credit Agreement.

The ABL Borrowers' obligations under the ABL Credit Agreement are guaranteed by the ABL Borrowers and the ABL Guarantors are secured by, among other things, the ABL Borrowers' cash, inventory and accounts, in each case pursuant to a guaranty and security agreement between the ABL Borrowers, ABL Guarantors and Cantor Fitzgerald Securities as agent. Availability of borrowings under the ABL Credit Agreement from time to time will be subject to a borrowing base calculation based upon a valuation of the ABL Borrowers' eligible inventories and eligible accounts receivable, each multiplied by an applicable advance rate, subject to adjustments in accordance with the ABL Credit Agreement. Borrowings under the ABL Credit Agreement will bear interest at the rate of LIBOR plus 7.50%. In addition, the ABL Borrowers will be required to pay a commitment fee on the undrawn commitments under the ABL Credit Agreement from time to time at a rate per annum of 0.25% on the unused commitments under the ABL Credit Agreement, payable monthly. The ABL Credit Agreement contains representations and warranties, affirmative and negative covenants, and events of default applicable to the Company, the other ABL Borrowers, the ABL Guarantors and their respective subsidiaries that are customary for credit facilities of this type. The ABL Credit Agreement will mature on July 21, 2022. As of December 31, 2017 the effective interest rate on this facility was 13.6% and the Company has borrowing availability of \$24.8 million under its \$40.0 million ABL Credit Agreement.

Interest expense was \$597,000 and \$0 for the years ended December 31, 2017 and 2016, respectively, related to the ABL Credit Agreement. Accrued interest on the ABL Credit Agreement was approximately \$19,000 and \$0 as of December 31, 2017 and December 31, 2016, respectively. The Company recorded debt issuance costs of \$2.9 million, which are being amortized using the effective interest method. As of December 31, 2017, \$581,000 and \$2.1 million are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Other assets, respectively. As of December 31, 2017 and 2016, the Company had outstanding borrowings of \$14.2 million and \$0, respectively, related to the ABL Credit Agreement.

*Wells Fargo*

On August 21, 2015, the Company entered into the Credit Agreement with 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.

The ABL Credit Facility entered into on July 21, 2017 replaced the Wells Fargo Credit Facility and the Company used the proceeds from the ABL Credit Facility to repay the outstanding obligation of the Wells Fargo Credit Facility.

The Company's obligations under the Wells Fargo Credit Facility were secured by, among other things, the Company's and certain subsidiaries' inventory and accounts receivable, and were guaranteed by certain of the Company's subsidiaries. As of December 31, 2017 and 2016, \$0 and \$14.0 million was outstanding under the Wells Fargo Credit Facility, respectively. The \$14.0 million outstanding at December 31, 2016 was classified as Credit facilities - long-term on the consolidated balance sheet. The Wells Fargo Credit Facility contained representations and warranties, affirmative, restrictive and financial covenants, and events of default (applicable to the Company and certain of its subsidiaries) which were customary for a credit facility of this type.

On April 18, 2017, the Borrowers entered into the Amendment with Wells Fargo and the lenders party thereto. The Amendment amends the Credit Agreement governing the Wells Fargo Credit Facility.

Pursuant to the Amendment, the Base Rate Margin (as defined in the Credit Agreement) was increased from 1.00% to 3.00% and the LIBOR Rate Margin (as defined in the Credit Agreement) was increased from 2.00% to 4.00%, in each case effective as of the date of the Amendment. The Company has previously disclosed that it was reviewing its strategic alternatives, including the potential sale of all or a portion of the Company. Consistent with this prior disclosure, the Borrowers agreed to market their businesses and assets for sale. Further, as the Company intended to transition to another financing source on or before July 31, 2017, it also agreed that a failure to repay all borrowings under the Credit Agreement on or before July 31, 2017 would constitute an event of default under the Credit Agreement. Furthermore, the Amendment reduced the lenders' commitment to \$14.2 million, the amount outstanding under the facility on the date of the Amendment (inclusive of a portion of the fee described below), and eliminated the ability to request letters of credit thereunder.

The Amendment also amended certain of the covenants with which the Borrowers must comply under the Credit Agreement. The Amendment replaced the financial covenant in the Credit Agreement with (i) the requirement to maintain a cash balance of at least \$8.0 million, tested weekly, and (ii) the requirement that the Borrowing Base (as defined in the Credit Agreement), less the principal amount of all loans outstanding, be greater than \$15.0 million from and after the date that is 30 days after the effective date of the Amendment. The Amendment also provides Wells Fargo, as Administrative Agent, with certain additional information rights and appraisal rights. In addition, Wells Fargo agreed to not impose certain reserves upon the Borrowing Base in connection with the previously disclosed arbitral award made to GSK. The Borrowers paid to Wells Fargo a fee of \$140,000 in connection with the execution of the Amendment.

Interest expense related to the Wells Fargo Credit Facility was \$378,000 and \$346,000 for the years ended December 31, 2017 and 2016, respectively. Accrued interest on the Wells Fargo Credit Facility was approximately \$0 and \$37,000 as of December 31, 2017 and 2016, respectively. The Company recorded debt issuance costs of \$270,000 as a result of the original agreement and an additional \$220,000 as a result of the Amendment, both of which were amortized using the effective interest method. As of December 31, 2017, \$0 is recorded on the consolidated balance sheet. As of December 31, 2016, \$90,000 and \$60,000 are recorded on the consolidated balance sheet in Prepaid expenses and other current assets and Other assets, respectively. Due to the Amendment discussed above, the Company accelerated the amortization of the remaining debt issuance costs in the quarter ended June 30, 2017.

### **Note 13. 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.

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.

#### *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, 2017, the Company sold 680,926 shares of common stock under the Sales Agreement at an average price of approximately \$3.05 per share for gross proceeds of \$2.1 million and net proceeds of \$2.0 million, after deducting Cantor's commission. As of December 31, 2017, approximately \$77.5 million of common stock remained available to be sold under this facility, subject to certain limitations to the extent the Company continues to have a public float of less than \$75 million.



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 \$19.7 million, after deducting Cantor's commission.

*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, 2017, the Company has 32,992 outstanding warrants in connection with these warrants.

*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 14. 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, 2017 and 2016, 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 December 31, 2017 and 2016:

<b>Gross Product Sales</b>	<u><b>2017</b></u>	<u><b>2016</b></u>
McKesson Corporation	34%	36%
AmerisourceBergen Drug Corporation	30%	31%
Cardinal Health, Inc.	<u>24%</u>	<u>26%</u>
Total	<u><u>88%</u></u>	<u><u>93%</u></u>

<b>Accounts Receivable</b>	<u><b>2017</b></u>	<u><b>2016</b></u>
Cardinal Health, Inc.	31%	28%
McKesson Corporation	29%	36%
AmerisourceBergen Drug Corporation	<u>27%</u>	<u>28%</u>
Total	<u><u>87%</u></u>	<u><u>92%</u></u>

**Note 15. 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 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 Pemix generates. Alternatively, Pemix 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. 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, 2017 and 2016, the Company recognized approximately \$22.2 million and \$18.2 million, respectively, in expense included in cost of goods sold from payments pursuant to co-promotion and other revenue sharing arrangements. Co-promotion, royalty and other revenues were \$321,000 and \$466,000 for the years ended December 31, 2017 and 2016, respectively.

In connection with the acquisition of Treximet, the Company is responsible for the payment of royalties to Aralez of 18% of net sales or lower under certain circumstances, with quarterly minimum royalty amounts of \$4.0 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018.

In connection with the acquisition of Zohydro, the Company is responsible for the payment of royalties to Recro of 6% of net sales.

#### **Note 16. 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, 2017 and 2016, the Company matched 100% of employee contributions up to 3% of employee pre-tax contributions and 50% of employee contributions 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 \$1.1 million and \$950,000 for the years ended December 31, 2017 and 2016, respectively.

In November 2017, the Company's shareholders approved the 2017 Omnibus Incentive Plan (the 2017 Plan). Subject to the adjustments described below, the maximum number of shares of the Company's common stock that will be available for issuance under the 2017 Omnibus Incentive Plan will be equal to the sum of (i) one million (1,000,000) shares of the Company's common stock plus (ii) the number of shares of our common stock available for future awards under the 2015 Omnibus Incentive Plan and the 2009 Stock Incentive Plan as of November 15, 2017, plus (iii) the number of shares of the Company's common stock related to awards outstanding under such plans as of November 15, 2017 that terminate after such date by expiration or forfeiture, cancellation, or otherwise without the issuance of such shares of the Company's common stock. Any or all shares of our common stock available for issuance under the 2017 Omnibus Incentive Plan will be available for issuance pursuant to incentive stock options. The following type of awards may be made under the 2017 Omnibus Incentive Plan, subject to the limitations set forth in the plan: stock options, which may be either incentive stock options or non-qualified stock options; restricted stock; restricted stock units and deferred stock units; performance shares or other performance-based awards; dividend equivalent rights; stock appreciation rights (SARs); other equity-based awards, including unrestricted stock; and cash awards. Following stockholder approval of the 2017 Omnibus Incentive Plan on November 15, 2017, no additional awards will be made under the existing equity incentive plans.

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.

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, 2017, the 2007 Plan has 2,700 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:

	<u>Year ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
Weighted average expected stock price volatility	87.2 %	77.9 %
Estimated dividend yield	- %	- %
Risk-free interest rate	2.1 %	1.4 %
Expected life of option (in years)	6.2	6.1
Weighted average grant date fair value per option	\$ 2.17	\$ 7.63

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 \$2.5 million and \$2.7 million for the years ended December 31, 2017 and 2016, 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, 2017, approximately 1,042,000 options are outstanding that have been issued to current officers and employees under the 2007 Plan, the 2009 Plan, the 2015 Plan and the 2017 Plan. As of December 31, 2017, there was approximately \$2.3 million of total unrecognized compensation cost related to non-vested stock options issued to employees and directors of the Company, which is expected to be recognized ratably over a weighted-average period of 1.9 years.

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, 2017 and 2016, the Company recorded \$0 and \$35,000, 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, 2017 (share and intrinsic values in thousands):

	<u>Shares</u>	<u>Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (years)</u>	<u>Aggregate Intrinsic Value</u>
Options Outstanding at December 31, 2016	650	\$ 25.85	9.0	\$ -
Granted	502	2.92		
Exercised	-	-		-
Cancelled	(110)	35.21		
Expired	-	-		
Options outstanding at December 31, 2017	<u>1,042</u>	\$ 13.80	8.8	\$ 3,178
Options vested and expected to vest as of December 31, 2017	725	\$ 18.07	8.5	\$ 1,759
Options vested and exercisable as of December 31, 2017	315	\$ 25.30	8.0	\$ -

The total intrinsic value of options exercised during the years ended December 31, 2017 and 2016 was \$0 and \$0, 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 Units*

The following table shows the Company's non-vested restricted stock units activity during the year ended December 31, 2017 (share and intrinsic values in thousands):

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>	<u>Aggregate Intrinsic Value</u>
Non-vested restricted stock outstanding at December 31, 2016	197	\$ 3.36	
Granted	60	2.82	
Vested	(116)	3.33	\$ 327
Forfeited	(6)	2.78	
Non-vested restricted stock outstanding at December 31, 2017	<u>135</u>	\$ 3.17	

The total intrinsic value of restricted stock vested during the years ended December 31, 2017 and 2016 was \$327,000 and \$63,000, respectively.

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

As of December 31, 2017, there was approximately \$169,000 of total unrecognized compensation cost related to non-vested restricted stock issued to employees and directors of the Company.

## Employee Stock Purchase Plan

Effective July 22, 2010, the Company adopted the 2010 Employee Stock Purchase Plan to provide substantially all employees an opportunity to purchase shares of its common stock through payroll deduction, up to 10% of eligible compensation with a \$25,000 maximum annual deferral. Semi-annually (on May 1 and November 1), participant account balances will be used to purchase shares of stock at the lesser of 85 percent of the fair market value of shares at the beginning or end of such six-month period. The Employee Stock Purchase Plan expires on July 22, 2020. A total of 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 \$0 and \$29,000 for the years ended December 31, 2017 and 2016, 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.

### Note 17. Income Taxes

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (H.R. 1) (the "Act"). The Act includes a number of changes in existing tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from 35% to 21%. The rate reduction takes effect on January 1, 2018. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period in which the new legislation is enacted. In the case of US federal income taxes, the enactment date is the date the bill becomes law (i.e., upon presidential signature). The Company does not expect any impact on recorded deferred tax balances, other than the reclassification of an alternative minimum tax credit of \$0.2 million as a recoverable asset (due to changes under the Act), as the remeasurement of net deferred tax assets will be fully offset by a change in valuation allowance having no impact on the Company's financial position or results of operations.

The Act provided for a one-time deemed mandatory repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") through the year ended December 31, 2017, with those earnings taxed at rates of 15.5% for earnings reflected by cash and cash equivalent items and 8% for other assets. Pemix has two wholly owned subsidiaries in Ireland operating under the names Pemix Ireland Limited and Pemix Ireland Pain Designated Activity Company. The Company's Irish subsidiaries have accumulated deficits in earnings and profits and thus the Company is not expecting a tax cost resulting from the deemed repatriation provisions.

The Act creates a new requirement that certain income (i.e., Global intangible low taxed income "GILTI") earned by foreign subsidiaries must be included currently in the gross income of the U.S. shareholder. Due to the complexity of the new GILTI tax rules, the Company is continuing to evaluate this provision of the Tax Act and the application of ASC 740. Under U.S. GAAP, the Company is permitted to make an accounting policy election to either treat taxes due on future inclusions in U.S. taxable income related to GILTI as a current-period expense when incurred or to factor such amounts into the Company's measurement of its deferred taxes. The Company has not yet completed its analysis of the GILTI tax rules and is not yet able to reasonably estimate the effect of this provision of the Tax Act or make an accounting policy election for the ASC 740 treatment of the GILTI tax. Therefore, the Company has not recorded any amounts related to potential GILTI tax in its financial statements and has not yet made a policy decision regarding whether to record deferred taxes on GILTI.

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 as of the year ended December 31, 2017 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, 2017 and 2016 (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Current:		
Federal	\$ 113	\$ 455
State	498	356
Foreign	-	(172)
Total current provision	<u>611</u>	<u>639</u>
Deferred Provision:		
Federal	(238)	(189)
State	-	(11)
Foreign	-	-
Total deferred provision (benefit)	<u>(238)</u>	<u>(200)</u>
Total	<u>\$ 373</u>	<u>\$ 439</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The sources of the temporary differences and their effect on deferred taxes are as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Deferred tax assets:		
Accruals and other reserves	\$ 19,752	\$ 36,064
Intangibles	17,718	4,414
Inventory	504	1,157
Stock awards	3,570	4,531
Net operating loss carryovers	<u>25,030</u>	<u>34,582</u>
Gross deferred tax assets	66,574	80,748
Valuation allowance	<u>(66,560)</u>	<u>(80,725)</u>
Net deferred tax asset	14	23
Deferred tax liabilities:		
Fixed Assets	(14)	(23)
Intangibles	<u>-</u>	<u>-</u>
Gross deferred tax liability	<u>(14)</u>	<u>(23)</u>
Net deferred tax asset/(liability)	<u>-</u>	<u>-</u>
Included in consolidated balance sheet:		
Deferred income tax assets/(liabilities) - current	-	-
Deferred income tax assets/(liabilities) - long-term	<u>-</u>	<u>-</u>
Net deferred tax asset/(liability)	<u>\$ -</u>	<u>\$ -</u>

The Company has federal net operating loss carryforwards (NOL's) of approximately \$61.0 million at December 31, 2017 ranging in expiration from 2032 to 2037. Of this amount, the utilization of approximately \$30.0 million will be subject to annual limitation due to the change in ownership provisions of IRC Section 382 ("382 regulations").

Somaxon has NOL's of approximately \$250.2 million at December 31, 2017 ranging in expiration from 2032 to 2037. However, due to the 382 regulations, \$22.4 million of those NOL are expected to be available for utilization, but subject to an annual limitation.

GTA has federal NOL's of approximately \$85.3 million at December 31, 2017 ranging in expiration from 2032 to 2037. However, due to the 382 regulations, approximately \$0.5 million of those NOL's are expected to be available for utilization.

Somaxon has federal research and development credit carryovers of approximately \$4.5 million at December 31, 2017. However, due to the 382 regulations, approximately \$0.3 million of those credits are expected to be available for utilization.

It should be noted that only those amounts that are available for utilization are included in the gross deferred tax assets (Somaxon and Pemix NOL's noted above).

The effective income tax rate from continuing operations is different from the federal statutory rate for the years ended December 31, 2017 and 2016 for the following reasons:

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Expected taxes at statutory rates	35.0 %	35.0 %
State taxes, net of federal tax benefit	(0.4)%	(0.1)%
Foreign income tax rate differential	(24.1)%	(9.8)%
Amortization and impairment of goodwill	(4.9)%	(8.5)%
Mark to market adjustment	0.3 %	4.2 %
Deductible inducement payment	(1.0)%	3.2 %
Change in valuation allowance	17.3 %	(25.4)%
Debt Reorganization and Exchangeable notes	1.7 %	- %
Revaluation of deferred tax balances	(24.5)	- %
Permanent differences and other	0.1 %	1.1 %
	<u>(0.5)%</u>	<u>(0.3)%</u>

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

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

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Balance at beginning of year	\$ 7,410	\$ 7,410
Tax positions taken in prior periods	(2,514)	-
Tax positions taken in current year	5,347	-
Accrual of interest related to tax positions taken	-	-
Settlements	-	-
Foreign currency translation	-	-
Balance at end of year	<u>\$ 10,243</u>	<u>\$ 7,410</u>

As of December 31, 2017 and 2016, the total amount of gross unrecognized tax benefits was \$10.2 million and \$7.4 million respectively. None of these amounts would impact the effective tax rate as of December 31, 2017 and 2016, respectively, 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. Due to the Company's net operating loss carryforward, interest and penalties related to unrecognized tax benefits have not been accrued to date. For unrecognized tax benefits that existed at December 31, 2017, 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, 2017, the Company's 2014 & 2015 Federal tax returns are under examination by the Internal Revenue Service. Other years subject to examination include 2016 and 2017.

## Note 18. Commitments and Contingencies

### *Legal Proceedings*

#### *GlaxoSmithKline (GSK) Arbitration*

The Company was involved in an arbitration proceeding with GSK. GSK claimed damages relating to an alleged breach by the Company of a covenant pertaining to a pre-existing customer agreement contained in the Asset Purchase and Sale Agreement (ASPA) relative to Treximet. The Company asserted counterclaims and defenses under the APSA and also asserted claims against GSK related to breaches of a supply agreement between the parties. The Company and GSK entered into the Interim Settlement Agreement under which the Company agreed to make payments to GSK and escrow additional funds. Additionally, the parties agreed to submit the matter to binding arbitration.

On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35.0 million, plus interest (estimated to be approximately \$2.0 to \$5.0 million). The tribunal also denied the Company's claim that GSK breached its obligations under the supply agreement. After discussions with GSK, an agreement was reached on March 17, 2017, to amend the Interim Settlement Agreement (Amendment No. 1) whereby the Company agreed to establish a payment schedule for satisfaction of the current balance of the award. The Company had already paid to GSK an aggregate of \$16.5 million, including \$6.2 million from the escrow account, which was to be applied as an offset to the total award. Pursuant to the amendment, the Company agreed that the outstanding balance owing to GSK as of the date of the amendment was approximately \$21.5 million and the Company further 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 our financial statements at December 31, 2016 and 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.

On July 20, 2017, the Company and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 superseded Amendment No. 1 and permitted payment by the Company to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, the Company was obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, the Company agreed that if on or before September 30, 2019, the Company (x) redeems or repurchases its 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchanges such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, the Company shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as the Company complies with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of December 31, 2017, the Company has recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in Arbitration Award on the Company's consolidated balance sheet as of December 31, 2017. Also, the Company recorded \$10.5 million as Gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

*Recro Gainesville LLC v. Actavis Laboratories FL, Inc.*, District of Delaware Case Nos. 14-1118, 15-413, 15-1196, and 17-cv-01535; *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 Orange Book as covering Zohydro ER with BeadTek. Actavis and Alvogen each filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval of proposed generic versions of Zohydro ER with BeadTek 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. The 30-month stay for Actavis expired on February 12, 2017 and on February 22, 2017, the United States District Court for the District of Delaware concluded that Actavis Laboratories FL, Inc.'s proposed generic versions of Zohydro ER with BeadTek infringe U.S. Patent Nos. 9,132,096 (which expires on September 12, 2034) and 6,902,742 (which expires on November 1, 2019). Further, the Court 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 these two patents. On March 22, 2017 Actavis filed an appeal, which was fully briefed as of September 13, 2017. Oral argument in the appeal has not yet been scheduled. On October 30, 2017, Recro brought suit against Actavis for infringement of U.S. Patent No. 9,713,611 ("the '611 Patent"), a continuation of the '096 Patent that issued on July 25, 2017 and was listed in the Orange Book as covering Zohydro ER with BeadTek. Pernix and Actavis entered into a settlement agreement on January 29, 2018 (discussed further in the litigation described immediately below). That settlement agreement resolved the pending disputes between Recro and Actavis.

*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 is the exclusive licensee of the Pernix Zohydro ER Patents and is the sole distributor of Zohydro ER with BeadTek 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 with BeadTek 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 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 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. 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 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's infringement allegations, and raising Counterclaims of non-infringement and invalidity as to each of the asserted Pernix patents. Pernix and Actavis entered into a settlement agreement on January 29, 2018. Under the terms of the agreement, Pernix will grant Actavis a license to begin selling a generic version of Zohydro ER with BeadTek on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER with BeadTek. Trial for the suit against Alvogen is scheduled for June 11, 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, Medicine to Go Pharmacies, Inc. (the Macoven 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, the Company filed an answer in defense of the allegations. The fax campaign that is the subject of this litigation was administered by a third party, Odyssey Services (Odyssey), that was not initially named as a defendant in this litigation. On

June 22, 2017, the Company filed a third-party complaint against Odyssey, seeking indemnity and contribution for any amounts that the Company may be liable to pay to the Macoven Plaintiff. Odyssey has since filed a motion for summary judgment, seeking to dismiss the third-party claims against it. That motion is currently pending before the court. The Company therefore may not be able to secure indemnification from Odyssey for costs that it might incur relative to this matter and insurance defense and indemnity do not appear available to the Company. The Company is still in discovery on this matter and is unable to predict probable outcomes at this time. The Company continues to dispute the Macoven Plaintiff's claims and, based upon known facts, intends to vigorously defend itself against the claims in this litigation.

*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. The Company leases cars for its salesforce. The terms of these leases expire over various dates through 2020.

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 extends 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. As a result of the 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, 2017 (in thousands):

	<u>Amount</u>
2018	\$ 1,620
2019	1,607
2020	679
2021	524
2022	309
Thereafter	-
Total	<u>\$ 4,739</u>

Future minimum lease payment income under non-cancelable operating subleases are as follows as of December 31, 2017 (in thousands):

	<u>Amount</u>
2018	\$ 121
2019	125
2020	-
2021	-
2022	-
Thereafter	-
Total	<u>\$ 246</u>

Total rent expense was approximately \$647,000 and \$760,000 for the years ended December 31, 2017 and 2016, respectively. Total sublease rental income was approximately \$118,000 and \$115,000 for the years ended December 31, 2017 and 2016, 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, 2017, remaining payment obligations owed under these settlement agreements are \$500,000, payable in equal annual installments of \$250,000 through 2019. These settlement agreements are recorded in other liabilities (both current and long-term) on the consolidated balance sheets as of December 31, 2017 and 2016.

#### *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 \$3.8 million and \$5.5 million as of December 31, 2017 and 2016, respectively and is included in other liabilities (both current and long-term) on the consolidated balance sheets.

#### **Note 19. 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 \$88,000 during the twelve months ended December 31, 2017 in contract termination costs associated with the 2016 Restructuring. To date, the Company has incurred \$2.4 million in costs related to the 2016 Restructuring, consisting of \$1.4 million related to employee termination benefits and \$1.0 million related to contract termination costs. All associated contract termination payments are expected to be made by June 30, 2018.

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 payments were 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):

	<u>December 31, 2016</u>	<u>Charges</u>	<u>Cash</u>	<u>Non-cash</u>	<u>December 31, 2017</u>
2016 restructuring costs	\$ 618	\$ 88	\$ (441)	\$ -	\$ 265
Totals	<u>\$ 618</u>	<u>\$ 88</u>	<u>\$ (441)</u>	<u>\$ -</u>	<u>\$ 265</u>

	<u>December 31, 2015</u>	<u>Charges</u>	<u>Cash</u>	<u>Non-cash</u>	<u>December 31, 2016</u>
2016 restructuring costs	\$ -	\$ 2,287	\$ (1,669)	\$ -	\$ 618
2015 restructuring costs	104	-	(104)	-	-
Totals	<u>\$ 104</u>	<u>\$ 2,287</u>	<u>\$ (1,773)</u>	<u>\$ -</u>	<u>\$ 618</u>

**Note 20. Supplemental Cash Flow Information** (in thousands, except shares)

	<u>Years ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
<i>Supplemental disclosures of Cash Flow Information:</i>		
Cash received for income taxes, net	\$ (928)	\$ (4,780)
Cash paid for interest	28,520	30,165
<i>Supplemental disclosures of Non-cash Investing and Financing Activities:</i>		
Reclassification of treasury stock	-	5,571
Issuance of 1,100,498 shares in exchange transaction	3,775	-
Fair value of conversion option of exchangeable notes	12,690	-
Conversion of 4.25% Convertible notes	(51,775)	-
Issuance of Exchangeable Notes	36,243	-

**Note 21. Subsequent Events**

**Sales Force Restructure**

On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to our Treximet® fixed dose combination product. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees, the majority of which were associated with our sales force and commercial infrastructure. In connection with this commercial reorganization, Pemix expects to realize annualized cost savings of \$7.0-\$8.0 million beginning in the first quarter of 2018. The Company anticipates recording a one-time charge of approximately \$1.0 million during the first quarter of 2018 as a result of this realignment.

**Patent Litigation Settlement Agreement with Actavis Concerning Zohydro ER**

The Company announced on January 29, 2018 that it has entered into a settlement agreement with Actavis Laboratories FL ("Actavis") resolving patent litigation related to Zohydro ER with BeadTek. The litigation has been pending in the U.S. District Court for the District of Delaware and resulted from Actavis's submission of an ANDA to the FDA seeking approval to market a generic version of Zohydro ER with BeadTek. Under the terms of the agreement, Pemix will grant Actavis a license to begin selling a generic version of Zohydro ER with BeadTek on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER with BeadTek. The settlement agreement also resolves a pending appeal related to a patent litigation between Recro Gainesville LLC and Actavis, which also relates to Actavis's proposed generic version of Zohydro ER with BeadTek. As required by law, the parties will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. A patent litigation brought by Pemix against Alvogen Malta Operations Ltd. related to Alvogen's proposed generic version of Zohydro with BeadTek remains pending in the U.S. District Court for the District of Delaware.

## Launch of Treximet Authorized Generic

On February 14, 2018, four patents covering Treximet expired, enabling up to three generic competitors to enter the market. As of February 28, 2018, one of these competitors entered the market and the Company is expecting the other two competitors to enter later in 2018. Concurrent with the launch of generics by third parties, the Company launched an authorized generic version of Treximet. The Company will also continue to distribute the branded versions of Treximet. The Company has one additional patent that covers Treximet that will expire in 2026 that the Company expects to prevent additional generic competitors from entering the market until that time. The Company expects that generic competition for Treximet will negatively impact its net revenues for the fiscal year ending December 31, 2018.

### Note 22. Quarterly Financial Data (Unaudited)

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

	<b>Three Months Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
<b>2017</b>				
Net revenues	\$ 29,742	\$ 34,316	\$ 40,469	\$ 41,541
Operating (loss) income	(20,094)	(12,637)	1,014	(24,742)
Net (loss) income	(29,462)	(21,616)	6,360	(32,423)
Basic (loss) income per common share	\$ (2.94)	\$ (2.16)	\$ 0.57	\$ (2.78)
Diluted (loss) income per common and potential common share	\$ (2.94)	\$ (2.16)	\$ 0.42	\$ (2.78)
<b>2016</b>				
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)

**Schedule II**  
**Pernix Therapeutics Holdings, Inc.**  
**Valuation and Qualifying Accounts**  
**Years Ended December 31, 2017 and 2016**

(in thousands)	<u>Balance at beginning of period</u>	<u>Additions charged to costs and expenses</u>	<u>Deductions</u>	<u>Balance at end of period</u>
<b>For the year ended December 31, 2017</b>				
Allowance for doubtful accounts (1)	\$ 500	\$ (25)	\$ (460)	\$ 15
Allowance for prompt pay discounts (1)	1,038	6,230	(6,422)	846
Inventory obsolescence allowance (2)	1,983	1,867	(2,392)	1,458
<b>For the year ended December 31, 2016</b>				
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

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

(2) Shown as a reduction of inventory. Charges related to obsolescence of inventory are reflected in cost of product sales in the consolidated statements of operations and comprehensive loss.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*(a) Evaluation of Disclosure Controls and Procedures*

We maintain "disclosure controls and procedures" within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Our disclosure controls and procedures (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 Principal 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 Principal Financial Officer. Based on the controls evaluation, our Chief Executive Officer and our Principal Financial Officer have concluded that, as of the date of their evaluation, our disclosure controls and procedures were effective as of December 31, 2017.

**(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, 2017. 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, 2017, our internal control over financial reporting is effective based on those criteria.

**(c) Change in Internal Control over Financial Reporting.**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 2018 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, 2017, 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 Pemix. The Code of Business Conduct and Ethics is available on our Internet website at [www.pernixtx.com](http://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](http://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*

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	77
Consolidated Balance Sheets as of December 31, 2017 and 2016	78
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2017 and 2016	79
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2017 and 2016	80
Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016	81
Notes to Consolidated Financial Statements	82

2. *Financial Statement Schedules.*

Schedule II - Valuation and Qualifying Accounts

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

3. *Exhibits.*



No.	Description	Filed or Furnished with this Form 10- K	Incorporated by Reference	
			Form	Date Filed
2.1	Securities Purchase Agreement, dated as of November 13, 2012, by and among Pemix Therapeutics Holdings, Inc., Cypress Pharmaceuticals, Inc., all of the stockholders of Cypress Pharmaceuticals, Inc. and an individual as agent of all of the stockholders of Cypress Pharmaceuticals, Inc.		8-K	<a href="#">11/15/2012</a>
2.2	First Amendment to Securities Purchase Agreement dated December 28, 2012 among Pemix Therapeutics Holdings, Inc., on the one hand, and Cypress Pharmaceuticals, Inc., a Mississippi corporation, all of the stockholders of Cypress, and for limited purposes set forth therein, an individual as agent of the Sellers, on the other hand.		8-K	<a href="#">01/04/2013</a>
2.3	Agreement and Plan of Merger dated December 10, 2012 by and among Pemix Therapeutics Holdings, Inc., Pemix Acquisition Corp I. and Somaxon Pharmaceuticals, Inc.		8-K	<a href="#">12/12/2012</a>
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	<a href="#">08/09/2013</a>
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	<a href="#">09/17/2013</a>
2.6	Asset Purchase and Sale Agreement, dated as of May 13, 2014, by and among Glaxo Group Limited, GlaxoSmithKline, LLC, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline Intellectual Property Management Limited, (collectively, the Sellers) and Pemix Therapeutics Holdings, Inc.		8-K	<a href="#">05/16/2014</a>
2.7	Letter Agreement dated August 14, 2014 among Pemix Therapeutics Holdings, Inc., Worrigan Limited, Glaxo Group, Limited, GlaxoSmithKline Intellectual Property Management Limited, GlaxoSmithKline Intellectual Property Holdings Limited, and GlaxoSmithKline, LLC.		8-K	<a href="#">08/22/2014</a>
2.8	Asset Purchase Agreement, dated as of March 10, 2015, between Zogenix Inc., Pemix Ireland Limited, and solely with respect to Sections 5.9.2, 10.2 and 10.14, Pemix Therapeutics Holdings Inc.		10-Q/A	<a href="#">08/19/2015</a>
2.9	Amendment to Asset Purchase Agreement, dated as of April 23, 2015, between Zogenix Inc., Pemix Ireland Limited and Pemix Therapeutics Holdings Inc.		10-Q	<a href="#">05/01/2015</a>
3.1	Articles of Incorporation of Pemix Therapeutics Holdings, Inc.		8-K	<a href="#">03/15/2010</a>
3.2	Bylaws of Pemix Therapeutics Holdings, Inc.	√		
3.3	Articles of Amendment to the Articles of Incorporation of Pemix Therapeutics Holdings, Inc.		8-K	<a href="#">07/28/2015</a>
3.4	Articles of Amendment to the Articles of Incorporation of Pemix Therapeutics Holdings, Inc.		8-K	<a href="#">10/13/2016</a>

3.5	First Amendment to the Bylaws of Pemix Therapeutics Holdings, Inc.	8-K	<a href="#">10/13/2016</a>
4.1	Form of certificate representing shares of common stock of Pemix Therapeutics Holdings, Inc.	10-K	<a href="#">03/29/2012</a>
4.2	Common Stock Purchase Warrant dated May 13, 2014 issued to Pozen, Inc.	8-K	<a href="#">05/16/2014</a>
4.3	Indenture, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association.	8-K	<a href="#">02/26/2014</a>
4.4	First Supplemental Indenture, dated as of August 19, 2014, among Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	<a href="#">08/22/2014</a>
4.5	Second Supplemental Indenture, dated as of August 19, 2014, among Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	<a href="#">08/22/2014</a>
4.6	Third Supplemental Indenture, dated as of April 21, 2015, between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	<a href="#">04/24/2015</a>
4.7	Indenture, dated August 19, 2014, among Pemix Therapeutics Holdings, Inc., the Guarantors named therein and U.S. Bank National Association, as Trustee and as Collateral Agent.	8-K	<a href="#">08/22/2014</a>
4.8	First Supplemental Indenture, dated as of April 21, 2015, between Pemix Therapeutics Holdings, Inc. and U.S. Bank National Association, as Trustee.	8-K	<a href="#">04/24/2015</a>
4.9	Second Supplemental Indenture, dated July 21, 2017, by and among Pemix Therapeutics Holdings, Inc., Pemix Holdco 1, LLC, Pemix Holdco 2, LLC, Pemix Holdco 3, LLC and U.S. Bank, National Association as the trustee.	8-K/A	<a href="#">07/21/2017</a>
4.10	Third Supplemental Indenture, dated December 29, 2017, by and among Pemix Therapeutics Holdings, Inc., and U.S. Bank National Association, as trustee.	8-K	<a href="#">12/29/2017</a>
4.11	Indenture, dated April 22, 2015, between Pemix Therapeutics Holdings, Inc. and Wilmington Trust, National Association, as Trustee.	8-K	<a href="#">04/24/2015</a>
4.12	Indenture, dated July 21, 2017, by and among Pemix Ireland Pain Limited, as issuer, the guarantors party thereto, and Wilmington Trust, National Association, as the trustee.	8-K/A	<a href="#">07/21/2017</a>
4.13	Form of 12% Senior Secured Notes due 2020 (included in Exhibit 4.7)	8-K	<a href="#">08/22/2014</a>
4.14	Form of 4.25% Convertible Senior Notes due 2021 (included in Exhibit 4.11)	8-K	<a href="#">04/24/2015</a>
4.15	Form of 4.25%/5.25% Exchangeable Senior Note due 2022 (included in Exhibit 4.12)	8-K/A	<a href="#">07/21/2017</a>
4.16	Form of Warrant to Purchase Common Stock, dated as of December 31, 2014, issued by Pemix Therapeutics Holdings, Inc.	S-3/A	<a href="#">01/30/2015</a>
			(No. 333-200011)
10.1*	Amended and Restated 2009 Stock Incentive Plan.	10-K	<a href="#">03/28/2017</a>
10.2*	Amended and Restated 2010 Employee Stock Purchase Plan.	10-K	<a href="#">03/28/2017</a>
10.3*	Amended and Restated Golf Trust of America, Inc. 2007 Stock Option Plan.	10-K	<a href="#">03/28/2017</a>
10.4	Form of Amended and Restated Merger Partner Stockholder Agreement.	8-K	<a href="#">05/31/2011</a>
10.5	Amended and Restated License Agreement by and between Pemix Sleep, Inc. (formerly Somaxon Pharmaceuticals, Inc.) and ProCom One, Inc. dated September 15, 2010.	10-Q	<a href="#">11/12/2013</a>
10.6	Form of Securities Purchase Agreement, dated February 4, 2014.	8-K	<a href="#">02/07/2014</a>
10.7	Form of Representation Agreement, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and the Investors party thereto.	8-K	<a href="#">02/26/2014</a>
10.8	Form of Registration Rights Agreement, dated February 21, 2014, by and between Pemix Therapeutics Holdings, Inc. and the Investors party thereto.	8-K	<a href="#">02/26/2014</a>

10.9*	Amendment No. 1 to the Pemix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan.	10-K	<a href="#">03/17/2014</a>
10.10*	Pemix Therapeutics Holdings, Inc. Amended and Restated 2009 Stock Incentive Plan.	DEF 14A	<a href="#">04/28/2014</a>
10.11	Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated November 7, 2014, by and between Pemix Therapeutics Holdings, Inc. and Cantor Fitzgerald & Co.	S-3 (No. 333-200005)	<a href="#">11/07/2014</a>
10.12	Consent Solicitation Support Agreement, dated as of April 13, 2015, between the Company and each of the Noteholders party thereto.	8-K	<a href="#">04/16/2015</a>
10.13	Inducement Agreement, dated as of April 16, 2015, by and among Pemix Therapeutics Holdings, Inc. and the investors listed on Schedule 1 thereto.	8-K	<a href="#">04/17/2015</a>
10.14*	Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan.	10-K	<a href="#">03/28/2017</a>
10.15	Credit Agreement by and among Wells Fargo Bank, National Association, as Administrative Agent, the Lenders that are parties thereto, as Lenders and Pemix Therapeutics Holdings, Inc., Pemix Therapeutics, LLC, Pemix 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.	8-K	<a href="#">08/28/2015</a>
10.16*	Employment Offer Letter, dated May 9, 2016, by and between Pemix Therapeutics Holdings, Inc. and John Sedor.	10-Q	<a href="#">08/11/2016</a>
10.17*	Offer Letter, dated October 27, 2016, by and between Pemix Therapeutics Holdings, Inc. and Dennis H. Langer, M.D., J.D.	8-K	<a href="#">11/07/2016</a>
10.18*	Employment Agreement, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and John A. Sedor.	8-K	<a href="#">11/07/2016</a>
10.19*	Nonqualified Stock Option Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and John A. Sedor.	8-K	<a href="#">11/07/2016</a>
10.20*	Nonqualified Stock Option Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and John A. Sedor.	8-K	<a href="#">11/07/2016</a>
10.21*	Restricted Share Unit Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and John A. Sedor.	8-K	<a href="#">11/07/2016</a>
10.22*	Employment Agreement, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and Graham G. Miao, Ph.D.	8-K	<a href="#">11/07/2016</a>
10.23*	Nonqualified Stock Option Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and Graham G. Miao, Ph.D.	8-K	<a href="#">11/07/2016</a>
10.24*	Restricted Share Unit Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan, dated November 3, 2016, by and between Pemix Therapeutics Holdings, Inc. and Graham G. Miao, Ph.D.	8-K	<a href="#">11/07/2016</a>

10.25*	Offer Letter, dated November 16, 2016, by and between Pemix Therapeutics Holdings, Inc. and Gabriel Leung.	8-K	<a href="#">11/22/2016</a>
10.26*	Form of Indemnification Agreement between Pemix Therapeutics Holdings, Inc. and Certain Executive Officers and Directors.	8-K	<a href="#">02/06/2018</a>
10.27*	Offer Letter, dated December 16, 2016, by and between Pemix Therapeutics Holdings, Inc. and Kenneth R. Pina.	10-K	<a href="#">03/28/2017</a>
10.28*	Form of Nonqualified Stock Option Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2009 Stock Incentive Plan.	10-K	<a href="#">03/28/2017</a>
10.29*	Form of Nonqualified Stock Option Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan.	10-K	<a href="#">03/28/2017</a>
10.30*	Restricted Share Unit Agreement under the Amended and Restated Pemix Therapeutics Holdings, Inc. 2015 Omnibus Incentive Plan.	10-K	<a href="#">03/28/2017</a>
10.31	Amendment to the Interim Settlement Agreement, dated March 17, 2017, by and between by and between Pemix Therapeutics Holdings, Inc., Glaxo Group Limited, GlaxoSmithKline LLC and the other signatories thereto.	8-K	<a href="#">03/21/2017</a>
10.32	Amendment No. 1 to the Credit Agreement by and among Wells Fargo Bank, National Association, as Administrative Agent, the Lenders that are parties thereto, as Lenders and Pemix Therapeutics Holdings, Inc., Pemix Therapeutics, LLC, Pemix Sleep, Inc., Cypress Pharmaceuticals, Inc., Macoven Pharmaceuticals, Inc., Gaine, Inc., Respicopea Inc. and Macoven Pharmaceuticals, L.L.C., as Borrowers, dated as of April 18, 2017.	8-K	<a href="#">04/20/2017</a>
10.33	Exchange Agreement dated July 20, 2017 by and among Pemix Ireland Pain Limited, Pemix Therapeutics Holdings, Inc. and certain of its subsidiaries as guarantors party thereto and 1992 MSF International Ltd. and 1992 Tactical Credit Master Fund, L.P.	8-K	<a href="#">07/20/2017</a>
10.34	Credit Agreement, dated as of July 21, 2017, by and among the lenders identified on the signature pages thereof, Cantor Fitzgerald Securities, as agent, Pemix Therapeutics Holdings, Inc., Pemix Therapeutics, LLC, Pemix Sleep, Inc., Cypress Pharmaceuticals, Inc., Gaine, Inc., Respicopea, Inc., Macoven Pharmaceuticals, L.L.C., and Hawthorn Pharmaceuticals, Inc., as borrowers, and the guarantors party thereto.	8-K/A	<a href="#">07/21/2017</a>
10.35	Credit Agreement, dated as of July 21, 2017, by and among the lenders identified on the signature pages thereof, Cantor Fitzgerald Securities, as agent, and Pemix Ireland Pain Limited.	8-K/A	<a href="#">07/21/2017</a>
10.36	Amendment No. 2 to the Interim Settlement Agreement dated July 21, 2017 by and among Pemix Therapeutics Holdings, Inc., Pemix Ireland Limited, Glaxo Group Limited, GlaxoSmithKline LLC, GlaxoSmithKline Intellectual Property Holdings Limited and GlaxoSmithKline Intellectual Property Management Limited.	8-K/A	<a href="#">07/21/2017</a>
10.37	Registration Rights Agreement dated July 21, 2017 between Pemix Therapeutics Holdings, Inc., Pemix Ireland Pain Limited and 1992 MSF International Ltd. and 1992 Tactical Credit Master Fund, L.P.	8-K/A	<a href="#">07/21/2017</a>
10.38*	Employment Agreement, dated July 21, 2017, by and between Pemix Therapeutics Holdings, Inc. and Kenneth R. Pina.	10-Q	<a href="#">11/07/2017</a>
10.39*	Pemix Therapeutics Holdings, Inc. 2017 Omnibus Incentive Plan.	8-K	<a href="#">11/15/2017</a>
10.40*	Employment Agreement, dated February 6, 2018, between Pemix Therapeutics Holdings, Inc. and Angus Smith.	8-K	<a href="#">02/06/2018</a>
10.41*	Offer Letter, dated September 22, 2017, by and between Pemix Therapeutics Holdings, Inc. and Douglas J. Swirsky.		<a href="#">√</a>
10.42*	Offer Letter, dated September 22, 2017, by and between Pemix Therapeutics Holdings, Inc. and John R. Leone.		<a href="#">√</a>
10.43	Waiver, Amendment and Consent Agreement, dated November 2, 2017, among Pemix Therapeutics Holdings, Inc. and the other signatories thereto.		<a href="#">√</a>
14.1*	Amended and Restated Code of Business Conduct and Ethics of Pemix Therapeutics Holdings, Inc.	8-K	<a href="#">09/22/2017</a>
21.1	Subsidiaries of the Company.		<a href="#">√</a>
23.1	Consent of Cherry Bekaert L.L.P.		<a href="#">√</a>
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 the Sarbanes-Oxley Act of 2002.		<a href="#">√</a>

31.2 Certification by Angus Smith (Principal Financial Officer) pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. [√](#)

32.1 Certification by John Sedor and Angus Smith 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

**ITEM 16. FORM 10-K SUMMARY**

None.

## SIGNATURES

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

PERNIX THERAPEUTICS HOLDINGS, INC.

Date: March 8, 2018

By: /s/ John A. Sedor  
John A. Sedor  
Chief Executive Officer and Chairman

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John Sedor</u> John Sedor	Chief Executive Officer and Chairman (Principal Executive Officer)	March 8, 2018
<u>/s/ Angus W. Smith</u> Angus W. Smith	Senior Vice President, Chief Business Officer (Principal Financial Officer)	March 8, 2018
<u>/s/ Glenn Whaley</u> Glenn Whaley	Interim Vice President of Finance and Corporate Controller (Principal Accounting Officer)	March 8, 2018
<u>/s/ Dennis Langer</u> Dennis Langer	Director	March 8, 2018
<u>/s/ Gabriel Leung</u> Gabriel Leung	Director	March 8, 2018
<u>/s/ Douglas Swirsky</u> Douglas Swirsky	Director	March 8, 2018
<u>/s/ John Leone</u> John Leone	Director	March 8, 2018

**BYLAWS**  
**OF**  
**PERNIX THERAPEUTICS HOLDINGS, INC.**

(in effect as of February 28, 2018)

---

## TABLE OF CONTENTS

ARTICLE I Offices	1
Section 1. Principal Office	1
Section 2. Additional Offices	1
Section 3. Fiscal and Taxable Years	1
ARTICLE II Definitions	1
ARTICLE III Meetings of Stockholders	1
Section 1. Place	1
Section 2. Annual Meeting	1
Section 3. Special Meetings	3
Section 4. Notice	3
Section 5. Organization	3
Section 6. Quorum	3
Section 7. Voting	3
Section 8. Proxies	3
Section 9. Voting of Shares by Certain Holders	4
Section 10. Inspectors	4
Section 11. Determination of Stockholders of Record	4
Section 12. Action Without a Meeting	5
Section 13. Voting by Ballot	5
Section 14. Control Share Acquisition Statute	5
ARTICLE IV Directors	5
Section 1. General Powers	5
Section 2. Number, Tenure and Qualifications	5
Section 3. Changes in Number, Vacancies	5
Section 4. Resignations	6
Section 5. Removal of Directors	6
Section 6. Annual and Regular Meetings	6
Section 7. Special Meetings	6
Section 8. Notice	6
Section 9. Quorum	6
Section 10. Voting	7
Section 11. Telephone Meetings	7
Section 12. Action Without a Meeting	7
Section 13. Compensation	7
ARTICLE V Committees	7
Section 1. Committees of the Board	7
Section 2. Telephone Meetings	8
Section 3. Action By Committees Without a Meeting	8
ARTICLE VI Officers	8
Section 1. General Provisions	8
Section 2. Subordinate Officers, Committees and Agents	8
Section 3. Removal and Resignation	8
Section 4. Vacancies	8
Section 5. General Powers	8
Section 6. Chief Executive Officer	8

---



Section 7.	Chief Operating Officer	9
Section 8.	Chairman and Vice Chairman of the Board	9
Section 9.	President	9
Section 10.	Vice Presidents	9
Section 11.	Secretary	9
Section 12.	Chief Financial Officer or Treasurer	9
Section 13.	Assistant Secretaries and Assistant Treasurers	9
Section 14.	Salaries	10
ARTICLE VII Contracts, Notes, Checks and Deposits		10
Section 1.	Contracts	10
Section 2.	Checks and Drafts	10
Section 3.	Deposits	10
ARTICLE VIII Capital Shares		10
Section 1.	Certificates of Shares	10
Section 3.	Lost Certificate	10
Section 4.	Transfer Agents and Registrars	10
Section 5.	Transfer of Shares	11
Section 6.	Share Ledger	11
ARTICLE IX Dividends		11
Section 1.	Declaration	11
Section 2.	Contingencies	11
ARTICLE X Indemnification and Limitation of Liability		11
Section 1.	Indemnification of Agents	11
Section 2.	Insurance	11
Section 3.	Indemnification Non-Exclusive	11
Section 4.	Limitation of Liability	12
ARTICLE XI Seal		12
Section 1.	Seal	12
Section 2.	Affixing Seal	12
ARTICLE XII Waiver of Notice		12
ARTICLE XIII Amendment of Bylaws		12

---

## ARTICLE I

### Offices

**Section 1. Principal Office.** The principal office of Pemix Therapeutics Holdings, Inc. (the “Corporation”) is located at 33219 Forest West Drive, Magnolia, Texas 77354, or at any other place as the Board may from time to time determine.

**Section 2. Additional Offices.** The Corporation may have additional offices at such places as the Board may from time to time determine or the business of the Corporation may require.

**Section 3. Fiscal and Taxable Years.** The fiscal and taxable years of the Corporation begin on January 1 and end on December 31.

## ARTICLE II

### Definitions

For purposes of these Bylaws, the following words have the meanings set forth below:

(a) An “Affiliate” of a person means (i) any person that, directly or indirectly, controls or is controlled by or is under common control with such person, (ii) any other person that owns, beneficially, directly or indirectly, 5% or more of the outstanding capital shares, shares or equity interests of such person, or (iii) any officer, director, employee, partner or trustee of such person or any person controlling, controlled by or under common control with such person (excluding trustees and persons serving in similar capacities who are not otherwise an Affiliate of such person). The term “person” means and includes individuals, corporations, general and limited partnerships, limited liability companies, stock companies or associations, joint ventures, banks, trust companies, land trusts, business trusts, any other association, company, trust or entity or governments or the agencies or political subdivisions thereof. For the purposes of this definition, “control” (including the correlative meanings of the terms “controlled by” and “under common control with”), as used with respect to any person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person, through the ownership of voting securities, partnership interests or other equity interests.

(b) “Independent Director” means a director of the Corporation who is not an officer or employee of the Corporation or an Affiliate of (i) any advisor to the Corporation under an advisory agreement, (ii) any lessee of or management company operating any of the properties owned by the Corporation or any Affiliate of the Corporation, (iii) any subsidiary of the Corporation, or (iv) any partnership that is an Affiliate of the Corporation.

## ARTICLE III

### Meetings of Stockholders

**Section 1. Place.** All meetings of stockholders will be held at such place within the United States as may be stated in the notice.

**Section 2. Annual Meeting.**

(a) Date and Time. The annual meeting of stockholders for the election of directors and the transaction of any other business as may be properly brought before the meeting will be held on such a day, in such a month and at such a time and place as may be designated by the Board.

(b) Postponement. The Board, acting by resolution, may postpone and reschedule any previously scheduled annual meeting of stockholders; *provided, however* that notice of the postponement of any properly-noticed annual meeting must be given, by any means specified in this Section 4, not less than ten days prior to the previously scheduled meeting date.

(c) *Effect of Failure to Hold Annual Meeting.* Failure to hold an annual meeting will not invalidate the Corporation's existence or affect any otherwise valid corporate acts.

(d) *Transaction of Business.* Nominations of persons for election to the Board and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders (i) pursuant to the Corporation's notice of meeting, (ii) by or at the direction of the Board, or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving of notice provided for herein, who is entitled to vote at the meeting and who complied with the notice procedures set forth herein.

(e) *Advance Notice Requirements.*

(i) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of subsection (d) of this Section 2, the stockholder must have given timely notice thereof in writing delivered to the Secretary of the Corporation by personal delivery or by first-class United States mail, postage prepaid. To be timely a stockholder's notice must be delivered to the Secretary at the principal executive offices of the Company not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; *provided, however*, that in the event that the date of the annual meeting is advanced by more than 30 days or delayed by more than 60 days from such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the 120th day prior to the actual annual meeting date and not later than the close of business on the later of the 90th day prior to the actual annual meeting date or the 20th day following the date on which public announcement of the date of such meeting is first made. Such stockholder's notice must set forth:

- (1) As to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected;
- (2) As to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made and a representation that the stockholder intends to appear in person or by proxy at the meeting to introduce such proposal; and
- (3) As to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (i) the name and address of such stockholder, as they appear on the Corporation's books, and of such beneficial owners, and (ii) the class and number of shares of the Corporation that are owned beneficially and of record by each stockholder and such beneficial owner.

(ii) With respect to stockholder nominations, only such persons who are nominated in accordance with the procedures set forth herein are eligible for election and to serve as directors. With respect to stockholder proposals, only such business may be conducted at an annual meeting of stockholders as has been brought before the meeting in accordance with the procedures set forth herein. The chairman of the meeting has the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made in accordance with the procedures set forth herein and, if any proposed nomination or business is not in such compliance, to declare that such defective proposal will be disregarded.

(f) *Inclusion of Stockholder Proposals in Proxy Statement.* Notwithstanding the foregoing provisions, a stockholder must also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth herein. Nothing herein will be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act. Any proposal that is properly included in the Corporation's proxy statement and not validly withdrawn will be brought before the annual meeting.

Section 3. **Special Meetings.**

(a) *Calling of Special Meetings.* The President, a majority of the Board or a majority of the Independent Directors may call special meetings of the stockholders. Special meetings of stockholders also may be called by the Secretary upon the written request of the holders of shares entitled to cast a majority (but not less than a majority) of all the votes entitled to be cast at such meeting. Such request must state the purpose of such meeting and the matters proposed to be acted on at such meeting. The Secretary will inform such stockholders of the reasonably estimated cost of preparing and mailing notice of the meeting and, upon payment to the Corporation of such costs by such stockholders, the Secretary will give notice to each stockholder entitled to notice of the meeting. Unless requested by stockholders entitled to cast a majority of all the votes entitled to be cast at such meeting, a special meeting need not be called to consider any matter that is substantially the same as a matter voted on at any special meeting of the stockholders held during the preceding 12 months. The Board has the sole power to fix the date, time and place of the special meeting, the record date for determining stockholders entitled to request a special meeting and the record date for determining stockholders entitled to notice of and to vote at the special meeting.

(b) *Postponement.* The Board, acting by resolution, may postpone and reschedule any previously scheduled special meeting of stockholders; *provided, however* that notice of the postponement of any properly-noticed special meeting must be given by any means specified in this Section 4, not less than ten days prior to the previously scheduled meeting date.

(c) *Transaction of Business.* Only such business may be conducted at a special meeting of stockholders as has been stated in the notice of meeting. The chairman of the meeting has the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made in accordance with the procedures set forth herein and, if any proposed nomination or business is not in such compliance, to declare that such defective proposal be disregarded.

**Section 4. Notice.** Not less than ten nor more than 60 days before each meeting of stockholders, the Secretary must give to each stockholder entitled to vote at such meeting and to each stockholder not entitled to vote who is entitled to notice of the meeting, written or printed notice stating the time and place of the meeting and, in the case of a special meeting or as otherwise may be required by statute, the purpose for which the meeting is called, either by mail or by presenting it to such stockholder personally or by leaving it at his residence or usual place of business. If mailed, such notice will be deemed given when deposited in the United States mail addressed to the stockholder at his post office address as it appears on the records of the Corporation, with postage thereon prepaid.

**Section 5. Organization.** At every meeting of the stockholders, the Chairman of the Board, if there be one, will conduct the meeting or, in the case of vacancy in office or absence of the Chairman of the Board, one of the following officers present will conduct the meeting in the order stated: the Vice Chairman of the Board, if any, the President, if any, the Vice Presidents in their order of rank and seniority, if any, or a chairman chosen by the stockholders entitled to cast a majority of the votes, which all stockholders present in person or by proxy are entitled to cast, will act as chairman of the meeting, and the Secretary, or, in his absence, an assistant secretary or, in the absence of both the Secretary and assistant secretaries, a person appointed by the chairman of the meeting will act as secretary.

**Section 6. Quorum.** At any meeting of stockholders, the presence in person or by proxy of stockholders entitled to cast 50% of all the votes entitled to be cast at such meeting constitutes a quorum; but this Section 6 does not affect any requirement under any statute, the charter of the Corporation (the "Charter") or these Bylaws for the vote necessary for the adoption of any measure. If such quorum is not present at any meeting of the stockholders, the stockholders representing a majority of the shares entitled to vote at such meeting, present in person or by proxy, may vote to adjourn the meeting from time to time to a date not more than 120 days after the original record date without notice other than announcement at the meeting, until such quorum is present. At such adjourned meeting at which a quorum is present, any business may be transacted that might have been transacted at the meeting as originally notified.

Section 7. **Voting.** A plurality of all the votes cast at a meeting of stockholders duly called and at which a quorum is present is sufficient to elect a director. There may be no cumulative voting. Each common share may be voted for as many individuals as there are directors to be elected and for whose election the share is entitled to be voted. A majority of the votes cast at a meeting of stockholders duly called and at which a quorum is present is sufficient to approve any other matter that may properly come before the meeting, unless more than a majority of the votes cast is required by statute, by the Charter or by these Bylaws. Each stockholder of record has the right, at every meeting of stockholders, to one vote for each share held, except shares that are the subject of a redemption notice as provided in the Charter.

Section 8. **Proxies.** A stockholder may vote the common shares owned of record by him, either in person or by proxy executed or authorized by the stockholder, or by his duly authorized attorney in fact, in any manner permitted by law. Such proxy must be filed with the Secretary of the Corporation before or at the time of the meeting. No proxy will be valid after 11 months from the date of its execution, unless otherwise provided in the proxy.

Section 9. **Voting of Shares by Certain Holders.**

(a) Shares registered in the name of a trust or another corporation, if entitled to be voted, may be voted by the president, a vice president or a proxy appointed by the president or a vice president of such trust or other corporation, unless some other person, who has been appointed to vote such shares pursuant to a bylaw or a resolution of the board of such trust or other corporation, presents a certified copy of such bylaw or resolution, in which case such person may vote such shares. Any fiduciary may vote shares registered in his name as such fiduciary, either in person or by proxy.

(b) Shares indirectly owned by the Corporation may not be voted at any meeting and will not be counted in determining the total number of outstanding shares entitled to be voted at any given time, unless they are held by it in a fiduciary capacity, in which case they may be voted and must all be counted in determining the total number of outstanding shares at any given time.

(c) The Board may adopt by resolution a procedure by which a stockholder may certify in writing to the Corporation that any shares registered in the name of the stockholder are held for the account of a specified person other than the stockholder. The resolution will set forth the class of stockholders who may make the certification, the purpose for which the certification may be made, the form of certification and the information to be contained in it, if the certification is with respect to a record date or closing of the share transfer books, the time after the record date or closing of the share transfer books within which the certification must be received by the Corporation and any other provisions with respect to the procedure that the Board considers necessary or desirable. On receipt of such certification, the person specified in the certification will be regarded as, for the purposes set forth in the certification, the stockholder of record of the specified shares in place of the stockholder who makes the certification.

Section 10. **Inspectors.**

(a) At any meeting of stockholders, the chairman of the meeting may, or upon the request of any stockholder must, appoint one or more persons as inspectors for such meeting. Such inspectors will ascertain and report the number of shares represented at the meeting based upon their determination of the validity and effect of proxies, count all votes, report the results and perform such other acts as are proper to conduct the election and voting with impartiality and fairness to all the stockholders.

(b) Each report of an inspector must be in writing and signed by him or by a majority of them if there is more than one inspector acting at such meeting. If there is more than one inspector, the report of a majority will be the report of the inspectors. The report of the inspector or inspectors on the number of shares represented at the meeting and the results of the voting will be *prima facie* evidence thereof.

**Section 11. Determination of Stockholders of Record.**

(a) The Board will fix a date, not more than 60 nor less than ten days preceding the date of any meeting of stockholders, and not more than 60 days preceding the date fixed for the payment of any dividend or distribution, the date for the allotment of rights or the date when any change or conversion or exchange of shares will be made or go into effect, as a record date for the determination of the stockholders entitled to notice of, or to vote at, any such meeting, or entitled to receive any such dividend or distribution or allotment of rights, or to exercise the rights in respect to any such change, conversion or exchange of shares.

(b) When a determination of stockholders entitled to vote at any meeting of stockholders has been made as provided in subsection (a) of this Section 11, such determination will apply to any adjournment thereof unless the meeting is adjourned to a date more than 120 days after the date fixed for the original meeting, in which case the Board will fix a new record date.

**Section 12. Action Without a Meeting.** Any action required or permitted to be taken at a meeting of stockholders may be taken without a meeting if a consent in writing, setting forth such action, is signed by each stockholder entitled to vote on the matter and any other stockholder entitled to notice of a meeting of stockholders (but not to vote thereat) has waived in writing any right to dissent from such action, and such consent and waiver are filed with the minutes of proceedings of the stockholders.

**Section 13. Voting by Ballot.** Voting on any question or in any election may be *viva voce* unless the chairman of the meeting orders or any stockholder demands that voting be by ballot.

**Section 14. Control Share Acquisition Statute.** Subtitle 7 of Title 3 of the Maryland General Corporation Law does not apply to any acquisition of shares of capital stock of the Corporation.

**ARTICLE IV**

**Directors**

**Section 1. General Powers.** The Board has full power to conduct, manage and direct the business and affairs of the Corporation, and all powers of the Corporation, except those specifically reserved or granted to the stockholders by statute or by the Charter or these Bylaws, will be exercised by, or under the authority of, the Board.

**Section 2. Number, Tenure and Qualifications.**

(a) At any regular meeting or at any special meeting called for that purpose, a majority of the entire Board may establish, increase or decrease the number of directors, provided that the number thereof will not be less than the minimum number required by the General Laws of the State of Maryland now or hereafter in force, nor more than nine, and further provided that the tenure of office of a director will not be affected by any decrease in the number of directors. The directors must be elected each year at the annual meeting of the stockholders. Each director will continue in office for the term for which he is elected until his successor has been elected and qualified, or until his earlier death, resignation, retirement or removal in accordance with the Charter and these Bylaws.

(b) At all times, except during a period not to exceed 60 days following the death, resignation, incapacity or removal from office of a director prior to the expiration of the director's term of office, a majority of the directors must be Independent Directors.

(c) Notwithstanding the foregoing requirement that a majority of the directors be Independent Directors, no action otherwise validly taken by the Board during a period in which a majority of its members are not Independent Directors will be invalidated or otherwise affected by such circumstance, nor will such circumstance subject the directors taking any such action to a higher standard of care or to liability other than that which would have applied to such action had a majority of the members of the Board been Independent Directors at the time such action was taken.

### **Section 3. Changes in Number; Vacancies.**

(a) Any vacancy on the Board may be filled by the affirmative vote of the remaining directors, unless such vacancy resulted from an increase in the number of directors, in which case such vacancy may be filled by a majority of the entire Board; *provided, however*, that in the case of a vacancy resulting from the removal of a director by the stockholders pursuant to subsection (a) of this Section 5, such vacancy may be filled in accordance with Article III, Section 7. Notwithstanding the foregoing, any vacancy on the Board among the directors elected by a class or series of equity shares (other than common shares), including any vacancy resulting from the removal of such director by the holders of such class or series of equity shares pursuant to subsection (b) of this Section 5, may be filled by a majority of the remaining directors elected by that class or series, the sole remaining director elected by that class or series or by the stockholders by a majority of the votes of that class or series. A director that fills a vacancy pursuant to subsection (a) of this Section 3 will continue in office until his successor has been elected and qualified, or until his earlier death, resignation, retirement or removal (in accordance with the Charter and these Bylaws).

(b) The Board may declare unqualified a director who has been declared of unsound mind by an order of court, who has pled guilty or *nolo contendere* to, or been convicted of, a felony involving moral turpitude or who has willfully violated the Charter or these Bylaws. The office of a director declared unqualified will be considered vacant until filled as herein provided.

**Section 4. Resignations.** Any director or member of a committee may resign at any time. Such resignation must be made in writing and will take effect at the time specified therein, or if no time be specified, at the time of the receipt by the Chairman of the Board, the President or the Secretary.

### **Section 5. Removal of Directors.**

(a) Any director may be removed, with or without cause, by the affirmative vote of the stockholders holding not less than two-thirds of all the votes entitled to be cast for the election of directors.

(b) Notwithstanding the provisions of subsection (a) of this Section 5, in the case of any director elected by holders of a class or series of equity shares (other than common shares), such directors may be removed, with or without cause, by the affirmative vote of all of such class or series of equity shares.

**Section 6. Annual and Regular Meetings.** An annual meeting of the Board will be held immediately after and at the same place as the annual meeting of stockholders, and no notice of such meeting of the Board will be necessary. The Board may provide, by resolution, the time and place, either within or without the State of South Carolina, for the holding of regular meetings of the Board without notice other than such resolution.

**Section 7. Special Meetings.** Special meetings of the Board may be called by or at the request of the President, a majority of the Board or a majority of the Independent Directors then in office. The person or persons authorized to call special meetings of the Board may fix any place, either within or without the State of South Carolina, as the place for holding any special meeting of the Board called by them.

**Section 8. Notice.** Notice of any special meeting of the Board must be in writing and must be either (a) delivered by hand, (b) mailed by United States registered mail, return receipt requested, postage prepaid, (c) sent by a reputable, national overnight delivery service, or (d) sent by facsimile (with the original being sent by one of the other permitted means or by regular United States mail), and addressed to each director at his business or resident address. Any such notice, request or other communication will be considered delivered on the date actually delivered or when delivery is refused or deemed impossible due to the recipient having changed its address without notifying the Company. Notice given pursuant to subsections (a) and (d) must be given at least two days prior to the meeting. Notice given pursuant to subsection (b) must be given at least five days prior to the meeting. Notice given pursuant to subsection (c) must be given at least three days prior to the meeting. Neither the business to be transacted at, nor the purpose of, any annual, regular or special meeting of the Board need be stated in the notice, unless required by statute or these Bylaws.

### **Section 9. Quorum.**

(a) A majority of the entire Board constitutes a quorum for transaction of business at any meeting of the Board, provided that, if less than a quorum is present at such meeting, a majority of the directors present may adjourn the meeting from time to time without further notice.

(b) The directors present at a meeting that has been duly called and convened may continue to transact business until adjournment, notwithstanding the withdrawal of enough directors to leave less than a majority of the entire Board, provided that at least one-third of the entire Board remains present at that meeting, in which case a quorum will still be deemed present.

**Section 10. Voting.** The action of the majority of the directors present at a meeting at which a quorum is present will be the action of the Board, unless the concurrence of a greater proportion is required for such action by the Charter, these Bylaws or applicable statute.

**Section 11. Telephone Meetings.** Members of the Board may participate in a meeting by means of a conference telephone or similar communications equipment if all persons participating in the meeting can hear each other at the same time. Participation in a meeting by these means constitutes presence in person at the meeting.

**Section 12. Action Without a Meeting.** Any action required or permitted to be taken at any meeting of the Board may be taken without a meeting if all members of the Board consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board.

**Section 13. Compensation.** Independent Directors will receive such reasonable compensation for their services as directors as the Board may fix or determine from time to time; such compensation may include a fixed sum or capital shares of the Corporation and directors may receive reimbursement of reasonable expenses incurred in traveling to and from or attending regular or special meetings of the Board or of any committee thereof.

## ARTICLE V

### Committees

#### **Section 1. Committees of the Board.**

(a) The Board may appoint from among its members committees comprised of one or more directors. The Board may delegate to any committee any of the powers of the Board except the power to elect directors, declare dividends or distributions on shares, recommend to the stockholders any action that requires stockholder approval, amend or repeal these Bylaws, approve any merger or share exchange that does not require stockholder approval or issue shares. However, if the Board has given general authorization for the issuance of shares, a committee of the Board, in accordance with a general formula or method specified by the Board by resolution or by adoption of a share option plan, may fix the terms of shares, subject to classification or reclassification, and the terms on which any shares may be issued.

(b) Notice of committee meetings must be given in the same manner as notice for special meetings of the Board.

(c) At least one-third, but not less than two (unless the committee has less than two members), of the members of any committee must be present in person at any meeting of such committee in order to constitute a quorum for the transaction of business at such meeting, and the act of a majority present will be the act of such committee. The Board may designate a chairman of any committee, and such chairman or any two members of any committee (unless the committee has less than two members, in which case one member of such committee) may fix the time and place of its meetings, unless the Board otherwise provides. In the absence or disqualification of any member of any such committee, the members thereof present at any meeting and not disqualified from voting, whether or not they constitute a quorum, may unanimously appoint another director to act at the meeting in the place of such absent or disqualified members; *provided, however*, that in the event of the absence or disqualification of an Independent Director, such appointee will be an Independent Director.

(d) Each committee will keep minutes of its proceedings and will report the same to the Board at the meeting next succeeding, and any action by the committees will be subject to revision and alteration by the Board, provided that no rights of third persons are affected by any such revision or alteration.



(e) Subject to the provisions hereof, the Board has the power at any time to change the membership of any committee, to fill all vacancies, to designate alternative members to replace any absent or disqualified members or to dissolve any such committee.

**Section 2. Telephone Meetings.** Members of a committee of the Board may participate in a meeting by means of a conference telephone or similar communications equipment if all persons participating in the meeting can hear each other at the same time. Participation in a meeting by these means constitutes presence in person at the meeting.

**Section 3. Action By Committees Without a Meeting.** Any action required or permitted to be taken at any meeting of a committee of the Board may be taken without a meeting, if all members of the committee consent thereto in writing or by electronic transmission and the writing or writings or transmission or transmissions are filed with the minutes of proceedings of such committee.

## ARTICLE VI

### Officers

**Section 1. General Provisions.** The officers of the Corporation may consist of a Chairman of the Board, a Vice Chairman of the Board, a President, a Chief Executive Officer, a Chief Operating Officer, one or more Vice Presidents, a Chief Financial Officer or Treasurer, one or more assistant treasurers, a Secretary, one or more assistant secretaries and such other officers as may be pursuant to this Section 2. The officers of the Corporation will be appointed annually by the Board at the first meeting of the Board held after each annual meeting of stockholders. If the appointment of officers is not held at such meeting, such election will be held as soon thereafter as may be convenient. Each officer will hold office until his successor is appointed and qualified, or until his death, resignation, retirement or removal (in accordance with the Charter and these Bylaws). Any two or more offices may be held by the same person. In its discretion, the Board may leave unfilled any office except that of President and Secretary. Appointment of an officer or agent does not of itself create contract rights between the Corporation and such officer or agent.

**Section 2. Subordinate Officers, Committees and Agents.** The Board may from time to time appoint such other officers and such committees, employees and other agents as the business of the Corporation may require, each of whom will hold office for such period, have such authority and perform such duties as are provided in these Bylaws, or as the Board may from time to time determine. The directors may delegate to any officer or committee the power to elect subordinate officers and to retain or appoint employees or other agents.

**Section 3. Removal and Resignation.** Any officer or agent of the Corporation may be removed by the Board if in its judgment the best interests of the Corporation would be served thereby, but such removal will be without prejudice to the contract rights, if any, of the person so removed. Any officer of the Corporation may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any resignation will take effect at the time specified therein or, if the time when it becomes effective is not specified therein, immediately upon its receipt. The acceptance of a resignation is not necessary to make it effective unless otherwise stated in the resignation.

**Section 4. Vacancies.** A vacancy in any office may be filled by the Board for the balance of the term.

**Section 5. General Powers.** All officers of the Corporation as between themselves and the Corporation will, respectively, have such authority and perform such duties in the management of the property and affairs of the Corporation as may be determined by resolution of the Board, or in the absence of controlling provisions in a resolution of the Board, as may be provided in these Bylaws.

**Section 6. Chief Executive Officer.** The Board may designate a Chief Executive Officer from among the elected officers. The Chief Executive Officer will have responsibility for implementation of the policies of the Corporation, as determined by the Board, and for the administration of the business affairs of the Corporation.

**Section 7. Chief Operating Officer.** The Board may designate a Chief Operating Officer from among the elected officers. The Chief Operating Officer will have the responsibility and duties as set forth by the Board or the Chief Executive Officer.

**Section 8. Chairman and Vice Chairman of the Board.** The Chairman of the Board, if there be one, will preside over the meetings of the Board and of the stockholders at which he is present. In the absence of the Chairman of the Board, the Vice Chairman of the Board, if any, will preside at such meetings at which he is present. The Chairman of the Board and the Vice Chairman of the Board will, respectively, perform such other duties as may be assigned to him or them by the Board.

**Section 9. President.** The President will in general supervise and control all of the business and affairs of the Corporation. Unless the President is not a member of the Board, in the absence of both the Chairman and Vice Chairman of the Board, he will preside at all meetings of the Board and of the stockholders at which he is present. In the absence of a designation of a Chief Executive Officer by the Board, the President will be the Chief Executive Officer. He may execute any deed, mortgage, bond, contract or other instrument to which the Corporation is a party, except in cases where the execution thereof is expressly delegated by the Board or by these Bylaws to some other officer or agent of the Corporation or is required by law to be otherwise executed. The President will perform all duties incident to the office of President and such other duties as may be prescribed by the Board from time to time.

**Section 10. Vice Presidents.** In the absence of the President or in the event of a vacancy in such office, the Vice President (or in the event there be more than one Vice President, the Vice Presidents in the order designated at the time of their appointment or, in the absence of any designation, then in the order of appointment) will perform the duties of the President and when so acting will have all the powers of and be subject to all the restrictions upon the President, and will perform such other duties as from time to time may be assigned to him by the President or by the Board. The Board may designate one or more Vice Presidents as executive Vice President or as Vice President for particular areas of responsibility.

**Section 11. Secretary.** The Secretary will (a) keep the minutes of the proceedings of the stockholders, the Board and committees of the Board in one or more books provided for that purpose, (b) see that all notices are duly given in accordance with the provisions of these Bylaws or as required by law, (c) be custodian of the corporate records and of the seal of the Corporation, (d) keep a register of the post office address of each stockholder that is furnished to the Secretary by such stockholder, (e) have general charge of the share transfer books of the Corporation, and (f) in general perform such other duties as from time to time may be assigned to him by the President or by the Board.

**Section 12. Chief Financial Officer or Treasurer.**

(a) The Chief Financial Officer or Treasurer will have the custody of the corporate funds and securities and will deposit all monies and other valuable effects in the name and to the credit of the Corporation in such depositories as may be designated by the Board.

(b) He will disburse the funds of the Corporation as may be ordered by the Board, taking proper vouchers for such disbursements, and will render to the President and Board, at the regular meetings of the Board or whenever they may require it, an account of all his transactions as Chief Financial Officer or Treasurer and of the financial condition of the Corporation.

If required by the Board, he will give the Corporation a bond in such sum and with such surety or sureties as may be satisfactory to the Board for the faithful performance of the duties of his office and for the restoration to the Corporation, in case of his death, resignation, retirement or removal from office, all books, papers, vouchers, moneys and other property of whatever kind in his possession or under his control belonging to the Corporation.

**Section 13. Assistant Secretaries and Assistant Treasurers.** The assistant secretaries and assistant treasurers, in general, will perform such duties as may be assigned to them by the Secretary or the Chief Financial Officer or Treasurer, respectively, or by the President or the Board. The assistant treasurers will, if required by the Board, give bonds for the faithful performance of their duties in such sums and with such surety or sureties as may be satisfactory to the Board.

**Section 14. Salaries.** The salaries of the officers will be fixed from time to time by the Board and no officer will be prevented from receiving such salary by reason of the fact that he is also a director of the Corporation.

## ARTICLE VII

### Contracts, Notes, Checks and Deposits

**Section 1. Contracts.** The Board may authorize any officer or agent to enter into any contract or to execute and deliver any instrument in the name of and on behalf of the Corporation and such authority may be general or confined to specific instances.

**Section 2. Checks and Drafts.** All checks, drafts or other orders for the payment of money, notes or other evidences of indebtedness issued in the name of the Corporation will be signed by such officer or officers, agent or agents of the Corporation and in such manner as will from time to time be determined by the Board.

**Section 3. Deposits.** All funds of the Corporation not otherwise employed will be deposited from time to time to the credit of the Corporation in such banks, trust companies or other depositories as the Board may designate.

## ARTICLE VIII

### Capital Shares

**Section 1. Certificates of Shares.** Shares of the Corporation's capital stock may be certificated or uncertificated, as provided under the Maryland General Corporation Law. Owners of the Corporation's capital stock will be recorded in the share transfer records of the Corporation and ownership of such shares will be evidenced by a certificate or book entry notation in the share transfer records of the Corporation. Any certificates representing shares of the Corporation's capital stock will be in such form as the Board prescribes and contain such information as may be required by the Maryland General Corporation Law or any securities exchanges on which any shares of the Corporation may be listed. At the time of issue or transfer of shares without certificates, the Corporation, or an agent or representative thereof, will send to the registered owner thereof a written statement of the information required on certificates by the Maryland General Corporation Law.

**Section 2. Facsimile Signatures.** Any or all the signatures on certificates representing the capital stock of the Corporation may be facsimiles. In case any officer who has signed or whose facsimile signature has been placed upon a certificate ceases to be such officer before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer at the date of issue.

**Section 3. Lost Certificate.** The Board may direct a new certificate to be issued in place of any certificate previously issued by the Corporation alleged to have been lost, stolen or destroyed upon the making of an affidavit of that fact by the person claiming the certificate to be lost, stolen or destroyed. When authorizing the issuance of a new certificate, the Board may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate or his legal representative to advertise the same in such manner as it may require and/or to give bond, with sufficient surety, to the Corporation to indemnify it against any loss or claim that may arise as a result of the issuance of a new certificate.

**Section 4. Transfer Agents and Registrars.** At such time as the Corporation lists its securities on a national securities exchange or qualifies for trading in the over the counter market, the Board may appoint one or more banks or trust companies in such city or cities as the Board may deem advisable, from time to time, to act as transfer agents and/or registrars of the shares of the Corporation; and, upon such appointments being made, no certificate representing shares will be valid until countersigned by one of such transfer agents and registered by one of such registrars.

**Section 5. Transfer of Shares.** Upon surrender to the Corporation or the transfer agent of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer, it will be the duty of the Corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction upon its books. Upon the receipt of proper transfer instructions from the registered owner of uncertificated shares, such uncertificated shares will be cancelled, issuance of new equivalent uncertificated shares or certificated shares will be made to the stockholder entitled thereto and the transaction will be recorded upon the books of the Corporation.

**Section 6. Share Ledger.** The Corporation will maintain at its principal office or at the office of its counsel, accountants or transfer agents an original or duplicate share ledger containing the name and address of each stockholder and the number of shares of each class held by such stockholder.

## ARTICLE IX

### Dividends

**Section 1. Declaration.** Dividends upon the shares of the Corporation may be declared by the Board, subject to applicable provisions of law and the Charter. Dividends may be paid in cash, property or shares of the Corporation, subject to applicable provisions of law and the Charter.

**Section 2. Contingencies.** Before payment of any dividends, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board may from time to time, in its absolute discretion, think proper as a reserve fund for contingencies, for equalizing dividends, for repairing or maintaining the property of the Corporation, its subsidiaries or any partnership for which it serves as general partner or for such other purpose as the Board will determine to be in the best interest of the Corporation. The Board may modify or abolish any such reserve in the manner in which it was created.

## ARTICLE X

### Indemnification and Limitation of Liability

**Section 1. Indemnification of Agents.** The Corporation will indemnify, in the manner and to the fullest extent permitted by law, any person (or the estate of any person) who is or was a party to, or is threatened to be made a party to, any threatened, pending or completed action, suit or proceeding, whether or not by or in the right of the Corporation, and whether civil, criminal, administrative, investigative or otherwise, by reason of the fact that such person is or was a director or officer of the Corporation, or such director or officer is or was serving at the request of the Corporation as a director, officer, agent or employee of another corporation, partnership, joint venture, trust or other enterprise. To the fullest extent permitted by law, the indemnification provided herein includes expenses (including attorneys' fees), judgments, fines and amounts paid in settlement and any such expenses may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding. The Corporation will indemnify other employees and agents to such extent as may be authorized by the Board or these Bylaws and as permitted by law. Any repeal or modification of this Article X by the stockholders of the Corporation will be prospective only, and will not adversely affect any right to indemnification or advancement of expenses hereunder existing at the time of such repeal or modification.

**Section 2. Insurance.** The Corporation will to the fullest extent permitted by law, purchase and maintain insurance on behalf of any such person against any liability that may be asserted against such person.

**Section 3. Indemnification Non-Exclusive.** The indemnification provided herein is not deemed to limit the right of the Corporation to indemnify any other person for any such expenses to the fullest extent permitted by law, nor will it be deemed exclusive of any other rights to which any person seeking indemnification from the Corporation may be entitled under any agreement, vote of stockholders or disinterested directors, or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

**Section 4. Limitation of Liability.** To the fullest extent permitted by Maryland statutory or decisional law, as amended or interpreted from time to time, no director or officer of the Corporation will be personally liable to the Corporation or its stockholders, or any of them, for money damages. No amendment of these Bylaws or repeal of any of its provisions will limit or eliminate the benefits provided to directors and officers under this provision with respect to any act or omission that occurred prior to such amendment or repeal.

## ARTICLE XI

### Seal

**Section 1. Seal.** The Corporation may have a corporate seal, which may be altered at will by the Board. The Board may authorize one or more duplicate or facsimile seals and provide for the custody thereof. Unless specifically required by law, a corporate seal is not required for the due execution of any document.

**Section 2. Affixing Seal.** Whenever the Corporation is required to place its corporate seal to a document, it is sufficient to meet the requirements of any law, rule or regulation relating to a corporate seal to place the word “(SEAL)” adjacent to the signature of the person authorized to execute the document on behalf of the Corporation.

## ARTICLE XII

### Waiver of Notice

Whenever any notice is required to be given pursuant to the Charter or these Bylaws of the Corporation or pursuant to applicable law, a waiver thereof in writing, signed by the person or persons entitled to such notice, whether before or after the time stated therein, is deemed equivalent to the giving of such notice. Neither the business to be transacted at, nor the purpose of any meeting, need be set forth in the waiver of notice, unless specifically required by statute. The attendance of any person at any meeting for the express purpose of objecting to the transaction of any business on the ground that the meeting is not lawfully called or convened will not be considered a waiver of notice.

## ARTICLE XIII

### Amendment of Bylaws

The Board will have the exclusive power to adopt, alter or repeal any Bylaws of the Corporation and to make new Bylaws, provided that any amendment to Section 2 or Section 3 of Article III, or any amendment to Section 2, Section 3, Section 5 or Section 9 of Article IV requires the affirmative vote of 80% of the entire Board.

**First Amendment to the Bylaws of Pernix Therapeutics Holdings, Inc.**

October 13, 2016

On October 13, 2016, the Board of Directors (the "Board") of Pernix Therapeutics Holdings, Inc. (the "Corporation"), in accordance with the Corporation's Bylaws (the "Bylaws") and the Maryland General Corporation Law, approved and adopted the following amendment to the Bylaws, to be effective immediately:

1. Article III, Section 7 of the Bylaws is hereby amended and restated in its entirety to read as follows:

**Section 7. Voting.**

- (a) Except for the election of directors, a majority of the votes cast at a meeting of stockholders duly called and at which a quorum is present is sufficient to approve any matter that may properly come before the meeting, unless more than a majority of the votes cast is required by statute, by the Charter or by these Bylaws. Each stockholder of record has the right, at every meeting of stockholders, to one vote for each share held, except shares that are the subject of a redemption notice as provided in the Charter.
- (b) There may be no cumulative voting with respect to the election of directors. Each common share may be voted for as many individuals as there are directors to be elected and for whose election the share is entitled to be voted. At all meetings of stockholders for the election of directors, each director shall be elected by a majority of the votes cast by the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors; provided that, if the election is contested, the directors shall be elected by a plurality of the votes cast by the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. An election shall be contested if, as determined by the Board, the number of nominees for director exceeds the number of directors to be elected. A majority of votes cast shall mean that the number of votes cast "for" a director's election exceeds the number of votes cast "against" that director's election by the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors (with "abstentions" and "broker non-votes" not counted as a vote cast either "for" or "against" that director's election). In an uncontested election, if a nominee for director who is a director at the time of election does not receive the vote of at least the majority of the votes cast at any meeting for the election of directors at which a quorum is present, the director shall promptly tender his or her resignation to the Board. The Nominating Committee of the Board (the "Nominating Committee") (or a similar committee) will make a recommendation to the Board as to whether to accept or reject the tendered resignation, or whether other action should be taken. The Board will act on the tendered resignation, taking into account the Nominating Committee's (or similar committee's) recommendation, and publicly disclose (by a press release, a filing with the Securities and Exchange Commission or other broadly disseminated means of communication) its decision regarding the tendered resignation within 90 days from the date of the certification of the election results. The Nominating Committee (or similar committee) in making its recommendation, and the Board in making its decision, may each consider any factors or other information that it considers appropriate and relevant. The director who tenders his or her resignation will not participate in the recommendation of the Nominating Committee (or similar committee) or the decision of the Board with respect to his or her resignation. If a director's resignation is not accepted by the Board, such director will continue to serve until his or her successor is duly elected and qualified, or until his or her earlier death, resignation, retirement or removal in accordance with the Charter and these Bylaws. If a director's resignation is accepted by the Board pursuant to this Bylaw, or if a nominee for director is not elected and the nominee is not an incumbent director, then the Board, in its sole discretion, may fill any resulting vacancy pursuant Article IV, Section 3 of these Bylaws or may decrease the size of the Board pursuant to the provisions of Article IV, Section 2 of these Bylaws.

**Second Amendment to the Bylaws of Pernix Therapeutics Holdings, Inc.**

February 28, 2018

On February 28, 2018, the Board of Directors (the "Board") of Pernix Therapeutics Holdings, Inc. (the "Corporation"), in accordance with the Corporation's Bylaws, as amended (the "Bylaws") and the Maryland General Corporation Law, approved and adopted the following amendment to the Bylaws, to be effective immediately:

1. Article XIII of the Bylaws is hereby amended and restated in its entirety to read as follows:

**Article XIII****Amendment of the By-Laws**

Any provisions of the Bylaws of the Corporation may be altered, amended or repealed or new Bylaws may be adopted by either (i) the Board of Directors; or (ii) by the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of all of the votes entitled to be cast on the matter at any annual or special meeting of stockholders.

2. The Bylaws are hereby amended by insertion of the following provision after Article XIII thereof:

**ARTICLE XIV****Exclusive Forum for Certain Litigation**

Unless the Corporation consents in writing to the selection of an alternative forum, the Circuit Court for Baltimore City, Maryland, or, if that Court does not have jurisdiction because the action asserts a federal claim, the United States District Court for the District of Maryland, Baltimore Division, shall be the sole and exclusive forum for (a) any derivative action or proceeding brought in the right of the Corporation, (b) any action asserting a claim of breach of any duty owed by any director, officer, other employee or agent of the Corporation to the Corporation or to the stockholders of the Corporation, or (c) any action asserting a claim against the Corporation or any director, officer, other employee or agent of the Corporation arising pursuant to any provision of the MGCL

(including, without limitation, Section 2-401), the Charter or these Bylaws.

---



September 22, 2017

Douglas J. Swirsky  
5221 Crown Street  
Bethesda, MD 20816

**Re: Nomination to Serve as a Member of the Pernix Therapeutics Holdings, Inc. Board of Directors**

Dear Mr. Swirsky,

I am pleased to inform you that the Board of Directors (the "Board") of Pernix Therapeutics Holdings, Inc., a Maryland corporation (the "Company"), has nominated you to serve as a member of the Board, subject to the Company's stockholders formally electing you to the Board at the Company's annual meeting of stockholders to be held at 9:30 a.m., eastern standard time, on November 15, 2017 at the Hyatt Morristown at Headquarters Plaza, 3 Speedwell Avenue, Morristown, New Jersey 07960 (the "Annual Meeting"). If elected, your term as a Director shall extend until the Company's next annual meeting of stockholders and for as long thereafter as you are re-elected by the Company's stockholders at each annual meeting. Also, subject to formal election by the Company's stockholders, I am extending an offer to you to chair the Board's Audit Committee and serve as a member of the Board's Compensation Committee. The Company's mission is to identify, develop and commercialize specialty pharmaceutical products that exceed the expectations of patients, customers and stockholders with a high-performance culture and preeminent ethical standards. I look forward to your guidance in helping the Company fulfill its mission.

The Company's non-employee director compensation policy currently provides for an annual cash fee of \$60,000 and the following additional cash fees for participating on various committees:

	<u>Committee</u> <u>Chairperson</u>	<u>Committee</u> <u>member</u>
Audit Committee:	\$24,000	\$12,000
Compensation Committee:	\$15,000	\$7,500
Nominating and Corporate Governance Committee:	\$10,000	\$7,500

Additionally, upon your formal appointment to the Board and subject to the approval by the Company's stockholders of the Company's 2017 Omnibus Incentive Plan, in accordance with the Company's non-employee director compensation policy, you will receive an initial option grant for 50,000 shares of the Company's common stock with an exercise price equal to the closing price of the common stock as reported on NASDAQ on the date of the grant. This initial option grant will vest over a four-year period, 25% vests on each year of the anniversary of the date of the grant provided you remain on the Board. Finally, the Company's non-employee director compensation policy provides for an annual option grant for 25,000 shares of the Company's common stock, which will vest over a four-year period with 25% vesting on each year of the anniversary of the date of the grant.

By signing this letter below, you hereby consent: (i) to be nominated to the Board and to be identified as a nominee for election to the Board in the Company's proxy statement and other solicitation materials to be filed with the Securities and Exchange Commission and distributed to the Company's stockholders and in other materials in connection with the solicitation of proxies by the Company; and (ii) if elected, to serve on the Company's Board and the Board committees referenced above, and agree that during the course of your tenure on the Board and thereafter, you shall not use or disclose, in whole or in part, any of the Company's or its customers' trade secrets, confidential and proprietary information to any person or any entity for any reason or purpose whatsoever other than in the course of your appointment with the Company. We are excited for this opportunity to work with you on the Board.



As noted above, your official appointment to the Board and the Board committees referenced above is subject to stockholder approval at the Annual Meeting. We will notify you promptly if and when the stockholders approve your election to the Board.

Sincerely yours,

/s/ John A. Sedor

John A. Sedor  
Chairman of the Board and Chief Executive Officer

I hereby acknowledge receipt of this letter and accept your appointment to the Board and the Board committees referenced above, if elected at the Annual Meeting.

/s/ Douglas J. Swirsky  
Douglas J. Swirsky

---



September 22, 2017

John Leone  
 225 Ravenscliff Road  
 St. Davids, PA 19087

**Re: Nomination to Serve as a Member of the Pernix Therapeutics Holdings, Inc. Board of Directors**

Dear Mr. Leone,

I am pleased to inform you that the Board of Directors (the "Board") of Pernix Therapeutics Holdings, Inc., a Maryland corporation (the "Company"), has nominated you to serve as a member of the Board, subject to the Company's stockholders formally electing you to the Board at the Company's annual meeting of stockholders to be held at 9:30 a.m., eastern standard time, on November 15, 2017 at the Hyatt Morristown at Headquarters Plaza, 3 Speedwell Avenue, Morristown, New Jersey 07960 (the "Annual Meeting"). If elected, your term as a Director shall extend until the Company's next annual meeting of stockholders and for as long thereafter as you are re-elected by the Company's stockholders at each annual meeting. Also, subject to formal election by the Company's stockholders, I am extending an offer to you to serve as a member of the Board's Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. The Company's mission is to identify, develop and commercialize specialty pharmaceutical products that exceed the expectations of patients, customers and stockholders with a high-performance culture and preeminent ethical standards. I look forward to your guidance in helping the Company fulfill its mission.

The Company's non-employee director compensation policy currently provides for an annual cash fee of \$60,000 and the following additional cash fees for participating on various committees:

	<u>Committee</u> <u>Chairperson</u>	<u>Committee</u> <u>member</u>
Audit Committee:	\$24,000	\$12,000
Compensation Committee:	\$15,000	\$7,500
Nominating and Corporate Governance Committee:	\$10,000	\$7,500

Additionally, upon your formal appointment to the Board and subject to the approval by the Company's stockholders of the 2017 Omnibus Incentive Plan, in accordance with the Company's non-employee director compensation policy, you will receive an initial option grant for 50,000 shares of the Company's common stock with an exercise price equal to the closing price of the common stock as reported on NASDAQ on the date of the grant. This initial option grant will vest over a four-year period, 25% vests on each year of the anniversary of the date of the grant provided you remain on the Board. Finally, the Company's non-employee director compensation policy provides for an annual option grant for 25,000 shares of the Company's common stock, which will vest over a four-year period with 25% vesting on each year of the anniversary of the date of the grant.

By signing this letter below, you hereby consent: (i) to be nominated to the Board and to be identified as a nominee for election to the Board in the Company's proxy statement and other solicitation materials to be filed with the Securities and Exchange Commission and distributed to the Company's stockholders and in other materials in connection with the solicitation of proxies by the Company; and (ii) if elected, to serve on the Company's Board and the Board committees referenced above, and agree that during the course of your tenure on the Board and thereafter, you shall not use or disclose, in whole or in part, any of the Company's or its customers' trade secrets, confidential and proprietary information to any person or any entity for any reason or purpose whatsoever other than in the course of your appointment with the Company. We are excited for this opportunity to work with you on the Board.

As noted above, your official appointment to the Board and the Board committees referenced above is subject to stockholder approval at the Annual Meeting. We will notify you promptly if and when the stockholders approve your election to the Board.

Sincerely yours,

/s/ John A. Sedor

John A. Sedor  
Chairman of the Board and Chief Executive Officer

I hereby acknowledge receipt of this letter and accept your appointment to the Board and the Board committees referenced above, if elected at the Annual Meeting.

/s/ John Leone  
John Leone

---

## WAIVER, AMENDMENT AND CONSENT AGREEMENT

THIS WAIVER, AMENDMENT AND CONSENT AGREEMENT dated as of November 2, 2017 (this "**Agreement**") is entered into among Pemix Therapeutics Holdings, Inc. (the "**Company**") and the Holders party hereto (the "**Consenting Holders**"), in their capacity as Holders of the Company's 12% Senior Secured Notes due 2020 (the "**Securities**").

WHEREAS, the Company, the guarantors party thereto and the Trustee have previously entered into that certain Indenture dated as of August 19, 2014 (the "**Indenture**"), as amended and supplemented by the First Supplemental Indenture dated as of April 21, 2015 and the Second Supplemental Indenture dated as of July 21, 2017, providing for the issuance and governance of the Securities;

WHEREAS, Pemix Ireland Limited, a subsidiary of the Company and a Credit Party under the Indenture, possesses the rights to market and distribute an authorized generic version (the "**Authorized Treximet Generic**") of the pharmaceutical product containing sumatriptan and naproxen sodium and currently marketed under the Treximet<sup>®</sup> trademark ("**Treximet**");

WHEREAS, the Company wishes to maintain inventory of the Authorized Treximet Generic at, and market and distribute the Authorized Treximet Generic through, its indirectly wholly owned subsidiary, Macoven Pharmaceuticals, L.L.C.;

WHEREAS, pursuant to Section 9.02(a) of the Indenture, the Holders of a majority in aggregate principal amount of the Securities then outstanding may waive compliance with and amend any provision of the Indenture, except as otherwise provided by Section 9.02(a) of the Indenture;

WHEREAS, the Consenting Holders collectively hold at least a majority in aggregate principal amount of the Securities outstanding as of the date hereof;

WHEREAS, the Company desires and has requested that the Consenting Holders give their written consent to waive compliance with and amend certain provisions of the Indenture as set forth in Section 2 of this Agreement; and

WHEREAS, the Consenting Holders desire on behalf of the Holders of all of the Notes to waive compliance with and amend certain provisions of the Indenture as set forth in Section 2 of this Agreement, subject to the satisfaction of the conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

**SECTION 1. *Defined Terms.*** For all purposes of this Agreement, except as otherwise defined herein, terms used herein in capitalized form and defined in the Indenture shall have the meaning set forth in the Indenture.

---

**SECTION 2. Waiver.** The Consenting Holders hereby waive compliance with each Credit Party's obligations as set forth in Section 4.10(b) of the Indenture solely to the extent necessary to permit Permex Ireland Limited, on the one hand, and Macoven Pharmaceuticals, L.L.C., on the other, to enter into the intercompany distribution agreement substantially in the form attached hereto as Exhibit A (the "**Macoven Distribution Agreement**"), for the sole purpose of granting Macoven Pharmaceuticals, L.L.C. the rights to market and distribute the Authorized Treximet Generic, and waive any Event of Default which may exist under Section 6.01(d) of the Indenture or which may arise from entry into the Macoven Distribution Agreement.

**SECTION 3. Notice.** The Company shall provide notice of this Agreement in accordance with Section 9.02(b) of the Indenture by providing to holders of the Securities a notice substantially in the form attached hereto as Exhibit B.

**SECTION 4. Amendments to Indenture.** The Parties hereby further agree that:

- a. Each of the following definitions appearing in section 1.01 of the Indenture shall be deleted and restated as follows:

"Intercompany Distribution Agreement" means, collectively, (a) the Product License and Distribution Agreement, dated as of August 19, 2014, between Ireland Newco and Permex Therapeutics, LLC as amended on November 2, 2017, and (b) the Product License and Distribution Agreement, dated as of November 2, 2017, between Ireland Newco and Macoven Pharmaceuticals, L.L.C., and any replacement or additional such agreement on substantially similar terms, provided, such replacement or additional agreement shall not be adverse to the interests of the Holders in any respect.

"Treximet" means the pharmaceutical product containing sumatriptan and naproxen sodium and currently marketed under the Treximet® trademark, and any authorized generic of Treximet.

- b. The following shall be inserted as clause (c) to Section 4.27 of the Indenture:

The Issuer shall provide a true and accurate copy of any amended, revised or updated Schedule 5.1 of the Intercompany Distribution Agreement to the Holders as soon as reasonably practicable and in any event no later than 30 days of such amendment taking effect. Each Credit Party shall not terminate the Intercompany Distribution Agreement, or otherwise exercise its rights pursuant to Section 11.3 of the Intercompany Distribution Agreement without the prior written consent of the Required Holders. Section 11.4 of the Intercompany Distribution Agreement shall not be amended, modified or waived, directly or indirectly, without the prior written consent of the Required Holders. Each Credit Party shall not, directly or indirectly, assign or permit to be assigned the Intercompany Distribution Agreement except as expressly permitted by Section 12.4 of the Intercompany Distribution Agreement, and any such assignee of the Intercompany Distribution Agreement shall, at all times during any such assignment, remain a wholly-owned subsidiary of the Issuer and Guarantor and shall not create, assume or suffer to exist any Lien on any of its assets.

---

c. The following shall be inserted as clause (n) to Section 6.01 of the Indenture:

failure by any Credit Party to comply with Section 4.27(c).

d. Section 6.01 (d) of the Indenture shall be deleted and replaced with the following:

failure by any Credit Party for 60 days (or, in the case of a failure to comply with Section 4.03, 4.04, 4.05, 4.06, 4.07, 4.10, 4.11, 4.20, 4.21, 4.22, 4.23, 4.24, 4.25, 4.26, 4.27 (a)-(b) or 5.01, 30 days) after written notice from the Trustee or the Holders of at least 25% in principal amount of the Securities then outstanding has been received by such Credit Party to comply with any of its other agreements contained in the Securities or this Indenture (the "other covenants provision")

**SECTION 5. Beneficial Ownership.** Each undersigned Consenting Holder (each a "**Beneficial Owner**") represents and warrants to the Trustee that, as of the date hereof, it is the legal or beneficial holder of or the investment manager with sole discretionary authority in respect of the principal amount of the Securities indicated under its name below and as evidenced by the confirmation with respect to such Beneficial Owner attached hereto as Exhibit C, and hereby directs the Trustee to execute and deliver this Agreement in accordance with Section 6.05 of the Indenture.

**SECTION 6. Conditions Precedent.** The effectiveness of this Agreement is subject to: (i) the delivery of an Officer's Certificate and Opinion of Counsel pursuant to Section 9.03 of the Indenture in the forms attached hereto as Exhibits D and E, respectively; (ii) (a) payment of \$100,000 to Sullivan & Cromwell LLP with respect to fees and expenses incurred in connection with the negotiation and execution of this Agreement and matters relating to the interpretation of the Indenture and (b) the payment of the reasonably incurred fees and expenses of Arthur Cox incurred in connection with the negotiation and execution of this Agreement; *provided* that the Company shall not reimburse any further fees or expenses related to this Agreement (except for the fees and expenses of the Trustee, including, without limitation, those of its counsel, payable in accordance with Section 7.06 of the Indenture), and it is understood and agreed that reimbursement of future fees relating to the interpretation of or future amendments of the Indenture shall require a separate express written consent of the Company; and (iii) the due authorization, execution and delivery of this Agreement by all parties.

**SECTION 7. Binding Effect; Ratification of Indenture.** Pursuant to Section 9.03(a) of the Indenture, this Agreement shall bind every Holder after it becomes effective. Except as expressly set forth herein, the Indenture and the rights of the Company, the Guarantors and the Holders thereunder are in all respects ratified and confirmed and all the terms thereof shall remain in full force and effect.

**SECTION 8. Successors and Assigns.** All covenants and agreements in this Agreement by the parties hereto shall bind their respective successors and assigns and inure to the benefit of their permitted successors and assigns, whether so expressed or not.

**SECTION 9. Multiple Originals; Telecopies.** The parties may sign any number of copies of this Agreement. Each signed copy shall be an original, but all of them together represent the same agreement. Delivery of an executed counterpart of a signature page to this Agreement by PDF or facsimile shall be effective as delivery of a manually executed counterpart of this Agreement.

**SECTION 10. Governing Law.** THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK (INCLUDING NEW YORK GENERAL OBLIGATION LAW 5-1401 AND ANY SUCCESSOR THERETO).

**SECTION 11. Effectiveness.** This Agreement shall become effective on the first date on which the Consenting Holders shall have received counterparts hereof signed by each of the Company and Trustee (or, in the case of any party as to which an executed counterpart shall not have been received, receipt by the Consenting Holders in form satisfactory to it of telegraphic, telex or other written confirmation from such party of execution of a counterpart hereof by such party) and all conditions precedent shall have been met or waived.

**SECTION 12. Trustee Not Responsible.** The recitals contained herein shall be taken as the statements of the Company and the Consenting Holders, and the Trustee assumes no responsibility for their correctness. The Trustee makes no representation as to the validity or sufficiency of this Agreement.

*[Remainder of page intentionally left blank; signature pages follow]*

---

IN WITNESS WHEREOF, the undersigned, being duly authorized, have executed this Agreement as of the date first above written.

PERNIX THERAPEUTICS HOLDINGS, INC.

By: /s/ John A. Sedor  
Name: John A. Sedor  
Title: Chief Executive Officer

---

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first written above.

DEERFIELD PARTNERS, L.P.  
By: Deerfield Mgmt, L.P., its General Partner  
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark  
Name: David J. Clark  
Title: Authorized Signatory

DEERFIELD INTERNATIONAL MASTER FUND, L.P.  
By: Deerfield Mgmt, L.P., its General Partner  
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark  
Name: David J. Clark  
Title: Authorized Signatory

DEERFIELD SPECIAL SITUATIONS FUND, L.P.  
By: Deerfield Mgmt, L.P., its General Partner  
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark  
Name: David J. Clark  
Title: Authorized Signatory

DEERFIELD PRIVATE DESIGN FUND II, L.P.  
By: Deerfield Mgmt, L.P., its General Partner  
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark  
Name: David J. Clark  
Title: Authorized Signatory

DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P.  
By: Deerfield Mgmt, L.P., its General Partner  
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark  
Name: David J. Clark  
Title: Authorized Signatory

---



**Athyrium Opportunities Fund (A) LP**  
**Athyrium Opportunities Fund (B) LP**

By: Athyrium Opportunities Associates LP, its general partner

By: Athyrium Opportunities Associates GP LLC, its general partner

By: /s/ Andrew Hyman

Name: Andrew Hyman

Title: Authorized Signatory

---

**Acknowledged By:**

U.S. BANK NATIONAL ASSOCIATION, as Trustee

By: /s/ Steven J. Gomes

Name: Steven J. Gomes

Title: Vice President

---

**Exhibit A**

**Macoven Distribution Agreement**

---

**Exhibit B**  
**Form of Notice to Holders**

---

**Exhibit C**

**Indenture, dated as of August 19, 2014 (the "Indenture"), as amended and supplemented by the First Supplemental Indenture dated as of April 21, 2015 and the Second Supplemental Indenture dated as of July 21, 2017 (the "Indenture"), among Pernix Therapeutics Holdings, Inc., (the "Issuer"), the Guarantors party thereto and U.S. Bank National Association, as Trustee, relating to the Issuer's 12% Senior Secured Notes due 2020**

**Beneficial Note Holder Certification Form**

---

**Exhibit D**  
**Officer's Certificate**

---

**Exhibit E**  
**Opinion of Counsel**

---

**LIST OF SUBSIDIARIES**

<b>Name</b>	<b>Jurisdiction</b>
Macoven Pharmaceuticals, LLC	Louisiana
Pemix Manufacturing, LLC	Texas
Pemix Ireland Limited	Ireland
Pemix Therapeutics, LLC	Louisiana
Pemix Sleep, Inc.	Delaware
Cypress Pharmaceuticals, Inc.	Mississippi
Gaine, Inc.	Delaware
Respicopea, Inc.	Delaware
Hawthorn Pharmaceuticals, Inc.	Mississippi
Pemix Ireland Pain Designated Activity Company	Ireland
Pemix Holdco 1, LLC	Delaware
Pemix Holdco 2, LLC	Delaware
Pemix Holdco 3, LLC	Delaware



**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-168877, No. 333-167327, No. 333-166062, No. 333-175992, No. 333-204997, No. 333-210852, and No. 333-221678), Form S-4 (No. 333-200042) and Forms S-3 (No. 333-186048, No. 333-174629, No. 333-200011, No. 333-219420, No. 333-221717) of Pernix Therapeutics Holdings, Inc. of our report dated March 8, 2018 relating to the consolidated balance sheets of the Company as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows and the related consolidated statement schedule for each of the two years in the period ending December 31, 2017.

*/s/ Cherry Bekaert LLP*

Atlanta, Georgia  
March 8, 2018

---

## CERTIFICATION

I, John A. Sedor, certify that:

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

March 8, 2018

/s/ JOHN A. SEDOR

John A. Sedor  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

---

## CERTIFICATION

I, Angus W. Smith, certify that:

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

March 8, 2018

/s/ ANGUS W. SMITH

Angus W. Smith

*Senior Vice President, Chief Business Officer*  
(Principal Financial Officer)

---

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

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

Date: March 8, 2018

/s/ JOHN A. SEDOR

John A. Sedor  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: March 8, 2018

/s/ ANGUS W. SMITH

Angus W. Smith  
*Senior Vice President, Chief Business Officer*  
*(Principal Financial Officer)*

---

