PERNIX THERAPEUTICS HOLDINGS, INC.
Form 10-K
March 18, 2013

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

FORM 10-K

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

For the fiscal year ended December 31, 2012

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

For the transition period from _____ to _____

Commission file number: 001-14494

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

Maryland	33-0724736
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification Number)
10003 Woodloch Forest Drive The Woodlands, TX 77380	
(Address of principal executive offices) (Zip Code)	(832) 934-1825 (Telephone number, including area code)

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

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

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

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

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

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

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

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

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

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 29, 2012 was approximately $95,321,765, based upon the closing sales price of the registrant's common stock as reported on the NYSE MKT LLC. 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 15, 2013, the registrant had 37,724,132 shares of its common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement prepared for use in connection with the registrant's 2013 annual meeting of shareholders scheduled to be held on June 20, 2013, have been incorporated by reference in Part III of this Form 10-K.

PERNIX THERAPEUTICS HOLDINGS, INC.
Annual Report on Form 10-K for the Year Ended December 31, 2012

TABLE OF CONTENTS

Table of Contents

Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management's prospects, plans and objectives; and any other statements about management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "project," "should," "target," "will," "would" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the risks described below in "Item 1A. Risk Factors." If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. 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, 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.

Table of Contents

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Introduction

Pernix Therapeutics Holdings, Inc. ("Pernix", the "Company, "we" or "our") is a specialty pharmaceutical company focused on the sales, marketing, manufacturing and development of branded, generic and over-the-counter, which we refer to herein as OTC, pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. We expect to execute our growth strategy which includes the horizontal integration of our branded prescription, generic and OTC businesses. We also plan to continue to make strategic acquisitions of products and companies, as well as develop and in-license additional products. We manage a portfolio of branded and generic products. Our branded products for the pediatrics market include CEDAX®, an antibiotic for middle ear infections, NATROBA®, a topical treatment for head lice marketed under an exclusive co-promotion agreement with ParaPRO, LLC, and a family of prescription treatments for cough and cold (ZUTRIPRO®, REZIRA®, BROVEX®, ALDEX® and PEDIATEX®). Our branded products for gastroenterology include OMECLAMOX-PAK®, a 10-day treatment for H. pylori infection and duodenal ulcer disease, and REZYST®, a probiotic blend to promote dietary management. Through our wholly-owned subsidiary Pernix Sleep, Inc. (formerly Somaxon Pharmaceuticals, Inc.), we market SILENOR® (doxepin), which is approved for the treatment of insomnia characterized by difficulty with sleep maintenance and is not a controlled substance. Through our license agreement with Pharmaceutical Associates, Inc., we market VERIPRED™, a prescription drug product indicated for the control of severe allergic conditions. In addition, a product candidate utilizing cough-related intellectual property is in development for the U.S. OTC market. We promote our branded pediatric and gastroenterology products through our sales force. We market our generic products in the areas of cough and cold, pain, vitamins, dermatology, antibiotics and gastroenterology through our wholly-owned subsidiaries, Macoven Pharmaceuticals and Cypress Pharmaceuticals. Our wholly-owned subsidiary, Pernix Manufacturing, manufactures and packages products for the pharmaceutical industry in a wide range of dosage forms.

On March 6, 2013, we acquired all of the outstanding common stock of Somaxon Pharmaceuticals, Inc. pursuant to an agreement and plan of merger dated December 10, 2012. As a result of the merger, each outstanding share of Somaxon common stock was converted into the right to receive approximately 0.477 shares of the Company's common stock, with cash paid in lieu of fractional shares. As a result of the merger, the Company issued an aggregate of approximately 3,665,689 shares of its common stock to the former stockholders of Somaxon. As a result of the merger, we changed the name of Somaxon Pharmaceuticals, Inc. to Pernix Sleep, Inc.

On December 31, 2012, we completed the acquisition of a privately-owned, generic pharmaceutical company, Cypress Pharmaceuticals, Inc. and its branded pharmaceutical subsidiary Hawthorn Pharmaceuticals, Inc., which we refer to collectively herein as Cypress. Cypress offers a wide array of generic pharmaceutical products in the areas of cough and cold, nutritional supplements, analgesics, urinary tract, women's health, prenatal vitamins and dental health, as well as allergy, respiratory, iron deficiency, nephrology and pain management. Hawthorn offers a broad portfolio of branded products including allergy, respiratory, iron deficiency, nephrology and pain management. We paid an aggregate purchase price of up to $102.3 million. This purchase price included $52 million in cash, 4,427,084 shares of our common stock having an aggregate market value equal to approximately $34.3 million based on our common stock's closing price per share of $7.75 as reported on the NYSE MKT LLC on December 31, 2012, up to $6.5 million in holdback and contingent payments, $4.5 million to be deposited in escrow on December 15, 2013, and $5.0 million in shares of our common stock contingent upon the occurrence of a milestone event. The Cypress acquisition is expected to significantly increase and broaden the Company's branded and generic product portfolio and to provide the Company with in-house product development and regulatory expertise. Since 2008, Cypress has been awarded nine ANDA and three NDA approvals (REZIRA, ZUTRIPRO and VITUZ) and currently has fifteen ANDAs and two NDAs on file with the FDA for future approvals.

We entered into a $42 million credit facility on December 31, 2012 with Midcap Funding V, LLC as administrative agent, as a lender and as co-bookrunner and sole lead arranger, and with Business Development Corporation of America, as co-bookrunner, and additional lenders from time to time party thereto. Subject to certain permitted liens, our obligations under this facility are secured by a first priority perfected security interest in substantially all of our assets and the assets of our subsidiaries. The proceeds from this facility were used to fund a portion of the cash consideration of the acquisition of Cypress. Our credit facility with MidCap contains restrictive covenants and financial covenants that are significantly more onerous than those contained in our prior credit facility. For additional information, see Note 13 – Debt and Lines of Credit to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Table of Contents

On July 2, 2012, we completed our acquisition of the business assets of Great Southern Laboratories (GSL), a pharmaceutical contract manufacturing company located in Houston, Texas. We closed on the related real estate on August 30, 2012. Upon the final closing, the Company paid an aggregate of approximately $4.9 million (including $300,000 deposited to an escrow that was subsequently refunded to the Company in payment of unrecorded liabilities), and assumed certain liabilities totaling approximately $5.9 million, for substantially all of GSL's assets including the land and buildings in which GSL operates. GSL has an established manufacturing facility with an existing base of customers in the pharmaceutical industry, which provides us with additional income and potential cost savings. We acquired the GSL assets through our wholly-owned subsidiary, Pernix Manufacturing, LLC.

Pernix was incorporated in November 1996, is headquartered in The Woodlands, Texas and employs approximately 251 people full-time. The words "we," "us" or "our" refer to Pernix and its consolidated subsidiaries, except where the context otherwise requires.

Business Strategy

Our objective is to be a leader in developing, marketing and selling prescription (branded and generic) and over-the-counter, or OTC, pharmaceutical products in the U.S. for pediatric and adult indications. Our strategy to achieve this objective includes the following elements:

Leveraging our focused sales and marketing organization- We have built an effective sales and marketing organization consisting of approximately 123 sales representatives as of March 15, 2013 who are focused on pediatric, gastroenterology, and targeted primary care physicians. In January 2013, the Company commenced the integration of the Pernix and Cypress sales forces which has resulted in the elimination of approximately 75 sales representatives across the Company.

We believe the concentration of high volume prescribers in our target markets enables us to effectively promote our products with a smaller and more focused sales and marketing organization than would be required for other markets. We intend to acquire or in-license products and late-stage product development candidates and to develop products that will leverage the capacity of our sales and marketing organization, as well as the relationships we have established with our target physicians. Further, we believe fixed costs from our field sales personnel are significantly less per representative than those incurred by larger, more established pharmaceutical companies, due to our higher ratio of incentive based compensation. This aligns representative pay to sales performance, providing upside commission potential and attracting top sales performers.

Develop and sell generic versions of selected branded products through our Macoven and Cypress subsidiaries- We intend to continue developing our Macoven and Cypress subsidiaries to diversify our product mix while creating a base business without branding, patent life or sales force detailing. However, certain generic products in specific geographic areas may be promoted by our sales force. Our business goals for Macoven and Cypress include launching authorized generic products for branded pharmaceutical companies including generic equivalents of our own branded products, generic products for patented or niche branded products, and generic products that have a limited number of alternatives.

Development of OTC Products- The Company has formed an OTC division which is dedicated to marketing and acquiring products for the consumer healthcare market. In 2013, the Company expects to launch a cough medicine for children. Four offerings are expected which will be indicated for cough, daytime and nighttime cough and cold, and cough, cold and fever. These products will be marketed in various retail outlets including food stores, drug stores and mass merchandise outlets. In addition, the OTC division is exploring the possibility of the Rx to OTC switch of SILENOR (doxepin). The Company continues to evaluate these opportunities as well as potential acquisitions or licensing opportunities for the OTC market.

5

Table of Contents

Acquiring or in-licensing late-stage product development candidates- We also selectively seek to acquire or in-license late-stage product development candidates. We are focused on product development candidates that are ready for or have already entered Phase III clinical trials and should therefore present less development risk than product candidates at an earlier stage of development. We focus on product development candidates that would be prescribed by our target physicians, especially in pediatrics, gastroenterology and certain other niche markets. We believe that our established sales and marketing organization and our cash position make us an attractive commercialization partner for many biotechnology and pharmaceutical companies with late-stage product development candidates. We are actively pursuing the acquisition of rights to product development candidates that, if successful, may require the use of substantial capital resources.

Acquiring or in-licensing approved pharmaceuticals- We have historically grown our business by acquiring or in-licensing rights to market and sell prescription and OTC pharmaceutical products, and we intend to continue to grow in this manner. We are particularly focused on products that are prescribed by pediatricians and that are under-promoted by large pharmaceutical companies. We believe that the revenue threshold for products that large pharmaceutical companies can promote effectively is increasing, potentially creating attractive opportunities for us to acquire additional products in pediatrics and certain other therapeutic areas where the market sizes are smaller. We are actively pursuing the acquisition of rights to market and sell additional products which, if successful, may require the use of substantial capital resources.

Expand into new geographical and therapeutic markets- We have established a sales force of approximately 18 representatives, consisting of new and existing representatives, dedicated exclusively to gastroenterology following our entry into the license and supply agreement for OMECLAMOX-PAK®. We may also hire additional representatives to our sales force in both existing and new geographic markets to promote products in our existing product line. We intend to continue to explore additional therapeutic areas which have similar characteristics to the pediatrics market, including areas that are underserved by current pharmaceutical companies, where there is a readily identifiable set of high prescribing physicians for efficient sales force deployment or where we can acquire promotion sensitive products that are currently under-promoted by existing large pharmaceutical companies. The acquisition of Cypress expanded our presence in the primary care area in our existing geographical markets.

Products and Product Candidates

Key Promoted Products

Pernix markets a broad branded product portfolio. We also market generic products through our wholly-owned subsidiaries, Macoven Pharmaceuticals and Cypress Pharmaceuticals. The table below provides information on our key branded product portfolio as of March 15, 2013.

Marketed Products	Primary Indication	Rights	Launched by Pernix
CEDAX	Bronchitis, ear and throat infections	Pernix	Q2:2010
NATROBA	Topical treatment of head lice	License from ParaPRO, LLC	Q3:2011
VERIPRED	Inflammation from asthma symptoms	License from Pharmaceutical Associates, Inc.	Q1:2013
OMECLAMOX-PAK	H.pylori infection and duodenal ulcers	License from GEL	Q2:2012

REZIRA	Cough and nasal congestion	Pernix	Q1:2013
ZUTRIPRO	Cough and nasal congestion	Pernix	Q3:2011
SILENOR	Sleep maintenance	Pernix	Q2:2013
REPREXAIN	Short term management of acute pain	License from Amneal Pharmaceuticals	Q1:2013

Table of Contents

CEDAX Line. CEDAX is a third generation oral cephalosporin indicated for the treatment of mild to moderate acute bacterial exacerbations of chronic bronchitis, middle ear infection due to haemophilus influenza or streptococcus pyogenes. We acquired the CEDAX product line from Shionogi in the first half of 2010, and launched our CEDAX product line in the second quarter of 2010. We sell a variety of dosages utilizing both capsule and oral suspension drug delivery methodologies.

Market Opportunity. According to the American Academy of Pediatrics, over 5 million cases of middle ear infections occur annually in children, which result in more than 10 million antibiotic prescriptions per year.

Other Treatments. Other branded and similar prescription treatments marketed in the U.S. that compete with our CEDAX line include Suprax, Amoxicillin, Omnicef, Cefzil, Ceclor and Ceftin.

Intellectual Property. We have a non-exclusive license to the patent used in our CEDAX product line. The patent will likely expire on February 4, 2014; however, we do not expect the expiration of this patent to have a material adverse impact on sales of CEDAX. We also own a trademark on the name CEDAX in the U.S. Please see the "Intellectual Property" section of this Item 1 for a more detailed description of the rights associated with the CEDAX line of products.

NATROBA Line. NATROBA Topical Suspension is a prescription medicine used to treat head lice (pediculosis capitis) in adults and children 4 years of age and older. NATROBA contains the active ingredient spinosad, which is derived from a naturally occurring soil bacterium. NATROBA received FDA approval for use in patients ages 4 and up in January 2011. We entered into a co-promotion agreement with ParaPRO for NATROBA in 2010 and launched NATROBA in the beginning of August 2011.

NATROBA Topical Suspension is available in a ready to use 4 oz. bottle for all hair types. NATROBA Topical Suspension is easily applied to the scalp and hair and is left on for ten minutes prior to rinsing with warm water. Once NATROBA Topical Suspension is rinsed off, a fine-tooth comb may be used to remove dead lice and nits from the hair and scalp, but combing is not required.

NATROBA's FDA approval was supported by superiority studies versus NIX® (permethrin 1%). In two Phase III clinical studies published in Pediatrics, nearly twice as many patients were free of head lice after treatment with NATROBA Topical Suspension compared with NIX® (permethrin 1%). NATROBA Topical Suspension has been shown to be effective in eliminating head lice infestations without the need for time consuming combing in a single treatment in most patients. Currently, other common prescription and over the counter medications require combing as part of the treatment regimen.

In Phase III clinical studies comparing NATROBA Topical Solution to NIX® (permethrin 1%), there were few adverse events reported. The most commonly occurring adverse events included application-site erythema (redness of the skin) which occurred in 3% of the NATROBA patients (vs. 7% of permethrin 1%), ocular hyperemia (redness and irritation of the eyes) which occurred in 2% of the NATROBA patients (vs. 3% of permethrin 1%) and application-site irritation which occurred in 1% of NATROBA patients (vs. 2% of permethrin 1%). Although adverse event rates were low for both products, application site redness occurred less frequently in patients treated with NATROBA than in patients treated with NIX® (permethrin 1%).

Market Opportunity. Head lice is a highly communicable condition that occurs primarily among school age children. As reported by Pediatrics in 2007, an estimated 6 to 12 million cases of head lice occur annually in the United States in children ages 3 to 11.

Other Treatments. Other similar branded and generic topical prescription lice treatments include NIX®, OVIDE®, LINDANE, ULESFIA TM, and SKLICE®.

Launch Focus. Our sales force promotes NATROBA primarily to the pediatric market, including pediatricians and school nurses. Pharmacist and consumer education are also an important element of our promotional efforts to market NATROBA. In the third quarter of 2012, the Company launched Spinosad, a generic version of NATROBA.

Table of Contents

Intellectual Property. The NATROBA product line is covered by four patents, which are owned by ParaPRO and for which we have exclusive co-promotion rights. The last patent covering the NATROBA product line will likely expire in 2021. Please see the "Acquisitions and License Agreements, Collaborations and Co-Promotions" section of this Item 1 for a more detailed description of our rights associated with the NATROBA line of products.

VERIPRED® 20 (20 mg prednisolone per 5 mL) is a prescription drug product indicated for the control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in adult and pediatric populations with seasonal or perennial allergic rhinitis, asthma, contact and atopic dermatitis, serum sickness, and drug hypersensitivity reactions. VERIPRED 20 was launched in January 2009 by Pharmaceutical Associates.

Market Opportunity: VERIPRED 20 is the most concentrated liquid prednisolone on the market. VERIPRED 20 also contains a proprietary anti-bitter mask. The main competitors of VERIPRED 20 are generic prednisolone (various concentrations/manufacturers), Shionogi Inc.'s Orapred brand and Laser Pharmaceuticals' Millipred™ Brand. VERIPRED 20's main promotional focus is the pediatric market.

Other Treatments. Laser Pharmaceuticals' Millipred Oral Solution, Millipred Tablets, Millipred DP (6 and 12 day packs); Shionogi's Orapred ODT, Orapred OS; Taro Pharma's Flo-Pred Oral Solution; and generics from various manufacturers in different strengths.

Intellectual Property. We receive all our rights to VERIPRED 20, including the registered trademark, from the Development, License and Supply Agreement between Pharmaceutical Associates, Inc. and Hawthorn Pharmaceuticals dated July 18, 2008, as amended, pursuant to which Hawthorn has the exclusive right to market, sell and distribute VERIPRED 20 in the United States.

OMECLAMOX-PAK is indicated for the treatment of patients with H.pylori infection and duodenal ulcer disease (active or one-year history of duodenal ulcer disease) to eradicate H.pylori. Eradication of H.pylori has been shown to reduce the risk of duodenal ulcer recurrence. Each OMECLAMOX-PAK box contains a full 10-day course of therapy, and 10 individual daily dose cards – one card for each day of therapy. Each daily card contains the clearly-marked AM and PM dose of: one 20 mg Omeprazole delayed-release capsule, one 500 mg Clarithromycin tablet, and two 500 mg Amoxicillin capsules. Patients should take one OMECLAMOX-PAK dose in the AM and one dose in the PM, as indicated on the daily dose card, before meals.

Market Opportunity. H pylori is a gram negative bacterium that colonizes in the stomach and duodenum. When present, this bacterial infection has been proven to be the cause of over 90% of duodenal ulcers. These ulcers commonly cause abdominal pain and may lead to serious bleeding. The U.S. prevalence of H.pylori is approximately 30%-40% in adults.

Other Treatments. Other treatments include PrevPac, Helidac, and Pylera.

Intellectual Property. We receive all of our rights to OMECLAMOX-PAK from our License and Supply Agreement with Gastro-Entero Logic, LLC. Please see the "Acquisitions and License Agreements, Collaborations and Co-Promotions" section of this Item 1 for a more detailed description of our rights associated with OMECLAMOX-PAK.

REZIRA (Hydrocodone Bitartrate and Pseudoephedrine HCI) is an oral solution 5 mg/60 mg per 5 mL indicated for the relief of cough and nasal congestion associated with the common cold in adults 18 years of age or older. REZIRA was launched in the third quarter of 2011 by Hawthorn/Cypress.

Market Opportunity. Over the five years preceding 2012, the cough and cold medicine manufacturing OTC industry has enjoyed stable growth. From 2007 to 2012, revenue was expected to rise at an average annual rate of 1.2% to $2.3 billion. Demand for over-the-counter (OTC) cough and cold medicines is primarily linked to the occurrence and severity of cold and flu seasons, and changes in private health insurance coverage.

Table of Contents

Since the FDA took action against unapproved hydrocodone products in October 2007, the options for prescribing physicians has been limited. Currently there are only six approved hydrocodone cough medications on the market. REZIRA is the only FDA approved cough medication containing only hydrocodone and pseudoephedrine.

Hydrocodone is a narcotic antitussive. Two commonly prescribed narcotic cough medications containing hydrocodone are UCB's Tussionex® and Endo Pharma's Hycodan®. Each of these medications is also available in generic alternatives.

Two commonly used decongestants are phenylephrine and pseudoephedrine. Phenylephrine is found in OTC treatments, such as Johnson and Johnson's Sudafed PE, Pfizer's Robitussin® CF, McNeil-PPC, Inc.'s Tylenol® Sinus and Novartis Consumer Health Inc.'s Theraflu®. Pseudoephedrine is found in OTC treatments, such as Johnson and Johnson's Sudafed®, Burroughs Wellcome Fund's Actifed®, GlaxoSmithKline plc's Contac® and Schering-Plough HealthCare Products Inc.'s Claritin®-D.

Other Treatments. Other branded and similar antihistamine, decongestant, and cough suppressants marketed in the U.S. include prescription and OTC cold, cough and allergy products.

Intellectual Property. We have a pending trademark application for the REZIRA name in the U.S. We believe REZIRA's status as an FDA approved product provides us with a limited opportunity to operate in this market without direct branded competitors, although nothing precludes a competitor from entering the market after receiving FDA approval.

ZUTRIPRO® (Hydrocodone Bitartrate, Chlorpheniramine Maleate and Pseudoephedrine HCI) is an oral solution 5mg/4mg/60 mg per 5 mL indicated for the relief of cough and nasal congestion associated with the common cold and relief of upper respiratory allergy symptoms including nasal congestion in adults 18 years of age or older. ZUTRIPRO was launched in the third quarter of 2011.

Market Opportunity. Over the five years preceding 2012, the cough and cold medicine manufacturing OTC industry has enjoyed stable growth. From 2007 to 2012, revenue was expected to rise at an average annual rate of 1.2% to $2.3 billion. Demand for over-the-counter (OTC) cough and cold medicines is primarily linked to the occurrence and severity of cold and flu seasons, and changes in private health insurance coverage.

Since the FDA took action against unapproved hydrocodone products in October 2007, the options for prescribing physicians has been limited. In March 2011, the FDA pulled over 400 unapproved cough and cold products from the market leaving a significant void in the cough and cold marketplace. Currently there are only six approved hydrocodone cough medications on the market. ZUTRIPRO is the only FDA approved cough medication containing a triple combination of hydrocodone (antitussive), pseudoephedrine (decongestant), and chlorpheniramine (antihistamine).

Hydrocodone is a narcotic antitussive. Two commonly prescribed narcotic cough medications containing hydrocodone are UCB's Tussionex® and Endo Pharma's Hycodan®. Each of these medications are also available in generic alternatives.

Other Treatments. Other branded and similar antihistamine, decongestant, and cough suppressants marketed in the U.S. include prescription and OTC cold, cough and allergy products.

Intellectual Property. We have a registered trademark for the ZUTRIPRO name in the U.S. We believe ZUTRIPRO's status as an FDA approved product provides us with a limited opportunity to operate in this market without direct branded competitors, although nothing precludes a competitor from entering the market after receiving FDA approval.

9

Table of Contents

SILENOR Line. SILENOR is a prescription medicine available in oral tablet formulation of 3 mg and 6 mg dosages of doxepin used to treat insomnia characterized by difficulty with sleep maintenance. Doxepin 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 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. However, we believe that SILENOR, which uses doxepin at low dosages of 3 mg and 6 mg, 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, an adverse event profile comparable to placebo, 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 by Pernix Sleep, Inc. (formerly Somaxon Pharmaceuticals, Inc.) in September 2010. We acquired the SILENOR line as a result of our merger with Somaxon on March 6, 2013, and intend to market SILENOR to high-prescribing physicians of insomnia treatments.

Market Opportunity. It is estimated that approximately one-third of, or 70 million, adult Americans are affected by insomnia. One study has found that only approximately 20% of those who suffer from insomnia are currently treated with prescription medications. 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. Pre-launch 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. Additionally, unlike many of the other insomnia treatments currently available, SILENOR is not designated as a controlled substance, and according to its FDA-approved labeling, SILENOR does not appear to have any potential for dependency, addiction or abuse. Because SILENOR is not a Schedule IV controlled substance, it can be made available to physicians, facilitating initial physician and patient trial without the additional sampling regulation that applies to controlled substances.

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

Other Treatments. There are many competitive products in the market designed to treat insomnia. The current market-leading prescription products for the treatment of insomnia include GABA-receptor agonists such as Ambien, zolpidem, the generic form of Ambien, in various formulations, Ambien CR, a controlled-release formulation of Ambien, zolpidem ER, the generic form of Ambien CR, Lunesta, Sonata and zaleplon, the generic form of Sonata, in various formulations, melatonin agonists such as Rozerem, several hypnotic benzodiazepines such as temazapam (Restoril) and flurazepam (Dalmane), and sedating antidepressants such as trazodone (Desyrel).

Intellectual Property. SILENOR is covered by 4 patents currently held by ProCom One, Inc. related to the development and commercialization of low dosages of doxepin and other antidepressants for the treatment of insomnia. We are the exclusive licensee of these patents, which should restrict the ability of competitors to market

doxepin with identical drug labeling until the last licensed patent expires, which is expected to occur no earlier than 2020. Additionally, we have an exclusive supply agreement with JRS Pharma L.P. for the exclusive use of ProSolv®HD90, an ingredient used in our formulation for SILENOR, in combination with doxepin. Please see the "Intellectual Property" section of this Item 1 for a more detailed description of the rights associated with the SILENOR.

REPREXAIN™ (Hydrocodone bitartrate and ibuprofen tablets) is indicated for the short-term (generally less than 10 days) management of acute pain. It is not indicated for the treatment of conditions such as osteoarthritis or rheumatoid arthritis. REPREXAIN was launched in January 2009 by Amneal Pharmaceuticals. REPREXAIN comes in 3 strengths: 2.5/200, 5/200 and 10/200.

Table of Contents

Market Opportunity. In January 2011, the FDA asked drug manufacturers to limit the strength of acetaminophen in prescription drug products, which are predominantly combinations of acetaminophen and opioids. These actions will help to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. Because of these FDA actions, several hydrocodone acetaminophen products did not return to the market.

Because REPREXAIN does not include acetaminophen, the risk of liver toxicity is not associated with the product. This gives REPREXAIN a great opportunity to be marketed as an alternative to the doctor prescribing a hydrocodone/acetaminophen combination. REPREXAIN is marketed primarily in primary care, pain management, oral surgery and denture clinics.

Other Treatments. The main competitors of REPREXAIN are generic hydrocodone/ibuprofen combinations, Abbvie's Vicoprofen, and Poly Pharmaceutical's Ibudone.

Intellectual Property. We receive all our rights to REPREXAIN, including the registered trademark, from the License and Promotion Agreement between Amneal Pharmaceuticals LLC and Hawthorn Pharmaceuticals Inc. dated August 7, 2012 pursuant to which Hawthorn has the exclusive right to promote REPREXAIN in certain states within the United States for all physician specialties except podiatry and dermatology.

Other Marketed Products

In addition to our products promoted by our sales force, we sell a variety of other products for pediatric indications, certain other therapeutic areas and generic versions of selected branded products through our Macoven and Cypress subsidiaries.

Product Candidates In Development

BC 1036. We entered into a joint venture (JV) with SEEK in December 2010 for the development of BC 1036. On May 14, 2012, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture's intellectual property (IP) in the areas of cough, cold, sinus and allergy in the United States and Canada for $5 million. The investment in the JV at termination was approximately $1,445,000 and there was approximately $2,687,000 arising from a deferred tax liability. The value of the license recorded was approximately $9,133,000. Under the terms of the agreement, Pernix will pay royalties to SEEK on sales of products utilizing the joint venture IP in the United States and Canada. Pernix will also receive royalties from SEEK for product sales outside of the United States and Canada. As a result, we no longer share in the development costs outside the United States and Canada. Pernix plans to introduce BC1036 as an OTC cough and cold product in the United States in the second half of 2013.

Market Opportunity. Persistent cough, a common condition affecting people worldwide, manifests itself with symptoms that persist for more than two weeks and may arise mainly from cough predominant asthma, oesophageal reflux and rhinitis. The cough market has seen little to no innovation over the past twenty years despite the side-effects associated with current treatments. The Commission on Human Medicines and its Pediatric Medicines Expert Advisory Group advised that codeine, a drug used in most common cough treatments, should be withdrawn from use by children under the age of 18 in the OTC market in the United Kingdom.

Other Treatments. Other branded antitussive products include Robitussin ® AC and Dimetane DC.

Intellectual Property. The intellectual property licensed to us by SEEK's joint venture entity includes certain patent and patent application rights in the United States and Canada.

11

Table of Contents

Other Product Candidates. The Company is working on several other product candidates, including a prescription product for the pediatrics market. In March 2012, the Company entered into a product development agreement with a private company for this product. Under the terms of the agreement, Pernix obtained exclusive marketing rights to this late-stage development product in the United States in consideration for our agreement to pay the costs related to the development of the product. Pernix expects to invest approximately $6 million over an estimated 36-month period which began August 2012 for development and regulatory expenses related to this product candidate, and Pernix's development partner will manage the development program. Pernix and its development partner expect to commence pivotal phase III studies in mid-year 2013.

Sales and Marketing

Our sales force, which consists of approximately 123 sales representatives as of March 15, 2013, promotes our branded products primarily in highly populated states, targeting pediatric and high-prescribing physicians that are in the top decile of physicians that prescribe our products. We believe that this highly specialized approach provides us with the opportunity for greater access to this group of health care professionals and increases our market coverage and frequency of visits to this target audience. In addition to our sales team, our corporate staff includes a sales management team consisting of pharmaceutical industry veterans experienced in management, business development, and sales and marketing, and has an average of nine years of sales management experience. We may choose to expand our sales force through hiring additional personnel.

We seek to differentiate our products from our competitors by emphasizing the clinical advantages and favorable side effect profiles. Our marketing programs to support our products include: patient co-payment assistance, health care provider education, information to further support patient compliance and participation in national medical conventions. In addition, we are establishing a key opinion leader advisory board with varying specialties to assist in developing our corporate strategy for both our promoted products and product candidates.

Manufacturing

On July 2, 2012, we completed our acquisition of the business assets of GSL, a pharmaceutical contract manufacturing company located in Houston, Texas. We closed on the related real estate on August 30, 2012. Upon the final closing, we paid an aggregate of approximately $4.6 million, and assumed certain liabilities totaling approximately $6.1 million, for substantially all of GSL's assets, including the land and buildings in which GSL operates. GSL has an established manufacturing facility with an existing base of customers in the pharmaceutical industry, which provides us with additional income and potential cost savings. We acquired the GSL assets through our wholly owned subsidiary, Pernix Manufacturing, LLC.

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

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

Table of Contents

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

Acquisitions and License Agreements, Co-Promotions and Collaborations

We have and continue to grow our business through the use of acquisitions, license agreements, co-promotions and collaborations. We enter into acquisition, license and co-promotion agreements to acquire, develop, commercialize and market products and product candidates. In certain of these agreements, we market the products of others and remit a specified profit share to them. In certain other agreements, the contracted third party under the agreement markets products to which we have rights and remits a specified profit share to us. Collaborative agreements often include research and development efforts and/or capital funding requirements of the parties necessary to bring a product candidate to market. License, co-promotion and collaboration agreements may require royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the product, as well as expense reimbursements or payments to third-party licensors.

Acquisitions, License and Co-Promotion Agreements

We have acquired a majority of our products, product candidates and technology through acquisitions, license and co-promotion agreements.

See discussion above of the acquisitions of Somaxon, Cypress and GSL.

U.S. License of Cough, Cold, Sinus & Allergy Intellectual Property. On May 14, 2012, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture's intellectual property (IP) in the areas of cough, cold, sinus and allergy in the United States and Canada for $5 million. The investment in the JV at termination was approximately $1,445,000 and there was approximately $2,687,000 arising from a deferred tax liability. The value of the license recorded was approximately $9,133,000. Under the terms of the agreement, Pernix will pay royalties to SEEK on sales of products utilizing the joint venture IP in the United States and Canada. Pernix will also receive royalties from SEEK product sales outside of the United States and Canada. As a result, the Company no longer shares in the development costs outside the United States and Canada.

Gastroenterology Product License and Supply Agreement. In January 2012, we entered into a license and supply agreement with a private company for OMECLAMOX-PAK, an FDA-approved prescription product designed to treat gastroenterology disease. Under the terms of the agreement, we obtained exclusive marketing rights to this product in the United States. We paid an up-front license fee of $2.0 million and an additional fee of $2.0 million upon commercial launch of the product in July 2012. In addition to these license fees, the agreement calls for us to pay royalties and milestone payments based on the sales of the product.

NATROBA Co-Promotion Agreement. We entered into an exclusive co-promotion agreement with ParaPRO for NATROBA in certain U.S. territories. In July 2012, the Company and ParaPRO replaced their then-existing co-promotion and supply agreements relating to NATROBA with a new agreement to restructure the terms for marketing and distributing NATROBA. Under the terms of the new agreement, the Company will no longer have the minimum purchase order commitments related to the marketing and promotion of NATROBA that were required under the previous agreements. If the Company fails to meet certain dispensed volumes, the Company or ParaPRO would have the option to either modify or terminate the new agreement. The previous options to acquire Pernix stock granted to ParaPRO under its services agreement with the Company were not impacted by this new agreement. The Company and ParaPRO currently co-promote and market NATROBA, as well as an authorized generic

equivalent. ParaPRO pays a co-promotion fee per unit prescribed which is recorded as co-promotion revenue. The cost that the Company pays for NATROBA is significantly higher than the direct manufacturing cost that the Company pays on the other products in our portfolio which impacts our gross profit margin.

CEDAX . On March 24, 2010, we acquired substantially all of the assets and rights relating to CEDAX from Shiongi (formerly Sciele Pharma, Inc.), a prescription antibiotic used to treat mild to moderate infections of the throat, ear and respiratory tract, for an aggregate purchase price of $6.1 million. In connection with our acquisition of CEDAX, we acquired a non-exclusive license to an oral suspension formulation patent used in CEDAX products for the remaining life of the patent, which expires February 4, 2014.

Table of Contents

BROVEX . In June 2009, Pernix entered into an asset purchase agreement with DaySpring, pursuant to which we obtained all rights to the BROVEX product line, including related trademarks and inventory, for $450,000 in cash paid at the closing.

TCT Drug Delivery Technology. In January 2009, Pernix entered into a license agreement with Kiel Laboratories, whereby Kiel granted Pernix exclusive use of the Kiel technology in return for royalties on sales of associated products. In August 2010, Pernix entered into a purchase agreement with Kiel whereby we acquired assets relating to Kiel's drug delivery technology, which included patents, trademarks, related intellectual property and existing inventory. The three patents covering the Kiel technology expire in 2022.

Collaborations

Development of Late-state Pediatric Product. In March 2012, we entered into a product development agreement with a private company for a prescription product for the pediatrics market. Under the terms of the agreement, Pernix obtained exclusive marketing rights to this late-stage development product in the United States, and in consideration for our agreement to pay the costs related to the development of the product. Pernix expects to invest approximately $6 million over an estimated 36-month period which began August 2012 for development and regulatory expenses related to this product candidate, and Pernix's development partner will manage the development program. Pernix and its development partner expect to commence pivotal phase III studies in mid-year 2013.

Intellectual Property

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

Patents

The following table shows the U.S. patents relating to our products. We own or license the rights to the intellectual property in these patents described in more detail below. (1)

Product(s) / Product Candidate(s)	Patent Owners	Patent Description	Expiration
CEDAX(2)	Schering Corporation	Stable hydrated cephalosporin dry powder for oral suspension formulation	February 4, 2014
BC 1036	Gaine, Inc.	Methods of stimulating mucociliary clearance to alleviate irritable cough	March 20, 2018
SILENOR	ProCom One, Inc.(4);	Use of doxepin and other antidepressants in low dosages for treatment of insomnia(4);	February 17, 2020(4), March 26, 2013(4), March 26, 2013 (4), June 2020(4);

	JRS Pharma, L.P.(5);	Use of ProSolv®HD90 in combination with Doxepin(5);	January 9, 2015(5);
	Pernix Sleep, Inc.(6)	Methods of application to improve the pharmacokinetics of doxepin use for treatment of insomnia(6)	August 24, 2027(6)

Table of Contents

(1) In addition to the patents owned and licensed by Pernix, ParaPRO owns and/or licenses certain patents relating to NATROBA. We have no ownership interest or license to any such patent relating to NATROBA by virtue of our co-promotion arrangement with ParaPRO.

(2) Pernix acquired a non-exclusive license for the remaining life of this patent in connection with its acquisition of CEDAX.

(3) In connection with the formation of its joint venture with SEEK, we granted an exclusive license in one of our patents to the joint venture. On May 14, 2012, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture's intellectual property (IP), including the patent licensed by Gaine in the areas of cough, cold, sinus and allergy in the United States and Canada for $5 million.

(4) In connection with our acquisition of Somaxon Pharmaceuticals, Inc. (now referred to as Pernix Sleep, Inc.), we became the exclusive licensee of four U.S. patents held by ProCom One, Inc. which claim the use of low dosages of doxepin and other antidepressants in connection with the treatment of insomnia. The term of this license extends until the last licensed patent expires, which is expected to occur no earlier than 2020.

(5) Pernix Sleep, Inc. is subject to an exclusive supply agreement with JRS Pharma, L.P. under which it purchases all of its requirements for ProSolv®HD90, an ingredient used in the formulation of SILENOR, from JRS. In August 2008, this agreement was amended to provide Pernix Sleep, Inc. with the exclusive right to use ProSolv®HD90 and any successor product in combination with doxepin, as well as the right to list the U.S. patents owned by JRS and covering ProSolv®HD90 in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations resource, commonly known as the Orange Book, with respect to the listing of SILENOR. The term of this agreement runs through January 1, 2014 and will automatically renew for one-year periods unless action is taken by us or JRS to terminate the agreement. All ProSolv®HD90 patents related to the manufacture of SILENOR are listed in the Orange Book with respect to SILENOR, and expire on January 9, 2015.

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

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

Trademarks

We own trademark interests in most of our current products and believe that having distinguishing marks is an important factor in marketing these products. We currently own 31 trademarks registered on the principal register of the United States Patent and Trademark Office. These registered marks include CARDEC, BROVEX (STYLIZED), BROVEX (WORD MARK), ALDEX, TUSSINAC, PERNIX, PERNIX THERAPEUTICS (DESIGN), ZEMA-PAK, REZYST, QUINZYME, NODOLOR, COCO-COF, Z-COF (STYLIZED), CEDAX, TCT (WORD MARK), TCT (STYLIZED), TCT TANNANTE CONVERSION TECHNOLOGY, PEDIATEX, CYPRESS PHARMACEUTICAL, INC., GRANISOL (STYLIZED), ARBINOXA, ZUTRIPRO, HYLIRA (DESIGN), VERIPRED (DESIGN), ZAMICET (DESIGN), ELIPHOS (STYLIZED), DYTAN (STYLIZED), ICAR (STYLIZED), XIRATUSS (STYLIZED), SILENOR, and SOMAXON PHARMACEUTICALS. In addition to the 31 registered marks listed above, we own 8 intent-to-use trademarks filed with the United States Patent and Trademark Office that can be registered as use-in-commerce trademarks as soon as we can file a statement of use illustrating use of the marks in commerce. We expect that having distinctive marks for any additional products that we develop will also be an important marketing characteristic. We have not sought any foreign trademark protection for our products or product candidates. U.S. trademark registrations generally are for fixed, but renewable, terms.

Table of Contents

Trade Secrets

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

Customers, Distribution, and Reimbursement

Customers and Dstribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the U.S. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Our top four customers, including concentration of Cypress sales, which represented 81% and 84% of gross product sales in 2012 and 2011, respectively, are all drug wholesalers and are listed below:

Customer	2012	2011
Cardinal Health	39%	37%
McKesson Corporation	26%	23%
AmerisourceBergen Drug Corporation	10%	11%
Morris and Dickson	6%	13%

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

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

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

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

In the acquisition of Cypress, we acquired the lease of their 51,830 square foot warehouse from which Cypress distributes all but one of its products. While we distribute certain of Pernix's products, including NATROBA, from our warehouse in Magnolia, Texas, we currently rely on DDN/Obergfel, LLC, or DDN, a third-party logistics provider, for the distribution of the majority of our products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. DDN ships our products from its warehouse in Memphis, Tennessee to our customers throughout the U.S. Our intention is to centralize our distribution operations to maximize efficiency in 2013.

16

Table of Contents

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 substantially all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for our products and ultimately the net proceeds realized from the sales of our products.

Competition

The pharmaceutical industry, including the pediatric market in which we primarily participate, is defined by rapidly advancing technologies, extreme competition and a focus on proprietary products. We face competition from numerous sources, including other commercial pharmaceutical companies and biotechnology organizations, academic institutions, government agencies and private and public research institutions. Our current products compete with existing and new therapies that may become available in the future.

Our competition may have greater financial resources and more sophisticated expertise in research and development, manufacturing, clinical trials, regulatory pathways and marketing approved products than we do. Usually, competition to our currently marketed products and product candidates have distinguished brand names, are distributed by large pharmaceutical companies with sizable amounts of resources and have achieved widespread acknowledgement in the healthcare market. Small or early stage companies may also prove to be serious competition, predominantly through collaborative agreements with large and established companies.

Issues influencing the success of our products and product candidates, if approved, are and should continue to be efficacy, safety, convenience, price, the availability of patent protection or regulatory marketing exclusivity, generic competition, position and availability within the wholesale trade and the availability of reimbursement from government and other third-party payors.

Our competitive position could be adversely affected if the competition develops and commercializes products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors may also obtain FDA or other regulatory approval faster than we do. Additionally, our ability to compete may be diminished by insurance companies or other third-party payors seeking to promote generic products, which could result in branded products becoming unattractive to consumers from a cost perspective.

The products we currently market face substantial competition from a variety of similar therapeutic branded and generic products. We are potentially subject to competition from generic versions of our branded products if a loss of regulatory marketing exclusivity or patent protection is recognized or as a result of regulatory pathway engineering strategies that provide for generic product introduction before key product patent expirations. Generics typically have lower prices than branded products and, therefore, may erode prescription demand and sales of our branded products, which we have mitigated through the acquisition of our generic subsidiary, Macoven.

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.

Table of Contents

FDA Regulation of Drug Products

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

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

- performance of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- an investigational new drug application, or IND, submitted to the FDA, which must become effective before human clinical trials may commence;
- an independent institutional review board (IRB) approval at each clinical site before each trial may begin;
- completion of approved, well-controlled human clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;
- submission of a new drug application, or NDA, to the FDA;
- adequate completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is produced to evaluate compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are satisfactory to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

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

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

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

18

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, an NDA or supplement to an NDA must contain data that is acceptable to properly assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective, according to the Pediatric

Research Equity Act of 2003, or PREA, as amended and reauthorized by the Food and Drug Administration Amendment Act of 2007, or FDAAA. The FDA is also authorized, under the FDAAA, to require sponsors of currently marketed drugs to perform pediatric studies if the drug is used for a substantial number of pediatric patients for the labeled indication and adequate pediatric labeling could benefit such patients, there is reason to believe the drug would provide a "meaningful therapeutic benefit" for pediatric patients, or the absence of pediatric labeling could pose a risk to pediatric patients. At the request of an applicant or by its own initiative, the FDA may grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or, may grant full or partial waivers from the pediatric data requirements. The pediatric data requirements do not apply to products with orphan designation, unless otherwise required by regulation.

Table of Contents

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

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

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

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. Based on the results of post-market studies or surveillance programs, the FDA may prevent or limit further marketing of a product. Some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further FDA review and approval even after initial approval has been granted.

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

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

required user fees upon submission of the first section of the NDA.

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

Table of Contents

The FDA may later decide that the drug no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened even if a drug product qualifies for one or more of these programs.

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

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

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

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

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

Prescription Drug Wrap-Up

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

Table of Contents

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

Over The Counter Drugs

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

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

The Hatch-Waxman Act

Abbreviated New Drug Applications. Through the NDA approval process, applicants are obligated to list with the FDA each patent with claims that cover the applicant's product or an approved use of the product. When the drug has been approved, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the

Orange Book can, in turn, be cited by potential competitors in pursuit of approval of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical ingredients in the same strengths, route of administration, conditions of use and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or efficacy of their drug product, other than the requirement for bioequivalence testing. ANDA approved drugs are commonly referred to as “generic equivalents” to the listed drug, and can be replaced by pharmacists under prescriptions written for the original listed drug.

Table of Contents

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

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

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

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

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

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

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

Marketing Exclusivity and Patent Term Restoration. Newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity under the Hatch-Waxman Act. The Hatch-Waxman Act grants five-year marketing exclusivity to the first applicant to achieve approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active pharmaceutical ingredient. The Hatch-Waxman Act prohibits the submission of a Section 505(b)(2) NDA or an ANDA for another version of such drug during the exclusivity period. But, submission of a Section 505(b)(2) NDA or an ANDA containing a Paragraph IV certification is allowed after four years, which may activate a 30-month stay of approval of the Section 505(b)(2) NDA or ANDA if the patent holder sues. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five year and three-year exclusivity will not block the submission or approval of another "full" NDA. The applicant submitting a full NDA would be required to conduct its own preclinical studies and clinical trials or obtain a right of reference to such studies or trials.

Table of Contents

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

Medical Devices

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

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

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

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

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

Medical Foods

The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are prescription foods specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that

cannot be met by normal diet alone. They were defined in the FDA's 1988 Orphan Drug Act Amendments and are subject to the general food safety and labeling requirements of the FDCA but are exempt from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990. Medical foods are distinct from the broader category of foods for special dietary use and from traditional foods that bear a health claim. In order to be considered a medical food the product must, at a minimum:

- be a specially formulated and processed product (as opposed to a naturally occurring food in its natural state) for oral ingestion or tube feeding (nasogastric tube);
- be labeled for the dietary management of a specific medical disorder, disease or condition for which there are distinctive nutritional requirements; and
- be intended to be used under medical supervision.

Table of Contents

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

Regulation of Controlled Substances

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

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

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

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

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

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

Foreign Regulation

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

Table of Contents

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

Hazardous Materials

As a by-product of its daily operations as a manufacturer of pharmaceutical finished products, Pernix Manufacturing consistently generates small quantities of hazardous waste, both as a result of its manufacturing processes and its analytical testing processes. Pernix Manufacturing contracts with certified third-party service providers to legally dispose of its hazardous waste in a manner required by local, state, and federal laws. The expense of responsibly disposing of its hazardous waste is factored into the cost of goods and is not expected to be of significance.

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

Pharmaceutical Pricing and Reimbursement

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

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

Table of Contents

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

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

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

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

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

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

Effects of Legislation on the Pharmaceutical Industry

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act, or Affordable Care Act. On March 30, 2010, the President signed H.R. 4872, the Healthcare and Education

Reconciliation Act of 2010, or Reconciliation Act, which included a package of corrective changes to the Affordable Care Act as well as additional elements to reform healthcare in the United States. We refer to the Affordable Care Act and the Reconciliation Act as Health Care Reform.

Table of Contents

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

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

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

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

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

The Budget Control Act, passed in 2011, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction was unable to reach required goals, triggering, among other things, automatic reductions to the budgets of federal health agencies and an automatic two-percent reduction to Medicare payments to healthcare providers. These spending reductions are scheduled to go into effect on April 1, 2013. Further, many current proposals for the 2013 federal budget contain spending reductions in the Medicare program. For

example, President Obama's proposed budget for 2013 would require drug manufacturers to pay the Medicare program new rebates for certain outpatient drugs covered under Medicare Part D. This proposal would allow the Medicare program to benefit from the same, relatively higher, rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the low-income subsidies under the Medicare Part D program and "dual eligible" beneficiaries.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including rules and regulations that will be issued to implement provisions of Health Care Reform. 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.

Table of Contents

Other Regulations

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

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

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

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

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

Federal Health Insurance Portability and Accountability Act of 1996. The HIPAA statute imposes criminal liability in connection with the delivery of or payment for health care benefits, items or services, for, among other things, knowingly and willfully (i) executing a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money of the health care benefit

program, or (ii) falsifying, concealing or covering up by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statements or representations, or making or using any materially false writing or document knowing it contains any materially false, fictitious or fraudulent statement or entry. Further, the HIPAA statute and implementing regulations established certain standards and requirements for the privacy and security of individuals' health information, which standards and requirements were expanded by the Health Information Technology for Economic and Clinical Health Act.

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

Table of Contents

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

CMS has published a proposed rule about the implementation of certain provisions of the Health Care Reform referenced in the above paragraph related to physician transparency. Various states have disclosure laws as well.

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

The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals and entertainment, among other things. In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) recently issued a Code of Practice relating to interactions with the heath care community, which replaces and expands upon its 2006 Code of Pharmaceutical Marketing Practices. Further, certain states have also imposed restrictions on relationships between health care professionals and the pharmaceutical industry.

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

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

Employees

As of March 15, 2013, we had approximately 251 full-time employees, consisting of 64 employed by Pernix Maufacturing; 123 sales representatives; 21 engaged in research, development and regulatory affairs; and 43 engaged in management, finance, administration and warehouse operations.

Table of Contents

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 shares could be negatively impacted. Although we believe that we have identified and discussed below the key risk factors affecting our business, there may be additional risks and uncertainties that are not presently known that may materially adversely affect our business.

Risks Related to our Acquisition Strategy and Managing Growth

We may incur substantial expenses related to the integration of Cypress and Somaxon.

We may incur relatively significant expenses in connection with integrating many of the operations, networks, systems, technologies, policies and procedures of both Cypress and Somaxon with those of the Company. There are a number of systems that must be integrated, including accounting, finance, payroll and certain human resource functions. While we have assumed that a certain level of transaction and integration expenses will be incurred, there are a number of factors beyond our control that could affect the total amount or the timing of our integration expenses. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately at the present time. Due to these factors, the transaction and integration expenses associated with the Cypress and Somaxon acquisitions could, particularly in the near term, exceed the savings that we expect to achieve from the elimination of duplicative expenses and the realization of economies of scale and cost savings related to the integration of these businesses.

We may be unable to successfully integrate Somaxon’s and/or Cypress’ businesses and realize the anticipated benefits of these acquisitions.

Management devotes significant attention and resources to integrating the business practices and operations of Cypress and Somaxon with those of Pernix. Potential difficulties we may encounter in the integration process include the following:

- the inability to successfully combine our businesses with the businesses of Cypress and Somaxon and meet the capital requirements of the combined business, in a manner that permits us to achieve the cost savings or revenue enhancements anticipated to result from these acquisitions, which would result in the anticipated benefits of the acquisitions not being realized in the time frame currently anticipated or at all;
- lost sales and customers as a result of certain customers of Pernix, Cypress or Somaxon deciding not to do business with the combined company;
- the additional complexities of integrating companies with different core products and markets;
- potential unknown liabilities and unforeseen increased expenses associated with the acquisitions of Cypress and Somaxon; and
- performance shortfalls as a result of the diversion of management’s attention caused by integrating Cypress’ and Somaxon’s operations with those of Pernix.

For all these reasons, you should be aware that it is possible that integrating Cypress and Somaxon 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.

We may not be able to continue to grow through acquisitions.

We have sought growth largely through acquisitions, including the acquisitions of Macoven in 2010, GSL and Cypress in 2012 and Somaxon in 2013.

Table of Contents

Effective December 31, 2012, we entered into a $42 million term loan credit facility in connection with our acquisition of Cypress. The credit agreement includes restrictive covenants for a secured credit facility, which include, among other things, restrictions on the incurrence of indebtedness, as well as certain consolidations, acquisitions, mergers, purchases or sales of assets and capital expenditures, subject to certain exceptions and permissions limited in scope and dollar value. In addition to these restrictive covenants our credit facility contains financial covenants that are significantly more onerous than those contained in our prior credit facility. For additional information, see Note 13, Debt and Lines of Credit, to our Consolidated Financial Statements for the year ended December 31, 2012 and 2011.

In the future, we may pursue growth opportunities through acquisitions that are not directly similar to those currently operated by the Company. We cannot assure you that acquisitions will be available on terms attractive to the Company. Moreover, we cannot assure you that such acquisitions will be permissible under our existing term loan credit facility or that we will be able to arrange financing on terms acceptable to the Company or to obtain timely federal and state governmental approvals on terms acceptable to the Company, or at all.

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

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

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

Our business and financial alternatives could be constrained by our current debt incurred in connection with our acquisition of Cypress and any future borrowings.

Effective December 31, 2012, we entered into a $42 million term credit facility with MidCap Funding V, LLC, as administrative agent, as a lender and as co-bookrunner and sole lead arranger, Business Development Corporation of America, as co-bookrunner, and additional lenders from time to time party thereto. Subject to certain permitted liens, the obligations under this facility are secured by a first priority perfected security interest in substantially all of our assets. The proceeds from this facility were used to fund a portion of the cash consideration of the acquisition of Cypress.

The term loan under this facility bears interest at a rate equal to the sum of the LIBOR rate plus an applicable margin of 6.50% per annum. Under the terms of the credit agreement, we are required to make quarterly repayments on the term loan beginning on March 31, 2013 and ending on December 31, 2017, when all remaining principal is due and payable. In addition, we may voluntarily repay outstanding loans at any time without premium or penalty.

The credit agreement includes restrictive covenants, which include, among other things, (a) restrictions on (i) the incurrence of indebtedness, (ii) the creation of or existence of liens, (iii) the incurrence or existence of contingent obligations, (iv) making certain dividends or other distributions, (v) certain consolidations, mergers or sales of assets, (vi) purchases of assets, investments and acquisitions and (vii) capital expenditures; (b) requirements to deliver financial statements, reports and notices to the administrative agent and other lenders and (c) requirements to maintain

a fixed charge coverage ratio and leverage ratio, provided that, the restrictions described in (a)(i)-(vii) above are subject to certain exceptions and permissions limited in scope and dollar value. The credit agreement contains customary representations and warranties and event of default provisions for a secured credit facility. The credit agreement also contains financial covenants that are significantly more onerous than those contained in our prior credit facility. For additional information on the financial covenants required by our credit facility, see Note 13, Debt and Lines of Credit, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Table of Contents

As a result of our entry into the term loan facility in connection with our acquisition of Cypress, we have become more leveraged. This could have material adverse consequences for the Company, including (i) raising our borrowing costs, (ii) hindering our ability to adjust to changing market, industry or economic conditions, (iii) limiting our ability to access the capital markets to fund acquisitions, (iv) limiting the amount of free cash flow available for future operations, acquisitions, dividends, stock repurchases or other uses, (v) making us more vulnerable to economic or industry downturns, including interest rate increases and (vi) placing us at a competitive disadvantage compared to less-leveraged competitors. In addition, an event of default under our credit agreement could result in all or a portion of our outstanding debt thereunder to become immediately due and payable. If this occurs, we might not be able to obtain waivers or secure alternative financing to satisfy all of our obligations simultaneously, which may force us to seek bankruptcy protection.

A significant portion of the Company’s planned expenditures for 2013 are expenses in connection with our development programs, notably our planned OTC launch for a pediatric cough/cold product in the second half of 2013 and our development project for a prescription pediatric product. As of March 15, 2013, Pernix believes that its existing cash and cash from operations will be sufficient to continue to fund its existing level of operating expenses, current development activities and general capital expenditure requirements through 2013. However, the Company's ability to execute all of its development programs and other business strategies during 2013 may be limited by the restrictive and financial covenants contained in our credit agreement. For additional information on the restrictive and financial covenants contained in our credit facility, see Note 13- Debt and Lines of Credit to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

As a result, the Company may seek an amendment to certain of the terms of the credit agreement with Midcap. At this time, we are unable to predict whether or not an amendment on terms acceptable to us and our lenders will be reached. In the event we are unable to enter into an amendment to our credit facility or our capital resources are otherwise insufficient to meet future capital requirements, Pernix may seek to finance its cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, a sale of selected assets, or other financing alternatives. Equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified managerial personnel. We are highly dependent upon our executive management team, particularly Cooper C. Collins, our Chief Executive Officer. The loss of the services of any one or more of the 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 an effort to attract and retain quality sales representatives, in February 2011, we increased the base salary of our sales representatives by 33%. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

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

Table of Contents

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

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

Our strategy of obtaining, through product acquisitions and in-licenses, rights to 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.

Part of our business strategy is to acquire rights to pharmaceutical products, pharmaceutical product candidates in the late stages of development and proprietary drug delivery and formulation technologies. Because we do not have discovery and research capabilities, the growth of our business will depend in significant part on our ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that we believe have significant commercial potential and are consistent with our commercial objectives. However, we may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons.

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

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

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

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

Table of Contents

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;
inability to maintain uniform standards, controls, procedures and policies;
the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and
subsequent loss of key personnel.

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

Risks Related to Commercialization

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

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

Table of Contents

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

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

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

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

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

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

products, which would substantially limit our ability to obtain a return on the investments we have made in those products. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates.

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

Table of Contents

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

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

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

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

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

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

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

If we are unable to attract, hire and retain qualified sales and management personnel, the commercial opportunity for our products may be diminished.

As of March 15, 2013, our sales force consisted of approximately 123 full-time sales representatives. We may not be able to attract, hire, train and retain qualified sales and sales management personnel in the future. If we are not successful in our efforts to maintain a qualified sales force, our ability to independently market and promote our products may be impaired. In such an event, we would likely need to establish a collaboration, co-promotion, distribution or other similar arrangement to market and sell such products. However, we might not be able to enter into such an arrangement on favorable terms, if at all. Even if we are able to effectively maintain a qualified sales force, our sales force may not be successful in commercializing our products.

Table of Contents

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

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

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

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

On July 2, 2012, we completed the acquisition of the business assets of Great Southern Laboratories, or GSL, a pharmaceutical contract manufacturing company through our wholly owned subsidiary, Pernix Manufacturing, LLC, or Pernix Manufacturing. Pernix Manufacturing serves as a contract manufacturer and as a potential manufacturer of our preclinical and clinical material. Pernix Manufacturing must comply with these cGMP requirements. While we believe Pernix Manufacturing currently meets these requirements, we cannot assure that our manufacturing facilities or those of our contract manufacturers will continue to meet cGMP requirements or will be sufficient to manufacture all of our needs and/or the needs of our customers for commercial materials.

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

may be materially harmed.

Table of Contents

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

We, our third party manufacturers and certain of our products including PEDIATEX TD, ZUTRIPO, REZIRA, our BROVEX line of products, their generic equivalents, and certain other generic products are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we must adhere to a number of requirements with respect to our controlled substance products including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

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

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

decreased demand for our products or any products that we may develop;
injury to reputation;
withdrawal of client trial participants;
withdrawal of a product from the market;
costs to defend the related litigation;
substantial monetary awards to trial participants or patients;
diversion of management time and attention;
loss of revenue; and
the inability to commercialize any products that we may develop.

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

Table of Contents

Seasonality may cause fluctuations in our financial results.

We generally experience some effects of seasonality due to increases in demand for cough and cold products during the winter season. Accordingly, sales of cough and cold products and associated revenue have generally increased at a higher rate during the winter season. In the future, 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 intend to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

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

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. In 2012, Cardinal Health accounted for 39% of our total gross sales, McKesson Corporation accounted for 26% of our total gross sales, and AmerisourceBergen Drug Corporation accounted for 10% of our total gross sales.

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

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

We enter into collaboration arrangements from time to time on a selective basis. Our collaborations may not be successful. Of our current product portfolio, we market NATROBA, its generic equivalent, VERIPRED, REPREXAIN and OMECLAMOX pursuant to collaboration arrangements. The success of our collaboration

arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

Table of Contents

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.

Risks Related to Intellectual Property

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

42

Table of Contents

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

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

On January 19, 2012, plaintiffs, Merck & Cie, South Alabama Medical Science Foundation and Pamlab, L.L.C. filed suit seeking unspecified damages and injunctive relief against our wholly owned subsidiary, Macoven Pharmaceuticals, for infringement of U.S. Patent Nos. 5,997,915, 6,254,904, 6,673,381, 7,172,778, 7,674,490 and 6,011,040 based on Macoven's commercialization of the following products: Vitaciric-B; ALZ-NAC; L-methylfolate PNV; L-methylfolate calcium 7.5mg; and L-methylfolate calcium 15mg. Macoven filed responsive pleadings denying liability for infringement and filed counter claims for non-infringement and patent invalidity. On September 19, 2012, the court stayed the action pending final determination of the International Trade Commission, which we refer to herein as the ITC, described below.

On September 10, 2012, plaintiffs, Merck & Cie, South Alabama Medical Science Foundation and Pamlab, L.L.C., filed a complaint with the ITC under Section 337 of the Tariff Act of 1930, as amended, against Macoven for infringement of U.S. Patent Nos. 5,997,915, 6,673,381, 7,172,778 and 6,011,040 based on Macoven's commercialization of the following products: Vitaciric-B; ALZ-NAC; and L-methylfolate calcium. The ITC initiated an investigation on October 10, 2012. Macoven filed a response, denying liability for patent infringement and asserting patent invalidity as a defense. Discovery is ongoing. ITC set a 16 month target date for completion. A hearing is scheduled for the week of June 24-28, 2013, before an administrative law judge. The administrative law judge's initial decision is set for October 17, 2013, with the ITC's decision set for February 15, 2014.

We believe that we have meritorious defenses to the substantive allegations asserted in the above-described proceedings and intend to aggressively defend ourselves in these proceedings.

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims, we may become a party to other

patent litigation and other proceedings. The cost to us of any patent litigation or other proceeding, 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.

Table of Contents

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, for development costs and to establish and expand our sales and marketing infrastructure. However, we may need substantial additional funding for these purposes and may be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or eliminate our acquisition strategies, development programs or commercialization efforts.

As of March 15, 2013, we had approximately $30 million of cash and cash equivalents. We believe that our existing cash and cash equivalents and revenue from product sales will be sufficient to enable us to fund our operating expenses, capital expenditures and debt service requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

our ability to successfully integrate the operations of Cypress and Somaxon;
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 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.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, additional debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be permissible under our term loan agreement or otherwise available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Additional debt financing, if permissible under our term loan agreement and available, may involve agreements that include covenants further limiting orrestricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any additional debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Table of Contents

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders' equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated charge backs, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. Actual sales allowances may vary from our estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. We cannot assure you, therefore, that there may not be material fluctuations between our estimates and the actual results.

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

On January 16, 2013, we received approval from the NASDAQ Stock Market to transfer our common stock listing from NYSE MKT LLC to the NASDAQ Global Market effective January 28, 2013. If we fail to meet all applicable listing requirements of the NASDAQ Global Market and it determines to delist our common stock, a trading market for our common stock may not be sustained and the market price of our common stock could decline. If a trading market for our common stock is not sustained, it will be difficult for our stockholders to sell shares of our common stock without further depressing the market price of our common stock or at all. A delisting of our common stock also could make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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

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

- our operating results, including the amount and timing of sales of our products and our ability to successfully integrate the operations of Cypress and Somaxon;
- the availability and timely delivery of a sufficient supply of our products;
- 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, 2012, 2011 and 2010. We are currently investing in our promoted product lines and product candidates and do not anticipate paying dividends in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our term loan agreement prohibits 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.

Table of Contents

Insiders have substantial control over the Company and could delay or prevent a change in corporate control, including a transaction in which the Company's stockholders could sell or exchange their shares for a premium.

As of March 15, 2013, our directors and executive officers together with their affiliates beneficially own, in the aggregate, approximately 47.5% of our common stock. As a result, our directors and executive officers, together with their affiliates, if acting together, have the ability to affect the outcome of matters submitted to stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, will have the ability to control our management and affairs. Accordingly, this concentration of ownership may harm the value of our common stock by:

delaying, deferring or preventing a change in control;
impeding a merger, consolidation, takeover or other business combination; or
discouraging a potential acquirer from making an acquisition proposal or otherwise attempting to obtain control.

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.

Risks Related to Product Development

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

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

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

Table of Contents

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

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

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

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

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

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

the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

- be delayed in obtaining marketing approval for one or more of our product candidates;
- not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as intended.

Table of Contents

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

Risks Related to Regulatory Matters

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

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

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

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

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

Table of Contents

The Company's authorized generic products that are OTC monograph products have not been affected by the FDA announcement. Certain Macoven generic products that were not marketed as OTC monograph were converted, and we did not experience any suspension, delay or interruption in our sales of these products. Our remaining generic DESI cough and cold products that were not being converted to OTC monograph were phased out by 2011 and did not have a material impact on the results of operations or financial condition of the Company. If the FDA were to disagree with our determination, it could ask or require the removal of our unapproved products from the market, which would significantly reduce our gross sales.

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

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

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

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

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

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product

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

Table of Contents

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

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

withdrawal of the products from the market;
restrictions on the marketing or distribution of such products;
restrictions on the manufacturers or manufacturing processes;
warning letters;
refusal to approve pending applications or supplements to approved applications that we submit;
recalls;
fines;
suspension or withdrawal of regulatory approvals;
refusal to permit the import or export of our products;
product seizure; or
injunctions or the imposition of civil or criminal penalties.

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

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

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs, varies but coverage is similar to other products within the same class of drugs. For example, CEDAX is covered by private insurance plans similar to other marketed, branded cephalosporins. However, the position of CEDAX as a branded product often requiring a higher patient copayment

may make it more difficult to expand the current market share for this 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 CEDAX. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, some of our products are purchased under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals.

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

Table of Contents

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

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

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

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services reimbursed under the Medicare and Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the

federal government.

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

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

Table of Contents

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

The Food and Drug Administration Amendments Act of 2007, or the FDAAA, grants a variety of new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

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

Under federal healthcare programs, some state governments and private payors investigate and have filed civil actions against numerous pharmaceutical companies alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated average wholesale price, which in turn may be alleged to have improperly inflated the reimbursements paid by Medicare, private insurers, state Medicaid programs, medical plans and others to healthcare providers who prescribed and administered those products or pharmacies that dispensed those products. These same payors may allege that companies do not properly report their “best prices” to the state under the Medicaid program. Suppliers of outpatient pharmaceuticals to the Medicaid program are also subject to price rebate agreements. Failure to comply with these price rebate agreements may lead to federal or state investigations, criminal or civil liability, exclusion from federal healthcare programs, contractual damages, and otherwise harm our reputation, business and prospects.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Pernix leases 5,561 square feet in office space on the ninth floor at 10003 Woodloch Forest Drive in The Woodlands, Texas which serves as the Company’s corporate headquarters. The term of the lease expires on May 8, 2015 and the Company’s lease payment is approximately $16,100 per month, which is subject to certain annual escalators, and 2.49% of excess building operating expenses. In addition, the Company leases 2,184 square feet in Mount Pleasant, South Carolina, which serves as the Company’s accounting office. The term of this lease expires on March 31, 2013, and the Company’s lease payment is approximately $2,500 per month, which is subject to certain annual escalators. The Company currently expects to renew this lease and add an additional 1,000 square feet of office space for a total monthly lease payment of approximately $4,100. The Company also leases a 5,000 square-foot office facility and a 7,200 square-foot warehouse facility in Magnolia, TX. The facilities are leased from a limited liability company wholly-owned by certain officers and directors of Pernix. The term of each lease is month to month and may be terminated by either party without penalty. As of December 31, 2012, Pernix pays rent of approximately $5,300 for this facility.

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

We own the real property in which we operate our manufacturing facility. It is located in Houston, Texas and comprises two non-adjacent properties with a total of 63,215 square feet of manufacturing, storage and office space.

We acquired the lease for the property in which we operate our Cypress and Hawthorn operations in Madison, Mississippi. It is comprised of 7,840 square feet of office space and 51,830 square feet of warehouse space and the lease expires June 30, 2014. The lease payment is approximately $29,800 per month. Additionally, we acquired the lease for the property on which we operate our Somaxon operations in San Diego, California. It is comprised of 4,595 square feet and the lease expires September 30, 2014. The lease payment is approximately $14,000 per month.

ITEM 3. LEGAL PROCEEDINGS

United States District Court for the Eastern District of Texas, Civil Action No. 6:12-cv-00027-LED

On January 19, 2012, plaintiffs, Merck & Cie, South Alabama Medical Science Foundation and Pamlab, L.L.C. filed suit seeking unspecified damages and injunctive relief against our wholly owned subsidiary, Macoven Pharmaceuticals, for infringement of U.S. Patent Nos. 5,997,915, 6,254,904, 6,673,381, 7,172,778, 7,674,490 and 6,011,040 based on Macoven's commercialization of the following products: Vitaciric-B; ALZ-NAC; L-methylfolate PNV; L-methylfolate calcium 7.5mg; and L-methylfolate calcium 15mg. Macoven filed responsive pleadings denying liability for infringement and filing counter claims for non-infringement and patent invalidity. On September 19, 2012, the court stayed the action pending final determination of the International Trade Commission, which we refer to herein as the ITC, described below.

Table of Contents

ITC Investigation No. 337-TA-2912, In the Matter of Reduced Folate Nutraceutical Products and L-methylfolate Raw Ingredients Used Therein.

On September 10, 2012, plaintiffs, Merck & Cie, South Alabama Medical Science Foundation and Pamlab, L.L.C., filed a complaint with the ITC under Section 337 of the Tariff Act of 1930, as amended, against Macoven for infringement of U.S. Patent Nos. 5,997,915, 6,673,381, 7,172,778 and 6,011,040 based on Macoven's commercialization of the following products: Vitaciric-B; ALZ-NAC; and L-methylfolate calcium. The ITC initiated an investigation on October 10, 2012. Macoven filed a response, denying liability for patent infringement and asserting patent invalidity as a defense. Discovery is ongoing. ITC set a 16 month target date for completion. A hearing is scheduled for the week of June 24-28, 2013, before an administrative law judge. The administrative law judge's initial decision is set for October 17, 2013, with the ITC's decision set for February 15, 2014.

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

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

On January 24, 2013, solely to avoid the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, Pernix and the other named defendants in such litigation signed a memorandum of understanding (the "MOU") to settle such litigation. Subject to the completion of certain confirmatory discovery by counsel to the plaintiffs, which we anticipate to be completed by the end of April 2013, as well as court approval and further definitive documentation in a stipulation of settlement, the MOU resolves the claims brought in such litigation and provides a release and settlement by the purported class of Somaxon's former stockholders of all claims against the defendants and their affiliates and agents in connection with the Merger. The asserted claims will not be released until such stipulation of settlement is approved by the court. There can be no assurance that the parties will ultimately enter into a stipulation of settlement or that the court will approve such settlement even if the parties were to enter into such stipulation. Additionally, as part of the MOU, Pernix made certain additional disclosures related to the Merger in the Proxy Statement/Prospectus. Finally, in connection with the proposed settlement, plaintiffs in such litigation intend to seek an award of attorneys' fees and expenses in an amount to be approved or determined by the court.

In addition to the above suit, Pernix is subject to various claims and litigation arising in the ordinary course of business. In the opinion of management, the outcome of such matters will not have a material effect on Pernix's financial position or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Executive Officers of the Registrant

The following table sets forth information regarding individuals who currently serve as our executive officers. The age of each individual in the table below is as of December 31, 2012. Pursuant to our certificate of incorporation and bylaws, our officers are appointed annually by the Board and hold office until their respective successors are qualified and appointed or until their resignation, removal or disqualification.

Name	Age	Position(s)
Cooper C. Collins	33	President, Chief Executive Officer & Director
David P. Becker	46	Chief Financial Officer

Table of Contents

Cooper C. Collins currently serves as President and Chief Executive Officer and a director of our Company. Mr. Collins joined Pernix's sales team in 2003. He was appointed a director of Pernix in January 2007, Pernix's President in December 2007, and Pernix's Chief Executive Officer in June 2008. From December 2005 to December 2007, Mr. Collins served as Vice President of Business and Product Development of Pernix, and from December 2003 to December 2005, he served as one of Pernix's Territory Managers. Over Mr. Collins' tenure as an executive with Pernix, he has been responsible for increasing the overall growth, profitability and efficiency of the organization, overseeing product development and acquisitions, and managing the capital structure of Pernix. Before joining Pernix, Mr. Collins was employed by the NFL franchise the New Orleans Saints in their media relations department. Mr. Collins received a Bachelor of Arts from Nicholls State University while on a football scholarship and received a Master of Business Administration from Nicholls State University.

David P. Becker currently serves as Chief Financial Officer but has resigned effective March 31, 2013. Prior to his appointment as Pernix's Chief Financial Officer on December 5, 2011, Mr. Becker was Interim Chief Financial Officer and Chief Restructuring Officer of LW Stores, a discount retail chain outlet. From 2008 to 2010, Mr. Becker served as Executive Vice President & Chief Financial Officer of MiddleBrook Pharmaceuticals, Inc. From 2007 to 2008, Mr. Becker worked as an independent consultant through his wholly-owned company, Becker Consulting, offering financial and accounting consulting services to portfolio companies of venture capital firms. From 2000 to 2007, Mr. Becker served as Executive Vice President, Chief Financial and Administrative Officer & Treasurer of Adams Respiratory Therapeutics, Inc. Mr. Becker is a certified public accountant in the state of California with over 10 years of accounting experience in the healthcare industry. Mr. Becker holds a bachelor of science in accounting from the University of Southern Mississippi. On January 17, 2013, Mr. Becker informed Pernix that he will resign as Chief Financial Officer due to personal reasons, effective March 31, 2013. Mr. Becker will be paid his current base salary through the effective date of his resignation. Mr. Becker has agreed to continue in a consulting role with Pernix following his resignation.

Table of Contents

PART II

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

Market Information

On January 16, 2013, Pernix received approval from the NASDAQ Stock Market to transfer its common stock listing from NYSE MKT LLC to the NASDAQ Global Market effective January 28, 2013. Pernix's common stock is listed on the NASDAQ Global Market under the symbol "PTX." On March 15, 2013, the most recent practicable date prior to the filing of this Annual Report on Form 10-K, the closing price of Pernix's common stock as reported on the NASDAQ Global Market was $6.24 per share. The following table sets forth, for the fiscal quarters indicated, the high and low intra-day sales prices per share of Pernix's common stock as quoted on the NYSE MKT LLC.

	Price range of common shares	
	High	Low
2011 :		
First Quarter	12.20	6.05
Second Quarter	13.23	7.85
Third Quarter	9.99	6.07
Fourth Quarter	11.50	6.79
2012:		
First Quarter	10.75	8.39
Second Quarter	9.51	5.90
Third Quarter	9.20	6.20
Fourth Quarter	8.70	6.70

Stockholder Information

On March 15, 2013, Pernix had 37,731,863 shares of common stock outstanding. As of March 15, 2013, those shares were held of record by approximately 102 registered holders.

Table of Contents

Dividends

Pernix did not make any distributions for the years ended December 31, 2012 and 2011, and does not anticipate paying dividends in the foreseeable future. Additionally, our credit agreement includes restrictions on our ability to make dividends and distributions. For additional information , see note 13, Debt and Lines of Credit.

Purchases of Equity Securities By the Issuer and Affiliated Purchasers

Issuer Purchases of Equity Securities

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly-announced plans or programs(1)	Maximum approximate dollar value of shares that may yet be purchased under the plans or programs
October 1, 2012 through October 31, 2012	---	$---	---	$ 1,150,130
November 1, 2012 through November 30, 2012	---	$---	---	$ 1,150,130
December 1, 2012 through December 31, 2012	---	$---	---	$ 1,150,130
Total	---	$---	---	$ 1,150,130

(1) On May 12, 2010, our Board of Directors authorized the repurchase of up to $5,000,000 in shares of our common stock. As of March 15, 2003, approximately $1,150,130 remained available under the repurchase plan. The repurchase plan does not have a termination date and may be eliminated by our Board at any time.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 in this Annual Report on Form 10-K for a discussion of securities authorized for issuance under our equity compensation plans.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

You should read the following discussion and analysis of Pernix's consolidated financial condition and results of operations together with the consolidated financial statements and accompanying notes included in this Annual Report on Form 10-K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Pernix's actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including, but not limited to, those set forth in "Item 1A – Risk Factors" of Part I of this Annual Report Form 10-K.

Overview

Pernix Therapeutics Holdings, Inc. (“Pernix”, the “Company”, “we” or “our”) is a specialty pharmaceutical company focused on the sales, marketing, manufacturing and development of branded, generic and over-the-counter, which we refer to herein as OTC, pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. We expect to execute our growth strategy which includes the horizontal integration of our branded prescription, generic and OTC businesses. We also plan to continue to make strategic acquisitions of products and companies, as well as develop and in-license additional products. We manage a portfolio of branded and generic products. Our branded products for the pediatrics market include CEDAX®, an antibiotic for middle ear infections, NATROBA®, a topical treatment for head lice marketed under an exclusive co-promotion agreement with ParaPRO, LLC, and a family of prescription treatments for cough and cold (ZUTRIPRO®, REZIRA®, BROVEX®, ALDEX® and PEDIATEX®). Our branded products for gastroenterology include OMECLAMOX-PAK®, a 10-day treatment for H. pylori infection and duodenal ulcer disease, and REZYST®, a probiotic blend to promote dietary management. Through our wholly-owned subsidiary Pernix Sleep (formerly Somaxon Pharmaceuticals, Inc.), we market SILENOR® (doxepin), which is approved for the treatment of insomnia characterized by difficulty with sleep maintenance and is not a controlled substance. Through our license agreement with Pharmaceutical Associates, Inc., we market VERIPRED™, a prescription drug product indicated for the control of severe allergic conditions. In addition, a product candidate utilizing cough-related intellectual property is in development for the U.S. OTC market. We promote our branded pediatric and gastroenterology products through our sales force. We market our generic products in the areas of cough and cold, pain, vitamins, dermatology, antibiotics and gastroenterology through our wholly-owned subsidiaries, Macoven Pharmaceuticals and Cypress Pharmaceuticals. Our wholly-owned subsidiary, Pernix Manufacturing, manufactures and packages products for the pharmaceutical industry in a wide range of dosage forms.

Table of Contents

The Company promotes its branded, and certain of its generic products, through an established U.S. sales force of approximately 123 sales representatives, as of March 15, 2013, including approximately 65 sales representatives acquired in the acquisition of Cypress as discussed below, primarily in highly populated states, targeting pediatric and high-prescribing physicians that are in the top decile of physicians that prescribe our products. Approximately 18 of these sales representatives are dedicated exclusively to the gastroenterology market focusing on the promotion of OMECLAMOX-PAK®. Since January 2011, we have added 46 new sales reps at varying dates throughout the two-year period. Our current operating plan focuses on maximizing sales of our existing expanded product portfolio. In addition, we plan to accelerate growth by launching new products, line extensions, new formulations and acquiring and licensing approved products.

Merger with Somaxon. On March 6, 2013, the Company acquired all of the outstanding common stock of Somaxon Pharmaceuticals, Inc. pursuant to an agreement and plan of merger dated December 10, 2012. As a result of the merger, each outstanding share of Somaxon common stock was converted into the right to receive approximately 0.478 shares of the Company's common stock, with cash paid in lieu of fractional shares. As a result of the merger, the Company issued an aggregate of approximately 3,665,689 shares of its common stock to the former stockholders of Somaxon.

Acquisition of Cypress. On December 31, 2012, we completed the acquisition of a privately-owned, generic pharmaceutical company, Cypress Pharmaceuticals, Inc. and its branded pharmaceutical subsidiary Hawthorn Pharmaceuticals, Inc., which we refer to collectively herein as Cypress. Cypress offers a wide array of generic pharmaceutical products in the areas of cough and cold, nutritional supplements, analgesics, urinary tract, women's health, pre-natal vitamins and dental health, as well as allergy, respiratory, iron deficiency, nephrology and pain management. Hawthorn offers a broad portfolio of branded products including allergy, respiratory, iron deficiency, nephrology and pain management. We paid an aggregate purchase price of up to $102.3 million. This purchase price included $52 million in cash, 4,427,084 shares of our common stock having an aggregate market value equal to approximately $34.3 million based on the closing price per share of $7.75 as reported on the NYSE MKT LLC on December 31, 2012, up to $6.5 million in holdback and contingent payments, $4.5 million to be deposited in escrow on December 15, 2013, and $5.0 million in shares of our common stock contingent upon the occurrence of a milestone event.

As part of the funding for this acquisition, we entered into a $42 million credit facility on December 31, 2012 with Midcap Funding V, LLC, as administrative agent, as a lender and as co-bookrunner and sole lead arranger, Business Development Corporation of America, as co-bookrunner, and additional lenders from time to time party thereto. Subject to certain permitted liens, our obligations under this facility are secured by a first priority perfected security interest in substantially all of our assets and the assets of our subsidiaries. The proceeds from this facility were used to fund a portion of the cash consideration of the acquisition of Cypress. The MidCap Credit Agreement includes customary covenants for a secured credit facility, which include, among other things, (a) restrictions on (i) the incurrence of indebtedness, (ii) the creation of or existence of liens, (iii) the incurrence or existence of contingent obligations, (iv) making certain dividends or other distributions, (v) certain consolidations, mergers or sales of assets, (vi) purchases of assets, investments and acquisitions and (vii) capital expenditures; and (b) requirements to deliver financial statements, reports and notices to the administrative agent and other lenders; provided that, the restrictions described in (a)(i)-(vii) above are subject to certain exceptions and permissions limited in scope and dollar value.

The MidCap Credit Agreement also contains certain financial covenants that require the Company not to permit: (1) the fixed charge coverage ratio for the twelve (12) month period ending on any date set forth below to be less than the ratio set forth below for such date (A) 1.15 to 1.00 on March 31, 2013; (B) 1.20 to 1.00 on June 30, 2013, September 30, 2013 and December 31, 2013; (C) 1.25 to 1.00 on March 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014; and (D) 1.30 to 1.00 from March 31, 2015 and the last day of each calendar quarter ending thereafter; and (2) a total debt to EBITDA ratio for the twelve (12) month period ending on any date set forth below to

exceed the ratio set forth below for such date: (A) 3.75 to 1.00 on March 31, 2013; (B) 3.60 to 1.00 on June 30, 2013; (C) 3.00 to 1.00 on September 30, 2013; (D) 2.50 to 1.00 on December 31, 2013, March 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014; (E) 2.00 to 1.00 on March 31, 2015 and June 30, 2015; (F) 1.75 to 1.00 on September 30, 2015 and December 31, 2015; (G) 1.50 to 1.00 on March 31, 2016; (H) 1.25 to 1.00 on June 30, 2016 and September 30, 2016; and (I) 1.00 to 1.00 on December 31, 2016 and the last day of each calendar quarter ending thereafter.The MidCap Credit Agreement also contains customary representations and warranties and event of default provisions for a secured credit facility.

For additional information regarding our credit facility, see Note 13, Debt and Lines of Credit, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011. For additional information regarding our acquisition of Cypress, see Note 4, Business Combinations and Other Acquisitions, and Note 10, Intangible Assets and Goodwill, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Table of Contents

Acquisition of New Product. In August 2012, the Company completed the purchase of a pediatric prescription product, including certain intellectual property rights, for a total purchase price of $1.35 million plus the assumption of certain liabilities. The Company paid $500,000 at the closing plus $250,000 on October 1, 2012, $600,000 on February 1, 2013, and assumed certain liabilities.

Amended and Restated Co-Promotion Agreement for NATROBA. We entered into an exclusive co-promotion agreement with ParaPRO for NATROBA in certain U.S. territories. In July 2012, the Company and ParaPRO replaced their then-existing co-promotion and supply agreements relating to NATROBA™ with a new agreement to restructure the terms for marketing and distributing NATROBA. Under the terms of the new agreement, the Company will no longer have the minimum purchase order commitments related to the marketing and promotion of NATROBA that were required under the previous agreements. If the Company fails to meet certain dispensed volumes, the Company or ParaPRO would have the option to either modify or terminate the new agreement. The previous options granted to ParaPRO under its services agreement with the Company were not impacted by this new agreement. The Company and ParaPRO currently co-promote and market NATROBA, as well as an authorized generic equivalent. The Company pays a co-promotion fee per unit prescribed which is recorded as co-promotion revenue. The cost that the Company pays for NATROBA is significantly higher than the direct manufacturing cost that the Company pays on the other products in our portfolio which impacts our gross profit margin.

Acquisition of GSL. On July 2, 2012, we completed our acquisition of the business assets of GSL, a pharmaceutical contract manufacturing company located in Houston, Texas. We closed on the related real estate on August 30, 2012. Upon the final closing, we paid an aggregate of approximately $4.6 million, net of the $300,000 escrow that was refunded to us subsequent to close, and assumed certain liabilities totaling approximately $5.9 million, for substantially all of GSL's assets, including the land and buildings in which GSL operates. GSL has an established manufacturing facility with an existing base of customers in the pharmaceutical industry, which provides us with additional income and potential cost savings. We acquired the GSL assets through our wholly owned subsidiary, Pernix Manufacturing, LLC. See Note 4, Business Combinations and Other Acquisitions, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011 for further discussion.

U.S. License of Cough, Cold, Sinus & Allergy Intellectual Property. On May 14, 2012, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture's intellectual property (IP) in the areas of cough, cold, sinus and allergy in the United States and Canada for $5 million. The investment in the JV at termination was approximately $1,445,000 and there was approximately $2,687,000 arising from a deferred tax liability. The value of the license recorded was approximately $9,133,000. Under the terms of the agreement, Pernix will pay royalties to SEEK on sales of products utilizing the joint venture IP in the United States and Canada. Pernix will also receive royalties from SEEK product sales outside of the United States and Canada. As a result, we no longer share in the development costs outside the United States and Canada. See Note 9, Investment in Joint Venture, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011 for further discussion.

License of Gastroenterology Product. In January 2012, we entered into a license and supply agreement with a private company for OMECLAMOX-PAK, an FDA-approved prescription product to treat gastroenterology disease. Under the terms of the agreement, we obtained exclusive marketing rights to this product in the United States. We paid an up-front license fee of $2.0 million and an additional fee of $2.0 million upon commercial launch of the product in July 2012. In addition to these license fees, the agreement calls for us to pay royalties and milestone payments based on the sales of the product.

For the years ended December 31, 2012 and 2011, our net sales were approximately $61,313,000 and $60,607,000, respectively, and our net (loss) income before income taxes was approximately ($1,410,000) and $12,937,000, respectively.

Our net cash provided by (used in) operating activities for the years ended December 31, 2012 and 2011 was approximately ($1,926,000) and $9,397,000, respectively.

Financial Operations Overview

The discussion in this section describes our consolidated income statement categories. For a discussion of our consolidated results of operations, see “Results of Operations” below.

Net Revenues

Pernix’s net revenues consist of net product sales, manufacturing revenue and revenue from co-promotion and other revenue sharing agreements. Pernix recognizes product sales net of estimated allowances for product returns, price adjustments (including customer rebates, service fees, chargebacks and other discounts), government program rebates (Medicaid, Medicare and other government sponsored programs) and prompt pay discounts. The primary factors that determine Pernix’s net product sales are the level of demand for Pernix’s products, unit sales prices, the applicable federal and supplemental government program rebates, contracted rebates, chargebacks and service fees and other discounts that Pernix may offer. In addition to our own product portfolio, from time to time we may enter into co-promotion or other revenue sharing arrangements pursuant to which we receive a percentage of revenue on sales of our products that they generate. Revenue from agreements pursuant to which contracted third parties market products to which we have rights and submit a specified profit share to us and other revenue such as sales of API (active pharmaceutical ingredients) was approximately $4,514,000 and $4,634,000 for the years ended December 31, 2012 and 2011, respectively. Manufacturing revenue from Pernix Manufacturing, acquired in July 2012 as discussed previously, was approximately $5,424,000 and 0 for the years ended December 31, 2012 and 2011.

Table of Contents

The following table sets forth a summary of Pernix's net sales revenue for the years ended December 31, 2012 and 2011.

	Year Ended December 31,	
	2012	2011
	(in thousands)	
Upper respiratory, allergy and antibiotic products	$ 39,094	$ 61,454
ENT	958	—
Gastroenterology	5,896	—
Dietary supplements and medical food products	11,964	4,509
Dermatology products (including NATROBA)	7,174	12,633
Other generic products	16,978	8,152
Gross Product Sales	82,064	86,748
Sales Allowances	(30,689)	(30,775)
Net Product Sales	51,375	55,973
Manufacturing revenue	5,424	—
Co-promotion and other revenue	4,514	4,634
Net Sales Revenues	$ 61,313	$ 60,607

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, 2012:

	Product Returns	Government Program Rebates	Price Adjustments
	(in thousands)		
Balance at December 31, 2010	$ 4,313	$ 4,432	$ 1,744
Current provision:			
Adjustments to provision for prior year sales	498	1,137	300
Provision – current year sales	4,784	9,969	12,311
Payments and credits	(3,883)	(9,695)	(8,904)
Balance at December 31, 2011	5,712	5,843	5,451
Allowances assumed in acquisition of Cypress	5,901	1,175	4,586
Current provision:			
Adjustments to provision for prior year sales	1,840	(1,075)	(272)
Provision – current year sales	5,426	7,689	15,368
Payments and credits	(6,822)	(6,595)	(14,173)
Balance at December 31, 2012	$ 12,057	$ 7,037	$ 10,960

Product Returns. Consistent with industry practice, we offer contractual return rights that allow our customers to return short-dated or expiring products within an 18-month period, commencing from six months prior to and up to twelve months subsequent to the product expiration date. Our products have a 15 to 36-month expiration period from the date of manufacture. We adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the forecast of future sales of the product, competitive issues such as new product entrants and other known changes in

sales trends. We estimate returns at percentages up to 14% of sales of branded products (including a 14% return estimate applied to launch-year sales of Omeclaxom-Pak®). We estimate returns at percentages up to 10% on sales of generic products. The returns estimate on certain generic products was increased approximately 2% effective April 1, 2012 from prior periods due to the potential impact of changes in Medicaid coverage on certain products. Also, the returns estimate was increased 5% on a generic product that contributes approximately 16% of our gross revenue to consider higher than expected returns as a result of a shorter shelf-life than the rest of the generic products in our portfolio. 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. In addition to the accrual on sales during the year ended December 31, 2012, we recorded an additional returns allowance of approximately $1,840,000 ($1,220,000 in the fourth quarter, $120,000 in the third quarter and $500,000 in the second quarter) as a result of higher than expected returns primarily on products that lost Medicaid coverage in 2012 and certain generic products launched in 2011. The returns reserve may be adjusted as we accumulate sales history and returns experience on our portfolio of products. We review and adjust these reserves quarterly. If estimates regarding product demand are inaccurate, if changes in the competitive environment effect demand for certain products, or if other unforeseen circumstances effect a product’s salability, actual returns could differ and such differences could be material. For example, a 1% difference in our provision assumptions for the year ended December 31, 2012 would have affected pre-tax earnings by approximately $834,000.

Table of Contents

Government Program Rebates. The liability for 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 and Medicare coverage of our products, we will continue to incorporate such changing circumstances into the estimates and assumptions that we use to calculate government program rebates. If our estimates and assumptions prove inaccurate, we may be subject to higher or lower government program rebates. For example, with respect to the provision for the year ended December 31, 2012, a 1% difference in the provision assumptions based on utilization would have effected pre-tax earnings by approximately $194,000 and a 1% difference in the provisions based on reimbursement rates would have affected pre-tax earnings by approximately $81,000.

Price Adjustments. Our estimates of price adjustments which include customer rebates, service fees, chargebacks 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. 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. For example, for the year ended December 31, 2012, a 1% difference in the assumptions based on the applicable sales would have affected pre-tax earnings by approximately $1,387,000.

We, from time to time, offer certain promotional product-related incentives to our customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. For example, we have initiated coupon programs for certain of our promoted products whereby we offer a point-of-sale subsidy to retail consumers. We estimate our liabilities for these coupon programs based on redemption information provided by a third party claims processing organization. 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. Approximately 18% of the provision relates to point-of-sale discounts to the wholesaler.

Prompt Payment Discounts. We typically require our customers to remit payments within the first 30 days for branded products (60 to 120 days for generics, depending on the customer and the products purchased). We offer wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2% to 3%, but may be higher in some instances due to product launches and/or industry expectations. Because our wholesale distributors typically take advantage of the prompt pay discount, we accrue 100% of the prompt pay discounts, based on the gross amount of each invoice, at the time of our original sale, and apply earned discounts at the time of payment. This allowance is recorded as a reduction of accounts receivable and revenue. We adjust the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. We do not anticipate that future changes to our estimates of prompt payment discounts will have a material impact on our net revenue. Prompt pay discounts were approximately $1,713,000 and $1,775,000 for the years ended December 31, 2012 and 2011, respectively.

Cost of Product Sales

Our cost of product sales is primarily comprised of the costs of manufacturing and distributing our pharmaceutical products and profit sharing and royalty expenses related to co-promotion and license agreements with third parties. In particular, cost of product sales includes manufacturing, packaging and distribution costs and the cost of active pharmaceutical ingredients. We partner with third parties to manufacture certain of our products and product

candidates while some of our products are manufactured by Great Southern Laboratories, the manufacturing plant that we acquired in July 2012. We expect to utilize Pernix Manufacturing to manufacture more of our products moving forward which should result in a reduction of the cost of certain of our products.

Table of Contents

Most of our manufacturing arrangements with third party manufacturers are not subject to long-term agreements and generally may be terminated by either party without penalty at any time. Changes in the price of raw materials and manufacturing costs could adversely affect our gross margins on the sale of our products. Changes in our mix of products sold also affect our cost of product sales.

From time to time in the ordinary course of business, the Company enters into agreements regarding royalty payments or other profit sharing payments. Royalty expenses include the contractual amounts Pernix is required to pay licensors from which it has acquired the rights to certain of its marketed products. Royalty and profit sharing expenses will vary based on changes in product sales and/or product mix.

For further discussion of our agreements that are subject to a profit split arrangement or royalty, see Note 4, Business Combinations and Other Acquisitions, and Note 17, Other Revenue Sharing Arrangements, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

The cost of NATROBA is included in our cost of product sales from August 2011 (the month of launch) to present. We pay wholesale average cost less a nominal discount when we purchase NATROBA inventory. Under the original agreement with ParaPRO, we received a contracted cost of goods rebate per unit when the product was shipped to retailers in our specified territories. Under the renegotiated terms effective August 12, 2012, we receive a flat co-promotion fee on NATROBA per unit based on prescriptions in our specified territories. Because of the structure of the NATROBA agreement, we recognize significantly lower margins on sales of NATROBA as compared to the other products we market.

Selling Expenses

Our selling expenses consist of the cost of product samples, program management fees, sales data fees, salaries, commission and incentive expenses for our sales force; all overhead costs of our sales force; and out-going freight, marketing collateral and promotion costs. The most significant component of our sales and marketing expenses is salaries, commissions and incentive expenses for our sales force. Sales commissions are based on when our products are dispensed by retail customers, not when we sell Pernix products to our wholesale customers. Therefore, there may be a lag between the time of Pernix’s sale to its customer and when the commission is ultimately earned and paid on that sale.

General and Administrative Expenses

General and administrative expenses primarily include salaries, benefits and overhead of management and administrative personnel; legal and professional fees; consulting fees; deal expenses, and all lines of insurance. Pernix’s general and administrative expenses have increased significantly from the year ended December 31, 2012 due to the acquisition of GSL and growth in our operating infrastructure resulting in personnel additions and their related overhead costs, costs related to the expansion of our product portfolio and expenses in support of growing a public company.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing and testing products and product candidates. Pernix either expenses research and development costs as incurred or, if Pernix pays manufacturers a prepaid research and development fee, Pernix will expense such fee ratably over the term of the development. Pernix believes that significant investment in research and development is important to its competitive position and may, in the future, increase its expenditures for research and development to realize the potential of the product candidates that it is developing or may develop, including the in-process research and development projects of

Cypress.

Other Income and Expenses

Depreciation Expense. Depreciation expense is recognized for our property and equipment, which depreciates over the estimated useful lives of the assets using the straight-line method.

Amortization Expense. Amortization expense is recognized for certain of our intangible assets, consisting primarily of licensing and acquisition agreements, including but not limited to, the customer relationships acquired in the acquisition of GSL in July 2012, the license related to the non-codeine antitussive drug in development (BC 1036) acquired in May 2012, the OMECLAMOX license acquired in February 2012, CEDAX in March 2010 and Macoven in September 2010, which are amortized over their estimated useful lives using the straight-line method. See Note 10, Intangible Assets, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011 for further discussion.

Table of Contents

Income Taxes. Deferred taxes are recognized for the tax consequences of "temporary differences" by applying enacted statutory rates applicable to future years to the difference between the financial statement carrying amounts and the tax bases of existing assets and liabilities. The effect on deferred taxes for a change in tax rates is recognized in income in the period that includes the enactment date. Pernix will recognize future tax benefits to the extent that realization of such benefits is more likely than not. Pernix recorded a deferred tax liability of approximately $31,824,000 related to the step-up in the basis of the assets acquired in the Cypress acquisition.

Critical Accounting Estimates

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

Pernix regards an accounting estimate or assumption underlying its financial statements as a "critical accounting estimate" where:

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

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

Our significant accounting policies are described in the notes to our Consolidated Financial Statements in Part II, Item 8, of this Annual Report on Form 10-K. Not all of these significant accounting policies, however, fit the definition of "critical accounting estimates." Pernix believes that its estimates relating to revenue recognition, sales allowances such as returns on product sales, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, depreciation, stock-based compensation, the determination of fair values of assets and liabilities in connection with business combinations and deferred income taxes fit the definition of "critical accounting estimates."

Revenue Recognition

We record revenue from product sales and co-promotion agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Product Sales. We record all of our revenue from product sales, manufacturing sales and co-promotion agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been performed and are billable; (3) the seller's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. We record revenue from product sales when the customer takes ownership and assumes risk of loss (free-on-board destination). Manufacturing revenue is recognized when the finished product is shipped to the customer. Co-promotion revenue is recognized in the period in which the product subject to the arrangement is sold. 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. Refer to the discussion of sales deductions above under Allowances for Product Returns, Medicaid Rebates, Price Adjustments (chargebacks,

rebates, vendor fees, coupons and point-of-sale discounts), and Prompt Pay Discounts.

Stock Based Compensation

Compensation expense is determined by reference to the fair value of an award on the date of grant and is amortized on a straight-line basis over the vesting period. Pernix accounts for its stock based compensation pursuant to ASC 718, Accounting for Stock Options and Other Stock Based Compensation. ASC 718 also establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. See Note 18, Employee Compensation and Benefits, and Note 21, Subsequent Events, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011, regarding the calculation of the value of options issued and other details regarding all stock based compensation awarded in the year ended December 31, 2012.

Table of Contents

Inventory

Inventory primarily consists of finished goods which include pharmaceutical products ready for commercial sale or distribution as samples as well as Pernix Manufacturing's inventory of raw materials and packaging supplies for the manufacture of products. Inventory is stated at the actual cost per bottle determined under the specific identification method. Pernix's estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of its inventories could vary significantly from its estimates and could have a material effect on its 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 the Company has in inventory are provided to certain of our manufacturers to utilize in the manufacture of our products and, from time to time, are sold to other companies to utilize in their own products. As of December 31, 2012 and 2011, Pernix had approximately $22,014,000 and $6,261,000 in inventory, respectively, which is net of a reserve of approximately $1,057,000 and $0 as of December 31, 2012 and 2011, respectively. Inventory at December 31, 2012 includes approximately $5,577,000 in inventory acquired in the acquisition of Cypress plus a step-up in the basis of this inventory of $8,600,000.

Results of Operations

Comparison of the Year Ended December 31, 2012 and 2011

Net Revenues. Net revenues were approximately $61,313,000 and $60,607,000 for the years ended December 31, 2012 and 2011, respectively, an increase of approximately $706,000, or 1.2%. The increase in net revenues during the year ended December 31, 2012 was primarily due to a decrease in deductions from revenue of approximately $86,000 and the addition of the manufacturing revenue from Pernix Manufacturing of approximately $5,424,000, partially offset by a decrease in gross product sales of approximately $3,792,000 and a decrease in co-promotion and other revenue of approximately $1,012,000. The decrease in gross product sales was primarily due to the phasing out of our legacy cough and cold products. The decrease in the deductions from revenue was primarily due to the decrease in the allowance from Medicaid rebates as a result of changes in Medicaid coverage on certain of our products and decreases in customer chargebacks and administrative fees due primarily to more direct sales to retailers, partially offset by increases in point of sales discounts, the allowances for coupon redemption and the allowance for product returns.

Allowances for Product Returns, Medicaid Rebates, Price Adjustments (chargebacks, rebates, vendor fees, coupons and point-of-sale discounts), and Prompt Pay Discounts. Product returns allowances are based on the products' expiration dates, which are generally 15 to 36-months from the date the product was originally sold. For the years ended December 31, 2012 and 2011, product returns allowances were approximately $7,266,000, or 8.8%, of gross product sales, and $5,283,000, or 6.1%, of gross sales, respectively. The increase in the product returns allowances as a percentage of gross product sales was primarily due to changes in Medicaid coverage in 2012 that reduced Medicaid prescriptions of our products as well as higher returns on a product with a 15-month shelf life that was launched in June 2011.

Government program rebates were approximately $6,614,000, or 8.0%, of gross product sales, and $11,106,000 or 12.8%, of gross product sales, respectively, for the years ended December 31, 2012 and 2011. The liability for 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. The decrease in rebates as a percentage of gross product sales was primarily due to changes in Medicaid coverage on certain of our products in 2012.

Price adjustments were approximately $15,096,000, or 18.4%, of gross product sales and $12,611,000, or 14.5%, of gross product sales, respectively, for the years ended December 31, 2012 and 2011. The increase in price adjustments

as a percentage of gross product sales was due primarily to an increase in coupon utilization on our products. Rebates and chargebacks are not typically a component of customer contracts for brand products so price adjustments are primarily impacted by generic sales.

Prompt pay discounts taken were approximately $1,713,000, or 2.0%, of gross product sales and $1,775,000, or 2.0%, of gross product sales, for the years ended December 31, 2012 and 2011, respectively. Approximately $728,000 and $393,000 in accrued allowances for prompt pay discounts was netted against accounts receivable at December 31, 2012 and 2011, respectively.

Cost of Sales. Cost of sales was approximately $23,377,000, or 28.5%, of gross product sales, and $20,921,000, or 24.1%, of gross product sales, for the years ended December 31, 2012 and 2011, respectively, an increase of approximately $2,456,000, or 11.7%. The increase in cost of sales was primarily due to approximately $2,742,000 in product manufacturing costs incurred by Pernix Manufacturing, approximately $1,730,000 in increased expense from co-promotion and other profit sharing arrangements on OMECLAMOX-PAK® (launched in June 2012) and certain generic products (launched during the fourth quarter of 2011), and a decrease of approximately $1,580,000 in cost of goods rebates as a result of the restructure of the NATROBA agreement. This increase was partially offset by a decrease of approximately $1,928,000 in the costs of product sales resulting from the decrease in gross product sales and a decrease of approximately $1,283,000 in inventory write-offs.

Table of Contents

Gross Margin. Gross profit margin on the sale of our products was 65% and 69% for the years ended December 31, 2012 and 2011, respectively. The decrease in gross profit margin is primarily due to the sale of lower margin products and profit sharing arrangements with various parties. For additional information on our gross profit margin, see Note 16, Concentrations, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Selling, General and Administrative Expenses (SG&A). SG&A expenses were approximately $35,452,000 and $22,538,000 for the years ended December 31, 2012 and 2011, respectively, an increase of approximately $12,914,000, or 57.3%. Pernix Manufacturing SG&A expense contributed approximately $3,503,000, costs related to the acquisitions of Cypress, Somaxon and GSL contributed approximately $1,001,000 and our OTC division, which was created in July 2012, contributed approximately $312,000 to this increase. In addition, litigation expense increased approximately $1,241,000 for the year ended December 31, 2012, consulting and professional fees increased approximately $1,137,000, advertising and marketing costs increased approximately $1,013,000 and sample costs increased approximately $687,000 (due in part to the launch of OMECLAMOX-PAK® in June 2012). The remaining increase in SG&A expenses of approximately $4,020,000 was due to increases in employee carrying costs (such as travel, vehicle, technology, etc. for the addition of certain key positions in December 2011 and the hiring of additional gastroenterology sales representatives to market OMECLAMOX-PAK® in May 2012), coupon program fees, marketing research, regulatory and license fees, insurance, leases, sales reporting expenses, information technology and software implementation expenses, stock compensation expense, certain public company costs, investor relations expenses and other expenses.

Overall compensation expense represented approximately $14,884,000, or 42.0%, and $13,054,000, or 57.9%, of total SG&A for the years ended December 31, 2012 and 2011, respectively. The increase in overall compensation expense is primarily due to an increase in stock compensation expense, the addition of Pernix Manufacturing employees in July 2012, the addition of certain positions in December 2011 and the hiring of additional sale representatives to market OMECLAMOX-PAK® in May 2012, partially offset by a decrease in bonus and incentive compensation.

Research and Development Expenses (R&D). R&D expenses were approximately $732,000 and $922,000 for the years ended December 31, 2012 and 2011, respectively. R&D expenses during the year ended December 31, 2012 were primarily related to development of the prescription product for the pediatrics market pursuant to a product development agreement. R&D expenses for the year ended December 31, 2011 were primarily due to the launch of a new generic product in 2011. Other research and development costs during the periods relate to the testing of product durability.

Loss from the Operations of the Joint Venture. The loss from the operations of our former joint venture with SEEK was approximately $240,000 and $814,000 for the years ended December 31, 2012 and 2011, respectively, which represents primarily research and development costs related to the development of a non-codeine antitussive drug designed to address the serious need for a safer and more effective, non-opiod treatment for persistent cough. The joint venture was terminated in May 2012. For further discussion, see Note 9, Investment in Joint Venture, to our Consolidated Financial Statements.

Depreciation and Amortization Expense. Depreciation expense was approximately $324,000 and $97,000 for the years ended December 31, 2012 and 2011, respectively. Amortization expense was approximately $2,878,000 and $2,205,000 for the years ended December 31, 2012 and 2011, respectively. The increase in amortization expense of approximately $673,000, or 30.5%, is due to the addition of intangible assets in the acquisition of GSL and other licenses acquired in 2012 (including the license for OMECLAMOX-PAK®). For further discussion, see Note 10, Intangible Assets and Goodwill, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Interest Expense, net. Interest income was approximately $74,000 and $41,000 for the years ended December 31, 2012 and 2011, respectively. Interest expense was approximately $169,000 and $212,000 for the years ended December 31, 2012 and 2011, respectively, related to our line of credit and insurance financing arrangements.

Liquidity and Capital Resources

Sources of Liquidity

Pernix's net (loss) income was approximately ($1,410,000) and $8,348,000 for the years ended December 31, 2012 and 2011, respectively.

Pernix requires cash to meet its operating expenses and for research and development, capital expenditures, acquisitions, and in-licenses of rights to products. To date, Pernix has funded its operations primarily from product sales, co-promotion agreement revenues, proceeds from equity offerings and debt facilities. As described in Note 15, Stockholders' Equity, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011, we received net proceeds of approximately $23.8 million from our controlled equity offering that commenced in February 2012 and concluded in April 2012. As described in Note 13, Debt and Lines of Credit, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011, we entered into a $42 million credit facility on December 31, 2012 with Midcap Funding V, LLC, as administrative agent, as a lender and as co-bookrunner and sole lead arranger, Business Development Corporation of America, as co-bookrunner, and additional lenders from time to time party thereto. We utilized the proceeds from this credit facility in the acquisition of Cypress.

Table of Contents

Cash Flows

The following table provides information regarding Pernix's cash flows for the years ended December 31, 2012 and 2011.

	Years Ended December 31,	
	2012	2011
Cash provided by (used in)		
Operating activities	$ (1,926,000)	$ 9,397,000
Investing activities	(64,897,000)	(2,175,000)
Financing activities	55,295,000	19,069,000
Net increase (decrease) in cash and cash equivalents	$ (11,528,000)	$ 26,291,000

Net Cash Provided By Operating Activities

Net cash (used in) provided by operating activities for the years ended December 31, 2012 and 2011 was approximately $(1,926,000) and $9,397,000, respectively. Net cash used in operating activities for the year ended December 31, 2012 primarily reflected Pernix's net loss of approximately $1,410,000, adjusted by non-cash expenses totaling approximately $6,807,000, partially offset by a non-cash deferred income tax benefit of approximately $1,837,000 and approximately $5,486,000 in net changes in accounts receivable, inventories, accrued expenses, and other operating assets and liabilities. Non-cash expenses for the year ended December 31, 2012 included depreciation of approximately $324,000, amortization of approximately $2,878,000, loss on disposal of assets of approximately $26,000, stock compensation expense of approximately $2,654,000, stock option expense for options issued to ParaPRO of approximately $685,000 and expenses from our former joint venture with SEEK of approximately $240,000.

Net cash provided by operating activities for the year ended December 31, 2011 primarily reflected Pernix's net income of approximately $8,347,000, adjusted by non-cash expenses totaling approximately $5,093,000, partially offset by a non-cash deferred income tax benefit of approximately $2,273,000 and approximately $1,770,000 in net changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash expenses included amortization of approximately $2,205,000, depreciation of approximately $97,000, an impairment charge of $380,000, stock compensation expense of approximately $1,284,000, stock option expense for options issued to ParaPRO of approximately $313,000 and expenses from our former joint venture with SEEK of approximately $814,000.

Accounts receivable increased by approximately $3,886,000 from the year ended December 31, 2011 to the year ended December 31, 2012 primarily attributable to higher generic product sales, which have longer payment terms than brand sales. Inventories decreased approximately $650,000 from December 31, 2011 primarily as a result of lower inventory purchases in the fourth quarter of 2012. Prepaid expenses and other assets increased by approximately $251,000 due to prepaid product related government fees and coupon program funding.

Accounts payable increased by approximately $1,842,000 from the year ended December 31, 2011 due primarily to the addition of GSL's accounts payable. Accrued expenses increased approximately $1,956,000 primarily due to an increase in accrued allowances for sales deductions.

Net Cash Used in Investing Activities

Net cash used in investing activities for the years ended December 31, 2012 and 2011 was approximately $64,897,000 and $2,176,000, respectively. The cash flow used in investing activities for the year ended December 31, 2012

consisted of $2,400,000 to acquire the license for OMECLAMOX®, $5,000,000 to acquire the license from SEEK for the non-codeine antitussive drug in development, approximately $4,667,000 to acquire GSL, approximately $51,662,000 to acquire Cypress, and approximately $850,000 for the acquisition of other product licenses and purchases of software, furniture and equipment of approximately $326,000. The cash flow from investing activities for the year ended December 31, 2011 of approximately $2,176,000 consisted of a $1,000,000 additional investment in our joint venture with SEEK, a $1,000,000 investment in TherapeuticsMD for which we received 2,631,579 shares of its common stock, and approximately $176,000 in purchases of equipment and furniture. For additional information see Notes 8, Property, Plant and Equipment, 9, Investment in Joint Venture, and 10, Intangible Assets and Goodwill, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Table of Contents

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2012 was approximately $55,294,000, which represented approximately (i) $23,751,000 in net proceeds from our controlled equity offering, (ii) $315,000 tax benefit on stock-based awards, and (iii) $835,000 in net proceeds from the issuance of stock to employees and board members, partially offset by approximately (1) $6,000,000 in payments on our line of credit, (2) $40,055,000, net of capitalized loan costs of approximately $1,945,000, in proceeds from the Midcap credit facility, (3) $3,540,000 in payments on contracts and (4) $121,000 in payments on the Pernix Manufacturing mortgage and capital lease obligations.

Net cash provided by financing activities for the year ended December 31, 2011 was approximately $19,069,000, which represented approximately (i) $1,000,000 in proceeds from our revolving line of credit, (ii) $19,260,000 in net proceeds from the registered equity offering completed on July 27, 2011, (iii) $500,000 in cash released from a letter of credit and transferred from restricted to unrestricted cash, (iv) $113,000 in payment received on notes receivable, (v) $137,000 tax benefit on stock-based awards, and (vi) $289,000 in proceeds from the issuance of stock under our employee stock purchase and incentive stock plans, partially offset by (1) approximately $1,200,000 in installment payments on the repurchase of stock from a related party, (2) $1,000,000 for the last scheduled installment on the acquisition of Gaine, and (3) $30,000 in payments under other installment contracts payable.

As of March 15, 2013, Pernix has approximately $30 million in cash. Pernix’s future capital requirements will depend on many factors, including:

- the level of product sales of its currently marketed products and any additional products that Pernix may market in the future;
- the extent to which Pernix acquires or invests in products, businesses and technologies;
- the level of inventory purchase commitments under supply, manufacturing, license and/or co-promotion agreements;
- the scope, progress, results and costs of development activities for Pernix’s current product candidates;
- the costs, timing and outcome of regulatory review of Pernix’s product candidates;
- the number of, and development requirements for, additional product candidates that Pernix pursues;
- the costs of commercialization activities, including manufacturing, product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of Pernix’s product candidates and products;
- the working capital funding required by the manufacturing plant that Pernix acquired on July 2, 2012;
- the extent to which Pernix chooses to establish collaboration, co-promotion, distribution or other similar arrangements for its marketed products and product candidates; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to Pernix.

A significant portion of the Company’s planned expenditures for 2013 are expenses in connection with our development programs, notably our planned OTC launch for a pediatric cough/cold product in the second half of 2013 and our development project for a prescription pediatric product. As of March 15, 2013, Pernix believes that its existing cash and cash from operations will be sufficient to continue to fund its existing level of operating expenses, current development activities and general capital expenditure requirements through 2013. However, the Company's ability to execute all of its development programs and other business strategies during 2013 may be limited by the

restrictive and financial covenants contained in our credit agreement. For additional information on the restrictive and financial covenants contained in our credit facility, see Note 13- Debt and Lines of Credit to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

As a result, the Company may seek an amendment to certain of the terms of the credit agreement with Midcap. At this time, we are unable to predict whether or not an amendment on terms acceptable to us and our lenders will be reached. In the event we are unable to enter into an amendment to our credit facility or our capital resources are otherwise insufficient to meet future capital requirements, Pernix may seek to finance its cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, a sale of selected assets, or other financing alternatives. Equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

Table of Contents

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. Further, obligations under employment agreements contingent upon continued employment are not included in the table below. The following table summarizes our contractual obligations as of December 31, 2012 (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases(1)	$1,593	$797	$716	$80	—
Capital leases(2)	55	55	—	—	—
Professional services agreements(3)	1,617	1,065	552	—	—
Supply agreements and purchase obligations(4)	2,920	2,920	—	—	—
License and development agreements(5)	990	990	—	—	—
Long-term debt obligations(6)	44,090	2,328	7,806	33,006	950
Other obligations(7)	600	600	—	—	—
Total contractual obligations	$51,865	$8,755	$9,074	$33,086	$950

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

(2) Capital leases include minimum payments under leases for certain manufacturing equipment at Pernix Manufacturing.

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

(4) Supply agreements and Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers and other providers of goods and services. The contractual obligations table set forth above does not reflect certain minimum sales requirements related to our co-promotion agreements. Our failure to satisfy minimum sales requirements under our co-promotion agreements generally allows the counterparty to terminate the agreement and/or results in a loss of our exclusivity rights. In addition to minimum sales requirements under our co-promotion

agreements, the table above does not include commitments under open purchase orders for inventory that can be cancelled without penalty, which are approximately $7.0 million.

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

(6) The long-term debt obligations represent the minimum payments under the credit facility that was entered into during 2012 and the mortgage on certain real estate assumed in the acquisition of Pernix Manufacturing.

(7) Other obligations represent the payments due under a privately negotiated stock repurchase.

See Notes 13, Debt and Lines of Credit, 15, Stockholder's Equity, and 20, Commitments and Contingencies, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011 for additional information.

Table of Contents

In addition to the material contractual cash obligations included the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution, acquisition and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets and have not been included in the table above. See Notes 4, Business Combinations and Other Acquisitions, and 10, Intangible Assets and Goodwill, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011 for additional information.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to our Consolidated Financial Statements for the years ended December 31, 2012 and 2011.

Seasonality

Historically, the months of September through March account for a greater portion of our sales than the other months of the fiscal year. This sales pattern is likely to continue if we sell primarily cough and cold products, which are subject to seasonal fluctuations. The following table shows gross product sales by quarter for the years ended December 31, 2012 and 2011.

	Gross Product Sales (in thousands)	
	2012	2011
Three months ending March 31	$ 20,268	$ 18,252
Three months ending June 30	16,982	15,626
Three months ending September 30	20,370	23,034
Three months ending December 31	24,444	29,836
Total gross product sales	$ 82,064	$ 86,748

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors
Pernix Therapeutics Holdings, Inc.
The Woodlands, Texas

We have audited the accompanying consolidated balance sheets of Pernix Therapeutics Holdings, Inc. and subsidiaries (collectively, the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pernix Therapeutics Holdings, Inc. and subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 18, 2013 express an unqualified opinion thereon.

/s/ Cherry Bekaert LLP

Atlanta, Georgia
March 18, 2013

Table of Contents

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,022,821	$ 34,551,180
Accounts receivable, net	36,647,087	20,601,360
Inventory, net	22,014,405	6,261,162
Prepaid expenses and other current assets	3,888,117	2,144,203
Prepaid income taxes	2,024,411	—
Deferred income tax assets – current	8,118,500	4,552,000
Total current assets	95,715,341	68,109,905
Property and equipment, net	6,946,944	911,948
Other assets:		
Investments	5,710,526	4,451,831
Goodwill	37,160,911	1,406,591
Intangible assets, net	104,054,431	7,469,913
Other long-term assets	1,858,534	213,783
Total assets	$ 251,446,687	$ 82,563,971
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,045,488	$ 2,987,913
Accrued personnel expense	2,881,967	2,044,121
Accrued allowances	30,054,551	17,006,409
Income taxes payable	—	585,931
Other accrued expenses	5,548,084	1,565,918
Contracts payable and other obligations	8,130,664	1,290,000
Debt – short term	2,286,513	—
Line of credit	—	6,000,000
Total current liabilities	53,947,267	31,480,292
Long-term liabilities		
Contracts payable and other obligations	7,765,511	600,000
Debt – long term	41,349,563	—
Deferred income taxes	35,535,500	860,000
Total liabilities	138,597,841	32,940,292
Commitments and contingencies		
Temporary Equity		
Common stock subject to repurchase (4,427,084 shares)	34,309,901	—
STOCKHOLDERS' EQUITY		
Preferred stock $.01 par value, 10,000,000 shares authorized, no shares outstanding	—	—

Common stock $.01 par value, 90,000,000 shares authorized, 35,723,161 and 27,820,004 issued, and 34,030,351 and 25,749,137 outstanding at December 31, 2012 and 2011, respectively		296,033		257,491
Treasury stock, at cost (2,072,810 and 2,070,867 shares held at December 31, 2012 and 2011, respectively)		(3,772,410)		(3,751,890)
Additional paid-in capital		58,606,942		30,185,292
Retained earnings		20,433,262		21,843,418
Other comprehensive income		2,975,118		1,089,368
Total stockholders' equity		78,538,945		49,623,679
Total liabilities and stockholders' equity	$	251,446,687	$	82,563,971

See accompanying notes to consolidated financial statements

Table of Contents

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

	Years Ended December 31,	
	2012	2011
Net revenues	$61,312,559	$60,606,855
Cost and expenses:		
Cost of sales	23,376,895	20,921,233
Selling, general and administrative expenses	35,451,653	22,537,966
Research and development expense	731,665	922,432
Loss from operations of the joint venture	240,195	814,351
Depreciation and amortization expense	3,201,483	2,302,894
Total costs and expenses	63,001,891	47,498,876
Income (loss) from operations	(1,689,332)	13,107,979
Other income (expense):		
Interest expense, net	(94,823)	(171,378)
Income (loss) before income taxes	(1,784,155)	12,936,601
Income tax provision (benefit)	(373,999)	4,589,000
Net income (loss)	(1,410,156)	8,347,601
Unrealized gain on securities, net of income tax of $1,061,000 and $674,000	1,885,750	1,089,368
Comprehensive income	$475,594	$9,436,969
Net income (loss) per share, basic	$(0.05)	$0.35
Net income (loss) per share, diluted	$(0.05)	$0.34
Weighted-average common shares, basic	28,146,207	23,990,734
Weighted-average common shares, diluted	28,146,207	24,460,291

See accompanying notes to consolidated financial statements.

Table of Contents

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2010	$ 226,277	$ 8,934,735	$ (3,751,890)	$ 13,495,817	$ ---	$ 18,904,939
Stock-based compensation						
Restricted stock	600	320,192	---	---	---	320,792
Stock options	---	861,507	---	---	---	861,507
Employee stock purchase plan	---	100,968	---	---	---	100,968
Issuance of stock options for services from non-employees	---	312,563	---	---	---	312,563
Issuance of common stock upon the exercise of stock options	279	78,122	---	---	---	78,401
Issuance of common stock in connection with employee stock purchase plan	335	210,460	---	---	---	210,795
Income tax benefit on stock based awards	---	137,000	---	---	---	137,000
Issuance of common stock upon registered direct offering, net of issuance costs of $255,254	30,000	19,229,745	---	---	---	19,259,745
Net income	---	---	---	8,347,601	---	8,347,601
Unrealized gain on securities, net	---	---	---	---	1,089,368	1,089,368
Balance at December 31, 2011	$ 257,491	$ 30,185,292	$ (3,751,890)	$ 21,843,418	$ 1,089,368	$ 49,623,679
Stock-based compensation						
Restricted stock	6,681	1,037,370	---	---	---	1,044,051
Stock options	---	1,546,885	---	---	---	1,546,885
Employee stock purchase plan	---	63,250	---	---	---	63,250
Issuance of stock options for services from non-employees	---	685,094	---	---	---	685,094
Issuance of common stock in lieu of cash	213	199,558	---	---	---	199,771

bonus						
Issuance of common stock upon the exercise of stock options	1,715	664,626	---	---	---	666,341
Forfeit of restricted common stock in payment of income tax liability	---	---	(20,520)	---	---	(20,520)
Issuance of common stock in connection with employee stock purchase plan	266	188,502	---	---	---	188,768
Income tax benefit on stock based awards	---	315,000	---	---	---	315,000
Issuance of common stock upon additional public offering, net of issuance costs of $846,202	29,667	23,721,365	---	---	---	23,751,032
Net loss	---	---	---	(1,410,156)		(1,410,156)
Unrealized gain on securities, net	---	---	---	---	1,185,750	1,885,750
Balance at December 31, 2012	$ 296,033	$ 58,606,942	$ (3,772,410)	$ 20,433,262	$ 2,275,118	$ 78,538,945

See accompanying notes to consolidated financial statements.

Table of Contents

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2012	2011
Cash flows from operating activities:		
Net (loss) income	$(1,410,156)	$8,347,601
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	323,644	97,498
Amortization	2,877,839	2,205,396
Impairment charge to fair value of land	—	380,000
Deferred income tax benefit	(1,836,329)	(2,273,000)
Loss on disposal of assets	25,802	—
Stock compensation expense	2,654,186	1,283,267
Expense for stock options issued in exchange for services	685,094	312,563
Loss from the operations of the joint venture	240,195	814,351
Changes in operating assets and liabilities:(net of effects of acquisitions)		
Accounts receivable	(3,885,502)	(5,843,120)
Income taxes	(1,335,077)	(2,237,121)
Inventory	(650,147)	(2,115,428)
Prepaid expenses and other assets	(251,479)	(325,568)
Other assets – long term	71,625	51,184
Accounts payable	(1,841,801)	739,570
Accrued expenses	2,406,495	7,960,249
Net cash (used in) provided by operating activities	(1,925,611)	9,397,442
Cash flows from investing activities:		
Acquisitions of licenses	(7,400,000)	—
Acquisition of Cypress Pharmaceuticals (“Cypress”), net of cash acquired	(51,661,505)	—
Acquisition of Great Southern Laboratories (“GSL”)	(4,666,964)	—
Investment in TherapeuticsMD	—	(1,000,000)
Investment in joint venture with SEEK	—	(1,000,000)
Other intangibles	(850,000)	—
Proceeds from sale of equipment	7,550	—
Purchase of software and equipment	(326,291)	(175,596)
Net cash used in investing activities	(64,897,210)	(2,175,596)
Cash flows from financing activities:		
Proceeds from line of credit	—	1,000,000
Payments on line of credit	(6,000,000)	—
Proceeds from credit facility, net of capitalized loan costs	40,054,528	—
Payments on contracts payable	(3,540,000)	(1,230,000)
Proceeds from issuance of stock in additional offering, net of issuance costs of $846,202 and $255,254 for the years ended December 31, 2012 and 2011, respectively	23,751,032	19,259,746
Transfer to/from restricted cash	—	500,000
Payments on Pernix Manufacturing mortgages and capital leases	(120,687)	—
Principal payments received on notes receivable	—	113,333
Payment on acquisition obligation – Gaine	—	(1,000,000)
Tax benefit on stock-based awards	315,000	137,000

Proceeds from issuance of stock	834,589	289,196
Net cash provided by financing activities	55,294,462	19,069,275
Net increase (decrease) in cash and cash equivalents	(11,528,359)	26,291,121
Cash and cash equivalents, beginning of year	34,551,180	8,260,059
Cash and cash equivalents, end of year	$23,022,821	$34,551,180
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$2,482,407	$8,911,190
Interest paid during the period	200,486	177,816
Write off/donation of inventory	822,403	2,001,464
Non-cash investing and financing activities:		
Acquisition of product licenses – contract payable balance	630,000	90,000
Accrued 2011 bonus paid in unrestricted stock	199,770	—

Effective December 31, 2012, Pernix acquired Cypress. Under the terms of the merger agreement, Cypress shareholders received approximately 4.42 million shares of Pernix common stock with a market value of $34.3 million (based on the closing price of our common stock on December 31, 2012) as part of the purchase consideration.

In July and August 2012, Pernix acquired GSL. Under the terms of the merger agreement, Pernix assumed a mortgage liability of $1.6 million and capital leases of $0.1 million as part of the purchase consideration.

See accompanying notes to consolidated financial statements.

Table of Contents

PERNIX THERAPEUTICS HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Company Overview

Pernix Therapeutics Holdings, Inc. ("Pernix", the "Company", "we", our") is a specialty pharmaceutical company focused on the sales, marketing, manufacturing and development of branded, generic and over-the-counter, which we refer to herein as OTC, pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. The Company expects to execute a growth strategy which includes the horizontal integration of the Company's branded prescription, generic and OTC businesses. The Company also plans to continue to make strategic acquisitions of products and companies, as well as develop and in-license additional products. The Company manages a portfolio of branded and generic products. Branded products for the pediatrics market include CEDAX®, an antibiotic for middle ear infections, NATROBA®, a topical treatment for head lice marketed under an exclusive co-promotion agreement with ParaPRO, LLC, and a family of prescription treatments for cough and cold (ZUTRIPRO®, REZIRA®, BROVEX®, ALDEX® and PEDIATEX®). Branded products for gastroenterology include OMECLAMOX-PAK®, a 10-day treatment for H. pylori infection and duodenal ulcer disease, and REZYST®, a probiotic blend to promote dietary management. Through the Company's wholly-owned subsidiary Pernix Sleep (formerly Somaxon Pharmaceuticals, Inc.), the Company markets SILENOR® (doxepin), which is approved for the treatment of insomnia characterized by difficulty with sleep maintenance and is not a controlled substance. Through a license agreement with Pharmaceutical Associates, Inc., the Company markets VERIPRED™, a prescription drug product indicated for the control of severe allergic conditions. In addition, a product candidate utilizing cough-related intellectual property is in development for the U.S. OTC market. The Company promotes branded pediatric and gastroenterology products through a sales force. The Company markets generic products in the areas of cough and cold, pain, vitamins, dermatology, antibiotics and gastroenterology through the Company's wholly-owned subsidiaries, Macoven Pharmaceuticals and Cypress Pharmaceuticals. The Company's wholly-owned subsidiary, Pernix Manufacturing, manufactures and packages products for the pharmaceutical industry in a wide range of dosage forms.

Business Combinations

On December 31, 2012, the Company completed the acquisition of Cypress Pharmaceuticals, Inc., a generic pharmaceutical company, and its subsidiary Hawthorn Pharmaceuticals, Inc, a brand pharmaceutical company, both of which were privately owned companies, collectively referred to herein as Cypress. The Company paid $52 million in cash, issued 4,427,084 shares of our common stock having an aggregate market value equal to approximately $34.3 million based on the closing price per share of $7.75 as reported on the NYSE MKT LLC on December 31, 2012, and agreed to pay up to $6.5 million in holdback and contingent payments, $4.5 million to be deposited in escrow on December 15, 2013 and $5.0 million in shares of our common stock upon the occurrence of a milestone event, for an aggregate purchase price of up to $102.3 million. Cypress offers a wide array of branded pharmaceutical products in the areas of cough and cold, nutritional supplements, analgesics, urinary tract, women's health, pre-natal vitamins and dental health, as well as allergy, respiratory, iron deficiency, nephrology and pain management. See Note 4, Business Combinations and Other Acquisitions, and Note 13, Debt and Lines of Credit, for further discussion.

On March 6, 2013, the Company acquired all of the outstanding common stock of Somaxon Pharmaceuticals, Inc. pursuant to an agreement and plan of merger dated December 10, 2012. As a result of the merger, each outstanding share of Somaxon common stock was converted into the right to receive 0.477730059 shares of the Company's common stock, with cash paid in lieu of fractional shares. As a result of the merger, the Company issued an aggregate of approximately 3,665,689 shares of its common stock to the former stockholders of Somaxon. Somaxon is a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded products and product candidates to treat important medical conditions where there is an unmet medical need and/or high level of patient dissatisfaction, mainly in the central nervous system therapeutic area. See Note 21,

Subsequent Events, for further discussion.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Pernix's wholly-owned subsidiaries Pernix Therapeutics, LLC, GTA GP, Inc., GTA LP, Inc., Gaine, Inc., Macoven, Pernix Manufacturing, Respicopea, Inc. and Cypress, but do not include Somaxon (acquired March 6, 2013). Pernix Manufacturing and Cypress are included only for the period subsequent to their acquisition. Transactions between and among the Company and its consolidated subsidiaries are eliminated.

Table of Contents

Basis of Accounting

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The Financial Accounting Standards Board (“FASB”) has established the FASB Accounting Standards Codification (“ASC”) as the single source of authoritative GAAP.

Management’s Estimates and Assumptions

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

Financial Instruments, Credit Risk Concentrations and Economic Dependency

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

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. Most of Pernix’s manufacturing arrangements are not subject to long-term agreements and generally may be terminated by either party without penalty at any time. Changes in the price of raw materials and manufacturing costs could adversely affect Pernix’s gross margins on the sale of its products. Changes in Pernix’s mix of products sold could also affect its costs of product sales. Our supplier concentration has become more diversified. For the year ended December 31, 2012, approximately, 35% of the inventory purchases, including Cypress inventory purchases but excluding NATROBA and its generic which is purchased exclusively from ParaPRO, were from four primary suppliers, allocated 10%, 9% , 8% and 8%, respectively, and approximately 17% of the inventory purchases were manufactured by Pernix Manufacturing. For the year ended December 31, 2011, approximately 65% of our product inventory purchases was from four primary suppliers, allocated 19%, 17%, 16% and 13%, 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.

Trade accounts receivable are unsecured and are due primarily from wholesalers and distributors that sell to individual pharmacies. The Company primarily sold to three major customers in 2012 and four in 2011. See Note 16, Concentrations, for additional information. The Company continually evaluates the collectability of accounts receivable and maintains allowances for potential losses when necessary.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. The Company places its cash and cash equivalents on deposit with financial institutions in the United States. Included in cash and cash equivalents is approximately $16 million invested by Regions Morgan Keegan Trust in short-term securities which are secured by government securities at an amount not less than 105% of the amount invested. The Federal Deposit Insurance Corporation ("FDIC") covers $250,000 for substantially all

depository accounts and temporarily provided unlimited coverage through December 31, 2012 for certain qualifying and participating non-interest bearing transaction accounts. The Company from time to time may have amounts on deposit in excess of the insured limits. As of December 31, 2012, the Company had approximately $3,693,000 on deposit in such accounts which exceeded these insured amounts.

Fair Value of Financial Instruments

A financial instrument is defined as cash equivalent, evidence of an ownership interest in an entity, or a contract that creates a contractual obligation or right to deliver or receive cash or another financial instrument from another party. The Company’s financial instruments consist primarily of cash equivalents (including our Regions Trust Account which invests in short-term securities consisting of sweep accounts, money market accounts and money market mutual funds) and an investment in equity securities (TherapeuticsMD). The carrying values of these assets approximate their fair value.

Table of Contents

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

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

Accounts Receivable

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

Current earnings are charged with a provision for bad debt expense based on experience and evaluation of the individual accounts. Write-offs of accounts are charged against this allowance once the amount is determined to be uncollectible by management. Recoveries of trade receivables previously written off are recorded when recovered. At December 31, 2012 and 2011, the allowance for doubtful accounts was approximately $39,000 and $0, respectively.

Inventories

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

Property, Equipment and Depreciation

Property and equipment are stated at cost. Depreciation is computed over the estimated useful lives of the assets using the straight-line method. Generally, the Company assigns the following estimated useful lives to these categories:

Category	Service Life
Leasehold improvements	Lesser of 15 years or lease term
Equipment	5-7 years
Furniture and fixtures	5-7 years
Computer software and website	3 years

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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, such as property and equipment, and purchased intangible assets 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. As of December 31, 2011, the Company recorded an impairment charge of approximately $380,000 to the value of the Company's land due to an appraisal of the property.

Intangible Assets

Intangible assets, such as patents, product licenses and product rights that are considered to have a definite useful life, are amortized on a straight-line basis over the shorter of their economic or legal useful life which ranges from three to fifteen years. Management reviews such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Table of Contents

Goodwill

Goodwill is recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value by applying the acquisition method of accounting. The ongoing evaluation for impairment of goodwill requires significant management estimates and judgment. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. There were no impairment charges in 2012 or 2011.

Equity Method of Accounting

The Company's investment in the joint venture with SEEK was accounted for at cost and adjusted for the Company's share (46%) of the joint venture's undistributed earnings or losses through May 14, 2012. On May 14, 2012, the Company acquired the exclusive rights from SEEK, its former joint venture partner, to commercialize and market products utilizing the joint venture's intellectual property (IP) in the areas of cough, cold, sinus and allergy in the United States and Canada for $5 million. The investment in the JV at termination was approximately $1,445,000 and there was approximately $2,687,000 arising from a deferred tax liability. The value of the license recorded was approximately $9,133,000, which is being amortized over thirteen years. Under the terms of the agreement, Pernix will pay royalties to SEEK on sales of products utilizing the joint venture IP in the United States and Canada. Pernix will also receive royalties from SEEK product sales outside of the United States and Canada. As a result, the Company no longer shares in the development costs outside the United States and Canada.

Revenue Recognition

The Company's consolidated net revenues represent the Company's net product sales and collaboration revenues. The Company records all of its revenue from product sales and collaboration or co-promotion agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) existence of persuasive evidence of an arrangement; (2) occurrence of delivery or rendering of services; (3) the seller's price to the buyer is fixed or determinable; and (4) reasonable assurance of collectability. The Company records revenue from product sales when the customer takes ownership and assumes risk of loss. Royalty revenue is recognized upon shipment from the manufacturer to the purchaser. Co-promotion revenue is recognized in the period in which the product subject to the arrangement is sold. At the time of 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.

The following table sets forth a summary of Pernix's consolidated net revenues (in thousands) for the years ended December 31, 2012 and 2011.

	Year Ended December 31, (in thousands)	
	2012	2011
Gross product sales	$ 82,064	$ 86,748
Sales allowances	(30,689)	(30,775)
Net product sales	51,825	55,973
Manufacturing revenue	5,424	—
Co-promotion, royalty and other revenues	4,514	4,634
Net revenues	$ 61,313	$ 60,607

Cost of Product Sales

Cost of product sales is comprised of (1) costs to manufacture or acquire products sold to customers; (2) royalty, co-promotion and other revenue sharing payments under license and other agreements granting the Company rights to sell related products; and (3) direct and indirect distribution costs incurred in the sale of products. The Company acquired the rights to sell certain of our commercial products through license and assignment agreements with the original developers or other parties with interests in these products. These agreements obligate us to make payments based on our net revenues from related products. These agreements obligate the Company to make payments under varying payment structures based on our net revenue from related products

Product Returns

Consistent with industry practice, the Company offers contractual return rights that allow its 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. The Company's products have a 15 to 36-month expiration period from the date of manufacture. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the forecast of future sales of the product, competitive issues such as new product entrants and other known changes in sales trends. The Company estimates returns at percentages up to 14% of sales of branded products (including a 14% return estimate applied to launch-year sales of Omeclaxom-Pak®). The Company estimates returns at percentages up to 10% on sales of generic products. The returns estimate on certain generic products was increased approximately 2% effective April 1, 2012 from prior periods due to the potential impact of changes in Medicaid coverage on certain products. Also, the returns estimate was increased 5% on a specific generic product to consider higher than expected returns as a result of a shorter shelf-life as comparedto the rest of the generic products in our portfolio. 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. In addition to the accrual on sales during the year ended December 31, 2012, the Company recorded an additional returns allowance of approximately $1,840,000 ($1,220,000 in the fourth quarter, $120,000 in the third quarter and $500,000 in the second quarter) as a result of higher than expected returns, primarily on products that lost Medicaid coverage in 2012 and certain generic products launched in 2011. The returns reserve may be adjusted as we accumulate sales history and returns experience on this portfolio of products. The Company reviews and adjusts these reserves quarterly.

Table of Contents

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.

Price Adjustments

The Company's estimates of price adjustments, which include customer rebates, service fees, chargebacks, shelf stock adjustments, and other fees and 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. In the event that the sales mix to third-party payors or the contract fees paid to the wholesalers are different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or incur chargebacks that differ from its original estimates and such difference may be significant.

The Company's estimates of discounts are applied pursuant to the contracts negotiated with certain customers and are primarily based on sales volumes. The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. For example, the Company has initiated coupon programs for certain of its promoted products whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these coupon programs based on redemption information provided by a third party claims processing organization. The Company accounts for the costs of these special promotional programs as price adjustments, resulting in a reduction in gross revenue.

Any price adjustments that are not contractual or are non-recurring but that are offered at the time of sale or when a specific triggering event occurs, such as sales stocking allowances or price protection adjustments, are recorded as a reduction in revenue when the sales order is recorded or when the triggering event occurs. These allowances may be offered at varying times throughout the year or may be associated with specific events such as a new product launch, the reintroduction of a product or product price changes.

Prompt Payment Discount

The Company typically requires its customers to remit payments within the first 30 days for branded products and within 60 to 120 days for generics, depending on the customer and the products purchased. The Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2-3%, but may be higher in some instances due to product launches and/or industry expectations. Because the Company's wholesale customers typically take the prompt pay discount, we accrue 100% of prompt pay discounts. These discounts are based on the gross amount of each invoice at the time of our original sale to them. Earned discounts are applied at the time of payment. This allowance is recorded as a reduction of accounts receivable.

Table of Contents

Freight

The Company includes freight costs for outgoing shipments in selling expenses except for the outgoing freight costs for Pernix Manufacturing which are included in cost of goods. Outgoing freight costs included in selling expenses were approximately $376,000 and $384,000 for the years ended December 31, 2012 and 2011, respectively.

Research and Development Costs

Research and development costs in connection with the Company's internal programs for the development of products are expensed as incurred. Pernix either expenses research and development costs as incurred or will advance third parties a research and development fee which is amortized over the term of the related agreement. Research and development expenses were approximately $732,000 and $922,000 during the years ended December 31, 2012 and 2011, respectively.

Segment Information

The Company markets two major product lines: a branded pharmaceuticals product line and a generic pharmaceuticals product line. These product lines qualify for reporting as a single segment in accordance with GAAP because they are similar in the nature of the products and services, production processes, types of customer, distribution methods and regulatory environment. The Company has a manufacturing subsidiary but the majority of its revenue is generated through intercompany sales and is eliminated in consolidation. It is deemed immaterial for segment reporting purposes.

Income Taxes

Deferred taxes are recognized for the tax consequences of "temporary differences" by applying enacted statutory tax rates applicable to future years to the difference between the financial statement carrying amounts and the tax basis of existing assets and liabilities. The effect on deferred taxes for a change in tax rates is recognized in income in the period that includes the enactment date. Pernix will recognize future tax benefits to the extent that realization of such benefits is more likely than not. Management has evaluated the potential impact in accounting for uncertainties in income taxes and has determined that it has no significant uncertain income tax positions as of December 31, 2012. Income tax returns subject to review by taxing authorities include 2009, 2010, and 2011.

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 restricted stock and common stock equivalents (i.e. stock options). Dilutive common share equivalents consist of the incremental common shares issuable upon exercise of stock options.

The following table sets forth the computation of basic and diluted net income per share:

	Year Ended December 31,	
	2012	2011
Numerator:		

Net income (loss)	$ (1,410,157)	$ 8,347,601
Denominator:		
Weighted-average common shares, basic	28,146,207	23,990,734
Dilutive effect of stock options	—	469,557
Weighted-average common shares, diluted	28,146,207	24,460,291
Net (loss) income per share, basic	$ (0.05)	$ 0.35
Net (loss) income per share, diluted	$ (0.05)	$ 0.34

As of December 31, 2012, total outstanding options are 1,711,167. Options not included above are anti-dilutive. See Note 18, Employee Compensation and Benefits, for information regarding the Company's outstanding options.

Table of Contents

Investments in Marketable Securities and Other Comprehensive Income

The Company holds investment marketable equity securities as available-for-sale and the change in the market value gives rise to other comprehensive income. The components of other comprehensive income are recorded in the consolidated statements of income and comprehensive income, net of the related income tax effect.

On October 5, 2011, the Company acquired 2.6 million shares of TherapeuticsMD for a purchase price of $1.0 million, or $0.38 per share, representing approximately 3.2% of TherapeuticsMD's outstanding common stock. The Company's purchase was contingent upon TherapeuticsMD's acquisition of VitaMedMD, which occurred on October 4, 2011. The Company has applied a 30% discount to the quoted market value of its TherapeuticsMD stock, which represents the Company's estimate of the discount for lack of marketability for its non-controlling interest. In connection with the Company's purchase of shares of TherapeuticsMD, the Company also entered into a software license agreement with VitaMedMD pursuant to which VitaMedMD granted the Company an exclusive license to use certain of its physician, patient and product data gathering software in the field of pediatric medicine for a period of five years for a monthly fee of $21,700. As of December 31, 2012, we have not activated this software license agreement and have not paid monthly fees pursuant thereto. Cooper Collins, the Company's Chief Executive Officer, was appointed to the board of TherapeuticsMD following the Company's acquisition of its interest in TherapeuticsMD.

TherapeuticsMD Common Stock	Cost	Appreciation	Discount	Fair Value
2,631,579 shares	$1,000,000	$ 7,157,895	$(2,447,369)	$5,710,526

Reclassifications

Certain reclassifications have been made to prior period amounts in our consolidated statements of income to conform to the current period presentation. These reclassifications related to the classification of cost of samples as a selling expense instead of including in cost of goods had no effect on net income as previously reported.

Recent Accounting Pronouncements

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220)—Presentation of Comprehensive Income (ASU 2011-05). ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. Instead, ASU 2011-05 requires entities to report all non-owner changes in stockholders' equity in either a single continuous statement of comprehensive income, or in two separate but consecutive statements. ASU 2011-05 does not change the items that must be reported in other comprehensive income, or when an item must be reclassified to net income.

In December 2011, the FASB issued ASU 2011-12, Comprehensive Income (Topic 220): Presentation of Comprehensive Income—Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 (ASU 2011-12). ASU 2011-12 defers indefinitely provisions contained in ASU 2011-05 that revise existing presentation requirements for reclassification adjustments from comprehensive income as the FASB further deliberates this issue. During the deferral period, reporting entities will continue to follow existing guidance prior to ASU 2011-05 under ASC Topic 220, Comprehensive Income, with respect to the disclosure of reclassifications adjustments. Both ASU 2011-12 and ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and ASU 2011-05 requires retrospective application. Other than the presentational changes to our basic consolidated financial statements required under ASU 2011-05 (as amended by ASU 2011-12), adoption of ASU 2011-05 did not have any impact on the Company's consolidated financial statements.

The FASB issued ASU 2012-02, Intangibles—Goodwill and Other (Topic 350)—Testing Indefinite-Lived Intangible Assets for Impairment, to establish an optional two-step analysis for impairment testing of indefinite-lived intangibles other than goodwill. The standards update will be effective for financial statements of periods beginning after September 15, 2012, with early adoption permitted. In particular, the two-step analysis establishes an optional qualitative assessment to precede the quantitative assessment, if necessary. In the qualitative assessment, the entity must evaluate the totality of qualitative factors, including any recent fair value measurements, that impact whether an indefinite-lived intangible asset other than goodwill has a carrying amount that more likely than not exceeds its fair value. The entity must proceed to conducting a quantitative analysis, according to which the entity would record an impairment charge for the amount of the asset's fair value exceeding the carrying amount, if (1) the entity determines that such an impairment is more likely than not to exist, or (2) the entity foregoes the qualitative assessment entirely. The standards update finalizes the proposal in Proposed Accounting Standards Update (ASU) No. 2012-100: Intangibles—Goodwill and Other (Topic 350)—Testing Indefinite-Lived Intangible Assets for Impairment, and brings the accounting treatment for determining impairment charges on other intangible assets into conformity with the treatment of goodwill, as established by Accounting Standards Update No. 2011-08: Intangibles—Goodwill and Other (Topic 350) - Testing Goodwill for Impairment. The adoption of this guidance did not have a material impact on the Company’s financial statements.

Table of Contents

In February 2013, the FASB issued ASU No. 2013-02, Comprehensive Income (Topic 220)—Reporting Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02). ASU 2013-02 provides guidance about disclosing reclassification adjustments, which was previously deferred for further deliberation by ASU 2011-12. ASU 2013-02 provides financial statement issuers the option to disclose significant amounts reclassified from accumulated other comprehensive income separately by each component in either (1) a single note to the financial statements, or (2) parenthetically on the face of the income statement for each line item(s) affected by the reclassification adjustment. ASU 2013-02 will be effective for all interim and annual financial statement reporting periods beginning after December 15, 2012, with early adoption permitted. The Company does not anticipate the adoption of ASU 2013-02 will have any impact on our 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

The following tables summarize the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring and nonrecurring basis as of December 31, 2012 and 2011 (in thousands):

	2012			
Assets	Level 1	Level 2	Level 3	Total
Investments in TherapeuticsMD	—	—	5,711	5,711
Total Assets	$—	$—	$5,711	$5,711
Liabilities				
Contingent consideration(1)	—	—	10,962	10,962
Put option(2)	—	—	3,365	3,365
Total Liabilities	$—	$—	$14,327	$14,327

	2011			
Assets	Level 1	Level 2	Level 3	Total
Investments in TherapeuticsMD	—	—	2,763	2,763
Total Assets	$—	$—	$2,763	$2,763

(1) Contingent consideration consists of certain holdback payments, contingent cash and equity payments and future cash to be placed in escrow with respect to our acquisition of Cypress. The fair value of the contingent consideration is included in contracts payable on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). The DCF incorporates Level 3 inputs including estimated discount rates that the Company believes market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to the Cypress acquisition agreement. The Company analyzes and evaluates these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements. Any increases or decreases in discount rates would have an inverse impact on the value of related fair value measurements, while increases or decreases in expected cash flows would result in a corresponding increase or decrease in fair value measurements. The cost of debt to discount projected cash flows relating to our contingent consideration was 4.6%. Refer also to Note 4, Business Combinations and Other Acquisitions.

(2) The $3.4 million fair value of the put option was calculated using a Black-Scholes valuation model with assumptions for the following variables: closing Pernix stock price on the acquisition date, risk-free interest rates, and

expected volatility.

Table of Contents

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 year.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

		Contingent Liability Consideration (in thousands)
Beginning balance at January 1, 2012	$	-
Contingent Consideration		10,962
Put option issued		3,366
Ending balance at December 31, 2012	$	14,327

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

		Investment in Therapeutics MD (in thousands)
Beginning balance at January 1, 2012	$	2,763
Total remeasurement adjustments:		
Unrealized gain on investments (1)		2,948
Ending balance at December 31, 2012	$	5,711