PERNIX THERAPEUTICS HOLDINGS, INC.
Form 10-K
March 29, 2012

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

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)

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	NYSE Amex

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	o
Non-accelerated filer	o	Smaller reporting company	þ
(Do not check if a smaller reporting company)			

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2011 was approximately $63,867,465, based upon the closing sales price of the registrant's common stock as reported on the NYSE Amex. 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 23, 2012, the registrant had 26,034,272 shares of its common stock outstanding.

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Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of 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 within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "target," "w 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.

ITEM 1. DESCRIPTION OF BUSINESS

Introduction

Pernix Therapeutics Holdings, Inc. (“Pernix” or the “Company”) is a specialty pharmaceutical company focused on the sales, marketing and development of branded and generic pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. We expect to continue to execute our growth strategy which includes the horizontal integration of our branded prescription, generic and over-the-counter ("OTC") businesses. We manage a portfolio of branded and generic products and theobromine, a non-codeine, cough suppressant product candidate in development. 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 (BROVEX®, ALDEX® and PEDIATEX®). We also market REZYST IM™, a proprietary probiotic blend to promote dietary management. The Company promotes its branded products through an established U.S. sales force. Pernix also markets generic products through its wholly-owned subsidiary, Macoven Pharmaceuticals.

In January 2012, we entered into a license and supply agreement with a private company for a new 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 expect to pay an additional fee of $2.0 million upon commercial launch of the product. In addition to these license fees, the agreement calls for us to pay royalties and milestone payments based on the sales of the product. The product is expected to launch in mid-year 2012. Prior to launching the product, Pernix plans to establish a sales force of up to 30 representatives, consisting of new hires and current sales representatives, dedicated to gastroenterology.

Pernix is the surviving corporation of a 2010 merger between Pernix Therapeutics, Inc., or PTI, and Golf Trust of America, Inc., or GTA. The words “we,” “us” or “our” refers to Pernix and its consolidated subsidiaries, except where the context otherwise requires.

Pernix was incorporated in November 1996 and is headquartered in The Woodlands, Texas and employs approximately 85 people full-time.

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 55 sales representatives as of December 31, 2011 that targets pediatric and high-prescribing physicians. 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.

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. We believe that our established sales and marketing organization and our sound 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, especially in pediatrics 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.

Develop and sell generic versions of selected branded products through our Macoven subsidiary-We intend to continue developing our Macoven subsidiary to diversify our product mix while creating a base business without branding, patent life or sales force detailing. Our business goals for Macoven include launching authorized generic products for branded pharmaceutical companies including Pernix, developing generic products for patented or niche branded products and developing generic products that have a limited number of alternatives.

Develop theobromine with our joint venture partner for both prescription and OTC markets-We are currently evaluating all of our potential opportunities for theobromine with our joint venture partner, SEEK, a leading drug discovery and development group based in the United Kingdom. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. On September 26, 2011, the Company funded an additional $1.0 million in cash to the JV for continuing operations. To date, the Company has funded an aggregate of $2.5 million in cash to the JV for continuing operations.

Expand into new geographical and therapeutic markets-As previously discussed, we intend to establish a sales force of approximately 30 representatives, consisting of new and existing representatives, dedicated to gastroenterology following our entry into the license and supply agreement described above. 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 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.

Products and Product Candidates

Our Promoted Products

Pernix has assembled a branded product portfolio that includes 6 promoted product families. We also promote a family of generic products through our wholly-owned subsidiary, Macoven Pharmaceuticals. Additionally, we plan to begin promoting an FDA-approved prescription product to treat gastroenterology in mid-year. We promote our products through our own direct sales force. The table below provides information on our branded promoted product portfolio as of March 23, 2012:

Marketed Product Family	Primary Indication	Rights	Launched by Pernix
ALDEX	Allergies, congestion and cough	Pernix	Q3:2006
BROVEX	Allergies, congestion and cough	Pernix	Q2:2009
CEDAX	Bronchitis, ear and throat infections	Pernix	Q2:2010
NATROBA	Topical treatment of head lice	Pernix(license from ParaPRO)	Q3:2011
PEDIATEX	Allergies and congestion	Pernix	Q3:2008
REZYST	Probiotic	Pernix	Q1:2009

ALDEX Line. ALDEX is a line of antihistamines, decongestants and cough suppressants that are indicated for the temporary relief of respiratory allergies, allergic rhinitis and symptoms of the common cold. We launched the ALDEX product line in the third quarter of 2006. Our ALDEX product line is marketed in a variety of formulations and combinations using different drug-delivery methodologies to target specific segments of the antihistamine, decongestant and cough suppressant markets.

We completed the conversion of the ALDEX product family from Drug Efficacy Study Implementation (DESI) to OTC monograph in May 2010, and believe we can continue to appropriately market this line as an OTC monograph product.

Market Opportunity. According to the American Academy of Allergy Asthma and Immunology, or AAAI, approximately 60 million people have seasonal allergic rhinitis, accounting for $11 billion spent on direct care. The AAAI also states that allergic disease affects more than 20% of the population (between 40 and 50 million Americans).

The U.S. oral antihistamine/decongestant market is fairly fragmented with numerous branded and generic antihistamines and decongestants. Pharmacists typically fill prescriptions for antihistamines and decongestants with generic products when available.

Four commonly used first generation antihistamines are diphenhydramine, doxylamine, pyrilamine and triprolidine. Diphenhydramine and doxylamine belong to the ethanolamines class of antihistamines, are potent and effective H-1 blockers that possess significant anticholinergic activity and have a pronounced tendency to induce sedation. Pyrilamine belongs to the ethylenediamines class of antihistamines. The drugs in this group are potent and effective H-1 receptor blocking agents that inhibit the actions of histamine on smooth muscle, capillary permeability, and can both stimulate and depress the central nervous system. Pyrilamine also possesses significant anticholinergic properties. It is one of the least sedating first generation antihistamines. Triprolidine belongs to the alkylamines class of antihistamines. The drugs in this group are potent and effective H-1 blockers which tend to produce more central nervous system stimulation and less drowsiness than other first generation antihistamines.

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. that compete with our ALDEX line include prescription and OTC cold, cough and allergy products.

Intellectual Property. The ALDEX line incorporates patent-protected drug delivery technology developed by Kiel Laboratories, which we purchased in 2010. The patents have claims for preparing a controlled delivery technology: two are for liquid and semi-solid dosage forms and one is for tablet, capsule, and solid dosage forms. We also own a trademark on the name ALDEX 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 ALDEX line of products. Please see the "Acquisitions and License Agreements, Collaborations and Co-Promotions" section of this Item 1 for a description of our rights to the drug delivery technology developed by Kiel.

BROVEX Line. The BROVEX line is a line of antihistamine combinations with the active pharmaceutical ingredient, or API, brompheniramine maleate, part of the first generation class of antihistamines called alkylamines that are indicated for the temporary relief of sneezing, itchy, watery eyes, itchy nose or throat, and runny nose due to hay fever or other respiratory allergies. We acquired the BROVEX product line from DaySpring and launched it in the second quarter of 2009. Our BROVEX product line is marketed in a variety of formulations and combinations to target specific segments of the antihistamine market.

We completed the conversion of the BROVEX product family to OTC monograph from DESI drugs in April 2011 and believe we can continue to appropriately market this line as an OTC monograph product.

Market Opportunity. See "Market Opportunity" in the discussion of our ALDEX product line above.

Other Treatments. Other treatment options available are Poly Pharmaceuticals' Alahist DM, Wockhardt Pediatric Care's Bromfed DM, and numerous other antihistamine and decongestant combination brands and similar generics.

Intellectual Property. BROVEX is covered by two trademarks registered in the U.S. Patent and Trademark Office, which we acquired in June 2009. Please see the "Intellectual Property" section of this Item 1 for a more detailed description of the rights associated with the BROVEX line of products.

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 resulted 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. 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 scalp 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 branded and similar generic topical prescription lice treatments include NIX®, OVIDE®, LINDANE and ULESFIA TM .

Launch Focus. Our sales force of approximately 55 sales representatives 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.

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.

PEDIATEX Line. Currently the only product that we market and sell in our PEDIATEX line is PEDIATEX TD. PEDIATEX TD is an antihistamine/nasal decongestant combination liquid for oral administration. Each 1mL dose contains the API Tripolidine HC1 and Pseudoephedrine HC1. Tripolidine HC1 is a first generation antihistamine in the alkylamine class. Pseudoephedrine, a decongestant, is a sympathomimetic, which acts predominantly on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction and having minimal effect on beta-receptors. It therefore functions as an oral nasal decongestant with minimal central nervous system stimulation. This decongestant also increases sinus drainage and secretions. PEDIATEX TD is indicated for the relief of runny nose, sneezing, itching of nose and throat, itchy, watery eyes due to hay fever or other respiratory allergies. We launched PEDIATEX TD in August 2008.

Market Opportunity. See "Market Opportunity" in the discussion of our ALDEX product line above.

Other Treatments. Other treatment options available include Hawthorn Pharmaceuticals' Nasohist, Jaymac Pharmaceuticals' J-Tan D PD and other branded and similar generic antihistamine, decongestant, and cough suppressants marketed in the U.S. that compete with our PEDIATEX line, which also includes prescription and OTC cold, cough and allergy products.

Intellectual Property. The PEDIATEX line incorporates the patent-protected drug delivery technology developed by Kiel. See "Intellectual Property" in the discussion of our ALDEX product line above. We also own a trademark on the name PEDIATEX in the U.S.

REZYST Line. REZYST IM is a proprietary probiotic blend that promotes the dietary management of patients with the distinctive nutritional requirements associated with the gastro-intestinal flora. It is specifically formulated to improve the digestive health of patients by replacing the active cultures altered by diet, stress, and antibiotics. We first launched this product in February 2009.

Market Opportunity. Probiotics represent one of the fastest growing market segments in the United States. According to the Nutrition Business Journal, overall market sales of probiotics in 2010 reached $636 million and were up 18.9% from the previous year. A recent study in November 2011 conducted by ConsumerLab.com found 34.1% of women and 27.7% of men use probiotics.

Other Treatments. There are many competitive products on the market today with Procter & Gamble's Align® and Biocodex | USA's Florastor® among the most significant.

Intellectual Property. We own the proprietary probiotic blend that we employ in our REZYST product as a trade secret. We also have a registered trademark for the REZYST name in the U.S.

Other Marketed Products

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

Product Candidates In Development

Theobromine. Theobromine is an alkaloid naturally present in dark chocolate which is an existing human metabolite of caffeine. Based on a review of available data, we believe theobromine has been shown to inhibit the inappropriate firing of the vagus nerve which is a key feature of persistent cough. We believe theobromine presents the potential to address the need for a safer and more effective, non-opioid treatment for persistent cough.

To date, both branded and generic cough suppression medicines regularly include codeine as an active ingredient. Codeine has been regarded as the most effective antitussive, but carries serious adverse side effects, including drowsiness, constipation and addictive qualities. These side effects limit its use and cause prescribers to recommend it only be used at night in adults and not in pediatric patients. Theobromine, unlike codeine, may be non-sedating, non-addictive and may not cause constipation.

We entered into a joint venture with SEEK in December 2010 for the development of theobromine. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. To date, the Company has funded an aggregate amount of approximately $2.5 million in cash to the JV for continuing operations.

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 Paediatric 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. By virtue of its ownership interest in the joint venture with SEEK, Pernix holds an indirect interest in certain U.S. and foreign patents and patent applications covering pharmaceutical compositions containing theobromine in mixtures with various agents or delivery systems and/or the use thereof for the treatment of irritable cough and other related conditions. Additionally, Pernix has an exclusive license to develop and market products in the United States utilizing or otherwise incorporating the theobromine U.S. patent rights for pediatric use to the extent development and clinical trials of such product are funded by Pernix. Please see the "Intellectual Property" and "Acquisitions and License Agreements, Collaborations and Co-Promotions" sections of this Item 1 for a more detailed description of the rights associated with the theobromine product candidate.

Other Product Candidates. The Company is working on several other product candidates. The most significant is 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, and Pernix will pay the costs related to the development of the product. Pernix expects to invest approximately $6 million over an estimated 36-month period 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 the next 12 months.

Sales and Marketing

Our sales force, which consists of approximately 55 full-time sales representatives as of December 31, 2011, promotes our ALDEX, BROVEX, CEDAX, PEDIATEX, REZYST and NATROBA families of 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 acquisitions or 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

We currently outsource all manufacturing of our promoted products and product candidates, but 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. We currently do not own or operate any manufacturing operations for our products or product candidates. To date, we have established relationships with several manufacturers to manufacture our products. We currently use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates or such quantities 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 manage 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 process. We plan to continue to develop product candidates that can be manufactured in a cost effective manner at third-party manufacturing facilities.

All of our 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.

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. The drug delivery technology acquired from Kiel is currently used in our ALDEX and PEDIATEX product lines.

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.

CEDAX . On January 8, 2010, we entered into an asset purchase agreement with Shionogi (formerly Sciele Pharma, Inc.) to acquire substantially all of Shionogi's assets and rights relating to CEDAX, 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. On March 24, 2010, we completed the acquisition and, subsequently, paid the aggregate purchase price in three installments. 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.

NATROBA Co-Promotion Agreement. We entered into an exclusive co-promotion agreement with ParaPRO for NATROBA in certain U.S. territories. In order to retain its exclusive license and co-promotion rights to market NATROBA, the Company must make purchase commitments of approximately $33,830,000 during year 1, $51,740,000 during year 2 and $75,620,000 during year 3 of the co-promotion term, which began on August 3, 2011.

We have made total purchases of approzimately $11,660,000 from the launch through March 23, 2012.

Gastroenterology Product License and Supply Agreement. In January 2012, we entered into a license and supply agreement with a private company for a new 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 expect to pay an additional fee of $2.0 million upon commercial launch of the product. In addition to these license fees, the agreement calls for us to pay royalties and milestone payments based on the sales of the product. The product is expected to launch in mid-year 2012. Prior to launching the product, Pernix plans to establish a sales force of up to 30 representatives, consisting of new hires and current sales representatives, dedicated to gastroenterology.

Collaborations

SEEK Joint Venture / Theobromine Collaboration. On December 20, 2010, we announced the establishment of a new joint venture with SEEK, a leading United Kingdom private drug-discovery group, for the late-stage development and registration of BC1036, theobromine, a first-in-class, non-codeine antitussive drug designed to address the serious need for a safer and more effective, non-opioid treatment for persistent cough. Both parties also licensed or assigned all of their theobromine intellectual property to the joint venture. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of Theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. On September 26, 2011, the Company funded an additional $1.0 million in cash to the JV for continuing operations. To date, the Company has funded an aggregate amount of approximately $2.5 million in cash to the JV for continuing operations.

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 Pernix will pay the costs related to the development of the product. Pernix expects to invest approximately $6 million over an estimated 36-month period 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 the next 12 months.

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 defend against others from infringing on our ownership rights. Most of our products face competition from generics. Our key intellectual property is described above.

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 Candidates(s)	Patent Owners	Patent Description	Expiration
ALDEX AN and ALDEX CT	Pernix Therapeutics, LLC	Process for preparing control delivery capsule or other solid dosage forms	April 9, 2022
ALDEX D, ALDEX DM, PEDIATEX TD and Z-COF 8 DM	Pernix Therapeutics, LLC	Process for preparing control delivery liquid and semi-solid dosage forms	April 9, 2022
CEDAX (2)	Schering Corporation	Stable hydrated cephalosporin dry powder for oral suspension formulation	February 4, 2014

THEOBROMINE (3)	Gaine, Inc.	Methods of stimulating mucociliary clearance to alleviate irritable cough	March 20, 2018

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(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 this remaining life of the 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 our theobromine patent to the joint venture. However, we retain the exclusive promotion rights in the U.S. to the extent we fund the development and clinical trial program for theobromine product(s) for use in the pediatric market. SEEK assigned ownership of all of its non-U.S. patent and intellectual property rights relating to the development of BC 1036 to the joint venture, which are omitted from the above table.

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 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 17 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, PERNIX, ZEMA-PAK, REZYST, QUINZYME, NODOLAR, COCO-COF, Z-COF (STYLIZED), CEDAX, TCT (WORD MARK), TCT (STYLIZED), TCT TANNANTE CONVERSION TECHNOLOGY, ALLRES and PEDIATEX. In addition to the 17 registered marks listed above, we own 8 intent-to-use trademarks file 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 (a statement on the use of the mark TUSSINAC has been filed and we await issue of the registration). 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.

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.

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Customers, Distribution, and Reimbursement

Customers and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the U.S. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Our top four customers, which represented 84% and 95% of gross product sales in 2011 and 2010, respectively, are all drug wholesalers and are listed below:

Customer	2011	2010
Cardinal Health	37%	43%
McKesson Corporation	23%	29%
Morris & Dickson	13%	13%
AmerisourceBergen Drug Corporation	11%	10%

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

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

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

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

While we distribute certain of our 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.

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.

FDA Regulation of Drug Products

The FDA regulates drugs under the Food Drug and Cosmetic Act and other implementing 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 not result in the FDA 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.

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 misstatements 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 full or partial waivers from the pediatric data requirements. The pediatric data requirements do not apply to products with orphan designation, unless otherwise required by regulation.

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

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

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information 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 either 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.

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 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. We currently rely on third parties to manufacture all of our products and product candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct. Accordingly, 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.

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 our promoted branded cough and cold products to OTC monograph from Drug Efficacy Study Implementation (DESI) drugs. For additional information, see "Risks Related to Regulatory Matters- Some of Pernix's specialty pharmaceutical products are now being marketed without FDA approvals."

Over The Counter Drugs

As for over the counter, or OTC, drugs, in 1972, 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 liable to regulatory action. We believe our promoted branded cough and cold 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 FDA reports of serious adverse events associated with such drugs when used in the United States, accompanied by a copy of the label on or within the retail package of such drug. In addition, the manufacturer, packer, or distributor must submit follow-up reports received within one year of the initial report.

The Hatch-Waxman Act

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

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

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

A Paragraph IV certification demonstrates that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable. Provided the applicant does not challenge the listed patents,

the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. ANDA approval will not be delayed if there are no listed patents or all patents have expired.

If a Paragraph IV certification has been provided to the FDA by the ANDA applicant, the NDA and patent holders must also receive notice from the applicant of the Paragraph IV certification. 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.

Pediatric Exclusivity. Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. It provides an additional six months of marketing security to the term of any existing regulatory exclusivity or listed patent term, if granted. 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, current good manufacturing practice 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 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 Food and Drug Administration’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. Medical foods require a prescription from a physician.

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 sell products that are “controlled substances” as defined in the Controlled Substances Act of 1970, or CSA, 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.

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.

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 DEA who desires to dispose of a controlled substance may request authority to dispose of the controlled substance from the Office of Controlled Substances. Additionally, particular authorization and notification requirements apply to imports and exports.

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

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

Foreign Regulation

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

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

We currently do not market any of our products outside of the United States. With respect to theobromine, pivotal phase III trials for theobromine (BC1036) are scheduled to begin in the European market in 2012.

Hazardous Materials

We depend on third parties to support us in manufacturing and developing all of our products and do not directly handle, store or transport hazardous materials or waste products. We depend on these third 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 these laws and regulations to be material.

Pharmaceutical Pricing and Reimbursement

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

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

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

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

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

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

In general, the amount of the Medicaid prescription drug rebate is calculated based in part on the average manufacturer’s price (AMP) for the drug. There has been historical and current legislation surrounding this calculation. The Health Care Reform legislation, discussed in more detail below, changed the definition of AMP to the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. The term expressly excludes certain payments and discounts, including customary prompt payment discounts to

wholesalers; service fees paid by manufacturers to wholesalers or retailers; and payments from managed care organizations, mail order pharmacies, long-term care providers, and any other entity that does not conduct business as a wholesaler or retail community pharmacy. On February 2, 2012, CMS published in the Federal Register a proposed rule providing details regarding the calculation and reporting requirements for such rebates. We cannot predict whether and in what form the regulations will be made final and what effect these regulations will 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.

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.

Since the passage of Health Care Reform legislation, a number of state governors have opposed certain of its provisions and have initiated lawsuits challenging the Act's constitutionality. In 2012, the United States Supreme Court is set to review certain provisions of the Affordable Care Act, including (a) the constitutionality of its individual mandate that requires most Americans to buy health insurance starting in 2014; (b) the severability of the individual mandate from the other provisions of the Act, (c) the Act's Medicaid expansion, which would require each state to expand its program or lose all federal Medicaid funds, and (d) the applicability of the Anti-Injunction Act, which would bar review of the individual mandate provision until at least 2014. The Court is scheduled to hear arguments in spring 2012. In addition, 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 Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Further, 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.

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.

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 recently 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 23, 2012, we had approximately 85 full-time employees, consisting of 55 sales representatives; 1 engaged in research, development and regulatory affairs; and 29 engaged in management, administration and finance.

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 Commercialization

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

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

- the prevalence and severity of any side effect;
- the efficacy and potential advantages over the alternative treatments;

the ability to offer our branded products for sale at competitive prices, including in relation to any generic products;

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 products do not have patent protection and in most cases face generic competition. All of our products face significant price competition from a range of branded and generic products for the same therapeutic indications.

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

Our patent rights will not protect our products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights.

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 subsidiary, Macoven, to attempt to retain market share from other generic competitors for these products. Additionally, products we sell through our collaborative or co-promotion arrangements may also face competition in the marketplace.

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

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

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

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

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

To combat the adverse impact of the introduction of generic equivalents of our products, we develop and commercialize generic versions of many of our own branded products through our wholly-owned subsidiary Macoven.

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 23, 2012, our sales force consists of approximately 55 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.

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

Our ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. Some of our products, including PEDIATEX TD, BROVEX PSE, BROVEX PSE DM, BROVEX PSB, and BROVEX PSB DM, 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. In some instances, third-party manufacturers have encountered 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 our manufacturers are unsuccessful in obtaining quotas, if we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged or if our inventory 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.

If we or our 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 manufacturers and certain of our products including PEDIATEX TD, BROVEX PSE, BROVEX PSE DM, BROVEX PSB and BROVEX PSB-DM, their generic equivalents, and certain other generic products are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturers must adhere to a number of requirements with respect to our controlled substance products including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements

can result in enforcement action that could have a material adverse effect on our business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

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

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

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

injury to reputation;

withdrawal of client trial participants;

withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to trial participants or patients;

diversion of management time and attention;

loss of revenue; and

the inability to commercialize any products that we may develop.

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

Seasonality may cause fluctuations in our financial results.

We generally experience some effects of seasonality due to increases in demand for cough and cold products during the winter season. Accordingly, sales of cough and cold products and associated revenue have generally increased at a higher rate 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 currently use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost, which could result in development and commercialization of our product candidates being delayed, prevented or impaired.

We do not currently own or operate any manufacturing facilities for our products or product candidates. Additionally, we have limited personnel with experience in drug manufacturing. As a result, we currently rely on third parties for the supply of the API in our products and product candidates, and the manufacture of the finished forms of these drugs and packaging. The current manufacturers of our products and product candidates are, and any future third party manufacturers that we enter into arrangements with will likely be, our sole suppliers of our products and product candidates for a significant period of time. These manufacturers are commonly referred to as single source suppliers. Some of our manufacturing arrangements may be terminated at-will by either party without penalty.

If any of these manufacturers should become unavailable to us for any reason, we may be unable to conclude arrangements with replacements on favorable terms, if at all, and may be delayed in identifying and qualifying such replacements. In any event, identifying and qualifying a new third party manufacturer could involve significant costs associated with the transfer of the active pharmaceutical ingredient or finished product manufacturing process. A change in manufacturer generally requires formal approval by the FDA before the new manufacturer may produce commercial supplies of our FDA approved products. This approval process can take a lengthy period of time and, during that time, we may face a shortage of supply of our products.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products or product candidates ourselves, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing arrangement by the third-party because of factors beyond our control; and
- the possible termination or nonrenewal of the manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Our products and product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under current good manufacturing practice, or cGMP, regulations and that are both capable of manufacturing for us and willing to do so. If the third parties that we engage to manufacture a product for commercial sale or for clinical trials should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our products for us to meet commercial demand or in advancing clinical trials while we identify and qualify replacement suppliers. If for any reason we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

We also import the API for substantially all of our products from third parties that manufacture such items outside the United States, and we expect to do so from outside the United States in the future. This may give rise to difficulties in obtaining API in a timely manner as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging. For example, in January 2009, the FDA released draft guidance on Good Importer Practices, which, if finalized, indicates that additional oversight of our third-party

manufacturers outside the United States will be necessary. The FDA has stated that it will inspect 100% of API that is imported into the United States. If the FDA requires additional documentation from third-party manufacturers relating to the safety or intended use of the API, the importation of the API could be delayed. While in transit from outside the United States or while stored with our third-party logistics provider, DDN, our API could be lost or suffer damage, which would render such items unusable. We have attempted to take appropriate risk mitigation steps and to obtain transit or casualty insurance. However, depending upon when the loss or damage occurs, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage.

Our current and anticipated future dependence upon others for the manufacture of our products and product candidates may adversely affect our profit margins and our ability to develop and commercialize products and product candidates on a timely and competitive basis.

We rely on our third party manufacturers for compliance with applicable regulatory requirements. This may increase the risk of sanctions being imposed on us or on a manufacturer of our products or product candidates, which could result in our inability to obtain sufficient quantities of these products or product candidates.

Our manufacturers may not be able to comply with cGMP regulations or other regulatory requirements or similar regulatory requirements outside the United States. DEA regulations also govern facilities where controlled substances are manufactured. Our manufacturers are subject to DEA registration requirements and unannounced inspections by the FDA, the DEA, state regulators and similar regulators outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including:

fines;

injunctions;

civil penalties;

failure of regulatory authorities to grant marketing approval of our product candidates;

FDA regulatory action against any currently marketed products or products in development;

delays, suspension or withdrawal of approvals;

suspension of manufacturing operations;

DEA registration revocation;

seizures or recalls of products or product candidates;

operating restrictions; and

criminal prosecutions.

Any of these sanctions could significantly and adversely affect supplies of our products and product candidates, our business and our financial condition. If the safety of any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for such product candidate or successfully commercialize such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our product candidates. Furthermore, if we fail to obtain the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for our products and product candidates, if approved, and would lose potential revenues.

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. We do not have experience conducting clinical trials or complying with these requirements. 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 2011, Cardinal Health accounted for 37% of our total gross sales, McKesson Corporation accounted for 23% of our total gross sales, Morris & Dickson accounted for 13% of our total gross sales and AmerisourceBergen Drug Corporation accounted for 11% 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. 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 commercializing 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.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

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

We rely on third parties to distribute our products. We have contracted with DDN/Obergfel, LLC, or DDN, for the distribution of certain of our products to wholesalers, retail drug stores, mass merchandisers and grocery stores in the United States.

This distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. Failure to maintain our contract with DDN, or the inability or failure of DDN to adequately perform as agreed under its contract with us, could negatively impact us. If we were unable to replace DDN or bring all of our warehouse functions in-house in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting DDN, the distribution of our products could be delayed or interrupted, which would damage our results of operations and market position. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product sales and fulfill our regulatory obligations. If we are unable to effectively manage and maintain our distribution network, sales of our products could be severely compromised and our business could be harmed.

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. For example, in the first quarter of 2008, several Cardinal Health distribution centers were placed on probation by the DEA and were prohibited from distributing controlled substances. Although Cardinal Health had a plan in place to re-route all orders to the next closest distribution center for fulfillment, system inefficiency resulted in a failure to effectively distribute our products to all areas.

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. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents 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.

Some of our products do not have patent protection and in some cases face generic competition. For a description of our patent protection, see the “Intellectual Property ” section of Part I, Item 1. - "Description of Business" of this Annual Report on Form 10-K.

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

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

We have acquired rights to products and product candidates under license and co-promotion agreements with third parties and expect to enter into additional licenses and co-promotion agreements in the future. Our existing licenses impose, and we expect that future licenses will impose, various development and commercialization, purchase commitment, royalty, sublicensing, patent protection and maintenance, insurance and other obligations on us. For example, we entered into an exclusive co-promotion agreement with ParaPRO for NATROBA in certain U.S. territories. In order to retain our exclusive license and co-promotion rights to market NATROBA, we must make purchase commitments of approximately $33,830,000 during year 1, $51,740,000 during year 2 and $75,620,000 during year 3 of the co-promotion term. Natroba was launched on August 3, 2011 and since that date we have made purchases totaling approximately $11,660,000.

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

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes 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 employees, consultants and third parties to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us be kept confidential and not disclosed to third parties except in specific circumstances and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

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

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and/or abroad. Such third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they 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 7.5 mg; and L-methylfolate calcium 15 mg. While formal discovery has not yet commenced, the Company believes it has meritorious defenses to the substantive allegations asserted and intends to aggressively defend itself in these proceedings.

If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceeding, we or our potential future collaborators could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign our products. 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 against us, 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.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors. We try to ensure that our employees do not use the proprietary information or know-how of others in their work for us. However, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or

personnel.

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, securing commercial quantities of product from our manufacturers, and distribution. In addition, we expect to make significant investments with respect to development, particularly to the extent we conduct clinical trials and seek FDA approval for product candidates. For example, in December 2010, we entered into a joint venture agreement with SEEK, a United Kingdom drug discovery group, to form a joint venture to develop and obtain regulatory approval in Europe and the United States for BC 1036, an antitussive cough suppressant pharmaceutical product utilizing theobromine as an active ingredient. Since our entry into the joint venture, we made aggregate capital contributions to the JV of approximately $2.5 million, and may contribute additional capital from time to time, to fund development and commercialization efforts. These amounts may be substantial to the extent clinical trials are commenced in the United States.

We have used, and expect to continue to use, revenue from sales of our marketed products to fund a significant portion of our development costs and establishing and expanding 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 development programs or commercialization efforts.

As of March 23, 2012, we had approximately $38.0 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 and capital expenditure requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

- 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, particularly BC1036;
- the costs, timing and outcome of regulatory review of our product candidates, particularly BC 1036;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates;
- 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, 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 available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any 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.

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 exceed 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 NYSE Amex and it determines to delist our common stock, the market liquidity and market price of our common stock could decline.

If we fail to meet all applicable listing requirements of NYSE Amex 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;
- 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 made distributions of approximately $121,000 in 2010 to cover certain 2009 state tax obligations of the shareholders when we were an S-corporation. We did not make any other distributions for the years ended December 31, 2011 and 2010. While Pernix has the ability to pay dividends from an earnings standpoint, 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 any future debt agreements may preclude 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.

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

Our directors and executive officers together with their affiliates beneficially own, in the aggregate, approximately 62% 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.

Resales of shares of common stock could materially adversely affect the market price of our common stock.

We issued shares of common stock in the merger to the former stockholders of PTI, representing approximately 84% of the aggregate common stock then outstanding, on a fully diluted basis.

These shares were issued in the merger pursuant to an exemption from the registration requirements of the 1933 Act and are therefore “restricted securities” as defined in Rule 144 under the 1933 Act. In addition to being subject to restrictions on transfer imposed under the securities laws, each former stockholder of PTI entered into a stockholder agreement (which together cover approximately 17.9 million shares), which among other things, restricts the sale or transfer of these shares for specified periods.

When the restrictions in the stockholder agreements described above lapse and all of the shares become available for resale, sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, could materially adversely affect the market price of our common stock.

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

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

- period-to-period fluctuations in financial results due to seasonal demands for certain of our products;
- issues in manufacturing 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.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our financial condition, results of operations and reputation.

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.

In December 2010, we entered into a joint venture agreement with SEEK, a United Kingdom drug discovery group, to form a joint venture to develop and obtain regulatory approval in both Europe and the United States for BC 1036, an antitussive cough suppressant pharmaceutical product utilizing theobromine as an active ingredient. Since our entry into the joint venture agreement, we have contributed an aggregate of approximately $2.5 million to the joint venture, and currently own an equity interest representing 50% of the total voting power and approximately 46% of the total economic power in the entity. We may contribute additional capital to the extent the entity proceeds with its attempts to obtain regulatory approval in the United States and Europe. Additionally, we granted an exclusive license to all of our theobromine intellectual property to a subsidiary of the joint venture, including United States Patent No. 6,348,470. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of heobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States.

While some of our partners in the joint venture have experience in obtaining European regulatory approval, we do not have experience with that process, nor do we or our joint venture partners have any experience in obtaining regulatory approval in the United States.

Our ability to bring BC 1036 to market in the United States 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;

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submission of an NDA;

receipt of marketing approvals from the FDA;

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of the product;

acceptance of the product by patients, the medical community and third party payors;

competition from other therapies;

achieving and maintaining compliance with all regulatory requirements applicable to the product; and

a continued acceptable safety profile of the product following approval.

There are no guarantees that we will be successful in completing these tasks. If we are not successful in commercializing BC 1036 (or any other product candidate we may seek to develop), 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 FDA or analogous foreign governmental entities may require us, to conduct additional clinical trials or we may abandon projects that we expect to be promising;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

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

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

Risks Related to Regulatory Matters

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

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has historically refrained from taking enforcement action against some marketed, unapproved new drugs. Specifically, some marketed prescription and nonprescription drugs are not the subject of an approved marketing application because they are thought to be identical, related, or similar to historically-marketed products, which were thought not to require pre-market review and approval, or which were approved only on the basis of safety, at the time they entered the marketplace. When enacted in 1938, the FDCA required proof of safety but not efficacy for new drugs. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar to the approved drug to be covered by that approval, and allowed those drugs to be marketed without independent approval, In 1962, Congress amended the FDCA to require that a new drug be proven effective, as well as safe, to obtain FDA approval. 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. 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.

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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 both the ALDEX and BROVEX product families. 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 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 has converted the ALDEX and BROVEX product families to OTC monograph from Drug Efficacy Study Implementation (DESI) drugs over the past two cold seasons. 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.

The Company's authorized generic products added through the acquisition of Macoven 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 already planned to be phased out 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.

The inclusion of our ALDEX and BROVEX lines in the FDA's announcement on March 3, 2011 regarding the removal of certain products from market may damage the reputation of these brands. Additionally, our conversion of these and other products to OTC monograph requirements may adversely affect the sales and/or marketability of these products.

As previously stated, on March 3, 2011, the FDA announced its intention to remove certain unapproved prescription cough, cold, and allergy products from the U.S. market and named products from both the ALDEX and BROVEX product families. The Company has discontinued certain of and converted the remainder of the named ALDEX and BROVEX products to OTC monograph from Drug Efficacy Study Implementation (DESI) drugs over the past two cold seasons, and believes it has and can continue to appropriately market these lines as OTC monograph products. However, the inclusion of these products in the FDA's March 3, 2011 announcement may cause harm to the reputation

of these products. Additionally, the conversion to OTC monograph requirements often requires changes to labeling and dosage requirements, among other things. Any such changes may adversely affect the sales and/or marketability of our converted products.

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 cough and cold 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 may materially and adversely affect our financial condition and operations.

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 and by comparable European authorities. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval from the FDA or demonstrated our ability to obtain regulatory approval for BC 1036 or any other drugs that we have developed or are developing. We have no significant experience in filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations to assist us in this process. 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.

Our lack of experience in obtaining FDA approvals could delay, limit or prevent such approvals for its product candidates.

We are currently evaluating all of our potential opportunities for theobromine with our joint venture partner, SEEK, a leading drug discovery and development group based in the United Kingdom. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. On September 26, 2011, the Company funded an additional $1.0 million in cash to the JV for continuing operations. To date, the Company has funded an aggregate of $2.5 million in cash to the JV for continuing operations.

While some of our partners in the joint venture have experience in obtaining European regulatory approval, we do not have experience with that process, nor do we or our joint venture partners have any experience in obtaining regulatory approval in the United States. Our limited experience in this regard could delay or limit approval of our product candidates if we are unable to effectively manage the applicable regulatory process with either the FDA or foreign regulatory authorities. In addition, significant errors or ineffective management of the regulatory process could prevent approval of a product candidate, especially given the substantial discretion that the FDA and foreign regulatory authorities have in this process. Further, even if we obtain regulatory approval in one jurisdiction, that does

not ensure regulatory approval in another jurisdiction. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory process in others.

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 requirement 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.

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.

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.

Risks Related to Employee Matters and Managing Growth

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified managerial personnel. We are highly dependent upon our executive management team. The loss of the services of any 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.

We may encounter difficulties in managing our growth, which could disrupt our operations.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 NYSE Amex, imposes various requirements on public companies, including with respect to corporate governance practices. Moreover, these rules and regulations increase legal and financial compliance costs and make some activities more time-consuming and costly.

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

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

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Risks Related to Our Acquisition Strategy

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.

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.

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 $15,000 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 $2,300 per month, which is subject to certain annual escalators. The Company also leases a 5,000 square-foot office facility and a 7,200 square-foot warehouse facility in Magnolia, TX and a 1,000 square-foot office facility and a 2,500 square-foot warehouse facility in Gonzalez, LA. 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, 2011, Pernix pays rent of approximately $5,100 and $3,000 per month for the Texas and Louisiana facilities, respectively. The Gonzales facility is expected to be phased out by the end of the second quarter of 2012. We believe these amounts approximate market rates.

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 7.5 mg; and L-methylfolate calcium 15 mg. While formal discovery has not yet commenced, the Company believes it has meritorious defenses to the substantive allegations asserted and intends to aggressively defend itself in these proceedings.

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.

PART II

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

Market Information

Pernix's common stock is listed on the NYSE Amex under the symbol "PTX." On March 23, 2012, 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 NYSE Amex was $9.45 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 Amex.

	Price range of common shares	
	High	Low
20101:		
First Quarter (3/10/10 – 3/31/10)	5.75	3.70
Second Quarter	4.52	3.32
Third Quarter	3.88	2.60
Fourth Quarter	6.75	3.14
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

(1) As previously disclosed, on March 9, 2010, Pernix completed its merger with GTA.

Stockholder Information

On March 23, 2012, Pernix had 26,034,272 shares of common stock outstanding. As of March 23, 2012, those shares were held of record by approximately 72 registered holders.

Dividends

We made distributions of approximately $121,000 in 2010 to cover certain 2009 state tax obligations of the shareholders when the Company was an S-corporation. We did not make any other distributions for the years ended December 31, 2011 and 2010. While Pernix has the ability to pay dividends from an earnings standpoint, we are currently investing in our promoted product lines and product candidates and exploring acquisition opportunities and do not anticipate paying dividends in the foreseeable future.

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, 2011 through October 31, 2011	---	$ ---	---	$ 1,150,130
November 1, 2011 through November 30, 2011	---	$ ---	---	$ 1,150,130
December 1, 2011 through December 31, 2011	—	$ —	—	$ 1,150,130
Total	---	$ ---	---	

(1) On May 12, 2010, our Board of Directors authorized the repurchase of up to $5,000,000 in shares of our common stock. The repurchase plan does not have a termination date and may be eliminated by our Board at any time. All shares of common stock were repurchased pursuant to open market transactions.

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. is a specialty pharmaceutical company focused on the sales, marketing and development of branded and generic prescription and over-the-counter pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. We expect to continue to execute our growth strategy which includes the horizontal integration of our branded prescription, generic and over-the-counter ("OTC") businesses. We manage a portfolio of branded and generic products and theobromine, a non-codeine, cough suppressant product candidate in development. 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, REZYST IM™, a proprietary probiotic blend to promote dietary management and a family of prescription treatments for cough and cold (BROVEX®, ALDEX® and PEDIATEX®). Pernix also markets generic products through its wholly-owned subsidiary, Macoven Pharmaceuticals, which Pernix acquired in September 2010.

The Company promotes its branded, and certain of its generic products, through an established U.S. sales force of approximately 55 sales representatives, primarily in highly populated states, targeting pediatric and high-prescribing physicians that are in the top decile of physicians that prescribe our products. Our current operating plan focuses on maximizing sales of our existing product portfolio. In addition, we plan to accelerate growth by launching new products, line extensions, new formulations and by acquiring and licensing approved products. We plan to begin promoting an FDA-approved prescription product to treat gastroenterology in 2012 pursuant to a license and supply agreement we entered into in January 2012. We intend to establish a sales force of approximately 30 representatives, consisting of new hires and current sales representatives, dedicated to gastroenterology to market this new product during the first half of 2012.

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 Pernix will pay the costs related to the development of the product. Pernix expects to invest approximately $6 million over an estimated 36-month period 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 the next 12 months.

In August 2010, we acquired co-promotion rights to NATROBA TM (spinosad) Topical Suspension, 0.9% (“NATROBA”), which received FDA approval for the treatment of head lice in January 2011 and was launched in August 2011. NATROBA is promoted by our approximately 55 sales representatives. In order to retain our exclusive license and co-promotion rights to market NATROBA, we must make purchase commitments of approximately $33,830,000 during Year 1, $51,740,000 during Year 2, and $75,620,000 during Year 3 of the co-promotion term which began on August 3, 2011. We have made total purchases of approximately $11,660,000 from the launch through March 23, 2012.

In December 2010, we entered into a joint venture for the development of theobromine, a first-in-class treatment for cough which we plan to develop for both the prescription and over-the counter, or OTC, markets. In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. To date, the Company has funded an aggregate amount of approximately $2.5 million in cash to the JV for continuing operations.

Certain products in our portfolio are marketed without a United States Food and Drug Administration (“FDA”) approved marketing application because we consider them to be identical, related or similar to products that have

existed in the market without an FDA-approved marketing application, and which were thought not to require pre-market approval, or which were approved only on the basis of safety, at the time they entered the marketplace, subject to FDA enforcement policies established with the FDA's Drug Efficacy Study Implementation, or DESI, program. On March 2, 2011, the FDA announced the removal of certain unapproved prescription cough, cold and allergy products from the U.S. market. We have converted the ALDEX and BROVEX product families, as well as certain generic products marketed through Macoven, to OTC monograph from DESI drugs over the past two cold seasons. We believe we have appropriately marketed, and can continue to appropriately market, these lines as OTC monograph products.

As of March 23, 2012, our sales force consists of approximately 55 full-time sales representatives who promote our products primarily in highly populated states targeting high prescribing physicians that treat pediatric patients. Since January 1, 2010, we have added a total of 29 new sales representatives, of which 21 were added in June 2010, four were added in August 2010, four were added in January 2011.

For the years ended December 31, 2011 and 2010, our net sales were approximately $60,607,000 and $33,227,000, respectively, and our net income before income taxes was approximately $12,937,000 and $10,794,000, respectively.

Our net cash provided by operating activities for the years ended December 31, 2011 and 2010 were approximately $9,397,000 and $4,667,000, 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 Sales

Pernix’s net sales consist of net product sales and revenue from co-promotion and other revenue sharing agreements. Pernix recognizes product sales net of estimated allowances for product returns, discounts, customer chargebacks and rebates and Medicaid rebates. 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 Medicaid rebates, contracted chargeback and rebate rates, and the discounts that Pernix recognizes. In addition to our own product portfolio, we have entered into co-promotion agreements and other revenue sharing arrangements with various parties in return for a percentage of revenue on the sales we generate or on the sales they generate. The total 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 $4,634,000 and $2,490,000 for the years ended December 31, 2011 and 2010, respectively.

The following table sets forth a summary of Pernix’s net sales revenue for the years ended December 31, 2011 and 2010.

	Year Ended December 31,	
	2011	2010
	(in thousands)	
Upper respiratory, allergy and antibiotic products	$ 61,454	$ 48,485
Dietary supplements and medical food products	4,509	691
Dermatology products (including NATROBA)	12,633	903
Other generic products	8,152	---
Co-promotion and other revenue	4,634	2,490
Gross Revenues	91,382	52,569
Sales Allowances	(30,775)	(19,342)
Net Sales Revenues	$ 60,607	$ 33,227

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, 2011:

	Product Returns	Government Program Rebates	Price Adjustments
		(in thousands)	
Balance at December 31, 2009	$ 3,975	$ 2,301	$ 647
Allowance assumed in acquisition of Macoven	245	55	325
Reclass accrual for prompt pay discounts	---	---	(127)
Current provision:			
Adjustments to provision for prior year sales	(682)	—	—
Provision – current year sales	2,882	9,288	6,517
Payments and credits	(2,107)	(7,212)	(5,618)
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

Product Returns. Consistent with industry practice, we offer contractual return rights that allow our customers to return the majority of our products within an 18-month period, from six months prior to and up to twelve months subsequent to the expiration date of our products. Most of our products have a 24 to 36–month shelf life 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 remaining shelf life of the product, the forecast of future sales of the product, and competitive issues such as new product entrants and other known changes in sales trends. We estimate returns of approximately 5% to 7% of sales of branded products (5% on sales of NATROBA) and approximately 5% - 12% for generic products based upon historical data and other facts and circumstances that may impact future expected returns to derive the average return percentages of our products. Under our co-promotion agreement with ParaPRO, certain returns of NATROBA sold within the first year of launch will be reimbursed by ParaPRO up to 65%. We review the reserve quarterly and adjust it accordingly. The provision for returns for the year ended December 31, 2011 includes a non-recurring adjustment of approximately $672,000 recorded in the second quarter for potential returns of estimated channel inventory of two generic DESI products that have been discontinued as a result of an FDA notice issued in March 2011. 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, 2011 would have affected pre-tax earnings by approximately $760,000.

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 Medicaid 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, 2011, a 1% difference in the provision assumptions based on utilization would have effected pre-tax earnings by approximately $145,000 and a 1% difference in the provisions based on reimbursement rates would have affected pre-tax earnings by approximately $89,000.

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, 2011, a 1% difference in the assumptions based on the applicable sales would have affected pre-tax earnings by approximately $863,000.

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 20% 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%, 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.

Cost of Product Sales

Our cost of product sales is primarily comprised of the costs of manufacturing and distributing Pernix's pharmaceutical products and samples and collaboration expense related to co-promotional agreements with third parties. In particular, cost of product sales includes third-party manufacturing, packaging and distribution costs and the cost of certain pharmaceutical ingredients. Pernix partners with third parties to manufacture all of its products and product candidates.

Most of our 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 also affect its cost of product sales.

The cost of NATROBA is included in our cost of product sales from August 2011 (the month of launch). We pay wholesale average cost less a nominal discount when we purchase NATROBA inventory and then receive a contracted cost of goods rebate when the product ships to retailers in our specified territories, resulting in significantly lower margins on sales of NATROBA as compared to the other products we market.

Selling Expenses

Our selling expenses consist of 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 Pernix's 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.

Royalty Expenses

From time to time in the ordinary course of business, the Company enters into agreements regarding royalty 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 expense will vary based on changes in product sales and/or product mix. As of December 31, 2011, the Company does not have any active royalty agreements. For a description of the new agreement that requires royalty fees, see Note 20 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K. Royalty expense will vary based on changes in product sales and/or product mix.

General and Administrative Expenses

General and administrative expenses primarily include salaries, benefits and overhead of management and administrative personnel; professional fees; consulting fees; and all lines of insurance. Pernix's general and administrative expenses have increased significantly from the year ended December 31, 2010 due to the growth in our operating infrastructure resulting in personnel additions and their related overhead costs along with costs relates to the expansion of our product portfolio and expenses in support of a growing 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 BC 1036 (theobromine).

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.

Income Taxes

Pernix elected to be taxed as an S Corporation effective January 1, 2002. As such, taxable earnings and losses after that date were included in the personal income tax returns of our stockholders. Effective January 1, 2010, Pernix terminated its S Corporation status. As a result of this election, income taxes are accounted for using the asset and liability method pursuant to Accounting Standards Codification ("ASC") Topic 740 - Income Taxes. Accordingly, we were required to record deferred taxes on its temporary differences at the date of termination. The resulting deferred tax asset recorded as a tax benefit was $1,839,000. 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 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. In connection with the merger of Pernix and GTA, a portion of the valuation allowance on operating loss carryforwards was released in an amount equal to the losses that are projected to be utilized in the five tax years following the acquisition. The resulting release of the valuation allowance that was recorded as a tax benefit was $779,000.

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."

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Revenue Recognition

We record 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) 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 recognize revenue from our product sales upon transfer of title, which occurs when product is received by our customers. We recognize product sales revenue when the goods are shipped and the customer takes ownership and assumes risk of loss (free-on-board destination), collection of the relevant receivable is probable, persuasive evidence of an arrangement exists and the sales price is fixed and determinable. Pernix sells its products primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return the products they purchase, as described below. At the time of sale, estimates for sales deductions such as product returns, government program rebates, price adjustments and prompt pay discounts are recorded.

Consistent with industry practice, Pernix offers customers the ability to return products in the six months prior to, and the twelve months after, the products expire. Pernix 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, competitive issues such as new product entrants and other known changes in sales trends or historical return experience.

Co-promotion revenue is recognized in the period in which the product subject to the arrangement is sold.

Allowances for Product Returns, Government Program Rebates, Price Adjustments (chargebacks, rebates, vendor fees, coupons and point-of-sale discounts), and Prompt Pay Discounts. See discussion above under " Financial Operations Overview."

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 Notes 17 and 20 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K, regarding the calculation of the value of options issued and other details regarding all stock based compensation awarded in the year ended December 31, 2011.

Inventory

Inventory consists primarily of finished goods which include pharmaceutical products ready for commercial sale or distribution as samples. 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 inventory reserve includes provisions for inventory that may become damaged in shipping or in distribution to the customer. We do not currently manufacture any products. 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, 2011 and 2010, Pernix had approximately $6,261,000 and

$4,146,000 in inventory, respectively, for which no reserve was deemed necessary as certain inventory nearing expiration was either donated or directly written off at December 31, 2011. The increase in inventory was primarily due to the addition of NATROBA and certain generic products to our portfolio during 2011.

Results of Operations

Comparison of the Year Ended December 31, 2011 and 2010

Net Revenues. Net revenues were approximately $60,607,000 and $33,227,000 for the years ended December 31, 2011 and 2010, respectively, an increase of approximately $27,380,000, or 82.4%. The increase in net revenues during the year ended December 31, 2011 consists of an increase in gross product sales of approximately $37,043,000, or 74.0%, and an increase in co-promotion and other product related revenue of approximately $1,770,000, or 71.1%, offset by an increase of approximately $11,433,000, or 59.1%, in sales allowances. The increase in gross product sales was attributed to approximately $9,764,000 in gross sales from the launch of NATROBA in August 2011, approximately $13,059,000 in gross sales of our new formulation of CEDAX launched in January 2011 and an increase in the sales of generic products through Macoven. Since we did not acquire Macoven until September 2010, generic product sales did not make up a significant amount of our gross sales for the year ended December 31, 2010. The increase in gross revenue was offset by an increase in deductions from gross product sales revenue (including allowance for returns, government program rebates and price adjustments) of approximately $11,433,000, or 59.1%, resulting from the overall increase in gross product sales and also due to changes in product mix with price adjustments (chargebacks, rebates, vendor fees and other discounts) that are primarily applicable to sales of our generic products. As previously noted, the allowance for returns was also impacted by returns of channel inventory (at wholesalers or retailers) of two generic DESI products that were discontinued as a result of an FDA notice issued in March 2011.

For a discussion of our revenue-sharing arrangements, See Note 16 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

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 within eighteen months from the date the product was originally sold. For the years ended December 31, 2011 and 2010, product returns allowances were approximately $5,283,000, or 6.1%, of gross product sales, and $2,200,000, or 4.4%, of gross sales, respectively. The increase in the product returns allowances as a percentage of gross product sales is based on the non-recurring adjustment due to certain discontinued generic products and increases in the return allowance percentage on certain products due to changes in Medicaid coverage.

Government program rebates were approximately $11,106,000, or 12.7%, of gross product sales, and $9,288,000 or 18.5%, of gross product sales, respectively, for the years ended December 31, 2011 and 2010. 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 is primarily due to the change in our product mix as we are only responsible for 37% of the Medicaid rebates submitted for NATROBA pursuant to our agreement with ParaPRO, the government program rebates on our generic products are significantly less than our brand products and we no longer have supplemental rebates in certain states. Also in the third quarter of 2010, we implemented strategic steps to reduce our Medicaid rebates including implementation of pricing strategies, product formulation changes, commission structure changes, and retargeting our sales representatives which we believe has had a positive impact on reducing our Medicaid rebates as a percent of gross product sales.

Price adjustments were approximately $12,611,000, or 14.5%, of gross product sales and $6,517,000, or 13.0%, of gross product sales, respectively, for the years ended December 31, 2011 and 2010. The increase in price adjustments as a percentage of gross product sales is due to the addition of the generic product portfolio in September 2010 with our acquisition of Macoven pursuant to which its customer contracts require rebates, chargebacks and other customer

fees on all sales. Rebates and chargebacks are not typically a component of customer contracts for brand products so the price adjustments are primarily impacted by generic sales.

Prompt pay discounts taken were approximately $1,775,000, or 2.0%, of gross product sales and $1,337,000, or 2.7%, of gross product sales, for the years ended December 31, 2011 and 2010, respectively. This decrease is attributable to renegotiated contracts with certain of our customers in 2010 to reduce their prompt pay discount to 2%. Approximately $393,000 and $306,000 in accrued allowances for prompt pay discounts was netted against accounts receivable at December 31, 2011 and 2010, respectively.

Cost of Product Sales. Cost of sales was approximately $20,536,000, or 23.6%, of gross product sales, and $5,443,000, or 10.9% of gross product sales, for the years ended December 31, 2011 and 2010, respectively, an increase of approximately $15,094,000, or 277.3%. The increase in cost of product sales is the result of the overall increase in gross product sales and the launch of NATROBA in August of 2011. As previously noted, the cost that the company pays for NATROBA pursuant to the Supply and Distribution Agreement with ParaPRO is significantly higher than the direct manufacturing cost that we pay on the other products in our portfolio. For additional information, see Note 16 to our Consolidated Financial Statements for the year ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K. In addition, cost of product sales for the year ended 2011 includes a non-recurring adjustment of approximately $2,001,000 for expiring and/or discontinued products that were destroyed or donated. Co-promotion expense, included in cost of sales, was apprximately $2,427,000 and $458,000 for the years ended December 31, 2011 and 2010, respectively, which is due to two new co-promotion arrangements on certain of our generic products. The cost of product samples is included in selling expenses.

Gross Margin. See Note 16 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Selling, General and Administrative Expenses (SG&A). SG&A expenses were approximately $22,538,000 and $15,189,000 for the years ended December 31, 2011 and 2010, respectively, an increase of approximately $7,349,000, or 48.3%. Overall compensation expense represented approximately $13,054,000 , or 58.9%, and $8,456,000, or 55.7%, of total SG&A for the years ended December 31, 2011 and 2010, respectively. The increase in overall compensation expense is due to increases in (i) commissions from the increase in gross sales and the higher commission rate paid on NATROBA in comparison to our other products, (ii) bonuses, (iii) an increase in the base salary of each sales representative effective February 1, 2011, (iv) an increase in the number of sales representatives year over year and (v) the addition of several new management positions in late 2010 and in 2011. Other SG&A expenses were approximately $9,104,000 and $6,733,000 for the years ended December 31, 2011 and 2010, respectively, an increase of approximately $2,371,000, or 35.2%. This increase in other SG&A expenses included an impairment charge of $380,000 on the fair value of 118 acres of land. The remaining increase in other SG&A expenses was primarily due to an increase in regulatory and license fees, professional and consulting fees (legal, accounting, corporate tax services, other professional services), insurance, leases, sales reporting expenses, freight, information technology expenses, management fees, certain public company costs and investor relations expenses, and increased overhead (such as travel, meals, telephone, and vehicle expenses) offset by a decrease in product sample expense.

Royalty Expenses, net. Royalty expenses, net were approximately $385,000 and $739,000 for years ended December 31, 2011 and 2010. Royalty expenses are related to obligations under license and co-promotional agreements. The royalty expenses for the year ended December 31, 2011 were offset by royalty revenue of approximately $247,000 related to our license of the TCT control delivery technology we acquired from Kiel in 2010. As of December 31, 2011, the Company does not have any active royalty agreements.

Research and Development Expenses (R&D). R&D expenses were approximately $922,000 and $998,000 for the years ended December 31, 2011 and 2010, respectively. R&D expenses during the year ended December 31, 2011 were primarily related to the launch of a new generic product in 2011. R&D expenses in the year ended December 31, 2010 were primarily due to the amortization of the development fee paid to Macoven in July 2009. 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 joint venture was approximately $814,000 for the year ended December 31, 2011 which represents primarily research and development costs related to the development of BC1036 (theobromine).

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Depreciation and Amortization Expense. Depreciation expense was approximately $97,000 and $61,000 for the years ended December 31, 2011 and 2010, respectively. Amortization expense was approximately $2,205,000 and $1,178,000 for the years ended December 31, 2011 and 2010. The increase in amortization expense of approximately $1,028,000, or 87.3%, is due to the amortization under certain of our commercial agreements that we entered into, including the agreements evidencing our acquisitions of CEDAX in March 2010 and Macoven in September 2010. For further discussion, see Note 10 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Interest Expense, net. Interest income was approximately $41,000 and $34,000 for the years ended December 31, 2011 and 2010, respectively. Interest expense was approximately $212,000 and $28,000 for the years ended December 31, 2011 and 2010, respectively, related to our line of credit and insurance financing arrangements.

Liquidity and Capital Resources

Sources of Liquidity

Pernix's net income was approximately $8,348,000 and $9,309,000 for the years ended December 31, 2011 and 2010, respectively.

Pernix requires cash to meet its operating expenses and for capital expenditures, acquisitions, and in-licenses of rights to products. Historically, Pernix has funded its operations primarily from product sales. As described below, in February 2012, we entered into a controlled equity offering agreement with Cantor Fitzgerald. In July 2011, we completed an underwritten registered direct offering of 4,000,000 shares of common stock from which we received net proceeds of approximately $19.3 million. Additionally, in September 2010, we obtained a $10 million line of credit from Regions Bank, consisting of a $5 million revolver and a $5 million guidance line of credit for certain acquisitions pre-approved by Regions Bank. The line of credit currently has a balance of $6.0 million leaving $4.0 million available to draw from the revolver. Certain acquisitions have been funded or partially funded from the proceeds of the offering and/or the line of credit. For further discussion of this Registered Offering and our line of credit, see Notes 1 and 13 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Registered Direct Offering

On July 27, 2011, the Company completed an underwritten registered direct offering of 4,000,000 shares of common stock pursuant to the terms of that certain underwriting agreement dated July 21, 2011 by and among the Company, the selling stockholders named therein and the underwriters named on Schedule I thereto, for whom Stifel, Nicolaus & Company, Incorporated acted as representative. As provided in the underwriting agreement, (i) the Company sold an aggregate of 3,000,000 shares of its common stock, and (ii) the selling stockholders sold 1,000,000 shares of common stock. The public offering price was $7.00 per share, and the underwriters purchased the shares subject to the offering at a price of $6.58 per share. The offering was led by Aisling Capital and OrbiMed Advisors, LLC. Net proceeds from the sale of the shares of common stock sold by the Company, after underwriting discounts and commissions and offering expenses, were approximately $19.3 million. The offering was made pursuant to an effective shelf registration statement filed with the Securities and Exchange Commission on May 31, 2011.

Controlled Equity Offering

On February 10, 2012, the Company entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co. pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $25,000,000 from time to time through Cantor, acting as agent, but in no event more than

5,000,000 shares of common stock. Sales of our common stock through Cantor, if any, will be made on the NYSE Amex by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by Cantor and us. Cantor will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cantor a commission rate of 3.0% of the gross sales price per share of any common stock sold through Cantor as agent. As of March 23, 2012, 264,000 shares have been sold pursuant to the controlled equity offering for aggregate net proceeds to the Company of approximately $2,486,000.

Cash Flows

The following table provides information regarding Pernix's cash flows for the years ended December 31, 2011 and 2010.

	Years Ended December 31,	
	2011	2010
Cash provided by (used in)		
Operating activities	$ 9,397,000	$ 4,667,000
Investing activities	(2,175,000)	(5,695,000)
Financing activities	19,069,000	4,710,000
Net increase (decrease) in cash and cash equivalents	$ 26,291,000	$ 3,682,000

Net Cash Provided By Operating Activities

Net cash provided by operating activities for the years ended December 31, 2011 and 2010 was approximately $9,397,000 and $4,667,000, respectively. 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 for the year ended December 31, 2011 included depreciation of approximately $97,000, amortization of approximately $2,205,000, 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 joint venture with SEEK of approximately $814,000.

Net cash provided by operating activities for the year ended December 31, 2010 primarily reflected Pernix's net income of approximately $9,309,000, adjusted by non-cash expenses totaling approximately $1,703,000 partially offset by the non-cash gain on the bargain purchase of Macoven of approximately $882,000, a non-cash deferred income tax benefit of approximately $3,055,000 and approximately $2,408,000 in net changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash expenses included amortization of approximately $1,178,000, depreciation of approximately $61,000 and stock compensation expense of approximately $464,000. The deferred income tax benefit of approximately $3,055,000 includes a one-time tax benefit of approximately $1,839,000 related to our change in tax status and a one-time tax benefit of approximately $779,000 related to the net operating losses acquired in the merger with GTA.

Accounts receivable increased by approximately $5,843,000 from the year ended December 31, 2010 to the year ended December 31, 2011 primarily attributable to an increase in net revenues, including an increase in generic product sales that have longer payment terms and the timing of receivables and payments related to collaboration arrangements entered into in 2011. No amounts were considered delinquent at December 31, 2011. Inventories increased approximately $2,115,000 from December 31, 2010 primarily attributable to the launch of the NATROBA product line in August 2011. Prepaid expenses and other assets increased by approximately $324,000, of which approximately $208,000 is for a prepaid contract for R&D services on a generic product launched in 2011.

Accounts payable increased by approximately $740,000 from the year ended December 31, 2010 due to timing differences in our payment of certain invoices and the increase in SG&A from our growth during 2011. Accrued expenses increased approximately $7,960,000 for the year ended December 31, 2011 as compared to December 31, 2010 primarily due to the increase in allowances for returns, government program rebates and price adjustments driven primarily by our increase in gross sales and the change in our product mix as price adjustments are primarily applicable to sales of generics.

Net Cash Used in Investing Activities

Net cash used in investing activities for the years ended December 31, 2011 and 2010 was approximately $2,176,000 and $5,695,000, respectively. The cash flow from investing activities for the year ended December 31, 2011 consisted of a $1,000,000 additional investment in our joint venture with SEEK and a $1,000,000 investment in TherapeuticsMD for which we received 2,631,579 shares of their common stock, offset by approximately $176,000 in purchases of equipment and furniture, primarily iPads for our sales team and furniture and office equipment for our new corporate headquarters in The Woodlands, Texas. The $5,695,000 used in the year ended December 31, 2010 primarily consisted of approximately (i) capital contributions of $1,503,000 to our joint venture with SEEK, (ii) $1,996,000, net of cash acquired of approximately $189,000, paid to acquire Macoven, (iii) the initial installment of the purchase price for CEDAX of $1,500,000, (iv) the initial installment, net of adjustments, in the Gaine acquisition of approximately $327,000, (v) the amount paid in the acquisition of the TCT control delivery technology to Kiel of

$250,000, and (vi) purchases of office furniture and equipment of approximately $119,000. For additional information, Notes 8, 10 and 14 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2011 was approximately $19,069,000, which represents 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.

Net cash provided by financing activities for the year ended December 31, 2010 was approximately $4,710,000, which represents (i) cash acquired in connection with the merger with GTA of approximately $5,966,000, (ii) proceeds from the guidance line of credit of approximately $5,000,000, (iii) proceeds from payment on notes receivable of approximately $86,000, and (iv) proceeds from the issuance of stock through the exercise of stock options of approximately $77,000, partially offset by (1) approximately $4,600,000 for the remaining installment payments on the acquisition of CEDAX, (2) $346,000 for the second installment net payment on the acquisition of Gaine, (3) $600,000 in installment payments on the repurchase of stock from a related party, (4) $250,000 in stock repurchases under our stock buyback program, (5) approximately $121,000 in distributions to stockholders and (6) $502,000 representing a transfer to restricted cash related to the issuance of a letter of credit pursuant to a manufacturing agreement. For further discussion of the registered equity offering, see Note 1 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

The Company is currently in discussions with Regions to potentially expand the revolver amount to provide additional funding for product acquisition and/or development opportunities. Pernix's future capital requirements will depend on many factors, including:

- the extent to which Pernix acquires or invests in products, businesses and technologies;
- the level of product sales of its currently marketed products and any additional products that Pernix may market in the future;
- 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, including the development of BC 1036;
- the number of, and development requirements for, additional product candidates that Pernix pursues;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of Pernix's product candidates and products;

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.

To the extent that Pernix's capital resources and line of credit are insufficient to meet its future capital requirements, Pernix will need to finance its cash needs through additional public or private equity offerings, additional debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

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, 2011 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases(1)	$ 888	$ 227	$ 396	$ 265	$ —
Purchase obligations(2)	154,022	46,903	107,083	36	—
Line of credit(3)	6,132	6,132	—	—	—
License Agreements(4)	90	90	—	—	—
Other long-term debt obligations (5)	1,800	1,200	600	—	—
Total contractual obligations	$ 161,932	$ 54,552	$ 108,079	$ 301	$ —

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

(2) 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. For example, our co-promotion agreement with ParaPRO for NATROBA requires that we meet certain annual sales targets. In the event we are unable to meet these requirements, ParaPRO may revoke our exclusivity to market NATROBA and/or terminate the co-promotion agreement. 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 $1.1 million.

Pursuant to the Supply and Distribution Agreement between the Company and ParaPRO, the Company has purchase commitments for NATROBA of approximately $43,729,000 in 2012, $61,690,000 in 2013 and $44,112,000 in 2014 in order to retain its exclusive co-promotion rights. The Supply and Distribution Agreement may be terminated pursuant to certain terms in conditions, including but not limited to, the failure of the parties to come to agreement on adjusted dispensed product minimums.

(3) See Note 13 of our Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

(4) License agreements include payments due under certain product license arrangements for which payments are not contingent on sales or other achievements.

(5) Other long-term liabilities represents the payments due under a privately negotiated stock repurchase. See Notes 12 and 14 of our Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

In addition to the material contractual cash obligations included the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution, acquisition and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. 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.

Recent Accounting Pronouncements

See Note 2 to our Consolidated Financial Statements for the years ended December 31, 2011 and 2010 contained in Part II, Item 8 of this Annual Report on Form 10-K.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Pernix Therapeutics Holdings, Inc. and subsidiaries (collectively, the “Company”) as of December 31, 2011 and 2010, 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 auditing 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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, 2011 and 2010, 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.

/s/ Cherry, Bekaert & Holland, L.L.P.

Charlotte, North Carolina
March 29, 2012

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,551,180	$ 8,260,059
Restricted cash	—	501,906
Accounts receivable, net	20,601,360	14,758,240
Inventory, net	6,261,162	4,145,734
Prepaid expenses and other current assets	2,144,203	1,930,062
Deferred income tax assets – current	4,552,000	2,494,000
Total current assets	68,109,905	32,090,001
Property and equipment, net	911,948	1,213,850
Other assets:		
Investments	4,451,831	1,502,814
Intangible assets, net	8,876,504	10,961,900
Other long-term assets	213,783	264,967
Total assets	$ 82,563,971	$ 46,033,532
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,987,913	$ 2,248,342
Accrued personnel expense	2,044,121	848,013
Accrued allowances	17,006,409	10,488,674
Income taxes payable	585,931	2,149,052
Other accrued expenses	1,565,918	1,319,512
Contracts payable	1,290,000	2,200,000
Line of credit	6,000,000	—
Total current liabilities	31,480,292	19,253,593
Long-term liabilities		
Line of credit	—	5,000,000
Contracts payable	600,000	1,800,000
Deferred income taxes	860,000	1,075,000
Total liabilities	32,940,292	27,128,593
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock $.01 par value, 90,000,000 shares authorized, 27,820,004 and 24,698,594 issued, and 25,749,137 and 22,627,727 outstanding at December 31, 2011 and 2010, respectively	257,491	226,277
Treasury stock, at cost (2,070,867 shares held at December 31, 2011 and 2010)	(3,751,890)	(3,751,890)
Additional paid-in capital	30,185,294	8,934,735
Retained earnings	21,843,416	13,495,817
Other comprehensive income	1,089,368	—
Total stockholders' equity	49,623,679	18,904,939

Total liabilities and stockholders' equity	$ 82,563,971	$ 46,033,532

See accompanying notes to consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

	Years Ended December 31,	
	2011	2010
Net sales	$ 60,606,855	$ 33,227,433
Costs and expenses:		
Cost of product sales	20,536,290	5,442,549
Selling, general and administrative expenses	22,537,966	15,188,525
Research and development expense	922,432	998,224
Loss from operations of the joint venture with SEEK	814,351	—
Royalties expense, net	384,943	738,868
Depreciation and amortization expense	2,302,894	1,238,922
Total costs and expenses	47,498,876	23,607,088
Income from operations	13,107,979	9,620,345
Other income (expense):		
Other income	—	286,868
Gain from bargain purchase	—	881,950
Interest income (expense), net	(171,378)	5,624
Total other income (expense), net	(171,378)	1,174,442
Income before income taxes	12,936,601	10,794,787
Income tax provision	4,589,000	1,486,000
Net income	8,347,601	9,308,787
Unrealized gain on securities, net of income tax of $674,000	1,089,368	—
Comprehensive income	$ 9,436,969	$ 9,308,787
Net income per share, basic	$ 0.35	$ 0.40
Net income per share, diluted	$ 0.34	$ 0.40
Weighted-average common shares, basic	23,990,734	23,415,449
Weighted-average common shares, diluted	24,460,291	23,418,398

See accompanying notes to consolidated financial statements.

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

	Common Stock	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Non-Controlling Interest	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2009	$ 209,000	$ 788,979	$ —	$ 4,308,491	$ 69,738	$ —	$ 5,376,208
Distributions to stockholders	—	—	—	(121,461)	—	—	(121,461)
Transfer of equity in reverse merger with GTA	36,586	7,073,911	—	—	—	—	7,110,497
Acquisition of Gaine non-controlling interest	—	(1,602,692)	—	—	(69,738)	—	(1,672,430)
Contributed capital in acquisition of Macoven	—	2,211,344	—	—	—	—	2,211,344
Stock repurchase program							
Open market repurchases	(709)	(1,772)	(247,390)	—	—	—	(249,871)
Negotiated repurchase from related party	(20,000)	(75,500)	(3,504,500)	—	—	—	(3,600,000)
Proceeds from issuance of common stock	400	77,200	—	—	—	—	77,600
Stock-based compensation							
Restricted stock	1,000	106,946	—	—	—	—	107,946
Stock options	—	356,319	—	—	—	—	356,319
Net income	—	—	—	9,308,787	—	—	9,308,787
	226,277	8,934,735	(3,751,890)	13,495,817	—	—	18,904,939

Balance at December 31, 2010							
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

See accompanying notes to consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2011	2010
Cash flows from operating activities:		
Net income	$ 8,347,601	$ 9,308,787
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	97,498	61,322
Amortization	2,205,396	1,177,600
Impairment charge to fair value of land	380,000	—
Deferred income tax benefit	(2,273,000)	(3,055,000)
Stock compensation expense	1,283,267	464,265
Expense for stock options issued in exchange for services	312,563	—
Gain from bargain purchase from Macoven acquisition	—	(881,950)
Loss from the operations of the joint venture with SEEK	814,351	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,843,120)	(8,361,058)
Income taxes	(2,237,121)	2,049,048
Inventory	(2,115,428)	(1,265,412)
Prepaid expenses and other assets	(325,568)	170,110
Other assets – long term	51,184	118,366
Accounts payable	739,570	1,575,621
Accrued expenses	7,960,249	3,304,915
Net cash provided by operating activities	9,397,442	4,666,614
Cash flows from investing activities:		
Investment in TherapeuticsMD	(1,000,000)	—
Investment in joint venture with SEEK	(1,000,000)	(1,502,814)
Acquisition of Macoven, net of cash acquired of $189,274	—	(1,996,432)
Acquisition of CEDAX – initial payment (see Note 4)	—	(1,500,000)
Acquisition of non-controlling interest in Gaine - initial payment	—	(326,623)
Purchase of intangible assets	—	(250,000)
Purchase of equipment and payments for construction in progress	(175,596)	(119,580)
Net cash used in investing activities	(2,175,596)	(5,695,449)
Cash flows from financing activities:		
Cash acquired in connection with the reverse merger, net of costs paid	—	5,965,529
Proceeds from line of credit	1,000,000	5,000,000
Payments on contracts payable	(1,230,000)	—
Transfer to/from restricted cash	500,000	(501,906)
Payments received on notes receivable	113,333	86,334
Payment on acquisition obligation – CEDAX (see Note 4)	—	(4,600,000)
Payment on acquisition obligation – Gaine (see Note 4)	(1,000,000)	(345,807)
Distributions to stockholders	—	(121,461)
Tax benefit on stock-based awards	137,000	—
Repurchase of common stock	—	(849,871)
Proceeds from issuance of common stock in registered direct offering, net of issuance costs of $255,254	19,259,746	—

Proceeds from issuance of common stock through exercise of stock options and employee stock purchase plan	289,196	77,600
Net cash provided by financing activities	19,069,275	4,710,418
Net increase in cash and cash equivalents	26,291,121	3,681,583
Cash and cash equivalents, beginning of year	8,260,059	4,578,476
Cash and cash equivalents, end of year	$ 34,551,180	$ 8,260,059
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 8,911,190	$ 2,653,043
Interest paid during the period	177,816	19,485
Non-cash transactions:		
Contract for product license – contract payable (total $120,000)	$ 90,000	$ —
Write off/donation of inventory	2,001,464	46,032
Negotiated repurchases of Pernix common stock from insider	—	3,600,000
Contribution of capital in acquisition of Macoven	—	2,211,344

See accompanying notes to consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NoteCompany Overview
1.

Pernix is a specialty pharmaceutical company focused on the sales, marketing and development of branded and generic pharmaceutical products for pediatric and adult indications in a variety of therapeutic areas. We expect to continue to execute our growth strategy which involves the horizontal intigration of our branded prescription, generic and OTC businesses. We manage a portfolio of branded and generic prescription products and theobromine, a non-codeine, cough suppressant product candidate in development. 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, REZYST IM™, a proprietary probiotic blend to promote dietary management and a family of prescription treatments for cough and cold (BROVEX®, ALDEX® and PEDIATEX®). The Company promotes its branded products through an established U.S. sales force. Pernix also markets generic products through its wholly-owned subsidiary, Macoven Pharmaceuticals. Founded in 1996, the Company is based in The Woodlands, TX.

Unless specifically noted otherwise, as used throughout these consolidated financial statements, the term “Company” or “Pernix” refers to the consolidated company after the reverse merger with Golf Trust of America, Inc. (“GTA”) on March 9, 2010 and the business of Pernix Therapeutics, Inc. (“PTI”) before the reverse merger. The term GTA refers to such entity’s standalone businesses prior to the reverse merger.

Registered Direct Offering

On July 27, 2011, the Company completed an underwritten registered direct offering of 4,000,000 shares of common stock pursuant to the terms of that certain underwriting agreement dated July 21, 2011 by and among the Company, the selling stockholders named therein and the underwriters named on Schedule I thereto, for whom Stifel, Nicolaus & Company, Incorporated acted as representative. As provided in the underwriting agreement, (i) the Company sold an aggregate of 3,000,000 shares of its common stock, and (ii) the selling stockholders sold 1,000,000 shares of common stock. The public offering price was $7.00 per share, and the underwriters purchased the shares subject to the offering at a price of $6.58 per share. The offering was led by Aisling Capital and OrbiMed Advisors, LLC. Net proceeds from the sale of the shares of common stock sold by the Company, after underwriting discounts and commissions and offering expenses, were approximately $19.3 million. The offering was made pursuant to an effective shelf registration statement filed with the Securities and Exchange Commission on May 31, 2011.

NoteSummary of Significant Accounting Policies
2.

Principles of Consolidation

The consolidated financial statements include the accounts of (i) Pernix’s wholly-owned subsidiaries Pernix Therapeutics, LLC, GTA GP, Inc. and GTA LP, Inc., (ii) Gaine, Inc. (“Gaine”), a patent and license holding company owned 50% by Pernix until June 24, 2010 when Pernix purchased the remaining 50% and (iii) Macoven Pharmaceuticals, LLC (“Macoven”), a company that promotes generic equivalents of pharmaceutical products that Pernix reacquired on September 8, 2010. Transactions between and among the Company and its consolidated subsidiaries are eliminated.

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. Pernix partners with third parties to manufacture all of its products and product candidates. 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. For the year ended December 31, 2011, approximately (excluding Natroba which is purchased exclusively from ParaPRO), 65% of the inventory purchases were from four primary suppliers, allocated 19%, 17% , 16% and 13%, respectively. For the year ended December 31, 2010, approximately 88% of our product inventory purchases was from three primary suppliers, allocated 46%, 22% and 20%, 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 sells to three major customers (see Note 15). 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 $21 million invested by Regions Morgan Keegan Trust in short-term securities which are secured by government securities at an amount not less than 105%. The Federal Deposit Insurance Corporation ("FDIC") covers $250,000 for substantially all depository accounts and temporarily provides unlimited coverage through December 31, 2012 for certain qualifying and participating non-interest bearing transaction acconts. The Company from time to time may have amounts on deposit in excess of the insured limits. As of December 31, 2011, the Company had approximately $3,077,000 which exceeded these insured amounts.

Fair Value of Financial Instruments

A financial instrument is defined as cash equivalents, 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 and equivalents (including our Regions Trust Account which invests in short-term securities consisting of sweep accounts, money market accounts and money market mutual funds), an investment in equity securities (TherapeuticsMD), and certain land. The carrying value of these assets approximate their fair value.

Effective May 1, 2008, the Company adopted FASB Accounting Standards Codification ASC 820 which provides a framework for measuring fair value under GAAP. The adoption of this statement had an immaterial impact on our consolidated financial statements. The Company also adopted the deferral provisions, which delayed the effective date of ASC 820 for all nonrecurring fair value measurements of non-financial assets and liabilities until our fiscal year ended December 31, 2011.

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. ASC 820 also expands disclosures about instruments measured at fair value and establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value as follows:

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

The following tables summarize the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring and nonrecurring basis as of December 31, 2011 and 2010 (in thousands):

	2011			
Financial Assets	Level 1	Level 2	Level 3	Total
Notes receivable	—	—	4	4
Investment in TherapeuticsMD	—	—	2,763	2,763
Land (1)	—	—	572	572
Total	$ —	$ —	$ 3,339	$ 3,339

	2010			
Financial Assets	Level 1	Level 2	Level 3	Total
Note receivable(1)	$ —	$ —	$ 114	$ 114
Land(1)	—	—	952	952
Total	$ —	$ —	$ 1,066	$ 1,066

(1) Measured on a non-recurring basis.

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, 2011 and 2010, management evaluated the need for an allowance and determined no allowance was necessary.

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 products is expensed and included in SG&A expenses when purchased.

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:

	Service Life
Leasehold improvements	15 years
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 a recent appraisal of the property.

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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.

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 2011 or 2010.

Equity Method of Accounting

The Company’s investment in the joint venture with SEEK is accounted for at cost and adjusted for the Company’s share (46%) of the joint venture’s undistributed earnings or losses.

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) 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. The Company records revenue from product sales when the customer takes ownership and assumes risk of loss (free-on-board destination). 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, 2011 and 2010.

	Year Ended December 31, (in thousands)	
	2011	2010
Gross Product Sales		
Upper respiratory, allergy and antibiotic products	$ 61,454	$ 48,485
Dietary supplements and medical food products	4,509	691
Other generic products	8,152	—
Dermatology products (including NATROBA)	12,633	903
Gross product sales	86,748	50,079
Sales allowances	(30,775)	(19,342)
Net product sales	55,973	30,737
Co-promotion, royalty and other revenues	4,634	2,490
Net Revenues	$ 60,607	$ 33,227

Product Returns

Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the majority of its 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 24 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 5% to 7% of sales of branded products based upon historical data compiled since 2004, as well as other facts and circumstances that may impact future expected returns. Under our co-promotion arrangement with ParaPRO, certain returns of NATROBA sold within the first year of launch will be reimbursed by ParaPRO up to 65%. The Company estimates returns at 5% - 12% on sales of generic products depending on assumptions and/or facts and circumstances existing for certain products. 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.

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 Medicaid utilization for each product.

Price Adjustments

The Company's 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 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 but that are offered at the time of sale, such as sales stocking allowance, are recorded as a reduction in revenue when the sales order is recorded. 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 the reintroduction of a product.

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%, 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.

Freight

The Company includes freight costs for outgoing shipments in selling expenses. Outgoing freight costs were approximately $384,000 and $224,000 for the years ended December 31, 2011 and 2010, 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 during the year ended December 31, 2011 were primarily related to the launch of a new generic product in 2011. Included in research and development expenses for the year ended December 31, 2010 is approximately $689,000 of amortization of the development fee that the Company paid to Macoven in July 2009 which, prior to the acquisition of Macoven on September 8, 2010, was being amortized over the 18-month term of the agreement. Other research and development costs in both years are related to the testing of current products' stability.

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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, the types of customer, the distribution methods and the regulatory environment.

Income Taxes

Income taxes are accounted for using the asset and liability method pursuant to ASC Topic 740 - 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 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. 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, 2011. Income tax returns subject to review by taxing authorities include 2008, 2009 and 2010.

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,	
	2011	2010
Numerator:		
Net income	$ 8,347,601	$ 9,308,787
Denominator:		
Weighted-average common shares, basic	23,990,734	23,381,676
Dilutive effect of stock options	469,557	33,773
Weighted-average common shares, diluted	24,460,291	23,415,449
Net income per share, basic	$ 0.35	$ 0.40
Net income per share, diluted	$ 0.34	$ 0.40

As of December 31, 2011, total outstanding options are 1,848,491. Options not included above are anti-dilutive. See Note 17 for information regarding the Company's outstanding options.

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.

TherapeuticsMD Common Stock	Cost	Appreciation	Discount	Fair Value
2,631,579 shares	$ 1,000,000	$ 2,947,368	$ (1,184,000)	$ 2,763,368

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 September 2011, the FASB issued Accounting Standards Update ("ASU") 2011-08, Intangibles—Goodwill and Other (Topic 350), Testing—Goodwill for Impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is determined through the qualitative assessment that a reporting unit's fair value is more likely than not greater than its carrying value, the remaining impairment steps would be unnecessary. The new standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. The Company adopted the provisions of this standard effective September 30, 2011. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220), Presentation of Comprehensive Income. In December 2011, ASU 2011-12, Comprehensive Income (Topic 220), Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income Presentation of Comprehensive Income in Accounting Standards Update No. 2011-05 indefinitely defers certain disclosures required by 2011-5. The new ASU, as amended, revises the manner in which entities present comprehensive income in their financial statements. The new guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. Under the two-statement approach, the first statement would include components of net income, which is consistent with the income statement format used today, and the second statement would include components of other comprehensive income ("OCI").

In May 2011, the FASB, together with the International Accounting Standards Board, jointly issued ASU 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS." The adoption of ASU 2011-04 gives fair value the same meaning between U.S. GAAP and International Financial Reporting Standards ("IFRS"), and improves consistency of disclosures relating to fair value. The provisions of ASU 2011-04 will be effective for years beginning after December 15, 2011. Public entities will begin adoption in the first interim period beginning after December 15, 2011. Changes as a result of this new standard are to be applied prospectively. However, changes in valuation techniques shall be treated as changes in accounting estimates. The adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

In 2010, the FASB issued an Accounting Standard Update ASU 2010-27, "Other Expenses (ASC Topic 720), Fees Paid to the Federal Government by Pharmaceutical Manufacturers." This guidance applies to the non-tax deductible annual fee that will be imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs as part of U.S. health care reform. This fee is allocated to companies based on their prior calendar year market share for branded prescription drug sales into these government programs. This guidance clarifies how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by U.S. Health Care Reform. This fee will be recorded as selling, general and administrative expense in the Company's condensed consolidated results of operations and will be amortized on a straight-line basis for the year. This guidance was effective on January 1, 2011. The Company is currently awaiting information from the Internal Revenue Service regarding the calculation of this fee. This fee did not have a material impact on the Company's results of operations for 2011.

In December 2010, the FASB issued ASU 2010-29, “Business Combinations (Accounting Standards Codification (“ASC”) Topic 805), Disclosure of Supplementary Pro Forma Information for Business Combinations.” This amendment expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The adoption of this new guidance did not have a material impact on the Company's consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition, Milestone Method of Revenue Recognition, under ASC No. 605. The new guidance defines specific criteria for evaluating whether the milestone method is appropriate for the purposes of assessing revenue recognition. ASU No. 2010-17 stipulates that consideration tied to the achievement of a milestone may only be recognized if it meets all of the defined criteria for the milestone to be considered substantive. The guidance also requires expanded disclosures about the overall arrangement, the nature of the milestones, the consideration and the assessment of whether the milestones are substantive. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years and interim periods beginning on or after June 15, 2010. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In March 2010, the FASB issued ASU No 2010-12, “Income Taxes (ASC Topic 740), Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts .” This update amends Subtopic 740-10 and adds paragraph 740-10-S99-4 related to SEC staff announcements. In essence, the announcements provide that the two healthcare bills (Health Care and Education Reconciliation Act of 2010, which reconciles the Patient Protection and Affordable Care Act) should be considered together when considering the accounting impact. This update was effective immediately. These health care bills have not had an impact on the Company’s consolidated financial statements.

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

Note 3. Fair Value Measurement

Fair value is defined as the price that would be received to sell 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 prescribed by the accounting literature contains three levels as follows:

Level 1— Quoted prices in active markets for identical assets or liabilities.

Level 2— Observable inputs other than Level 1 prices 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.

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. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

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In addition, ASC 820 - Fair Value Measurements and Disclosures requires the Company to disclose the fair value for financial assets on both a recurring and non-recurring basis.

The carrying value of cash and cash equivalents including restricted cash, accounts receivable, other assets and trade accounts payable approximate fair value due to the short-term nature of these instruments. As of December 31, 2011 and 2010, the Company did not have any funds in overnight repurchase accounts.

The Company has a note receivable of approximately $4,000 at December 31, 2011 which is measured at fair value on a nonrecurring basis. The Company reviews intangible assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. As of December 31, 2011, the Company recognized an impairment charge of $380,000 on 118 acres of undeveloped land in Charleston County, South Carolina based on an updated appraisal.

Note 4. Business Combinations and Other Acquisitions

Acquisition of Macoven

On September 8, 2010, Pernix purchased 100% of the outstanding membership interests of Macoven for an aggregate purchase price of $2,200,000.

Pernix acquired Macoven in order to expand its portfolio to offer generic products to its customers and to enter into collaborative arrangements with third parties to promote generic products. From July 2009 until the closing of Pernix's acquisition of Macoven, Macoven held a non-exclusive license to develop, market and sell authorized generics of Pernix branded products.

Acquisition of CEDAX

On March 24, 2010, the Company completed the acquisition of substantially all of the assets and rights relating to CEDAX, 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 paid in three installments as follows: (i) $1.5 million paid at closing, (ii) $1.5 million paid on May 23, 2010 and (iii) $3.1 million paid on December 20, 2010.

On June 21, 2010, Pernix purchased the remaining 50% ownership interest in Gaine from certain employees of Kiel Laboratories, Inc. As a result of the transaction, Gaine became a wholly-owned subsidiary of Pernix. In consideration for the sellers' 50% ownership interest in Gaine, Pernix paid the sellers as follows: (i) an aggregate of $500,000 in cash, net of adjustments of approximately $173,000, at closing, (ii) an aggregate of $500,000 in cash, net of adjustments of approximately $179,000, on October 31, 2010, and (iii) an aggregate of $1,000,000 in cash on January 31, 2011. The first two installments were adjusted for outstanding royalties and obligations owed at the time of closing. The net purchase price for the remaining non-controlling interest was recorded as a reduction to additional paid-in capital.

In the event a new drug application is approved by the United States Food and Drug Administration (the "FDA") for an antitussive product candidate incorporating the invention claimed in a United States antitussive patent owned by Gaine, Pernix will then be obligated to pay the sellers an aggregate of $10,000,000 in cash or Pernix common stock. Alternatively, upon a transfer of ownership of the patent, Pernix will be obligated to pay the sellers an aggregate amount equal to the greater of (i) $5,000,000, or (ii) fifty percent (50%) of the aggregate purchase price, up to a maximum aggregate amount not to exceed $10,000,000, payable in cash or Pernix common stock at the Company's election. In connection with its formation of the joint venture with SEEK, Pernix granted a subsidiary of the joint venture an exclusive license to all of its theobromine intellectual property, including the antitussive patent owned by Gaine. For additional information, see Note 9 – Investment in Joint Venture.

Note 5. Accounts Receivable

Accounts receivable consist of the following:

	December 31,	
	2011	2010
Trade accounts receivable	$18,844,320	$13,383,021
Less allowance for customer discounts	(393,174)	(305,917)
Total trade receivables	18,451,146	13,077,104
Other receivables	4,000	2,203
Receivables from third parties – collaboration arrangements	2,146,214	1,678,933
Total account receivables	$20,601,360	$14,758,240

The Company typically requires our customers to remit payments within the first 30 for brand purchases or 60 to 120 days for generic purchases (depending on the customer and the products purchased). The Company offers wholesale distributors a prompt payment discount, which is typically 2%, as an incentive to remit payment within these deadlines. Accounts receivable are stated net of the estimated prompt pay discount. The Company's management evaluates accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. As of December 31, 2011 and 2010, no receivables were outstanding for longer than the agreed upon payment terms. The net amount of accounts receivable was considered collectible and no allowance for doubtful accounts was recorded.

Note 6. Inventory

Inventories consist of the following:

	December 31,	
	2011	2010
Purchased finished goods	$ 5,848,295	$ 4,145,734
Purchased raw materials	412,867	—
	$ 6,261,162	$ 4,145,734

The Company does not currently manufacture any products. The raw materials the Company has in inventory are provided to certain of its manufacturers to utilize in the manufacture of its products and, from time to time, are sold to other companies to utilize in their own products. Sample inventory of approximately $627,000 was expensed to SG&A when received.

Note 7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2011	2010
Prepaid expenses	$ 885,558	$ 759,559
Deposits on inventory and prepaid royalties	1,046,691	1,020,541
Prepaid contracts	208,333	—
Other current assets	3,621	113,962
Total	$ 2,144,203	$ 1,930,062

Note 8. Property, Plant & Equipment

	December 31, 2011	2010
Land	$ 572,342	$ 952,342
Buildings	35,421	25,485
Equipment	444,959	319,016
Furniture and fixtures	92,715	52,998
Computer software and website	88,500	88,500
	1,233,937	1,438,341
Less accumulated depreciation	(321,989)	(224,491)
	$ 911,948	$ 1,213,850

Depreciation expense amounted to approximately $97,000 and $61,000 for the years ended December 31, 2011 and 2010, respectively.

In March 2010, the Company acquired land and furniture and fixtures valued at approximately $952,000 and $12,000, respectively, in the merger with GTA. The $572,000 represents the estimated fair value of 118.67 acres of undeveloped land in Charleston County, South Carolina after the Company recorded an impairment charge of $380,000 at December 31, 2011 based on the current appraised value of the land.

NoteInvestment in Joint Venture 9.

On December 17, 2010, the Company entered into a Joint Venture Agreement (the “JV Agreement”) with SEEK, a United Kingdom drug discovery group, to form a joint venture structured as a private company limited by shares incorporated in the United Kingdom (the “JV”). The purpose of the JV is to develop and obtain regulatory approval in both Europe and the United States for BC 1036, an antitussive cough suppressant pharmaceutical product utilizing theobromine as an active ingredient. Pernix contributed approximately $1.5 million to the JV, in consideration for 50% of the voting interest and approximately 46% of the total economic interest in the JV.

The JV Agreement contemplates that shareholders will contribute additional capital to the JV from time to time to fund the development and commercialization of BC 1036, as the JV’s board of directors may determine. In the event any shareholder elects not to contribute its pro rata share of the aggregate amount of additional capital sought to be raised, such shareholder will experience a dilution of its equity position in the JV.

The JV Agreement grants the Company the ability to appoint two of the four members of the JV’s board of directors. All decisions of the JV’s board of directors require the affirmative consent of a majority of its members.

As contemplated by the JV Agreement, the Company granted an exclusive license to all of its theobromine intellectual property to a subsidiary of the JV. Under its license arrangement, Pernix may fund the development costs to seek approval for a new drug application from the FDA for a suspension product utilizing theobromine for pediatric use. To the extent these costs are funded by Pernix and a new drug application is approved by the FDA, Pernix will receive an exclusive license to market and distribute the suspension product in the United States for pediatric use, subject to the payment of certain royalties on sales of such product to the licensor.

In March 2011, Pernix and SEEK appointed a financial advisor in connection with an auction of theobromine (BC 1036). While the JV has not received an offer to purchase the theobromine assets that was acceptable by its board of directors, the JV continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of this asset. The JV expects to initiate its pivotal Phase III trial in the European Union in 2012, and is currently evaluating over-the-counter strategies in certain countries, including the United States. On September 26, 2011, the Company funded an additional $1.0 million in cash to the JV for continuing operations. The Company has funded a total of $2.5 million since the formation of the joint venture.

Below is the condensed balance sheet of the JV prepared in accordance with GAAP:

Condensed Balance Sheet as of: (unaudited) (in thousands)	December 31, 2011	2010
Cash and other current assets	$ 1,512	$ 1,332
Intellectual property and other rights (including capitalized development costs)	1,719	1,676
Total assets	$ 3,231	$ 3,008
Equity	$ 3,231	$ 3,008
Loss from operations of the joint venture with SEEK	$ 814	$ —

Note 10. Intangible Assets

Intangible assets consist of the following:

	Life	December 31 , 2011	2010
Patents	12 - 15 years	$ 1,442,000	$ 1,442,000
Brand – CEDAX	8 years	3,887,000	3,887,000
Product license	1 year	120,000	—
Non-compete and supplier contract – Macoven	3 years	5,194,571	5,194,571
Trademark rights – BROVEX	Indefinite	238,758	238,758
Non-compete- Ubiquinone	2 years	—	250,000
Goodwill	Indefinite	1,406,591	1,406,591
		12,288,920	12,418,920
Accumulated amortization		(3,412,416)	(1,457,020)
		$ 8,876,504	$ 10,961,900

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

	Amount
2012	$ 1,791,000
2013	1,055,000
2014	1,055,000
2015	1,055,000
2016	1,055,000
Thereafter	1,220,000
	$ 7,231,000

Amortization expense is approximately $2,205,000 and $1,178,000 for the years ended December 31, 2011 and 2010, respectively.

Patents

On August 24, 2010, the Company and Kiel Laboratories, Inc. ("Kiel") entered into a patent purchase agreement whereby the Company acquired Kiel assets relating to its TCT control delivery technology, which included three United States patents, certain trademarks and related intellectual property and existing inventory. Prior to the acquisition, the Company licensed the right to utilize the TCT technology in its ALDEX and PEDIATEX brand product lines from Kiel in consideration for certain royalty payments. The TCT technology is also utilized in the Pyril, Pyril DM and Trip PSE generic product lines acquired in the acquisition of Macoven.

Note 11. Accrued Allowances

Accrued allowances consist of the following:

	December 31, 2011	2010
Accrued returns allowance	$ 5,712,500	$ 4,313,000
Accrued price adjustments	5,450,619	1,743,674
Accrued government program rebates	5,843,290	4,432,000
Total	$ 17,006,409	$ 10,488,674

Note 12. Contracts Payable

Contracts payable consist of the following:

	December 31, 2011	2010
Stock repurchase contract with related party (see Note 14)	$ 1,200,000	$ 1,200,000
Gaine acquisition	—	1,000,000
Product license contract	90,000	—
Total contracts payable – short term	$ 1,290,000	$ 2,200,000
Stock repurchase contract with related party (see Note 14) – long term	$ 600,000	$ 1,800,000

Note 13. Lines of Credit

On September 8, 2010, the Company entered into a loan agreement with Regions Bank. The loan agreement provides for a $5 million secured revolving line of credit (the “RLOC”) and a $5 million secured guidance line of credit (the “GLOC” and together with the RLOC, the “Loans”). The Loans are secured by a lien on substantially all the Company's assets. The RLOC may be used to fund working capital needs and the GLOC may be used for acquisitions approved by Regions. The Loans mature on September 8, 2012 and bear interest at LIBOR plus 2.5%. Any unused amounts under the loan agreement is subject to a 0.25% availability fee.

The loan agreement contains customary restrictive covenants and events of default, including breaches of representations and warranties and breaches of covenants. As of December 31, 2011, the Company was in compliance with all financial covenants.

In consideration for Regions entering into the Loan Agreement, the Company granted Regions a first priority security interest in substantially all of its assets except for all patents owned by Pernix as well as certain trademarks. Regions is also entitled to a first priority security interest on any intellectual property assets acquired with proceeds from the GLOC.

The outstanding balances under the GLOC and the RLOC were $5,000,000 and $1,000,000, respectively, as of December 31, 2011, and $5,000,000 and $0, respectively, as of December 31, 2010.

NoteStockholders' Equity
14.

Stock Repurchase Authorization

On May 12, 2010, the Company's board of directors authorized the repurchase of up to $5,000,000 in shares of the Company's common stock. Stock repurchases under this authorization may be made through open market or privately negotiated transactions at times and in such amounts as management deems appropriate. The timing and actual number of shares repurchased will depend on a variety of factors, including price, cash balances, general business and market conditions, the dilutive effects of share-based incentive plans, alternative investment opportunities and working capital needs. The stock repurchase authorization does not have an expiration date and may be limited or terminated by the board of directors at any time without prior notice. The purchases will be funded from available cash balances and repurchased shares will be designated as treasury shares. Each individual stock repurchase will be subject to board approval.

On September 10, 2010, Pernix entered into an agreement, pursuant to the above stock repurchase authorization, to purchase 2,000,000 shares of its common stock from an employee of Pernix, at $1.80 per share. The aggregate purchase price of $3,600,000 will be paid in equal quarterly payments of $300,000 over three years.

In addition to the 2,000,000 shares acquired from the employee discussed above, the Company repurchased 70,867 shares of the Company's common stock from June 2010 through November 2010 in open market purchases for an aggregate price of approximately $250,000.

As of December 31, 2011, after consideration of the repurchase of 2,070,867 shares discussed above, there remained $1,150,000 of the authorized amount to repurchase shares of the Company's outstanding common stock under the repurchase program.

NoteConcentrations
15.

The Company's customers consist of drug wholesalers, retail drug stores, mass merchandiser and grocery store pharmacies in the United States. The Company primarily sells products directly to drug wholesalers, which in turn, distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. The following tables list all of the Company's customers that individually comprise greater than 10% of total gross product sales (before gross to net deductions) and their aggregate percentage of the Company's total gross product sales for the years ended December 31, 2011 and 2010, and all customers that comprise more than 10% of total accounts receivable and such customers' aggregate percentage of the Company's total accounts receivable as of the years ended December 31, 2011 and 2010:

Gross Product Sales	For the years ended December 31,	
	2011	2010
Cardinal Health, Inc.	37%	43%
McKesson Corporation	23%	29%
AmerisourceBergen Drug Corporation	11%	8%
Morris & Dickson	13%	13%
Total	84%	93%

Accounts Receivable	As of December 31,	
	2011	2010
Cardinal Health, Inc.	30%	50%
McKesson Corporation	32%	27%
Morris & Dickson	5%	11%
Total	67%	88%

Note 16. Other Revenue Sharing Arrangements

The Company enters into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities might include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the product. Revenues related to products sold by the Company pursuant to these arrangements are included in product sales, while other sources of revenue such as royalties and profit share receipts are included in collaboration, royalty and other revenue as further discussed below. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item.

Co-promotion Agreements

The Company seeks to enter into co-promotion agreements to enhance the promotional efforts and sales of products. The Company may enter into co-promotion agreements whereby it obtains rights to market other parties' products in return for certain commissions or percentages of revenue on the sales Pernix generates. Alternatively, Pernix may enter into co-promotion agreements with respect to its products whereby it grants another party certain rights to market or otherwise promote one or more of its products. Typically, the Company will enter into this type of co-promotion arrangement when a particular product is not aligned with its product focus or it lacks sufficient sales force representation in a particular geographic area. Co-promotion revenue is included in net revenues. Expense from co-promotion agreements is included in cost of goods sold.

In addition to the co-promotion agreement that the Company has with ParaPRO, the Company also has a Supply and Distribution Agreement. The cost that the Company pays for NATROBA pursuant to the Supply and Distribution Agreement with ParaPRO 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 on product sales. The impact on gross profit margin of the NATROBA cost of sales is reflected in the table below for the latter half of 2011 since NATROBA was launched in August 2011.

	Year Ended December 31,		Six Months Ended December 31(2),	
	2011(1)	2010	2011(1)	2010
Pernix Consolidated Gross Margin - including Natroba	69%	N/A	64%	N/A
Pernix Consolidated Gross Margin - excluding Natroba	78%	84%	77%	82%

1Excludes approximately $2,001,000 and $1,183,000 in write offs of obsolete, expired and/or donated product inventory for the year and six months ended December 31, 2011, respectively.

2The six-month period (third and fourth quarters of 2011) is presented for comparative purposes due to the fact that NATROBA was launched during the third quarter of 2011.

Note 17. Employee Compensation and Benefits

The Company participates in a 401(k) plan (the "Plan"), which covers substantially all full-time employees. The Plan is funded by employee contributions and discretionary matching contributions determined by management. At the Company's discretion, it may match up to 100 percent of each employee's contribution, not to exceed the first 6 percent of the employee's individual salary. There is a six-month waiting period from date of hire to participate in the Plan. Employees are 100 percent vested in employee and employer contributions. Contribution expense was approximately $292,000 and $216,000 for the years ended December 31, 2011 and 2010, respectively.

Stock Options

The Company's 2009 Stock Incentive Plan (the "2009 Plan") was approved concurrent with its merger with GTA on March 9, 2010. At the 2011 Annual Meeting held on June 23, 2011, the Company's stockholders approved the proposal to amend and restate the 2009 Plan in order to (1) increase the number of issuable shares from 3,683,787 to 5,000,000, (2) increase the number of shares issuable as full-value awards from 1,500,000 to 3,000,000, (3) add a maximum dollar value limitation on certain awards to any one person in a given year, and (4) extend the term of the 2009 Plan to June 23, 2021, which is 10 years after the 2011 Annual Meeting.

As amended and restated, the maximum number of shares that can be offered under this plan is 5,000,000. Incentives may be granted under the 2009 Plan to eligible participants in the form of (a) incentive stock options, (b) non-qualified stock options, (c) restricted stock, (d) restricted stock units ("RSU"), (e) stock appreciation rights ("SARs") and (f) other stock-based awards.

As of December 31, 2011, approximately 233,333 options remain outstanding that were issued to current officers and directors under former incentive plans of GTA. The remaining average contractual life of these options is approximately fourteen months.

The Company currently uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company's expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

During the year ended December 31, 2011, 431,000 options were issued under the 2009 Stock Incentive Plan for an average exercise price of $7.37. All of the options expire ten years from the date of the grant.

During the year ended December 31, 2011, 27,842 options were exercised; 10,000 options previously granted to non-employee former board members expired and 30,667 options previously granted to former employees were cancelled.

The following table shows the weighted average of the assumptions used to value stock options on the date of grant (excluding the ParaPRO options), as follows:

	Year Ended December 31,			
	2011		2010	
Expected stock price volatility - range	69.2 - 77.4	%	69.3 - 76.3	%
Estimated dividend yield	0.00	%	0.00	%

Risk-free interest rate	1.45	%	2.51	%
Expected life of option (in years)	6.02		6.00	
Weighted-average grant-date fair value per share	$ 4.68		$ 2.42	

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for the stock options is based on historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of the stock options granted was estimated based on the historical exercise patterns over the option lives.

The following table shows the option activity, described above, during the year ended December 31, 2011:

Option Shares	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2010	1,026,000	$ 3.81		
Granted(1)	891,000	5.45		
Exercised	(27,842)	2.81		
Cancelled	(30,667)	4.04		
Expired	(10,000)	15.7		
Outstanding at December 31, 2011	1,848,491	$ 4.55	8.0	$ 8,742,755
Vested and exercisable, end of period	480,154	$ 3.73	4.9	$ 2,655,702

(1)Includes 460,000 options granted to ParaPRO, LLC on August 3, 2011 at an exercise price of $3.65 , that vest over seven years, pursuant to the commercial terms of the co-promotion arrangement between the Company and ParaPRO for the marketing and sale of NATROBA.

The following table shows the details by range of exercise price for the total options outstanding at December 31, 2011:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Shares	Remaining Contractual Life (years)	Shares	Price	
1.94	20,000	1.2	20,000	$	$1.94
2.20	30,833	1.2	30,833		2.20
3.31 - $3.98 (1)	1,233,158	8.8	289,321		3.72
4.20	137,500	1.2	137,500		4.20
6.10	197,000	9.6	-		-
7.90	40,000	9.0	-		-
8.20	150,000	9.9	-		-
10.14	40,000	9.2	2,500		-
	1,848,491	8.1	480,154	$	$3.73

(1)Includes 460,000 options granted to ParaPRO, LLC on August 3, 2011, that vest over seven years, pursuant to the commercial terms of the co-promotion arrangement between the Company and ParaPRO for the marketing and sale of

NATROBA. For additional information, see Note 12.

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As of December 31, 2011, there was approximately $2,429,000 of unrecognized compensation cost related to unvested stock options issued to employees and/or directors of Pernix, which is expected to be recognized ratably over a weighted-average period of 2.2 years.

Restricted Stock

During the year ended December 31, 2011, 60,000 restricted common shares were issued, all in the first three months of the period. With the exception of changes in the vesting of certain restricted shares described below, the restricted shares will vest ratably over three years from the date they were issued. As of December 31, 2011, 160,000 restricted common shares have been issued, 39,998 of which have vested. Approximately $532,000 of total unrecognized compensation cost related to unvested restricted stock is expected to be recognized over a weighted-average period of 1.67 years.

On August 29, 2011, Jan H. Loeb informed the Company of his resignation from the Company's Board of Directors, effective August 31, 2011. In connection with his resignation, the Company entered into a consulting agreement with Mr. Loeb pursuant to which all of Mr. Loeb's 26,667 outstanding options issued under the Company's equity incentive plans that were not yet exercisable became exercisable over a twelve month period (with one-fourth of such options becoming exercisable on the first day of each fiscal quarter beginning with the fourth quarter of 2011), and all outstanding shares of restricted stock held by Mr. Loeb shall be fully vested and free of restriction over a twelve-month period (with one-fourth of such restricted shares becoming vested and free of restriction on the first day of each fiscal quarter beginning with the fourth quarter of 2011).

Employee Stock Purchase Plan

Effective July 22, 2010, the Company adopted the 2010 Employee Stock Purchase Plan to provide substantially all employees an opportunity to purchase shares of its common stock through payroll deduction, up to 10% of eligible compensation with a $25,000 maximum deferral. Semi-annually, participant account balances will be used to purchase shares of stock at the lesser of 85% of the fair market value of shares at the beginning or ending of such six-month period. The Employee Stock Purchase Plan expires on July 22, 2020. A total of 1,000,000 shares will be available for purchase under this plan. For the year ended December 31, 2011, 33,568 shares were issued under this plan. Compensation expense related to the Employee Stock Purchase Plan and included in the table below for the years ended December 31, 2011 and 2010 was approximately $101,000 and $0, respectively.

Stock-Based Compensation Expense

The following table shows the approximate amount of total stock-based compensation expense recognized for employees and directors:

	Years Ended December 31,	
	2011	2010
Employees	$ 834,000	$ 287,000
Non-employees/Directors	449,000	177,000
Total	$ 1,283,000	$ 464,000

Note 18. Income Taxes

Effective January 1, 2010, Pernix filed an election to terminate its S Corporation status. Accordingly, it was required to record deferred taxes on its temporary differences at the date of termination. The resulting deferred tax asset recorded as a tax benefit was approximately $1,839,000.

As a result of the merger, GTA experienced a change in ownership pursuant to Internal Revenue Code Section 382, resulting in a severe limitation on the use of its net operating loss carryovers in future years. The expected tax benefit of the GTA net operating loss carryovers has been recorded as a deferred tax asset based on the maximum amount of losses that can be utilized in future years. The net tax benefit as of the date of the merger was approximately $779,000. The tax benefit of losses in excess of the maximum amount that may be used in future years has been eliminated.

The income tax provision consisted of the income tax expense (benefits) for the years ended December 31, 2011 and 2010, as presented in the table below. The tax expense for the year ended December 31, 2010 is shown net of a one-time benefit associated with the recognition of deferred tax assets arising upon termination of the S election.

The components of the provision for income taxes are as follows for the years ending December 31, 2011 and 2010:

	Year Ended December 31,	
	2011	2010
Current:		
Federal	$ 6,566,000	$ 3,765,000
State	970,000	776,000
	7,536,000	4,541,000
Deferred Provision:		
Federal	(2,551,000)	(2,807,000)
State	(396,000)	(248,000)
	(2,947,000)	(3,055,000)
	$ 4,589,000	$ 1,486,000

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

	Year Ended December 31,	
	2011	2010
Deferred tax assets:		
Accounts receivable	$ 149,000	$ 118,000
Accruals	3,831,000	2,268,000
Stock awards	515,000	42,000
Investment in joint venture with SEEK	312,000	—
NOL carryovers	493,000	649,000
Differences in carry value of property and equipment	66,000	—
Gross deferred tax assets	5,366,000	3,077,000
Deferred tax liabilities:		
Differences in carrying value of property and equipment	$ —	$ (33,000)
Other	(99,000)	(90,000)
Intangibles	(901,000)	(1,535,000)
Investments	(674,000)	—
Gross deferred tax liability	(1,674,000)	(1,658,000)
Net deferred tax asset/(liability)	3,692,000	1,419,000
Included in consolidated balance sheet:		
Deferred income tax assets/deferred income tax liabilities–current	4,552,000	2,494,000
Deferred income tax assets/deferred income tax liabilities–long-term	(860,000)	(1,075,000)
Net deferred tax asset	$ 3,692,000	$ 1,419,000

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods that the deferred tax assets are deductible, management believes that it is more likely than not that the Company will realize the benefits of these deductible differences. The amount of the deferred tax assets at the Company level are considered realizable based on the reversal of deferred tax liabilities and the Company’s projected levels of taxable income.

The effective income tax rate from continuing operations is different from the federal statutory rate for the years ended December 31, 2011 and 2010 for the following reasons:

	December 31, 2011	2010
Expected taxes at statutory rates	35.0%	35.0%
State taxes, net of federal tax benefit	2.9%	3.2%
Establishment of deferred tax asset due to tax status change	—	(17.0)%
Release of valuation allowance	—	(7.2)%
Other	(2.4)%	(0.2)%
	35.5%	13.8%

Note 19 Commitments and Contingencies

Letter of Credit

The Company was required to provide a letter of credit to one of its manufacturers as security for its performance of payment in the amount of $500,000. On June 13, 2011, this letter of credit was released by the manufacturer due to proven payment history. These funds were transferred from restricted cash to cash.

Purchase Commitments

Pursuant to the Supply and Distribution Agreement between the Company and ParaPRO, the Company has purchase commitments for NATROBA of approximately $33,830,000 during year 1, $51,740,000 during year 2 and $75,620,000 during year 3 of the supply and distribution agreement in order to retain its exclusive co-promotion rights, with the purchase commitment obligations commencing on August 3, 2011. The Company purchased approximately $10,671,000 under the agreement for the year ended December 31, 2011. The Supply and Distribution Agreement may be terminated pursuant to certain terms in conditions, including but not limited to, the failure of the parties to come to agreement on adjusted dispensed product minimums.

Stock Options Issued in Exchange for Services

Pursuant to an agreement for support services entered into between the Company and ParaPRO on August 27, 2010 which commenced upon the launch of NATROBA on August 3, 2011, 460,000 stock options were issued to ParaPRO. The options have an exercise price of $3.65 which is the closing price of the Company's stock as of the date of the support services agreement. The options are exercisable in seven installments in the following amounts: (i) 30,000 on August 1, 2012; (ii) 40,000 on August 1, 2013; (iii) 50,000 on August 1, 2014; (iv) 60,000 on August 1, 2015; (v) 70,000 on August 1, 2016; (vi) 90,000 on August 1, 2017; and (vii) 120,000 on August 1, 2018. The options are exercisable for a period of five years from the date each becomes exercisable and are valued at approximately $2,841,000. These options were granted in a private offering under Rule 4(2) of the Securities Act of 1933. As of December 31, 2011, there was approximately $2,528,000 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized ratably over a weighted-average period of 4.7 years.

Leases

The Company leases it office facilities in The Woodlands, Texas under a lease with an unrelated third party. The term of the current lease expires on May 8, 2015. Pursuant to this lease, the Company pays rent of approximately $15,000 per month with stated annual escalators and shares in 2.49% of the excess operating expenses of the building.

The Company leases certain of its office and warehouse facilities under triple net leases with an entity owned by the former stockholders of PTI. The term of each lease is month to month and may be terminated by either party without penalty. Pursuant to these leases, the Company pays rent of approximately $5,100 and $3,000 per month for the Texas and Louisiana facilities, respectively, with an annual CPI escalator. The Company believes these amounts reflect market rates that are as favorable to the Company as could be obtained with unrelated third parties.

The Company leases it office facilities in South Carolina under a lease with an unrelated third party. The term of the current lease expires April 1, 2013. Pursuant to this lease, the Company pays rent of approximately $2,300 per month with annual escalators of 10%.

The Company leases certain equipment under operating leases pursuant to which future expected payments are approximately $7,000 in 2012, $6,000 in 2013 and $5,000 thereafter.

Acquisitions, License and Co-promotion Agreements

The Company has entered into certain revenue sharing arrangements that require payments based on a specified percentage of net sales or a specified cost per unit sold. For the years ended December 31, 2011 and 2010, we recognized approximately $2,427,000 and $458,000, respectively, in expense included in cost of goods sold from payments pursuant to co-promotion and other revenue sharing arrangements.

Other Commitments

From time to time in the ordinary course of business, the Company enters into agreements regarding royalty payments and/or receipts. The total royalty revenue recognized for the fiscal year ended December 31, 2011 and 2010 is approximately $247,000 and $94,000, respectively. The total royalty expense recognized for the fiscal year ended December 31, 2011 and 2010 was approximately $632,000 and $832,000 respectively.

As of December 31, 2011, the Company no longer has any active royalty agreements but will continue to have minimal royalty expense from the amortization of certain prepaid royalties as certain products are sold.

Uninsured Liabilities

The Company is exposed to various risks of losses related to torts; theft of, damage to, and destruction of assets; errors and omissions; injuries to employees; and natural disasters for which the Company maintains a general liability insurance with limits and deductibles that management believes prudent in light of the exposure of the Company to loss and the cost of the insurance.

The Company is subject to various claims and litigation arising in the ordinary course of business. In the opinion of management, the outcome of such matters will not have a material effect on the consolidated financial position or results of operations of the Company.

For further details on commitments and contingencies, see Subsequent Events, Note 20

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Note 20. Subsequent Events

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 7.5 mg; and L-methylfolate calcium 15 mg. While formal discovery has not yet commenced, the Company believes it has meritorious defenses to the substantive allegations asserted and intends to aggressively defend itself in these proceedings.

License of Gastroenterology Product. In January 2012, the Company entered into a license and supply agreement with a private company for a new FDA-approved prescription product to treat gastroenterology disease. Under the terms of the agreement, the Company obtained exclusive marketing rights to this product in the United States. The Company paid an up-front license fee of $2.0 million and expects to pay an additional fee of $2.0 million upon commercial launch of the product. In addition to these license fees, the agreement calls for the Company to pay royalties and milestone payments based on the sales of the product. VelocityHealth Securities, Inc. acted as the exclusive financial advisor to Pernix on this transaction and was paid a fee of $400,000.

Controlled Equity Offering. On February 10, 2012, the Company entered into a controlled equity offering sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $25,000,000 from time to time through Cantor, acting as agent, but in no event more than 5,000,000 shares of common stock. Sales of the Company's common stock through Cantor, if any, will be made on the NYSE Amex by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by Cantor and the Company. Cantor will use its commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company pays Cantor a commission rate of 3.0% of the gross sales price per share of any common stock sold through Cantor as agent under the Sales Agreement. The Company has also reimbursed Cantor for certain expenses incurred in connection with entering into the Sales Agreement and has provided Cantor with customary indemnification rights. The Company will use the proceeds of this financing to provide funding for future acquisitions and for general corporate purposes. As of March 23, 2012, 264,000 shares have been sold pursuant to the controlled equity offering for aggregate net proceeds to the Company of approximately $2,486,000.

Development and License Agreement for Pediatric Product. In March 2012, the Company 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 Pernix will pay the costs related to the development of the product.

Amendment to Employment Agreement. On March 23, 2012, the Company, Macoven and John McMahon, Macoven's Vice President of Product Sales, entered into an amendment to Mr. McMahon's amended and restated employment agreement pursuant to which all provisions relating to quarterly bonuses and a bonus pool were removed. The amendment also provided for the issuance of 165,000 shares of restricted stock pursuant to the Company's 2009 Amended and Restated Stock Incentive Plan with certain volume limitations on the sale of such shares after vesting.

Also on March 23, 2012, the Company granted Michael Venters, Macoven's Executive Vice President of Corporate Development, 85,000 shares of restricted stock pursuant to the Company's 2009 Amended and Restated Stock Incentive Plan with the same volume limitations as Mr. McMahon. Both grants vest in equal installments on each of

the first three anniversaries of the date of grant.

Director Compensation. On March 22, 2012, each non-executive director received a grant of options to purchase 10,000 shares of our common stock and a grant of 10,000 shares of restricted stock. The options and restricted stock each vest on-third per year on the first three anniversaries of the grant date. The options were granted at the market price of $9.02, the closing market price on March 21, 2012. In addition, our Board approved a $5,000 increase in the annual cash compensation of the non-executive Chairman; otherwise, the compensation program was unchanged.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the “Act”). The rules refer to the controls and other procedures designed to ensure that information required to be disclosed in reports that we file or submit under the Act is (1) recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms and (2) accumulated and communicated to its management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As of December 31, 2010, management, including the CEO and CFO, performed an evaluation of the effectiveness of our disclosure controls and procedures. Based on that evaluation, management, including the CEO and CFO, concluded that as of December 31, 2010, our disclosure controls and procedures were effective.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Any evaluation or projection of effectiveness to future periods is also subject to risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this assessment, management has concluded that, as of December 31, 2010, our internal control over financial reporting was effective.

Based on the most recent evaluation, our management has concluded that no change in its internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, its internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

In choosing our directors, we have sought persons with the highest personal and professional ethics, integrity, and values, who can commit themselves to representing the long-term interests of our stockholders. Our directors must also have an inquisitive and objective perspective, practical wisdom, and mature judgment. Our directors must be willing to devote sufficient time to carrying out their duties and responsibilities effectively and should be committed to serve on our Board of Directors (the "Board") for an extended period of time. In addition to these attributes, each of our directors has a strong and unique background and experience which led us to conclude that he should serve as a director of our Company. These qualifications are set forth below in each director's biography. Additionally, in determining the composition of our Board, we consider the director independence and committee requirements of NYSE Amex rules and all legal requirements.

The following table sets forth information regarding individuals who currently serve as our executive officers and directors. The age of each individual in the table below is as of December 31, 2011. 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. Our Board currently consists of five members, all of whom are elected annually to the Board.

Name	Age	Position(s)
Michael C. Pearce	50	Chairman of the Board
Cooper C. Collins	32	President, Chief Executive Officer and Director
David P. Becker	45	Chief Financial Officer
Charles S. Hrushka	60	Vice President of Sales and Marketing
Anthem H. Blanchard	32	Director
Steven A. Elms	52	Director
James E. Smith	59	Director

Michael C. Pearce currently serves as a director and Chairman of the Board. He is a private investor with emphasis on the cleantech and healthcare industries. Prior to the merger between Pernix and GTA, Mr. Pearce previously served as a director of GTA since September 17, 2007 and Chairman since December 17, 2007. From his appointment as Chairman until the consummation of the merger between GTA and Pernix on March 9, 2010, Mr. Pearce served as GTA's Chief Executive Officer and President. Over the course of twenty-five years, he has been employed in various technology industry management positions. From late 1999 through 2001, he served as Chief Executive Officer of iEntertainment Network during a corporate restructuring. From 1996 to 1998, he served as Senior Vice President of Sales and Marketing of publicly-traded VocalTec Communications, returning in 1999 in a consulting capacity to its chairman on matters pertaining to strategic alternatives, business development, and mergers and acquisitions. From 1983 to 1996, he was employed in various technology industry management positions, including Senior Vice President of Sales and Marketing at Ventana Communications, a subsidiary of Thomson Corporation; Vice President of Sales at Librex Computer Systems, a subsidiary of Nippon Steel; and National Sales Manager at Hyundai Electronics America. From 1979 to 1983, he attended Southern Methodist University. Mr. Pearce has served on the board of directors of Reliability, Inc., Swiss Precision Corporation, and AVP, Inc., and he currently serves on the board of Spatializer Audio Laboratories, Inc.

Relevant Experience:

- Public company management
- Strategic planning
- Business development

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 2002. 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.

Relevant Experience:

- Operational knowledge of our business
- Sales and marketing knowledge and experience
- Strategic planning

David P. Becker currently serves as Chief Financial Officer. Prior to his appointment as the Company'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.

Charles S. ("Chuck") Hrushka was appointed Vice President of Sales and Marketing December 5, 2012. Prior to joining the Company, Mr. Hrushka served as a senior consultant for Giles & Associates Consultancy, offering strategic and business development consulting services to the pharmaceutical industry, prior to his appointment as the Company's Vice President of Sales & Marketing. From 2007 to 2009, Mr. Hrushka served as Vice President of Marketing of Shionogi Pharma, Inc. (formerly Sciele Pharma, Inc.). From 2005 to 2007, Mr. Hrushka served as Vice President of Marketing of Sucampo Pharmaceuticals, Inc. Mr. Hrushka has over twenty five years' experience in the pharmaceutical and biotechnology industries. He holds a bachelor of science in biology from Lynchburg College, and a master's in business administration from Georgia State University.

Anthem Hayek Blanchard has been an independent director of the Company since March 9, 2010 and serves as a member of the Company's Audit and Compensation Committees and as the Chairman of the Company's Nominating Committee. Mr. Blanchard is the founder and CEO of Blanchard Vault, Inc., a U.S.-based online precious metal retailer providing customers with an easy and secure way to buy, hold and sell physical gold and silver bullion insured and stored with Brink's Inc. in Salt Lake City. Prior to Blanchard Vault, Mr. Blanchard served as CEO of nuMetra, Inc., a software manufacturer enabling IPTV service via delivery of broadband across the Internet. From September 2002 through August 2008, Mr. Blanchard served as one of the founding members and the Director of Strategic Development & Marketing of online precious metal retailer and currency provider GoldMoney.com. During his tenure at GoldMoney, Mr. Blanchard identified and served in an advisory role to several entrepreneurs including precious metals expert and Rich Dad author Michael Maloney of GoldSilver.com and author Trace Mayer, J.D. of RunToGold.com. Mr. Blanchard holds a Bachelor of Business Administration in Finance & Accounting from Emory University.

Relevant Experience:

- Emerging company management
- Business development
- Financial expertise

Steven Elms currently serves as an independent director of the Company and also as the Chairman and financial expert of the Audit Committee. He also serves on the Company's Nominating and Compensation Committees. Mr. Elms is currently a Managing Partner at Aisling Capital, a leading private equity fund investing in life science companies. Previously, he was a senior member of the Life Sciences Investment Banking Group of Hambrecht & Quist and was involved in over 60 financing and M&A transactions, which helped clients raise in excess of $3.3 billion in capital. He received an M.B.A. from the Kellogg Graduate School of Management at Northwestern University, and a B.A. in Human Biology from Stanford University.
Relevant Experience:

- Financial expertise
- Public company management
- Audit committee experience

James E. ("Jim") Smith, Jr. currently serves as an independent director of the Company and as Chairman of the Company's Compensation Committee and as a member of the Company's Nominating Committee. Mr. Smith previously served as Chairman of the Board of Pernix from June 2008 until the closing of the merger between Pernix and GTA on March 9, 2010, at which time he became a director of the combined company. Mr. Smith currently serves as managing partner of Stewart Title of Louisiana since 1987. Prior to joining Stewart Title, Mr. Smith founded Smith Law Firm, where he practiced from 1984 to 1987. Before founding the Smith Law Firm in 1984, Mr. Smith was a staff attorney for the Federal Energy Regulatory Commission of the U.S. Department of Energy from 1978 to 1980. From 1980 to 1983, he was Corporate Counsel for T. Smith & Son, Inc. Mr. Smith received his undergraduate degree from Boston College in 1975. He attended Cambridge University in England where he received an L.L.B. in 1978 and earned an L.L.M. in 1980 from George Washington University. Mr. Smith also obtained postgraduate legal training in admiralty law at Tulane University. Mr. Smith practices before the U.S. District Court for the Eastern District of Louisiana, the U.S. Court of Appeals for the Fifth Circuit, the U.S. Tax Court and the Supreme Court of Louisiana. He is a member of the New Orleans Bar Association, Louisiana State Bar Association (sections on Real Estate, Business,

and Corporate Law), American Bar Association (sections on Real Estate, Corporations, Banking and Business Law, and Tax Law), Board of Trustees of the International Association of Gaming Attorneys, and the American Bar Association Committee on Gaming Law. Mr. Smith also serves as a director of various private corporations.
Relevant Experience:

- Legal expertise

- Private company management

- Operational knowledge of our Company

Code of Ethics

We have a written Code of Conduct and Ethics that applies to the directors, officers, and employees of, and consultants and contractors to, Pernix, including our Chief Executive Officer and Chief Financial Officer. The Code of Business Conduct and Ethics is a set of policies on key integrity issues that will encourage representatives of Pernix to act ethically and legally. It includes our policies with respect to conflicts of interest, compliance with laws, insider trading, corporate opportunities, competition and fair dealing, discrimination and harassment, health and safety, record-keeping, confidentiality, protection and proper use of our assets, payments to government personnel and reports to and communications with the SEC and the public. Any waivers of the Code of Ethics for directors or executive officers must be approved by our Board and disclosed in a Form 8-K filed with the SEC within four days of the waiver. The full text of the Code of Ethics can be found under the Corporate Governance tab of our website, www.pernixtx.com.

Corporate Governance

Our bylaws authorize our Board to appoint one or more committees, each consisting of one or more directors. Our Board has established three standing committees: an Audit Committee, a Compensation Committee and a Nominating Committee. Our Board has adopted a charter for each committee, which describes the authority and responsibilities delegated to that committee by the Board. A copy of the Audit Committee Charter can be found under the Corporate Governance tab of our website at www.pernixtx.com.

The Audit Committee

Under its charter, the Audit Committee's responsibilities include:

- the appointment, compensation, retention, evaluation and oversight of the work of our independent registered public accounting firm;

- reviewing the experience and qualifications of the senior members and lead partner of the independent registered public accounting firm;

- reviewing, evaluating and approving the annual engagement proposal of the independent registered public accounting firm;

- the pre-approval of all auditing services and all non-audit services permitted to be performed by the independent registered public accounting firm;

- determining the independence of our independent registered public accounting firm;

- reviewing any audit problems or difficulties the independent registered public accountants may encounter in the course of their audit work.

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- reviewing all proposed "related-party" transactions for potential conflict-of-interest situations;

- reviewing and discussing with management and our independent registered public accounting firm annual audited financial statements, quarterly financial statements, material accounting principles applied in financial reporting and any other release of financial information;

- reviewing and discussing with management our policies with respect to risk assessment and risk management;

- reviewing the integrity, adequacy, and effectiveness of our accounting and financial controls, both internal and external, with the assistance of our independent registered public accounting firm, any internal auditors and accounting personnel;

- discussing with our Chief Executive Officer and Chief Financial Officer the processes involved in, and any material required as a result of, their Annual Report on Form 10-K and Quarterly Report on Form 10-Q certifications regarding the operation of the internal controls of Pernix;

- reviewing reports from management, the independent registered public accountants, counsel, tax advisors or any regulatory agency relating to the status of compliance with laws, regulations, and internal procedures;

- approving and monitoring our compliance with our Code of Business Conduct and Ethics, which covers the conduct and ethical behavior of the directors, officers, and employees of Pernix; and

- establishing procedures for the receipt, retention and treatment, on a confidential basis, of complaints received by Pernix.

Our Audit Committee is also responsible for any audit reports the SEC requires us to include in our proxy statements. Currently, our Audit Committee consists of Messrs. Elms and Blanchard, each of whom is independent under the rules of the NYSE Amex. Each member of our Audit Committee also meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act of 1934, as amended. Mr. Elms was appointed Chairman of the Audit Committee on August 31, 2011 when he replaced Mr. Jan Loeb. None of the members of our Audit Committee has participated in the preparation of our consolidated financial statements or those of our subsidiaries during the past three years, and all are able to read and understand fundamental financial statements and are financially literate under the applicable rules of the NYSE Amex. Our Board has determined that Mr. Elms is an "audit committee financial expert" under SEC rules.

The Compensation Committee

Under its charter, the Compensation Committee's responsibilities include:

- reviewing the compensation practices and policies of Pernix to ensure they provide appropriate motivation for corporate performance and increased stockholder value;

- approving (or recommending, where stockholder approval is required) any adoption, amendment or termination of compensation programs and plans;

- overseeing the administration of our compensation programs and plans, including the determination of the directors and employees who are to receive awards and the terms of those awards;

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- conducting periodic surveys of compensation practices of comparable companies;

- conducting an annual review and approval of compensation and benefits to directors and senior executives;

- reviewing and approving the Company's policies and procedures with respect to expense accounts and perquisites of the executive officers;

- reviewing and approving our corporate goals and objectives for our Chief Executive Officer;

- reviewing the performance of our Chief Executive Officer with regard to such goals and objectives with the independent members of our Board and communicating to our Chief Executive Officer the Board 's evaluation of his performance;

- reviewing and recommending to the Board of Directors the "Compensation Discussion and Analysis " if required to be included, as applicable, in our Annual Report on Form 10-K, annual proxy statement, or any information statement;

- composing the "Compensation Committee Report, " if required to be included in our annual proxy statement;

- reviewing and making recommendations to our Board regarding the directors ' and officers' indemnification and insurance matters; and

- conducting an annual performance evaluation of the Compensation Committee.

The Compensation Committee of the Board of Directors consists of Messrs. Smith, Elms, and Blanchard, each of whom is independent under the rules of the NYSE Amex. The Chairman of the Compensation Committee is Mr. Smith. A copy of the Compensation Committee Charter can be found under the Corporate Governance tab of our website, www.pernixtx.com.

The Nominating Committee

Under its charter, the Nominating Committee's responsibilities include:

- establishing criteria for selecting new directors;

- considering and recruiting candidates to fill new positions on our Board, including any candidate recommended by the stockholders;

- conducting appropriate inquiries to establish a candidate's compliance with the qualification requirements established by the Nominating Committee;

- assessing the contributions of individual directors, including those directors slated for re-election;

- recommending director nominees for approval by our Board;

- evaluating of the performance of our Board as a whole and of the Nominating Committee at least annually; and

- reviewing and making recommendations to our Board with respect to any proposal properly presented by a stockholder for inclusion in our annual proxy statement (which may be referred to any other Board committee as appropriate in light of the subject matter of the proposal).

The Nominating Committee of our Board consists of Messrs. Smith, Blanchard, and Loeb, each of whom is independent under the rules of the NYSE Amex. The Chairman of the Nominating Committee is Mr. Smith.

Nomination Procedures For Appointment of Directors

As of March 23, 2012, we had not effected any material changes to the procedures by which our stockholders may recommend nominees to our board of directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and 10% beneficial owners to file with the SEC reports of ownership and changes in ownership of our equity securities. Based solely on a review of copies of such forms, or written representations that no filings were required, we believe that all such required reports were filed on a timely basis during fiscal year 2011 other than a Form 3 filed by Mr. Elms on February 1, 2012 that was due on September 8, 2011.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

As of December 31, 2011, Pernix had three executive officers, Mr. Collins, Mr. Becker and Mr. Hrushka. Ms. Clifford served as chief financial officer until December 5, 2011 when Mr. Becker was appointed to this position. Mr. Hrushka was appointed Vice President of Sales and Marketing effective December 5, 2011. On September 30, 2010, the Board unanimously approved a change in the office held by Mr. Venters from Executive Vice President of Operations to Vice President of Corporate Development, whereby Mr. Venters ceased being an executive officer of Pernix. Mr. Pearce was an executive officer until March 9, 2010, the date of the merger between Pernix and GTA. The following table sets forth the 2011 and 2010 annual and long-term compensation paid or provided to Pernix's executive officers.

Name and Position (1)	Year	Salary ($)	Bonus (2) ($)	Option Awards (3) ($)	All Other Compensation ($)	Total ($)
Cooper C. Collins	2011	290,000	300,000	—	39,104(4)	629,104
President and Chief Executive Officer	2010	290,000	300,000	—	40,155(4)	630,155
David P. Becker	2011	17,398	—	759,329	750	777,477
Chief Financial Officer	2010	—	—	—	—	—
Tracy S. Clifford	2011	188,000	110,500	65,098	31,820(5)	395,418
Former Chief Financial Officer; Current Controller, Finance Director Secretary and Treasurer	2010	143,060	100,000	181,392	34,187(5)	458,639
Charles S. Hrushka	2011	13,237	—	—	750	13,987
Vice President of Sales and Marketing						

(1) The individuals listed in this table were named executive officers of Pernix as of December 31, 2011 except as otherwise described herein.

(2) Cash bonuses are awarded to Pernix's executive officers to reward commendable performance of specially designated tasks or outstanding performance of assigned responsibilities. Bonuses are discretionary and are not calculated or paid according to a formula or specific time frame or schedule.

(3) These amounts reflect the aggregate grant date fair value of the options granted to the named executive officers, determined using the Black-Scholes option model. See further discussion of these options below under the caption "Awards of Equity Compensation."

(4) "All Other Compensation" in 2011 for Mr. Collins includes (i) auto allowance, (ii) medical and dental insurance coverage, (iii) Company contributions to his 401(k) account and (iv) other miscellaneous items that total less than $5,000. "All Other Compensation" in 2010 for Mr. Collins includes (i) auto allowance, (ii) medical and dental insurance coverage, and (iii) our contributions to his 401(k) account.

(5) "All Other Compensation" in 2011 for Ms. Clifford includes (i) auto allowance, (ii) medical and dental insurance coverage, (iii) Company contributions to her 401(k) account and (iv) other miscellaneous items that total less than $5,000. "All Other Compensation" in 2010 for Ms. Clifford includes (i) auto allowance, (ii) medical and dental

insurance coverage, (iii) our contributions to her 401(k) account, (iv) a non-cash trip incentive, and (v) the pay-out of accrued vacation time in transferring her employment from GTA to Pernix.

Employment Agreements with Executive Officers

Mr. Collins. Pernix entered into a three-year employment agreement with Mr. Collins on June 1, 2008, which was assumed by Pernix in connection with the merger with GTA. Under the agreement, Mr. Collins received an annual base salary of $290,000, and was eligible to receive bonus payments in such amounts as our Board determined. On June 1, 2011, the term of Mr. Collins' employment agreement expired, and he serves as President and Chief Executive Officer on at at-will basis.

Mr. Becker. Pernix entered into an employment letter with Mr. Becker on December 5, 2011 pursuant to which Mr. Becker receives an annual base salary of $230,000, a monthly car allowance, family health benefits and is eligible to receive bonus payments as our Board may determine. Mr. Becker also received a stock option award of 150,000 stock options on his first day of employment. These options vest ratably over three years and expire ten years from the date of issuance. Upon termination without cause, Mr. Becker is eligible to receive severance equivalent to one year of annual salary at his then current rate and the cash equivalent of one year of his health benefits.

Mr. Hrushka. Pernix entered into an employment letter with Mr. Hrushka on December 5, 2011 pursuant to which Mr. Hrushka receives an annual base salary of $175,000, a monthly car allowance, family health benefits and is eligible to receive bonus payments as our Board may determine. Mr. Hrushka was also eligible to receive a stock option award of 50,000 stock options subject to certain terms and conditions which were met on January 20,2012. These options vest ratably over three years and expire ten years from the date of grant. Upon termination without cause, Mr. Hrushka is eligible to receive severance equivalent to one year of annual salary at his then current rate and the cash equivalent of one year of his health benefits.

Change in Control

Our Amended and Restated 2009 Stock Incentive Plan (the "Plan") provides that upon a change in control of our Company, as defined in the Plan or in an incentive agreement, or immediately prior to the closing of a transaction that will result in a change in control if consummated, all outstanding awards ("Incentives") granted pursuant to the Plan shall automatically become fully vested and exercisable, all restrictions or limitations on any Incentives shall lapse, and all performance criteria and other conditions relating to the payment of Incentives shall be deemed to be achieved or waived by the Company without the necessity of action by any person.

In addition, upon a change in control our Compensation Committee of Pernix's Board of Directors will have the authority to take a variety of actions regarding outstanding Incentives. Within certain time periods and under certain conditions, our Committee may:

- require that all outstanding Incentives be exercised by a certain date;

- require the surrender to Pernix of some or all outstanding Incentives in exchange for a stock or cash payment for each incentive equal in value to the per-share change in control value, calculated as described in the Plan, over the exercise or base price;

- make any equitable adjustment to outstanding Incentives as the Committee deems necessary to reflect such change of control; or

- provide that an Incentive shall become an Incentive relating to the number and class of shares of stock or other securities or property (including cash) to which the participant would have been entitled in connection with the change of control transaction if the participant had been a stockholder.

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Outstanding Equity Awards

The following table sets forth information concerning the outstanding equity awards of each of the named executive officers of Pernix as of December 31, 2011. The value of unexercised in-the-money options at December 31, 2011 (the last business day of the year) is based on a value of $9.26 per share, the closing price of our common stock on the NYSE Amex on December 31, 2011.

	Outstanding Equity Awards at December 31, 2011			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option Exercise Price	Option Expiration Date
Cooper Collins	—	—	—	—
President and Chief Executive Officer				
David Becker	—	150,000(1)	8.20	12/05/2021
Chief Financial Officer				
Tracy Clifford	25,000	—	3.80	3/9/2013
Former Chief Financial Officer; Current Controller,	5,000	—	2.20	3/9/2013
Director of Finance, Secretary and Treasurer	25,000	50,000 (2)	3.73	5/12/2020
	—	17,000 (2)	6.10	8/12/2021
Charles Hrushka(3)	—	—	—	—
Vice President of Sales and Marketing				

(1) Mr. Becker was awarded 150,000 options on December 5, 2011, his first day of employment, as described above. These options vest ratably over three years and expire ten years from the date of issuance.

(2) Ms. Clifford was awarded 75,000 options on May 12, 2010 and 17,000 on August 12, 2011, both of which vest ratably over three years and expire ten years from the date of issuance.

(3)Mr. Hrushka was hired on December 5, 2011, but was granted an option to purchase 50,000 shares in January 2012, none of which is currently vested.

Director Compensation

As of December 31, 2011, Pernix had five directors, Mr. Pearce, Mr. Collins, Mr. Blanchard, Mr. Elms and Mr. Smith. The following table sets forth compensation for our directors for fiscal year 2011.

Name and Position	Fees Earned or Paid in Cash ($)	Stock Awards (1) ($)	Option Awards (1) ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Michael C. Pearce	59,879	101,400	69,089	—	—	11,438	241,806
Cooper C. Collins	—	—	—	—	—	—	—
Anthem H. Blanchard	47,177	101,400	69,089	—	—	—	217,666
Jan H. Loeb	44,043	101,400	69,089	—	—	—	214,532
Steven A. Elms	5,916	---	---	---	---	---	5,916
James E. Smith, Jr.	41,371	101,400	69,089	—	—	—	211,860

(1) Reflects the aggregate grant date fair value of equity awards granted in 2011 and calculated in accordance with FASB ASC 718, excluding effect of estimated forfeitures.

On March 11, 2011, each non-executive director received a grant of options to purchase 10,000 shares of our common stock and a grant of 10,000 shares of restricted stock. The options and the restricted stock each vest one-third per year on the first three anniversaries of the grant date. The options were granted at the market price of $10.14, the closing market price on March 10, 2011. In addition, our Board approved the following new compensation program for our non-management directors:

Annual Cash Compensation:

- $30,000 per director;
- additional $35,000 for the non-executive Chairman of the Board (increased to $40,000 on March 22, 2012);
- additional $7,000 for each committee on which the director serves (except as chairman); and
- additional $10,000 for each committee on which the director serves as chairman.

Equity Compensation:

- annual grant of shares of restricted stock, vesting over a three-year period; and
- annual grant of options to purchase shares of common stock, vesting over a three-year period with the number of shares and options to be issued will be determined by the Compensation Committee annually.

On March 22, 2012, each non-executive director received a grant of options to purchase 10,000 shares of our common stock and a grant of 10,000 shares of restricted stock. The options and restricted stock each vest on-third per year on the first three anniversaries of the grant date. The options were granted at the market price of $9.02, the closing market price on March 21, 2012. In addition, our Board approved a $5,000 increase in the annual cash compensation

of the non-executive Chairman; otherwise, the compensation program was unchanged.

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

Equity Compensation Plan Information

The following table sets forth information with respect to our common stock that has been authorized for issuance under all of Pernix's equity compensation plans as of December 31, 2011. Pernix does not have any equity compensation plans which were not approved by its stockholders.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)(1)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans(Excluding Securities Reflected in Column (a)) (c)(2)
Equity Compensation Plans Approved by Security Holders	1,848,491	$ 4.55	4,640,099
Equity Compensation Plans Not Approved by Security Holders	---	---	---
Total	1,848,491	4.55	4,460,099

(1) Includes 233,333 options, in the aggregate, issued under GTA's 2007 Stock Incentive Plan which were assumed by Pernix in the reverse merger transaction on March 9, 2010. The weighted-average exercise price of all of the outstanding options under these plans is $3.65. All other outstanding options were issued from our Amended and Restated 2009 Stock Incentive Plan (the "Plan").

(2) Includes 3,673,667 shares remaining available for issuance under our 2009 Plan, which may be issued as options, stock appreciation rights, restricted stock, restricted stock units or performance awards, and 966,432 shares remaining to be granted under our 2010 Employee Stock Purchase Plan."

Security Ownership of Directors and Executive Officers

The following table describes, as of March 23, 2012, the beneficial ownership of our common stock by each of our current directors, each of our named executive officers, and all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days after March 16, 2012, but excludes unvested stock options, which contain an early exercise feature. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially

owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of March 23, 2012. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Percentage ownership calculations for beneficial ownership for each person or entity are based on 26,034,272 shares outstanding as of March 23, 2012. Addresses of the named beneficial owners below are in care of Pernix Therapeutics Holdings, Inc., 10003 Woodloch Forest #950, The Woodlands, TX 77380.

Name of Beneficial Owner	Shares Acquirable within 60 Days upon Exercise of Stock Options	Shares of Restricted Stock (1)	Total Number of Shares Beneficially Owned (2)	Percentage of Class (3)
Directors				
Michael Pearce	158,333	36,667	195,000	.74%
Anthem Blanchard	20,000	45,000	65,000	.25%
Steve Elms(5)	---	10,000	2,010,000	7.63%
James Smith, Jr.	20,000	45,000	5,025,904	19.06%
Named Executive Officers				
Cooper Collins(4)	---	---	8,906,571	33.80%
David Becker	---	---	---	---
Tracy Clifford	80,000	---	81,706	.31%
Charles Hrushka	---	---	---	---
All Current Directors and Officers as a Group (7 Persons)	358,333	136,667	16,284,181	61.16%

(1) Each holder of restricted stock has sole voting power but no investment power over the shares he or she beneficially owns.

(2) The figures in this column includes all shares currently beneficially owned by the respective holder with full voting and investment power, plus the amounts reported in the previous two columns (“Shares Acquirable within 60 Days upon Exercise of Stock Options” and “Shares of Restricted Stock”).

(3) Based on 26,034,272 shares of our common stock outstanding on March 23, 2012.

(4) Mr. Collins is also a named executive officer.

(5) The reporting person is a managing member of the general partner of the general partner of the partnership that owns the reported securities. The reporting person disclaims beneficial ownership of the reported securities except to the extent of any pecuniary interest he has therein.

The following table describes, as of March 23, 2012, the beneficial ownership of our common stock by each person other than our directors and named executive officers listed above, known to us to be the beneficial owner of five percent or more of our outstanding common stock.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class (1)
Brandon Belanger 10003 Woodloch Forest #950 The Woodlands, TX 77380	1,979,238(2)	7.51%
Emily E. Bonner Deville 10003 Woodloch Forest #950 The Woodlands, TX 77380	1,979,238(3)	7.51%
Orbimed Advisors, LLC 601 Lexington Avenue, 54th Floor New York, NY 10022	2,135,300(4)	8.10%

(1) Based on 26,034,272 shares of our common stock outstanding on March 23, 2012.

(2) Based on a Schedule 13D/A filed on July 29, 2011 with the SEC by Mr. Belanger, who has sole voting and investment power over all shares reported. Mr. Belanger is employed as our National Sales Director – Gastroenterology.

(3) Based on a Schedule 13D/A filed on July 29, 2011 with the SEC by Ms. Bonner Deville, who has sole voting and investment power over all shares reported. Ms. Bonner Deville is employed as our Vice President of Sales Training and Compliance.

(4) Based on a Schedule 13G filed on February 4, 2012 with the SEC by Orbimed Advisors, LLC, who has sole voting and shared dispositive power over 782,800 shares; Orbimed Capital LLC who has shared voting and shared dispositive power over 1,353,000 shares; Samuel D. Isaly who has shared voting and shared dispositive power over the total of 2,135,800 shares.

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

Certain Relationships and Related Transactions

The Board of Directors has adopted a written Related Person Transaction Approval Policy (referred to as the “Related Person Policy”) that is administered by the Audit Committee of the Board of Directors. The Related Person Policy applies to any transaction or series of transactions in which Pernix is a participant, the amount involved exceeds $120,000 and a “related person” as defined by the SEC (Item 404 of Regulation S-K) has a direct or indirect material interest.

Under the Related Person Policy, the facts and circumstances of the proposed transaction will be provided to senior management, which will determine whether the proposed transaction is a related person transaction that requires further review. Transactions that fall within the definition will be submitted to the Audit Committee for approval, ratification or other action at the next Audit Committee meeting or, in those instances in which senior management determines that it is not practicable or desirable to wait until the next Audit Committee meeting, to the Chairman of the Audit Committee. The Audit Committee or the Chairman, as applicable, may approve, based on good faith consideration of all the relevant facts and circumstances, only those related person transactions that are in, or not inconsistent with, the best interests of Pernix and its stockholders. In addition, senior management will review quarterly reports of amounts paid or payable to, or received or receivable from, any related person and determine if there are any related person transactions that were not previously approved or ratified under the Related Person Policy. The Audit Committee will evaluate all options available, including, but not limited to, ratification, amendment, termination or rescission and, where appropriate, take disciplinary action. The Audit Committee will request that senior management evaluate our controls to ascertain the reason the transaction was not submitted to the Audit Committee for prior approval.

Director Independence and Board Leadership Structure

As required by our articles, our bylaws, and Rule 802 of the rules of the NYSE Amex, our Board consists of a majority of independent directors (as defined in NYSE Amex Rule 121(A)). Periodically, and at least annually in connection with its annual recommendation to the Board of a slate of director nominees, the Nominating Committee of our Board reviews the independence of the Board's current members (and director nominees who are not current members) and reports its findings to the full Board. Our Board then considers all relevant facts and circumstances in making an independence determination, including an analysis from the standpoint of the director and from that of persons or organizations with which the director has an affiliation. Our Board has determined that Messrs. Elms, Smith and Blanchard are independent under NYSE Amex rules. Neither Mr. Collins, our current chief executive officer, nor Mr. Pearce, who served as our chief executive officer prior to the merger of Pernix and GTA on March 9, 2010, qualifies as independent. Mr. Pearce is no longer employed by us; however, he currently serves as Chairman of our Board. Our Board has determined that separating the roles of Chief Executive Officer and Chairman is in the best interest of stockholders at this time. The structure ensures a greater role for the independent directors in the oversight of Pernix and active participation of the independent directors in setting agendas and establishing priorities and procedures for our Board. We schedule executive sessions at which independent directors meet without the presence or participation of management. The Chairs of the Audit Committee, Compensation Committee, Nominating Committee each act as presiding director of such executive sessions on a rotating basis.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table shows the fees paid or accrued by Pernix for the audit and other services provided by Cherry, Bekaert & Holland, L.L.P. for fiscal years 2011 and 2010.

	2011	2010
Audit Fees (1)	$228,018	$ 221,907
Audit-Related Fees(2)	57,827	103,674
Tax Fees(3)	52,455	44,250
All Other Fees	—	—
Total	$338,300	$ 369,831

(1) "Audit Fees" represent fees for professional services rendered by Cherry, Bekaert & Holland, L.L.P for fiscal years 2011 and 2010 for the audit of our annual consolidated financial statements included in our Annual Reports on Form 10-K for those respective fiscal years, the review of financial statements included in our Quarterly Reports on Form 10-Q for those respective years and any services normally provided by these firms in connection with statutory and regulatory filings or engagements.

(2) "Audit-Related Fees" represent fees for assurance and related services by Cherry, Bekaert & Holland, L.L.P. for fiscal years 2011 and 2010 that are reasonably related to the performance of the audit or review of our consolidated financial statements for those respective fiscal years and are not reported under "Audit Fees." These fees consisted primarily of accounting consultations relating to the preparation and filing of our definitive proxy statement and the Form 8-K relating to the merger of GTA and Pernix.

(3) "Tax Fees" represent fees for professional services rendered by Cherry, Bekaert & Holland, L.L.P. for fiscal years 2011 and 2010 for tax compliance, tax advice and tax planning.

Audit Committee Pre-Approval Policies

Our Audit Committee is required to pre-approve the audit and non-audit services performed for us by our independent registered public accounting firm in order to assure that the provision of such services does not impair the independence of our independent registered public accounting firm. Prior to the beginning of our fiscal year, our Audit Committee typically pre-approves certain general audit and non-audit services up to specified cost levels. Any audit or non-audit services that are not generally pre-approved in this manner require specific pre-approval by our Audit Committee. While our Audit Committee may delegate pre-approval authority to one or more of its members, the member or members to whom such authority is delegated must report any pre-approval decisions to our Audit Committee at its next scheduled meeting. Our Audit Committee does not delegate its responsibilities to pre-approve services performed by our independent registered public accounting firm to management.

All of the services described in "Audit-Related Fees," "Tax Fees" and "All Other Fees" in the table above were approved by the Audit Committee as required by the SEC (in Rule 2-01 of Regulation S-X, paragraph c(7)(i)(C)).

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements.

For a list of the financial information included herein, see “Index to Consolidated Financial Statements” on page 63 of this annual report on Form 10-K.

(2) Financial Statement Schedules.

Not applicable.

(3) Exhibits

The exhibits listed in the accompanying Index to Exhibits are filed or incorporated by reference as part of this report.

SIGNATURES

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

PERNIX THERAPEUTICS HOLDINGS, INC.

Date: March 29, 2012

By: /s/ Cooper C. Collins
Cooper C. Collins
President & Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael C. Pearce Michael C. Pearce	Chairman of the Board and Director	March 29, 2012
/s/ Cooper C. Collins Cooper C. Collins	President, Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2012
/s/ David P. Becker David P. Becker	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2012
/s/ Anthem H. Blanchard Anthem H. Blanchard	Director	March 29, 2012
/s/ Steven A. Elms Steven A. Elms	Director	March 29, 2012
/s/ James E. Smith James E. Smith, Jr	Director	March 29, 2012

INDEX TO EXHIBITS

No.	Description	Filed or Furnished with this Form 10-K	Incorporated by Reference	
			Form	Date Filed
1.1	Underwriting Agreement dated July 21, 2011 between Pernix Therapeutics Holdings, Inc., the selling stockholders named therein and Stifel, Nicolaus & company, Incorporated, as representatives of the several underwriters named in Schedule I thereto		8-K	07/21/2011
2.1	Agreement and Plan of Merger By and Among Golf Trust of America, Inc., GTA Acquisition, LLC and Pernix Therapeutics, Inc. dated as of October 6, 2009		8-K	10/07/2009
2.2	Asset Purchase Agreement dated January 8, 2010 by and between Sciele Pharma, Inc. and Pernix Therapeutics, Inc. as Buyer		8-K	03/30/2010
2.3	Membership Interest Purchase Agreement by and between Pernix Therapeutics, LLC and Michael Venters, John McMahon, Robert Cline, Jr. and Zinterests, L.L.C., dated September 8, 2010		8-K	09/14/2010
3.1	Articles of Incorporation of the Company.		8-K	03/15/2010
3.2	Bylaws of the Company.		8-K	03/15/2010
4.1	Form of certificate representing shares of common stock of the Company.	ü		
10.1*	2009 Stock Incentive Plan		8-K	03/15/2010
10.2*	2010 Employee Stock Purchase Plan		S-8	08/16/2010
10.3	Amended and Restated Pharmaceuticals Agreement dated as of June 22, 2010, by and between Pernix Therapeutics, Inc. and Macoven Pharmaceuticals, L.L.C.		8-K	06/28/2010
10.4*	Employment and Non-Compete Agreement, dated December 31, 2008, by and between Pernix Therapeutics, Inc. and Michael Venters		8-K	03/15/2010
10.5*	Employment Non-Compete Agreement, dated June 1, 2008, by and between Pernix Therapeutics, Inc. and Cooper Collins		8-K	03/15/2010
10.6*	Amended and Restated Employment and Non-Compete Agreement, dated March 14, 2011, by and between Pernix Therapeutics Holdings, Inc. and John McMahon		10-K	03/30/2011
10.7	Form of Merger Partner Stockholder Agreement		8-K	10/07/2009
10.8	Joint Venture Agreement by and between Gaine, Inc., Pernix Therapeutics, LLC, Biocopea Limited and Kulik Investments (1) IC Limited dated December 17, 2010.		8-K	12/22/2010
10.9*	Golf Trust of America, Inc., 2007 Stock Option Plan		S-8	06/04/2010
10.10	Loan Agreement, dated September 8, 2010, by and among Pernix Therapeutics Holdings, Inc., Pernix Therapeutics, LLC and Regions Bank		8-K	09/14/2010
10.11	Stock Purchase Agreement by and between Pernix Therapeutics Holdings, Inc. and David Waguespack dated September 10, 2010		8-K	09/14/2010
10.12	Sales Agreement dated Febuary 10, 2012, between Pernix Therapeutics Holdings, Inc. and Cantor Fitzgerald & Co.		8-K	02/10/2012
10.13	2007 Stock Option Plan		Def14A	11/16/2007
10.14	1997 Non-Employee Director's Plan		S-11/A†	11/15/1997
10.15	Form of Amended and Restated Merger Partner Stockholder Agreement		8-K	05/31/2011

10.16	Consulting Agreement by and between Pernix Therapeutics Holdings, Inc. and Jan Loeb dated August 29, 2011			10-Q	11/14/2011
10.17*	Employment Offer Letter, dated December 1, 2011, by and between Pernix Therapeutics Holdings, Inc. and David Becker	ü			
10.18*	Employment Offer Letter, dated December 1, 2011, by and between Pernix Therapeutics Holdings, Inc. and Chuck Hrushka	ü			
10.19	Amendment No. 1 to Amended and Restated Employment and Non-Compete Agreement, dated March 23, 2012, by and between Pernix Therapeutics Holdings, Inc. and John McMahon	ü			
14.1	Code of Business Conduct and Ethics			8-K	11/6/2007
21.1	Subsidiaries of the Company		ü		
23.1	Consent of Cherry, Bekaert & Holland L.L.P		ü		
31.1	Certification by Cooper C. Collins pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		ü		
31.2	Certification by David P. Becker pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		ü		
32.1	Certification by Cooper C. Collins and David P. Becker pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		ü		
	101.INS XBRL Instance Document				
	101.SCH XBRL Taxonomy Extension Schema Document				
	101.CAL XBRL Taxonomy Extension Calculation Linkbase Document				
	101.DEF XBRL Taxonomy Extension Definition Linkbase Document				
	101.LAB XBRL Taxonomy Extension Label Linkbase Document				
	101.PRE XBRL Taxonomy Extension Presentation Linkbase Document				

* Indicates a management contract or compensatory plan or arrangement

† Commission File No. 001-14494