PERNIX THERAPEUTICS HOLDINGS, INC.
Form 10-K
March 30, 2011

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

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2010

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)
33219 Forest West Street Magnolia, TX 77354 (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 o 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 (Do not check if a smaller reporting company)	o	Smaller reporting company	þ

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, 2010 was approximately $33,645,111, 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 25, 2011, the registrant had 22,687,727 shares of its common stock outstanding.

Documents Incorporated By Reference: Certain exhibits are incorporated by reference to Pernix's prior reports on Forms 10-Q and 8-K, and Registration Statements in Part IV hereof.

PERNIX THERAPEUTICS HOLDINGS, INC.

Annual Report on Form 10-K for the Year Ended December 31, 2010

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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., or Pernix, is a specialty pharmaceutical company focused on the sales, marketing and development of branded and generic pharmaceutical products primarily for the pediatric market. Our pediatric products, designed to improve the health and well-being of children, are focused in the specific areas of (i) allergy, (ii) upper respiratory, including nasal and chest congestion and cough, (iii) antibiotics and (iv) dermatology, including head lice, poison ivy and contact dermatitis. We promote our products through our sales and marketing organization with 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.

As of December 31, 2010, our principal promoted product families included: ALDEX, BROVEX, CEDAX, PEDIATEX and ZEMA-PAK. In addition, we have acquired co-promotion rights to NATROBA™ (spinosad) Topical Suspension, 0.9% ("NATROBA"), which received FDA approval for the treatment of head lice in January 2011. We have also entered into a joint venture for the development of Theobromine, a first-in-class treatment for cough. In addition, we develop and launch generic and authorized generic products through Macoven Pharmaceuticals, LLC, or Macoven, our wholly-owned subsidiary.

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.

Since inception, Pernix has engaged in a number of acquisitions and license agreements to expand its product offerings. In 2009, Pernix entered into an asset purchase agreement with DaySpring Pharma, LLC, or DaySpring, for all rights related to the BROVEX product line. In 2010, Pernix entered into an asset purchase agreement with Shionogi Pharma, Inc., or Shionogi, for all assets and rights related to CEDAX. Pernix also acquired from Kiel Laboratories, Inc., or Kiel, all assets related to its TCT control delivery technology, which is used in PEDIATEX and ALDEX. Pernix also acquired several products, including the ZEMA-PAK product line through its acquisition of 100% of the membership interest in Macoven in September 2010. Pernix also purchased the remaining 50% ownership interest in Gaine, Inc., the owner of the U.S. Theobromine patent. Also in 2010, we entered into a co-promotion agreement with ParaPRO LLC, or ParaPRO, for NATROBA. Finally, in December 2010, we entered into a new joint venture with SEEK, a United Kingdom drug-discovery group, for the development of Theobromine.

Pernix (formerly Golf Trust of America, Inc.) was incorporated in November 1996 and is headquartered in The Woodlands, Texas and employs approximately 77 people.

Business Strategy

Our objective is to be a leader in developing, marketing and selling pharmaceutical products in the U.S. primarily for pediatric indications and potentially for additional therapeutic areas. 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 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 their territorial performance, provides upside commission potential and attracts top sales performers.

Acquiring or in-licensing approved pharmaceuticals: We have historically grown our business by acquiring or in-licensing rights to market and sell prescription and over-the-counter, or OTC, pharmaceuticals 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.

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.

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. Pernix and SEEK may fully develop Theobromine globally, license the product, sell the development and marketing rights to another company, or co-develop or co-promote the product. On March 24, 2011, we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets of the joint venture. The auction will be for the global commercialization rights (excluding Korea) of Theobromine. Pivotal phase III trials for Theobromine (BC1036) are scheduled to begin in the European market in the second half of 2011, and a regulatory filing is

expected in 2012. We are in ongoing discussions with the FDA to determine the clinical trial program and regulatory requirements in the U.S. In addition, Pernix has exclusive pediatric promotion rights in the U.S. to the extent we fund the development and clinical trial program for such Theobromine products. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

Expand into new geographical and therapeutic markets: We may add additional sales representatives to our sales force in both existing and new geographical markets to bolster our sales and marketing organization. We intend to opportunistically explore additional therapeutic areas which have the same characteristics as 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 product portfolio that currently includes 5 promoted product families. In addition, we expect to launch NATROBA in the second quarter of 2011. We promote our products through our own direct sales force. The table below provides information on our promoted product portfolio as of March 25, 2011:

Product Family	Primary Indication	Marketed 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, ParaPRO	Q2:2011 (anticipated)
PEDIATEX	Allergies and congestion	Pernix	Q3:2008
ZEMA-PAK	Dermatological disease	Pernix	Q2:2010(1)

(1) Initially launched by Macoven Q4:2009; launched by Pernix Q2: 2010 through co-promotion agreement with Macoven.

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 converted the ALDEX product family from Drug Efficacy Study Implementation (DESI) to OTC monograph, 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 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 the patent protected drug delivery technology developed by Kiel, 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 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 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 converted the BROVEX product family to OTC monograph from Drug Efficacy Study Implementation (DESI) drugs 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 Pamlab LLC’s Palgic® and McNeil-PPC, Inc.’s Zyrtec®.

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. We launched our CEDAX product line in the second quarter of 2010, targeting pediatricians. We sell a variety of dosages utilizing both capsule and oral suspension drug delivery methodologies, and in January 2011, launched our new 180mg formulation.

Market Opportunity. 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 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 would 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. NATROBA is expected to be launched in the second quarter of 2011.

Natroba Topical Suspension will be 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 the journal 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, 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 significantly 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. In the United States, an estimated 6 to 12 million cases of head lice occur annually in children ages 3 to 11.

Other Treatments. Other branded topical prescription lice treatments include NIX®, OVIDE®, LINDANE and ULESFIATM.

Launch focus. Our sales force of approximately 55 sales representatives will focus the launch of NATROBA primarily on the pediatric market, including pediatricians and school nurses. Healthcare providers will be presented with the above mentioned studies indicating NATROBA's superiority within its therapeutic class. Pharmacist and consumer education will also be an important element to the launch of NATROBA, as product awareness within communities where infestations occur should prompt new treatment protocol discussions with healthcare providers. NATROBA's safety, efficacy and indication for use without a comb will be the core message behind the promotion of the product.

Intellectual Property. The NATROBA product line is covered by four patents. The last patent covering the NATROBA product line would 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, and are evaluating opportunities to expand our PEDIATEX line in 2011.

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

Other Treatments. Other branded antihistamine, decongestant, and cough suppressants marketed in the U.S. that compete with our PEDIATEX line include 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.

ZEMA-PAK Line. ZEMA-PAK is an oral corticosteroid tablet used for the treatment of dermatological diseases including poison ivy, allergic states and contact dermatitis. ZEMA-PAK helps diversify our product mix from winter season cough and cold products. Currently, ZEMA-PAK is marketed in recommended dosage ranges of 6-day, 10-day and 13-day packs. We acquired the rights to market ZEMA-PAK in the second quarter of 2010, through a co-promotion agreement with Macoven. ZEMA-PAK was initially launched by Macoven in the fourth quarter of 2009.

Market Opportunity. More than 13 million prescriptions in 2010 were written for corticosteroids, most of which are primarily generic.

Other treatments. Similar treatments to ZEMA-PAK include MEDROL® and MEDROL® Dosepak, Decadron and DexPak and other generic corticosterioids.

Intellectual Property. We own a trademark on the name ZEMA-PAK 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, including REZYST IM, a proprietary probiotic blend that promotes microflora growth and colonization, specifically formulated to replace active cultures that are destroyed by diet and antibiotics. Other marketed products include generic versions of selected branded products through our Macoven subsidiary.

Other Product Candidates In Development

The Company is working on several product candidates. Of these product candidates, we believe the largest market opportunity exists for Theobromine, a first-in-class, non-codeine and non-opiod treatment for cough.

Theobromine. Theobromine is an alkaloid naturally present in dark chocolate and that 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. Pernix and SEEK may fully develop Theobromine globally, license the product, sell the development and market rights to another company, or co-develop or co-promote the product. On March 24, 2011, we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets of the joint venture. The auction will be for global commercialization rights (excluding Korea) to Theobromine (BC1036) based on the strong level of interest shown for this drug candidate. Pivotal Phase III studies for Theobromine in Europe are expected to begin during the second half of 2011. We are in ongoing discussions with the FDA to determine the clinical trial program and regulatory requirements in the U.S. In addition, we have exclusive pediatric promotion rights in the U.S. to the extent we fund the development and clinical trial program for such Theobromine products. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

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, Dimetane DC and many additional generic options.

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 mixture 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.

Sales and Marketing

Our sales force, which consists of approximately 55 full-time sales representatives as of December 31, 2010, promotes our ALDEX, BROVEX, CEDAX, PEDIATEX, and ZEMA-PAK families of 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. We plan to use our current sales force for the launch of NATROBA in the second quarter of 2011. 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 opportunistically 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 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, and will continue to 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 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 use third parties to manufacturer 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, Collaborations and Co-Promotions

We have and continue to grow our business through the use of acquisitions, license agreements, co-promotions and collaborations. We enter into these agreements to continue to develop, commercialize and better market our current product portfolio and other product candidates. Collaborative and co-promotion 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, as well as expense reimbursements or payments to the third party. Our acquisition, collaboration and co-promotion agreements are summarized below.

Acquisitions and License Agreements

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

ALDEX and PEDIATEX. In November 2006, Pernix entered into a license agreement whereby Gaine sub-licensed to Pernix an exclusive license to use Kiel's patented drug delivery technology to market and manufacture products from the ALDEX and PEDIATEX families in 17 states, primarily in the southeastern U.S. In addition, Pernix gained an option to a worldwide license to use Kiel's patented drug delivery technology to develop the ALDEX and Z-COF (which has subsequently been discontinued) product families for OTC use. In May 2008, Pernix acquired a 50% ownership interest in Gaine and subsequently purchased the remaining 50% ownership interest in June 2010. As a result, Gaine became a wholly-owned subsidiary of Pernix.

Kiel Technology. In January 2009, Pernix entered into a license agreement with Kiel, 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.

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.

Generic Products. On July 27, 2009, Pernix entered into an agreement with Macoven, whereby Pernix granted Macoven a non-exclusive license to develop, market and sell generic products based on Pernix's branded products for a one-time development fee of $1,500,000. The initial term of the agreement was 18 months, and was automatically renewable for successive 12-month terms unless terminated by either party. On September 8, 2010, Pernix purchased 100% of the outstanding membership interests of Macoven for an aggregate purchase price of $2,200,000 (which included approximately $1,200,000 in inventory) and Macoven became a wholly-owned subsidiary of Pernix. We acquired our ZEMA-PAK product line as a result of our acquisition of Macoven.

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.

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. The joint venture will undertake 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. Pernix and SEEK may fully develop Theobromine globally, license the product, sell the development and market rights to another company, or co-develop or co-promote the product. On March 24, 2011 we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets. Following consultation with a European regulatory authority, the new venture will conduct a single pivotal Phase III trial of BC1036, which is expected to begin in the second half of 2011. We are in ongoing discussions with FDA to determine the clinical trial program and regulatory requirements in the U.S. In addition, Pernix has the exclusive pediatric promotion rights in the U.S. to the extent we fund the development and clinical trial program for such Theobromine products. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

Co-Promotion Agreements

In addition to our own product portfolio, we have entered into co-promotion agreements with various parties regarding the marketing of certain products in return for commissions or percentages of revenue on the sales generated. 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. For the calendar year ended December 31, 2010, we recognized approximately $2,490,000 in collaboration revenue and approximately $458,000 in collaboration expense. As of December 31, 2010, we had four active co-promotion agreements pursuant to which certain products are being marketed. Two of these agreements are for products marketed by us on behalf of others and two of these agreements are for products marketed by others on our behalf.

Further, as of December 31, 2010, we had two active agreements pursuant to which certain products were being marketed in exchange for a royalty fee. For the calendar year ended December 31, 2010, we recognized approximately $739,000 in royalty expenses under such agreements.

NATROBA Co-Promotion Agreement. We entered into an exclusive co-promotion agreement with ParaPRO for NATROBA in our territories, a medication to treat head lice (pediculosis capitis) in humans. Under the agreement with ParaPRO, Pernix expects to receive payments between approximately 35%-42% of net sales by Pernix.

Intellectual Property

Our performance relies partly on our capacity to achieve and maintain proprietary protection for our products and product candidates, technology and know-how, to function without infringing on the ownership rights of others and 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.

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(1)	Schering Corporation	Stable hydrated cephalosporin dry powder for oral suspension formulation	February 4, 2014
THEOBROMINE(2)	Gaine, Inc.	Methods of stimulating mucociliary clearance to alleviate irritable cough	March 20, 2018

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

(2) 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 trail 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.

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 24 trademark interests, of which 15 are trademarks registered on the principal trademark register. These marks include BROVEX (WORD MARK), BROVEX (DESIGN MARK), ALDEX, PERNIX, ZEMA-PAK, REZYST, QUINZYME, COCO-COF, Z-COF, CEDAX, TCT (WORD), TCT (DESIGN), TCT TANNANTE CONVERSION TECHNOLOGY, ALLRES and PEDIATEX. There are two different registrations for BROVEX. One is for the word “BROVEX” and the other registration is for the stylized

BROVEX mark. In addition to the 15 registered marks listed above, we own 7 intent-to-use trademarks 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. Pernix also owns 2 intent-to-use trademark applications that are currently pending in the U.S. Patent and Trademark Office. 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.

Customers, Distribution, and Reimbursement

Customers and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the U.S. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Our top three customers, which represented 85% and 82% of gross product sales in 2010 and 2009 respectively, are all drug wholesalers and are listed below:

Customer	2010	2009
Cardinal Health	43%	37%
McKesson Corporation	29%	32%
Morris & Dickson	13%	13%

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

We actively market our products to authorized distributors through regular sales calls. We have many years of experience working with various industry distribution channels. We believe that this significantly enhances our performance by ensuring product stocking in major channels in the geographic areas where we do business; continually following up with accounts and monitoring of 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.

We currently rely on DDN/Obergfel, LLC, or DDN, a third-party logistics provider, for the distribution 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.

We believe DDN to be the largest privately held provider of outsourced services to the life-science industry. DDN works with emerging companies who seek to launch quickly and retain their virtual structure, and with market leaders who look to streamline and simplify their distribution efforts. DDN's clients receive supervised operations without spending the time and money to develop and manage them, subsequently freeing up resources for research and development, acquisitions and other core initiatives.

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 similarly 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 partner, 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, imports and exports of pharmaceutical products that we market, sell and are developing.

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 rely, and expect to continue to 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 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. The ANDA application will not be approved until all the listed patents claiming the referenced product have expired and if the applicant does not challenge the listed patents. 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

We launched two medical food products in 2009 that do not constitute a significant portion of our revenues. 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. 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 the second half of 2011, and a regulatory filing is expected 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

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 the 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, 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 in which they agree to pay a rebate to the states that is decided on the basis of a calculation specified by CMS. Pharmaceutical companies may also be 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 our currently marketed products.

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.

We are unable to foresee what future legislation, regulations or policies, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation, regulations or policies would have on our business. Any cost containment initiatives or other health care system reforms that are adopted could hinder our ability to price our products above our costs, limit our ability to generate revenue from government-funded or private third-party payors, curb the potential revenue and profitability of our customers, suppliers and partners and impede our access to capital needed to operate and grow. Any of these circumstances could considerably limit our capacity to operate profitably.

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 fixes 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. In addition, there are significant health insurance reforms that will improve patients' ability to obtain and maintain health insurance. Such measures include the elimination of lifetime caps, no rescission of policies, and no denial of coverage due to preexisting conditions. 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 our products. In 2010, the new law increased the minimum basic Medicaid rebate for brand name prescription drugs from 15.1% to 23.1%, increased the minimum basic Medicaid rebate for generic drugs from 11% to 13%, increased the additional Medicaid rebate calculation for "line extensions" of oral solid dosage forms of innovator products, expanded the entities eligible for 340B pricing and revised the average manufacturer price definition to exclude certain payments and discounts.

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 also provides a $250 Medicare rebate to Part D beneficiaries who reach the coverage gap during 2010, and mandates the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020. Moreover, Health Care Reform reduces Part D premium subsidies for higher-income beneficiaries, expands medication therapy management requirements, and makes a number of other revisions to Part D program requirements. The elimination of the coverage gap may result in greater access to our products for Part D beneficiaries.

The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2011). In addition, Health Care Reform requires manufacturers of prescription drugs to submit reports about distribution of product samples to health care practitioners.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including 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.

Fraud and Abuse Regulation

A number of federal and state laws and regulations, loosely referred to as fraud and abuse laws, are used to prosecute health care providers, suppliers, physicians and others that fraudulently or wrongfully obtain reimbursement for health care products or services from government programs, such as Medicare and Medicaid. These laws may constrain our business and the financial arrangements through which we market, sell and distribute our products.

The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and intentionally to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to encourage the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid. The term “remuneration” has been interpreted broadly and includes both direct and indirect compensation and other items and services of value. Some courts have interpreted the anti-kickback law to cover any situation where one purpose of the remuneration is to encourage purchases or referrals, even if there are also legitimate purposes for the arrangement. There are narrow exemptions and regulatory safe harbors, but to qualify for a safe harbor an arrangement must precisely meet each of the requirements. Transactions that are not specifically excluded or granted safe harbor protection are not per se violations of the Anti-Kickback Statute but are evaluated by the OIG on a case-by-case basis. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus $50,000 for each violation of the statute.

In addition to the anti-kickback law, the False Claims Act prohibits anyone from knowingly and willingly presenting, or causing to be presented for payment to the federal government, claims for payment that are false or fraudulent.

Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. 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.

Employees

As of March 25, 2011, we had 77 full-time employees, consisting of 55 engaged in marketing and sales; 1 engaged in research, development and regulatory affairs; and 21 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 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.

Many 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.

As 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, 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 25, 2011, 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. 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. Certain of our products, including PEDIATEX TD, BROVEX PSE, BROVEX PSE DM, BROVEX PSB, and BROVEX PSB DM and their generic equivalents 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, 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 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 own or operate, and do not currently have plans to establish, any manufacturing facilities for our products or product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our products or product candidates on a clinical or commercial scale.

We currently rely, and expect to continue to rely, on third parties for the supply of the active pharmaceutical ingredients 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 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 adopted, will impose additional requirements on us with respect to oversight of our third-party manufacturers outside the United States. 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 2010, Cardinal Health accounted for 43% of our total gross sales, McKesson Corporation accounted for 29% of our total gross sales and Morris & Dickson accounted for 13% 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 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 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. 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 agreements with third parties and expect to enter into additional licenses in the future.

Our existing licenses impose, and we expect that future licenses will impose, various development and commercialization, purchase commitment, royalty, sublicensing, patent protection and maintenance, insurance and other obligations on us. If we fail to comply with these obligations or otherwise breach the 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 abroad. These 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.

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. In connection with our entry into the joint venture, we made an initial capital contribution of approximately $1.5 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 25, 2011, we had approximately $12.6 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 scope, progress, results and costs of clinical development activities for our product candidates, particularly BC 1036;
- 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 acquire or invest in products, businesses and technologies;
- 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.

- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates;

- the extent to which we acquire or invest in products, businesses and technologies;

- 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 acquired Pernix Therapeutics, Inc. by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.

On March 9, 2010, Pernix Therapeutics, Inc., or PTI, merged with and into a transitory subsidiary of GTA, with the transitory subsidiary surviving the merger, and became a wholly-owned subsidiary of Pernix. Additional risks to our investors may exist because we acquired PTI through a “reverse merger.” Prior to the merger, security analysts of major brokerage firms did not provide coverage for us. In addition, because of past abuses and fraud concerns stemming primarily from a lack of public information about new public businesses, there are many people in the securities industry and business in general who view reverse merger transactions with suspicion. Without brokerage firm and analyst coverage, there may be fewer people aware of the combined company and its business, resulting in fewer potential buyers of our securities, less liquidity, and depressed stock prices for our investors.

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 year ended December 31, 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 67% 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 18.8 million shares), which among other things, restricts the sale or transfer of these shares for specified periods.

We may waive the restrictions on transfer under the stockholder agreements described above, although we currently have no intention to do so. When the restrictions in the stockholder agreements described above lapse and 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;
- issues in manufacturing products;
- unanticipated potential product liability 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.

Moreover, stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

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. Upon execution of the joint venture agreement, we contributed approximately $1.5 million to the joint venture, representing approximately 50% of the aggregate capital initially contributed by all of the joint venture's shareholders, in consideration for an equity interest representing 50% of the total voting power and approximately 46% of the total economic power in the entity. We expect to 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. On March 24, 2011, we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets of the joint venture. The auction will be for the global commercialization rights (excluding Korea) of Theobromine. Pivotal phase III trials for Theobromine (BC1036) are scheduled to begin in the European market in the second half of 2011, and a regulatory filing is expected in 2012. We are in ongoing discussions with FDA to determine the clinical trial program and regulatory requirements in the U.S. In addition, Pernix has the exclusive pediatric promotion rights in the U.S. to the extent we fund the development and clinical trial program for such Theobromine products. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

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 investigational new drug application or IND application, becoming effective, which must occur before human clinical trials may commence;
- successful completion of clinical trials;
- 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 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.

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 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 are not expected to be affected by the FDA announcement. Certain Macoven generic products that are not currently marketed as OTC monograph are in the process of being converted, and we do not expect any suspension, delay or interruption in our sales of these products. Our remaining generic DESI cough and cold products that are not being converted to OTC monograph were already planned to be phased out and are not expected to 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 standards 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 standards 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 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 an FDA OTC monograph. However, if the FDA determines that our products do not conform to 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 effect 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.

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. The joint venture intends to commence a single phase III trial of BC 1036 in the first half of 2011 in order to obtain regulatory approval in Europe. With respect to United States regulatory approval, the joint venture has initiated preliminary discussions with the FDA and anticipates meeting with the FDA sometime in the first quarter of 2011 to discuss a regulatory approval program in 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 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.

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

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

withdrawal of the products from the market;

restrictions on the marketing or distribution of such products;

restrictions on the manufacturers or manufacturing processes;

warning letters;

refusal to approve pending applications or supplements to approved applications that we submit;

recalls;

fines;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

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

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs varies but coverage is similar to other products within the same class of drugs. For example, CEDAX is covered by private insurance plans similar to other marketed, branded cephalosporins. However, the position of CEDAX as a branded product often requiring a higher patient copayment may make it more difficult to expand the current market share for this product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for CEDAX. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, some of our products are purchased under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, created a new Medicare benefit for prescription drugs. More recently, the Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. In addition, private insurers, such as MCOs, may adopt their own reimbursement reductions in response to federal or state legislation. Any reduction in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product, and the amount for which that product will be reimbursed, are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products may change at any time.

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 regulations 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.

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 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. Due to our limited financial resources and the inexperience of our management team in managing a company during a period of such anticipated growth, we may not be able to effectively manage the expansion of our operations or 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.

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, and 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 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 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, 2010, Pernix pays rent of $5,000 and $3,000 per month for the Texas and Louisiana facilities, respectively. We believe these amounts approximate market rates.

ITEM 3. LEGAL PROCEEDINGS

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. (REMOVED AND RESERVED)

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 25, 2011, 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 $11.90 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
20091:		
First Quarter	2.72	1.70
Second Quarter	2.98	2.06
Third Quarter	3.70	2.42
Fourth Quarter	5.74	3.36
2010:		
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

(1) As previously disclosed, on March 9, 2010, Pernix completed its merger with GTA. The 2009 data refers to sales prices per share of GTA common stock prior to the merger but giving effect to the reverse stock split that was effective on March 10, 2010.

Stockholder Information

On March 25, 2011, Pernix had 22,687,727 shares of common stock outstanding. As of March 25, 2011, those shares were held of record by 32 registered holders and by an estimated 619 beneficial owners.

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 year ended December 31, 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.

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, 2010 through October 31, 2010	8,200	$ 3.57	8,200	$ 1,159,688
November 1, 2010 through November 30, 2010	2,600	$ 3.65	2,600	$ 1,150,130
December 1, 2010 through December 31, 2010	—	$ —	—	$ 1,150,130
Total	10,800	$ $3.59	10,800	

(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 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., or Pernix, is a specialty pharmaceutical company focused on the sales, marketing and development of branded and generic pharmaceutical products primarily for the pediatric market. Our pediatric products, designed to improve the health and well-being of children, are focused in the specific areas of (i) allergy, (ii) upper respiratory, including nasal and chest congestion and cough, (iii) antibiotics and (iv) dermatology, including head lice, poison ivy and contact dermatitis. We promote our products through our sales and marketing organization with 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.

As of December 31, 2010, our product portfolio included five promoted product families: ALDEX, BROVEX, CEDAX, PEDIATEX, and ZEMA-PAK. We also develop and launch authorized generic products through Macoven, our generic subsidiary. In addition, we have acquired co-promotion rights to NATROBATM (spinosad) Topical Suspension, 0.9% (“Natroba”), which received FDA approval for the treatment of head lice in January 2011. We expect to commence sales of Natroba during the second quarter of 2011. Natroba will be promoted by our approximately 55 sales representatives. 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. Pivotal phase III trials for Theobromine (BC1036) are scheduled to begin in the European market in the second half of 2011, and a regulatory filing is expected in 2012. We are in ongoing discussions with the FDA to determine the clinical trial program and regulatory requirements in the U.S. On March 24, 2011, we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets of the joint venture. The auction will be for the global commercialization rights (excluding Korea) of Theobromine. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

On September 8, 2010, Pernix purchased 100% of the outstanding membership interests of Macoven for an aggregate purchase price of $2,200,000 (which included approximately $1,200,000 in inventory). We engaged an independent valuation specialist to assist the special committee of the board in estimating the fair value of the net assets acquired in accordance with ASC 820 – Fair Value Measurements utilizing the guideline public company method, an application of the market approach, and the discounted cash flow method, an application of the income approach, in estimating the fair value of Macoven’s net assets. Due to the unavailability of similar transactions, the comparative transactions method, another application of the market approach, was considered and researched but not utilized.

Six publicly traded generic pharmaceutical companies were selected to serve as guideline public companies based on their reasonable similarity with respect to operating characteristics to Macoven. In applying the guideline public company method, the relevant median multiples implied by the market capitalization of the selected guideline public companies as of September 8, 2010, the re-acquisition date, were qualitatively adjusted to account for differences in size and long-term growth as compared to Macoven.

In applying the discounted cash flow method, the specialist examined financial projections of Macoven reflecting future economic benefits attributable to its current product portfolio and growth opportunities related to certain collaboration agreements. The calculation of discounted future benefits was based on projections provided by Macoven. These projections were reviewed at length by the members of the independent committee of Pernix’s board of directors approving the transaction. Our review of the assumptions underlying the projections included review and

discussion of the following:

- Anticipated new product lines;
- Profit share agreements and profit splits;
- Cost of goods sold;
- R&D expenses;
- Returns, allowances, Medicaid rebates and discounts offered;
- Required working capital; and
- Capital expenditures.

We believe that that the projections were reasonably reflective of market participant expectations and devoid of any buyer specific synergies uniquely attributable to Pernix. The net cash flows to invested capital indicated by the projections were discounted to present value utilizing a rate of return that was deemed to be commensurate with the risk in the forecast. The rate of return was developed using a weighted average cost of capital in which the cost of equity was derived using the modified capital asset pricing model (MCAPM) and the cost of debt was based on a premium over the yield for Baa rated debt as of the re-acquisition date. Key valuation assumptions including marginal tax rate, capital structure weights, re-levered equity beta and working capital requirements were based on analysis of the guideline public companies. The continuing or terminal value was estimated using the Gordon growth methodology in which a long-term growth rate slightly above expected long-term inflation was utilized.

The indications of value from each of the valuation methods employed in estimating the business enterprise value i.e., the guideline public company method (an application of the market approach) and the discounted cash flow method (an application of the income approach) resulted in a reasonably close range (less than 10%) from which to reach a valuation conclusion. Further, we believe that the indication of value from each method provides valid insights into the value of the subject company and we have, therefore, applied equal weight to each indication to reach a value conclusion. The fair value was then allocated in accordance with ASC 805 – Business Combinations to applicable tangible and intangible assets at their respective fair values. The intangible assets that were deemed material included the non-compete agreement with a key Macoven employee and an exclusive supply agreement for a key ingredient. The re-acquisition of Macoven enables Pernix to grow its market share in the sales and marketing of generic products. See discussion of the acquisition of our generic partner, Macoven, under the heading "Acquisitions and License Agreements, Collaborations and Co-Promotions" in Part I, "Item 1. Description of Business" of this Annual Report on Form 10-K.

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 to OTC monograph from DESI drugs over the past two cold seasons. We believe we have and can continue to appropriately market these lines as OTC monograph products.

Our authorized generic products added through the acquisition of Macoven that are not currently marketed as OTC monograph are in the process of being converted, and we do not expect any suspension, delay or interruption in our sales of these products. Our remaining generic DESI cough and cold products that are not being converted to OTC monograph were already planned to be phased out and are not expected to have a material impact on the results of operations or financial condition of the Company. For a more complete discussion regarding FDA drug approval requirements, please see "Item 1- Description of Business- Governmental Regulations" and "Item 1A.-Risk Factors - Risks Related to Regulatory Matters" of Part 1 of this Annual Report on Form 10-K.

In addition to our own product portfolio, we have entered into co-promotion agreements with various parties regarding the marketing of certain products in return for commissions or percentages of revenue on the sales generated. As of December 31, 2010, we have four co-promotion agreements pursuant to which certain products are being marketed. Two of these agreements are for products marketed by us on behalf of others and two of these agreements are for products marketed by others on our behalf.

On June 21, 2010, Pernix purchased the remaining 50% ownership interest in Gaine from certain employees of Kiel Laboratories, Inc., or Kiel. As a result of the transaction, Gaine became a wholly-owned subsidiary of Pernix. Prior to the acquisition, Pernix had the exclusive rights to certain products and product candidates developed through patents and licenses held by Gaine, and Gaine's single source of income had historically been solely from royalties paid by Pernix. In consideration for the sellers' 50% ownership interest in Gaine, Pernix was required to pay the sellers as follows: (i) an aggregate of $500,000 in cash, net of adjustments of approximately $173,000, that was paid at closing, (ii) an aggregate of $500,000 in cash, net of adjustments of approximately $179,000, that was paid on October 31, 2010 and (iii) an aggregate of $1,000,000 in cash that was paid on January 31, 2011. The first two installments were adjusted for outstanding royalties and obligations owed at the time of closing. Additionally, in the event a new drug application is approved by the FDA, prior to any sale of the intellectual property, for one of Pernix's antitussive cough suppressant pharmaceutical products utilizing the invention claimed in the U.S. patent owned by Gaine, or ownership of the Theobromine patent is transferred, Pernix will be obligated to pay the sellers an aggregate of

$10,000,000 in cash or Pernix common stock.

On August 24, 2010, Pernix and Kiel entered into a patent purchase agreement whereby Pernix 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. These patents were previously utilized by Pernix through contracted licenses. For more discussion, see Note 10 to Pernix's Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

As of March 25, 2011, 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 and four were added in January 2011.

For the years ended December 31, 2010 and 2009, our net sales were approximately $33,227,000 and $27,930,000, respectively, and our net income before income taxes and non-controlling interest was approximately $10,794,000 and $9,238,000, respectively.

Our net cash provided by operating activities for the years ended December 31, 2010 and 2009, was approximately $4,667,000 and $9,943,000, 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 collaboration 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 commissions or percentages of revenue on the sales we generate or on the sales they generate. The total revenue from co-promotion agreements was approximately $2,490,000 and $292,000 for the years ended December 31, 2010 and 2009, respectively.

The following table sets forth a summary of Pernix's gross sales for the years ended December 31, 2010 and 2009.

	Year Ended December 31,	
	2010	2009
Gross Sales	(in thousands)	
Upper respiratory, allergy and antibiotic products	$ 48,485	$ 38,463
Medical food products	691	354
Dermatology products	903	—
Collaboration revenue	2,490	292
Gross Sales	52,569	39,109
Prompt pay discounts	(1,337)	(1,941)
Allowance for returns	(2,200)	(2,810)
Allowance for price adjustments (rebates, chargebacks and customer fees)	(6,517)	(1,604)
Allowance for Medicaid rebates	(9,288)	(4,824)
Net Sales Revenues	$ 33,227	$ 27,930

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, prompt pay discounts, price adjustments and Medicaid rebates, including prompt pay discounts which are netted in accounts receivable, as of December 31, 2010:

	Product Returns	Medicaid Rebates	Price Adjustments
		(in thousands)	
Balance at December 31, 2008	$ 2,386	$ 738	$ 709
Current provision:			
Adjustments to provision for prior year sales	(33)	—	—
Provision – current year sales	2,843	4,824	2,938
Payments and credits	(1,221)	(3,261)	(3,000)

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

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 expiration period from the date of manufacture. We adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. We estimate returns ranging from approximately 5% to 7% of sales of branded products and 1% to 3% 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 its products. We review the reserve quarterly and adjust it accordingly. Although we do not believe that there will be a material change in the future estimates or assumptions we use to calculate returns, 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 salebility, 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, 2010 would have affected net earnings by approximately $483,000.

Medicaid Rebates. The liability for Medicaid 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. The increase in rebates as a percentage of gross product sales is primarily due to new legislation, specifically Health Care Reform and the fact that we have more products covered by Medicaid currently than in prior years. As we continue to expand our product line and more of our products become eligible for Medicaid coverage in various states, we will incorporate assumptions related to changes in rates and utilization which could potentially have a material impact on future estimates and assumptions that we use to calculate Medicaid rebates. For example, with respect to the provision for the year ended December 31, 2010, a 1% difference in the provision assumptions based on utilization and reimbursement rate would have affected net earnings by approximately $186,000 and $111,000, respectively.

Price Adjustments. Our estimates of price adjustments which include customer rebates, service fees, and chargebacks are based on our estimated mix of sales to various third-party payors, which 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 and/or chargebacks than it originally estimated. For example, a 1% difference in the assumptions based on the applicable sales would have affected net earnings by approximately $94,000.

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 as sales stocking allowance are recorded as a reduction of revenue when the sales order is recorded. These sales stocking allowances 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 39% 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 or 60 days, 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 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 to them, and we 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 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 sales includes third-party manufacturing, packaging and distribution costs and the cost of active 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 sales.

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 customers sell Pernix products to 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 on that sale.

Royalty Expenses

Royalty expenses include the contractual amounts Pernix is required to pay the licensors from which it has acquired the rights to certain of its marketed products. For a description of the agreements that currently require royalty fees, see Notes 10 and 19 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 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. Effective August 31, 2010, we entered into an agreement that requires future royalties on one of our products from July 1, 2010 through June 30, 2012. The royalty expense recognized in the year ended December 31, 2010 related to this agreement was approximately $565,000. On March 18, 2011, we negotiated and paid a final payment related to future royalties.

General and Administrative Expenses

General and administrative expenses primarily include salaries and benefits of management and administrative personnel; professional fees; consulting fees; management and administrative personnel overhead expenses; and insurance. Pernix general and administrative expenses have increased significantly from the year ended December 31, 2009 due to the public company costs including, but not limited to, accounting and legal professional fees, exchange listing fees, and printing and reporting fees and also due to the increase in personnel to expand our operations and product portfolio and support 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. For discussion of the certain research and development expenses see Note 2 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

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 carryovers 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.

Non-controlling interest

On June 21, 2010, Pernix purchased the remaining 50% ownership interest in Gaine from certain employees of Kiel. For additional information, see Note 4 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

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, allowances for returns, discounts, customer rebates and chargebacks, Medicaid rebates, price adjustments, sales commissions, stock based compensation, amortization, depreciation, accrued expenses and the determination of fair values of assets and liabilities in connection with business combinations described below fit the definition of "critical accounting estimates."

Revenue Recognition

We record revenue from product sales and collaboration 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 sell our products primarily to large national wholesalers, which have the right to return the products they purchase. We estimate the amount of future returns at the time of revenue recognition. We recognize product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, vendor fees, prompt payment and other discounts. We recognize product sales 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. Pernix recognizes product sales net of estimated allowances for discounts, customer rebates and chargebacks, product returns and Medicaid rebates.

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.

Allowances for Product Returns, Medicaid 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 Note 17 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 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, 2010.

Inventory

Inventory consists 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. As of December 31, 2010 and 2009, Pernix had approximately $4,146,000 and $1,082,000 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, 2010. The increase in inventory was primarily due to the addition of generic products to our portfolio through our acquisition of Macoven on September 8, 2010.

Results of Operations

Comparison of the Year Ended December 31, 2010 and 2009

Net Sales

Net sales were approximately $33,227,000 and $27,930,000 for the year ended December 31, 2010 and 2009, respectively, an increase of approximately $5,297,000, or 19.0%. The increase in net sales during the year ended December 31, 2010 consists of (i) an increase in gross product sales of approximately $11,262,000, or 29.0%, (ii) an increase in collaboration revenue of approximately $2,198,000, (iii) a decrease in the returns allowance of approximately $610,000, and (iv) a decrease in prompt pay discounts of approximately $604,000, partially offset by increases in Medicaid rebates of approximately $4,464,000 and price adjustments, customer fees and chargebacks of approximately $4,913,000.

For a discussion of our collaboration arrangements, See Note 16 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 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

Sales 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, 2010 and 2009, sales returns allowances were approximately $2,200,000, or 4.4%, of gross product sales, and $2,810,000, or 7.2%, of gross sales, respectively. The decrease in the sales returns allowances as a percentage of gross product sales is based on (i) the fact that more of our products have Medicaid coverage which results in product moving more rapidly through the

channel due to the increase in demand, (ii) a change in our return policy to disallow return credit on partial bottles, and (iii) an audit process and procedure that was put in place in the second quarter of 2010 to validate the appropriateness of all return deductions from our customers and recover any disallowed deductions.

Medicaid rebates were approximately $9,288,000, or 18.5%, of gross product sales, and $4,824,000 or 12.4%, of gross product sales, respectively, for the years ended December 31, 2010 and 2009. The liability for Medicaid 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. The increase in rebates as a percentage of gross product sales is primarily due to the adoption of new legislation effective January 2010 that increased the federal Medicaid rate from 11% to 13% on generics and 15.1% to 23.1% effective on brand products effective January 1, 2010. Also contributing to the increase was our purchase of CEDAX which, at the time of purchase, had a Medicaid rebate rate of 76% which we assumed. 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 will have a positive impact on reducing our Medicaid rebates as a percent of gross product sales in future years.

Price adjustments were approximately $6,517,000, or 13.0%, of gross product sales and $1,604,000, or 4.1%, of gross product sales, respectively, for the years ended December 31, 2010 and 2009. The increase in price adjustments as a percentage of gross product sales is due primarily to the addition of the generic product portfolio in September 2010 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. In addition, the point of sale discounts were higher in 2010 due to customer discounts given on price increases and other stocking allowances that were not necessary in 2009 due to the demand created by the swine flu.

Prompt pay discounts taken were approximately $1,337,000, or 2.7%, of gross product sales, and $1,941,000, or 5.0%, of gross product sales for the years ended December 31, 2010 and 2009, respectively. This decrease is attributable to renegotiated contracts with certain of our customers in 2010 to reduce their prompt pay discount to 2%. Approximately $306,000 and $127,000 in accrued allowances for prompt pay discounts was netted against accounts receivable at December 31, 2010 and 2009, respectively.

Cost of Product Sales

Cost of sales was approximately $6,500,000 and $5,437,000 for the years ended December 31, 2010 and 2009, respectively, an increase of approximately $1,063,000, or 19.6%. The cost of product samples included in cost of product sales was approximately $1,058,000 and $1,251,000 for the years ended December 31, 2010 and 2009, respectively, a decrease of approximately $193,000, or 15.4%. The decrease is primarily due to the fact that we decreased our sampling to physicians in 2010, coupled with the lower cost mix of sampled products in 2010. Collaboration expense, included in cost of sales, was approximately $458,000 and $0 for the years ended December 31, 2010 and 2009, respectively. See Note 16 to our Consolidated Financial Statements for the year ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K. Cost of product sales in the years ended December 31, 2010 and 2009 consisted primarily of the expenses associated with manufacturing and distributing Pernix's products. Cost of product sales, excluding samples and collaboration expense, increased approximately $799,000, or 19.1%, for the year ended December 31, 2010, due to the increase in our volume of sales, partially offset by a decrease in the freight costs, increase in the percentage of lower cost products sold in 2010 and decreased manufacturing costs as a result of changing certain manufacturers.

Selling Expenses

Selling expenses were approximately $6,672,000 and $5,180,000 for the years ended December 31, 2010 and 2009, respectively, an increase of approximately $1,492,000, or 28.8%. Sales salaries, commissions, health benefits and incentives represented approximately $4,685,000, or 70.2%, and $4,032,000, or 77.8%, of total selling expenses for the years ended December 31, 2010 and 2009, respectively. For the years ended December 31, 2010 and 2009, approximately $253,000 and $123,000 respectively, represents health benefits expenses for sales employees which

had previously been reported in general administrative expenses in prior periods. These expenses were reclassified to selling expenses at year end to reflect these benefits as a component of sales compensation. The increase in sales salaries, commissions, health benefits and incentives of approximately $653,000, or 16.2%, is primarily due to the addition of twenty-five sales representatives in 2010 which increased compensation, benefits and incentives by approximately $1,794,000. This increase included approximately $212,000 of incentives paid to sales representatives in December 2010. These incentives were awarded in recognition of the representatives' dedication to the Company in light of the fact that the change in our product mix and our corresponding change in the commission policy which resulted in a decrease in commissions of approximately $1,141,000, or 38.1%, for year ended December 31, 2010 as compared to the year ended December 31, 2009. Other selling expenses, which include expenses incurred for sales data, training, printing and marketing collateral, out-going freight, promotional items, cell phone, office supplies, vehicle expenses, travel and entertainment, and other miscellaneous overhead expenses of our sales force, were approximately $1,987,000 and $1,147,000 for the years ended December 31, 2010 and 2009, respectively. This increase of approximately $839,000, or 73.1%, was primarily due to increases in sales data expenses and program management fees in addition to certain expenses that increase with staff levels such as training expenses, travel and meals, cell phone and office supplies.

Royalty Expenses

Royalty expenses were approximately $739,000 and $1,224,000 for years ended December 31, 2010 and 2009. Royalty expenses are related to obligations under license and co-promotional agreements. The decrease of approximately $485,000 is due to the decrease in the royalty fees payable under the arrangements with Kiel. For a description of the agreements that currently require royalty fees, see Notes 10, 19 and 20 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

General and Administrative Expenses

General and administrative expenses were approximately $7,458,000 and $5,951,000 for the years ended December 31, 2010 and 2009, respectively, an increase of approximately $1,507,000, or 25.3%. Management and administrative compensation including salaries, health benefits, 401k match, bonuses and all payroll taxes represented approximately $3,306,000, or 44.3%, and $2,598,000, or 43.7%, of the total general and administrative expenses (excluding stock compensation expense) for the years ended December 31, 2010 and 2009, respectively. The increase in management and administrative compensation and benefits of approximately $708,000, or 27.2%, was primarily due to the hiring of (i) a vice president of supply chain management in October 2009, (ii) a regional sales director in September 2009, (iii) a chief financial officer in March 2010, (iv) an accounting supervisor in March 2010, (v) a director of government programs in June 2010, and (vi) three employees in the acquisition of Macoven on September 8, 2010. Stock compensation expense was approximately $464,000 and $681,000 for the years ended December 31, 2010 and 2009, respectively. Other general and administrative costs were approximately $3,688,000 and $2,672,000 for the years ended December 31, 2010 and 2009, respectively, an increase of approximately $1,016,000, or 38.0%. This increase was primarily due to increases in professional fees including legal, accounting, tax and technology support, board fees, directors and officers insurance, stock exchange fees, reporting and filing fees and annual meeting expenses. These expenses increased as a result of becoming a public company effective with the merger with GTA (as discussed in Note 1 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K).

Research and Development Expense

Research and development expenses were approximately $998,000 and $712,000 for the years ended December 31, 2010 and 2009, respectively. Research and development expenses during these periods consist primarily of the amortization of the $1.5 million development fee that we paid to Macoven in July 2009 which, prior to our re-acquisition of Macoven on September 8, 2010, was amortized over the 18-month term of the agreement. Other research and development costs relate to the testing of current products' durability. For further discussion of research and development expense pertaining to the agreement with Macoven see Note 2 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Depreciation and Amortization Expense

Depreciation expense was approximately $61,000 and $32,000 for the years ended December 31, 2010 and 2009, respectively. Amortization expense was approximately $1,178,000 and $179,000 for the years ended December 31, 2010 and 2009. The increase in amortization expense of approximately $999,000, or 557.5%, 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, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Other Income

Other income of approximately $287,000 for the year ended December 31, 2010 includes the forgiveness of an obligation of approximately $277,000 related to a generic co-promotion agreement that was renegotiated on September 29, 2010.

See discussion of the gain of approximately $882,000 from a bargain purchase related to the acquisition of Macoven in Note 4 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K.

Interest Income-net

Interest income was approximately $34,000 and $29,000 for the years ended December 31, 2010 and 2009, respectively. Interest expense was approximately $28,000 and $10,000 for the years ended December 31, 2010 and 2009, respectively.

Liquidity and Capital Resources

Sources of Liquidity

Pernix's net income before income taxes and non-controlling interest was approximately $10,794,000 and $9,238,000 for the years ended December 31, 2010 and 2009, respectively. As an S Corporation for the year ended December 31, 2009, Pernix generally did not pay federal income taxes. Instead, Pernix's income and losses were generally included in the taxable income of its stockholders, who reported the income and losses on their individual income tax returns and paid the appropriate tax individually. Effective January 1, 2010, Pernix revoked its S Corporation election, and began to pay income taxes at prevailing federal and state corporate income tax rates.

Pernix requires cash to meet its operating expenses and for capital expenditures, acquisitions, and in-licenses of rights to products. To date, Pernix has funded its operations primarily from product sales and co-promotion agreement revenues. We obtained a $10 million line of credit from Regions Bank on September 8, 2010, consisting of a $5 million revolver and a $5 million guidance line of credit for certain acquisitions pre-approved by Regions Bank. Certain acquisitions have been funded or partially funded using the $5 million secured guidance line of credit. As of December 31, 2010, Pernix had approximately $8,260,000 in cash and cash equivalents and approximately $5,000,000 available under the revolver. The $5,000,000 guidance line of credit has been fully funded as of December 31, 2010.

Cash Flows

The following table provides information regarding Pernix's cash flows for the years ended December 31, 2010 and 2009.

	Years Ended December 31,	
	2010	2009
Cash provided by (used in)		
Operating activities	$ 4,667,000	$ 9,943,000
Investing activities	(5,695,000)	(732,000)
Financing activities	4,710,000	(9,506,000)
Net increase (decrease) in cash and cash equivalents	$ 3,682,000	$ (295,000)

Net Cash Provided By Operating Activities

Net cash provided by operating activities for the years ended December 31, 2010 and 2009 was approximately $4,667,000 and $9,943,000, respectively. 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 items of $1,694,000, non-cash gain on bargain purchase of approximately $882,000, non-cash deferred income tax benefit of approximately $3,055,000, approximately $7,228,000 in increases in accrued expenses, income taxes payable, prepaid expenses and other assets offset by approximately $9,626,000 in increases in accounts receivable and inventory. Non-cash expenses included amortization of approximately $1,177,600, depreciation of approximately $61,000, stock compensation expense of approximately $464,000, and non-cash interest income of approximately $10,000. 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 $8,361,000 from the year ended December 31, 2009 to the year ended December 31, 2010 primarily due to additional sales resulting from the addition of generic products to our portfolio for which the terms are typically 60 to 75 days , the timing of net product sales and customer payments and receivables related to collaboration arrangements entered into or acquired during the year ended December 31, 2010. Approximately $2,225,000 in accounts receivable was acquired in the acquisition of Macoven. No amounts were considered delinquent as of December 31, 2010. Inventory increased by approximately $1,265,000 due to the addition of generic products and the CEDAX product family to our product portfolio through our acquisitions of Macoven and CEDAX. Approximately $1,790,000, in the aggregate, of inventory was acquired in the acquisitions of CEDAX and Macoven. Prepaid expenses and other assets decreased by approximately $298,000 due to the elimination of a development agreement with Macoven and the elimination of prepaid royalties with Gaine following our acquisition of these entities in 2010. Accounts payable increased by approximately $1,576,000 from the year ended December 31, 2009 due to timing differences in our payment of certain invoices, including our Medicaid rebate invoices. Accrued expenses increased approximately $3,305,000 from the year ended December 31, 2009 to the year ended December 31, 2010 primarily due to the increase in allowances for Medicaid rebates and the allowances related to our new generic offerings such as accrued customer rebates, chargebacks, fees and discounts. We record a provision against revenue for product returns that is also included in accrued expenses as discussed above.

Net cash provided by operating activities for the year ended December 31, 2009 primarily reflected Pernix's net income of approximately $9,199,000, adjusted by non-cash expenses totaling $892,000 and approximately $148,000 in net changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash items included amortization and depreciation of approximately $211,000 and stock compensation expense of approximately $681,000.

Net Cash Used in Investing Activities

Net cash used in investing activities for the years ended December 31, 2010 and 2009 was approximately $5,695,000 and $732,000, respectively. The investing activities of approximately $5,695,000 for the year ended December 31, 2010 consisted of approximately (i) $1,503,000 in the investment in the joint venture with SEEK, (ii) $1,996,000, net of cash acquired of approximately $189,000, paid in the acquisition of 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 of $250,000, and (vi) purchases of office furniture and equipment of approximately $119,000. The investing activities of approximately $732,000 for the year ended December 31, 2009 consisted of approximately (i) $100,000 to Kiel to amend an existing development agreement, (ii) $250,000 related to the cancellation of a license agreement related to certain products we no longer market offset by a non-cash adjustment of approximately $180,000 for the write-off of unamortized balance under the cancelled agreement, (iii) $450,000 for the acquisition of BROVEX assets including

the trade name and related inventory, and (iv) $112,000 for the purchase of certain office equipment . For additional information, Notes 4 and 10 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 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, 2010 was approximately $4,710,000, which represents cash acquired in connection with the merger with GTA of approximately $5,966,000, proceeds from the guidance line of credit of approximately $5,000,000, proceeds from payment on notes receivable of approximately $86,000, proceeds from the issuance of stock through the exercise of stock options of approximately $77,000, less approximately $4,600,000 for the remaining installment payments on the acquisition of CEDAX, $346,000 for the second installment net payment on the acquisition of Gaine, $600,000 in installment payments on the repurchase of stock from a related party, $250,000 in stock repurchases under our stock buyback program, approximately $121,000 in distributions to stockholders and $502,000 representing a transfer to restricted cash for the issuance of a letter of credit pursuant to a manufacturing agreement. See Note 1 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 contained in Part II, Item 8 of this Annual Report on Form 10-K for a discussion of the merger with GTA. Net cash used in financing activities for the year ended December 31, 2009 was approximately $9,506,000 which included distributions to stockholders of approximately $9,456,000 and approximately $51,000 representing the distribution of Pernix’s 60% interest in Macoven to the then-stockholders of Pernix in July 2009.

Funding Requirements

As of December 31, 2010, Pernix had a line of credit with approximately $5.0 million available for working capital under our revolving line of credit. One million of this available balance was used to pay the final scheduled installment on January 31, 2011 related to the acquisition of Gaine leaving, $4.0 million available under the revolver. Pernix's future capital requirements will depend on many factors, including:

- the level of product sales of its currently marketed products and any additional products that Pernix may market in the future;
- the scope, progress, results and costs of development activities for Pernix's current product candidates;
- the costs, timing and outcome of regulatory review of Pernix's product candidates;
- the number of, and development requirements for, additional product candidates that Pernix pursues;
- the costs of commercialization activities, including 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 acquires or invests in products, businesses and technologies;
- 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 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.

As of December 31, 2010, Pernix has approximately $8.3 million of cash and cash equivalents on hand. Based on its current operating plans, Pernix believes that its existing cash and cash equivalents and revenues from product sales and the line of credit proceeds will be sufficient to continue to fund its existing level of operating expenses and general capital expenditure requirements for the foreseeable future.

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, 2010 (in thousands):

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	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases(1)	$ 46	$ 29	$ 13	$ 4	$ —
Purchase obligations(2)	563	512	51	—	—
Line of credit(3)	5,242	138	5,104	—	—
Other long-term debt obligations (4)	3,000	1,200	1,800	—	—
Total contractual obligations	$ 8,851	$ 1,879	$ 6,968	$ 4	$ —

(1) Operating leases include minimum payments under leases for our facilities and certain equipment. Effective March 15, 2011, we entered into a new lease for the location of our corporate headquarters in The Woodlands, Texas which is not reflected in the table above. Our total minimum lease payments for the corporate headquarters under this lease are $61,000 in 2011, $96,000 in 2012, $99,000 in 2013, $102,000 in 2014 and $145,000 thereafter.

(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 Natoroba 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 which can be cancelled without penalty, which are approximately $1.8 million.

(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) 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.

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Stock Repurchase Authorization

On May 12, 2010, our Board of Directors authorized the repurchase of up to $5,000,000 in shares of our common stock. Stock repurchases under this authorization may be made through open market and 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.

As of March 25, 2011, we repurchased 2,070,867 shares of our common stock for an aggregate purchase price of approximately $3,850,000.

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.

Recent Accounting Pronouncements

See Note 2 to our Consolidated Financial Statements for the years ended December 31, 2010 and 2009 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, 2010 and 2009, and the related consolidated statements of income, 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, 2010 and 2009, 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, 2011

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,260,059	$ 4,578,476
Restricted cash	501,906	—
Accounts receivable,net	14,758,240	4,133,357
Note receivable	113,962	—
Inventory, net	4,145,734	1,081,970
Prepaid expenses and other current assets	1,816,100	1,625,719
Deferred income tax assets – current	2,494,000	61,000
Total current assets	32,090,001	11,480,522
Property and equipment, net	1,213,850	139,456
Other assets:		
Investment in joint venture	1,502,814	—
Intangible assets, net	10,961,900	1,409,337
Other long-term assets	264,967	383,333
Total assets	$ 46,033,532	$ 13,412,648
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 2,248,342	$ 436,663
Accrued personnel expense	848,013	560,657
Accrued allowances	10,488,674	6,795,542
Income taxes payable	2,149,052	100,000
Other accrued expenses	1,319,512	101,196
Contracts payable	2,200,000	42,382
Total current liabilities	19,253,593	8,036,440
Long-term liabilities		
Line of credit	5,000,000	—
Contracts payable	1,800,000	—
Deferred income taxes	1,075,000	—
Total liabilities	27,128,593	8,036,440
Commitments and contingencies		
EQUITY		
Common stock $.01 par value, 90,000,000 shares authorized, 24,698,594 and 20,900,000 issued, and 22,627,727 and 20,900,000 outstanding at December 31, 2010 and 2009, respectively	226,277	209,000
Treasury stock, at cost (2,070,867 shares held at December 31, 2010)	(3,751,890)	—
Additional paid-in capital	8,934,735	788,979
Retained earnings	13,495,817	4,308,491
Total stockholders' equity	18,904,939	5,306,470
Non-controlling interest	—	69,738

Total equity	18,904,939	5,376,208
Total liabilities and equity	$ 46,033,532	$ 13,412,648

See accompanying notes to consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF INCOME

	Years Ended December 31,	
	2010	2009
Net sales	$ 33,227,433	$ 27,930,352
Costs and expenses:		
Cost of product sales	6,500,377	5,436,818
Selling expenses	6,672,197	5,179,504
General and administrative expense	7,458,500	5,951,313
Research and development expense	998,224	711,780
Royalties expense	738,868	1,223,825
Depreciation and amortization expense	1,238,922	210,785
Total costs and expenses	23,607,088	18,714,025
Income from operations	9,620,345	9,216,327
Other income		
Other income	286,868	2,036
Gain from bargain purchase	881,950	—
Interest income, net	5,624	19,587
Total other income, net	1,174,442	21,623
Income before income taxes and non-controlling interest	10,794,787	9,237,950
Provision for income taxes	1,486,000	39,000
Net income before non-controlling interest	9,308,787	9,198,950
Net loss attributable to non-controlling interest	—	(40,754)
Net income attributable to controlling interest	$ 9,308,787	$ 9,239,704
Net income per share, basic and diluted	$ 0.40	$ 0.44
Weighted-average common shares, basic	23,415,449	20,900,000
Weighted-average common shares, diluted	23,418,398	20,900,000

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	Total
Balance at December 31, 2008	$ —$	—$	—$	6,331,210	$ 110,492	$ 6,441,702
Retroactive adjustment for issuance of shares in reverse merger with GTA	209,000	(209,000)	—	—	—	—
Distributions to stockholders:						
Transfer of land and buildings to affiliate	—	316,979	—	(1,310,000)	—	(993,021)
Deconsolidation of Macoven	—	—	—	(496,823)	—	(496,823)
Distributions	—	—	—	(9,455,600)	—	(9,455,600)
Stock based compensation	—	681,000	—	—	—	681,000
Net income (loss)	—	—	—	9,239,704	(40,754)	9,198,950
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)
	(20,000)	(75,500)	(3,504,500)	—	—	(3,600,000)

Negotiated repurchase from related party						
Proceeds from issuance of 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
Balance at December 31, 2010	$ 226,277	$ 8,934,735	$ (3,751,890)	$ 13,495,817	$ —	$ 18,904,939

See accompanying notes to consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31, 2010	2009
Cash flows from operating activities:		
Net income before non-controlling interest	$ 9,308,787	$ 9,198,950
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	61,322	31,707
Amortization	1,177,600	179,078
Deferred income tax benefit	(3,055,000)	—
Stock compensation expense	464,265	681,000
Gain from bargain purchase from Macoven acquisition	(881,950)	—
Non-cash interest	(9,634)	—
Changes in operating assets and liabilities:		
Accounts receivable	(8,361,058)	(1,650,858)
Income taxes	2,049,048	—
Inventory	(1,265,412)	579,012
Prepaid expenses and other assets	179,744	(1,709,378)
Other assets – long term	118,366	(383,333)
Accounts payable	1,575,621	389,464
Accrued expenses	3,304,915	2,627,430
Net cash provided by operating activities	4,666,614	9,943,072
Cash flows from investing activities:		
Investment in joint venture	(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)	—
Acquisition of BROVEX	—	(450,000)
Purchase of intangible assets	(250,000)	(170,277)
Purchase of equipment and payments for construction in progress	(119,580)	(112,183)
Net cash used in investing activities	(5,695,449)	(732,460)
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	5,000,000	—
Transfer to restricted cash for issuance of letter of credit	(501,906)	—
Payments received on notes receivable	86,334	—
Payment on acquisition obligation – CEDAX (see Note 4)	(4,600,000)	—
Payment on acquisition obligation – Gaine (see Note 4)	(345,807)	—
Distributions to stockholders	(121,461)	(9,455,600)
Deconsolidation of Macoven	—	(50,832)
Repurchase of common stock	(849,871)	—
Proceeds from issuance of common stock	77,600	—
Net cash provided by (used in) financing activities	4,710,418	(9,506,432)
Net increase (decrease) in cash and cash equivalents	3,681,583	(295,820)
Cash and cash equivalents, beginning of year	4,578,476	4,874,296

Cash and cash equivalents, end of year	$ 8,260,059	$ 4,578,476
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 2,653,043	$ —
Interest paid during the period	19,485	—
Non-cash transactions:		
Distribution of property including gain of approximately $317,000 recognized in additional paid-in-capital	$ —	$ 1,310,000
Deconsolidation of Macoven	—	445,991
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

Note 1. Organization and Merger

Pernix Therapeutics Holdings, Inc. and subsidiaries ("Pernix" or the "Company") is a specialty pharmaceutical company focused on developing and commercializing branded and generic pharmaceutical products to meet unmet medical needs primarily in pediatrics.

On October 6, 2009, Pernix Therapeutics, Inc. ("PTI") entered into an Agreement and Plan of Merger with Golf Trust of America, Inc. ("GTA"). At the closing of the merger on March 9, 2010, PTI merged with and into a wholly-owned subsidiary of GTA and GTA issued 20,900,000 shares of its common stock to PTI's stockholders, representing approximately 84% of the consolidated company's outstanding common stock on a fully diluted basis. Immediately following the closing of the merger, the Company changed its name from Golf Trust of America, Inc. to Pernix Therapeutics Holdings, Inc. PTI was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with accounting principles generally accepted in the United States ("GAAP"). Accordingly, the Company's financial statements for periods prior to the merger reflect the historical results of PTI and not GTA. The Company's financial statements for all subsequent periods reflect the results of the consolidated company. Stockholders' equity has been retroactively restated to reflect the number of shares of common stock received by former PTI stockholders in the merger, after giving effect to the difference between the par value of the common stock of PTI and GTA, with the offset to additional paid-in capital. The 2009 financial statements have been restated to reflect the 2-to-1 reverse split of GTA's common stock that became effective immediately prior to the closing of the merger.

Unless specifically noted otherwise, as used throughout these consolidated financial statements, the term "Company" or "Pernix" refers to the consolidated company after the merger and the business of PTI before the merger. The terms PTI and GTA refer to such entities' standalone businesses prior to the merger.

Note 2. Summary of Significant Accounting Policies

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") which is a patent and license holding company that was owned 50% by Pernix and was considered a controlled entity until June 24, 2010 when Pernix purchased the remaining 50% of Gaine making it a wholly-owned subsidiary of Pernix and (iii) Macoven Pharmaceuticals, LLC ("Macoven"), which is a company that promotes authorized generic products that Pernix reacquired on September 8, 2010. From January 1, 2009 through July 13, 2009, the financial statements of Pernix included the operations of Macoven; however, operations for this subsidiary were not material. From July 13, 2009 to September 8, 2010, Macoven was no longer consolidated because it was spun off from Pernix and was owned 60% by the former stockholders of PTI (in proportion to their ownership of PTI), 20% by an officer of the Company and 20% by an officer of Macoven. As discussed in Note 4 below, as of September 8, 2010, Macoven became a wholly owned subsidiary of Pernix and, therefore, Macoven's operations are consolidated subsequent to this date. Transactions between and among the Company and its consolidated subsidiaries are eliminated.

Basis of accounting

The accompanying financial statements have been prepared on the accrual basis of accounting 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, contracted vendor discounts, returns on product sales, sales commissions, Medicaid rebates, customer rebates and chargebacks, amortization, depreciation, and the determination of fair values of assets and liabilities in connection with business combinations.

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, 2010, approximately 88% of the inventory purchases were from three primary suppliers, allocated 46% and 22% and 20%, respectively. For the year ended December 31, 2009, approximately 85% of the inventory purchases was from three primary suppliers, allocated 22%, 29% and 34%, 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. 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. The Company is exposed to credit risk in the event of a default by the financial institution holding its cash deposits to the extent such deposits exceed federally insured limits. The Company has not experienced any losses due to such concentration of credit risk. The Federal Deposit Insurance Corporation (FDIC) covers $250,000 for substantially all depository accounts. The Company from time to time may have amounts on deposit in excess of the insured limits. As of December 31, 2010, the Company had approximately $6,275,000 which exceed these insured amounts.

Accounts Receivable

Accounts receivable result primarily from sales of pharmaceutical products and amounts due under collaboration 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 days for generic sales. Current earnings are charged with an allowance for doubtful accounts based on experience and evaluation of the individual accounts. Write-offs of doubtful 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, 2010 and 2009, 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 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. This analysis is highly subjective. 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 market value. As of December 31, 2010, the Company did not have any such impairment loss.

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 2010 or 2009.

Equity method of Accounting

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

Revenue Recognition

The Company records revenue from product sales when 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. At the time of sale, estimates for a variety of sales deductions, such as Medicaid rebates, customer contracted rebates, chargebacks and discount service fees, and product returns are

recorded. Costs associated with sales revenues are recognized when the related revenues are recognized. The following table sets forth a summary of Pernix's net sales for the years ended December 31, 2010 and 2009.

	Year Ended December 31, (in thousands)	
	2010	2009
Gross Product Sales		
Upper respiratory, allergy and antibiotic products	$ 48,485	$ 38,463
Medical food products	691	354
Dermatology products	903	—
Collaboration revenue	2,490	292
Gross Sales	52,569	39,109
Prompt pay discounts	(1,337)	(1,941)
Allowance for returns	(2,200)	(2,810)
Allowance for price adjustments (rebates, chargebacks and customer fees)	(6,517)	(1,604)
Medicaid rebate expense	(9,288)	(4,824)
Net Sales Revenues	$ 33,227	$ 27,930

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 expiration date of its product. 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 remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. The Company estimates returns ranging from approximately 5% to 7% of sales of branded products based upon historical data compiled since 2004 and other facts and circumstances that may impact future expected returns to derive the average return percentages of its products. The Company estimates approximately 1% to 3% on sales of generics. The Company reviews the reserve quarterly and adjusts it accordingly.

Medicaid Rebates

The liability for Medicaid 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, and chargebacks are based on our estimated mix of sales to various third-party payors which 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 voucher programs for its promoted products whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher 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, which are a reduction of 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 of 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 to reintroduce a product.

Prompt Payment Discount

The Company typically requires its customers to remit payments within the first 30 or 60 days, 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 distributors typically take the prompt pay discount, we accrue 100% of the 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 $175,000 and $129,000 for the years ended December 31, 2010 and 2009, 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. Included in research and development costs 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 are related to the testing of current products' durability.

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 type of customer, the distribution method and the regulatory environment.

Income Taxes

Income taxes are accounted for using the asset and liability method pursuant to 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, 2010. Prior to the merger with GTA, Pernix had elected to be an S corporation; as such, taxable earnings and losses were included in the personal income tax returns of Pernix's shareholders prior to January 1, 2010.

Earnings per Share

Earnings per common share are presented under two formats: basic earnings per common share and diluted earnings per common share. Earnings per share are 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 are computed by dividing net income by the weighted average number of common shares outstanding during the period, plus the potential 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 the exercise of stock options.

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

	Year Ended December 31,	
	2010	2009
Numerator:		
Net income	$9,308,787	$9,239,704
Denominator:		
Weighted-average common shares, basic	23,381,676	20,900,000
Dilutive effect of stock options	33,773	—

Weighted-average common shares, diluted	23,415,449	20,900,000
Net income per share, basic and diluted	$0.40	$0.44

Total outstanding options are 1,026,000. Options not included above are anti-dilutive as of December 31, 2010. See Note 17 for information regarding the Company's outstanding options.

Reclassifications

Certain reclassifications have been made to prior period amounts to conform to the current period presentation. These reclassifications had no effect on net income as previously reported.

Recent Accounting Pronouncements

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 nondeductible 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 our consolidated results of operations and will be amortized on a straight-line basis for the year. This guidance is effective for us January 1, 2011. We are currently awaiting information from the Internal Revenue Service regarding the calculation of this fee. We do not currently expect that this fee will have a material impact on our results of operations for 2011.

In December 2010, the FASB issued ASU 2010-29, “Business Combinations (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. Early adoption is permitted. We intend to adopt this guidance in 2011. Other than requiring additional disclosures with respect to the CEDAX and Macoven acquisitions, the adoption of this new guidance will not have a material impact on our consolidated financial statements.

In January 2010, the FASB amended ASU 2010-06, “Fair Value Measurements and Disclosures (ASC Topic 820)—Improving Disclosures about Fair Value Measurements,” the existing disclosure guidance on fair value measurements, which is effective January 1, 2010, except for disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements, which is effective January 1, 2011. Among other things, the updated guidance requires additional disclosure for the amounts of significant transfers in and out of Level 1 and Level 2 measurements and requires certain Level 3 disclosures on a gross basis. Additionally, the updates amend existing guidance to require a greater level of disaggregated information and more robust disclosures about valuation techniques and inputs to fair value measurements. Since the amended guidance requires only additional disclosures, the adoption of the provisions effective January 1, 2010 did not, and for the provisions effective in 2011 will not, impact our consolidated financial position or results of operations.

In March 2010, the FASB issued ASU No 2010-12, Income Taxes (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 announcement provides 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 is effective immediately. The Company does not expect the health care bills to affect the Company’s tax positions.

In February 2010, the FASB issued ASU No. 2010-09, Subsequent Events: Amendments to Certain Recognition and Disclosure Requirements. The amendment removes the requirement for an SEC filer to disclose the date through which subsequent events have been evaluated in both issued and revised financial statements. SEC filers are still required to evaluate subsequent events through the date that the financial statements are issued. ASU No. 2010-09 was effective upon issuance and had no material impact on the Company’s consolidated financial statements or disclosures.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, under ASC No. 605. The new guidance provides a more flexible alternative to identify and allocate consideration among multiple elements in a bundled arrangement when vendor-specific objective evidence or third-party evidence of selling price is not available. ASU No. 2009-13 requires the use of the relative selling price method and eliminates the residual method to allocation arrangement consideration. Additional expanded qualitative and quantitative disclosures are also required. The guidance is effective prospectively for revenue arrangements entered into or materially modified in years beginning on or after June 15, 2010. The Company does not believe that the adoption of ASU No. 2009-13 will have a material impact on its 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 Company does not believe that the adoption of ASU No. 2009-13 will have a material impact on its 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.

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, 2009, the Company had approximately $4,236,000 invested in an overnight repurchase account which is classified as Level 2. As of December 31, 2010, the Company did not have any funds in overnight repurchase accounts.

The Company has a note receivable of approximately $113,000 at December 31, 2010 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.

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 (which includes inventory of approximately $1,200,000) .

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. Since July 2009, Macoven has held a non-exclusive license to develop, market and sell authorized generics of Pernix branded products. To date, Macoven has launched five Pernix-based generic products. With the acquisition of Macoven, Pernix expects the development, marketing and sale of all of Pernix's authorized generic products to be performed exclusively by Macoven.

Prior to the acquisition, Macoven was owned approximately 60% by an entity controlled by certain officers and a director of Pernix, approximately 20% by a member of Pernix management and approximately 20% by an officer of Macoven.

Concurrent with the closing of the Macoven acquisition on September 8, 2010, we entered into an employment agreement with an officer of Macoven which provides the opportunity for him to receive equity grants based on Macoven's performance over six fiscal quarters, beginning with the quarter ending December 31, 2010. For the quarter ended December 31, 2010, no equity award was earned. On March 14, 2011, the parties entered into an amended and restated employment agreement. See Note 20, Subsequent Events, for further discussion.

The Company engaged a valuation specialist to assist in deriving the estimated fair value for Macoven. The estimated fair value of $5.3 million was allocated among the acquired assets in the summary below. Approximately $2.2 million, which represents approximately 80% of the fair value in excess of the purchase price, was recorded as contributed capital due to the fact that 80% of the membership interests in Macoven were owned by common stockholders and/or employees of Pernix. The remaining excess fair value of approximately $0.88 million was recorded as a bargain purchase gain.

The following summarizes the final fair values of the assets acquired and liabilities assumed at the date of acquisition:

Cash	$ 189,000
Receivables	2,622,000
Prepaids and other assets	200,000
Inventories	1,186,000
Equipment	3,000
Intangibles, including non-compete and certain contracts	5,194,000
Accounts payable	(236,000)
Accrued expenses	(64,000)
Accrued allowances	(625,000)
Due to related party	(72,000)
Contracts payable	(277,000)
Deferred revenue – related to Macoven Pharmaceuticals, LLC contract with Pernix (eliminated in consolidation)	(394,000)
Deferred tax liability	(1,697,000)
Dividends payable	(750,000)
Total fair value	$ 5,279,000

Acquisition of CEDAX

For the purpose of adding an additional branded product line that would complement our cough and cold products, 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 to be paid in three installments as follows: (i) $1.5 million which was paid at closing, (ii) $1.5 million which was paid on the 60th day following the closing, or May 23, 2010 and (iii) $3.1 million, which was paid on the 270th day following the closing, or December 20, 2010.

The following summarizes the final fair values of the acquired assets at the date of acquisition:

Inventories	$ 718,000
Due from Seller	40,000
Equipment	48,000
Brand	3,887,000
Goodwill	1,407,000
Total purchase price	$ 6,100,000

Pro Forma

Set forth below are the Company’s summary unaudited pro forma results of operations for the years ended December 31, 2010 and 2009. The unaudited pro forma results of operations for the years ended December 31, 2010 and 2009 include the historical results of the Company and give effect to the above acquisitions as if they had occurred at

the beginning of the earliest period presented.

The unaudited pro forma results of operations do not purport to represent what the Company's results of operations would actually have been had these acquisitions occurred as of January 1, 2010 or January 1, 2009, as the case may be, or to project the Company's results of operations for any future period. Actual future results may vary considerably based on a variety of factors beyond the Company's control.

	For the six months ended June 30,		For the nine months ended September 30,		For the years ended December 31,	
	2010	2009	2010	2009	2010	2009
	(in thousands) (unaudited)					
			(except per share data)			
Net Sales	$13,814	$16,147	$25,994	$21,851	$37,414	$31,275
Income before taxes	5,036	6,909	8,750	7,786	12,753	8,686
Net income allocated to common stockholders	5,694	6,465	8,585	7,445	10,495	8,898
Basic earnings per share	0.23	0.31	0.36	0.38	0.45	0.38
Diluted earnings per share	0.23	0.31	0.33	0.38	0.45	0.38

The pro forma results include (i) the elimination of an advisory fee and legal fee incurred by the Company in connection with the acquisition of CEDAX in the year ended December 31, 2010, (ii) amortization expense recognized on identifiable intangible assets resulting from the acquisitions, (iii) recognition of the bargain purchase gain in the Macoven acquisition, (iv) stock compensation expense related to employment agreement executed concurrent with closing of Macoven acquisition and (v) the recording of income tax expense resulting from the pro forma adjustments before tax at the effective rate of 38 percent.

Acquisition of Non-controlling interest in Gaine

On May 29, 2008, Pernix acquired a 50% ownership interest in Gaine, a patent and licensing holding company. Following this acquisition, Pernix considered Gaine a controlled entity and included Gaine's financial statements with Pernix's consolidated financial statements.

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 was required to pay the sellers as follows: (i) an aggregate of $500,000 in cash, net of adjustments of approximately $173,000, that was paid at closing, (ii) an aggregate of $500,000 in cash, net of adjustments of approximately $179,000, that was paid on October 31, 2010 and (iii) an aggregate of $1,000,000 in cash that was paid 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.

Additionally, in the event a new drug application is approved by the United States Food and Drug Administration (the "FDA") for one of Pernix's antitussive product candidates incorporating the invention claimed in a United States antitussive patent owned by Gaine or ownership of the patent is transferred, Pernix will then be obligated to pay the sellers an aggregate of $10,000,000 in cash or Pernix common stock.

Note 5. Accounts Receivable

Accounts receivable consist of the following:

	December 31,	
	2010	2009
Trade accounts receivable	$13,383,021	$3,963,852
Less allowance for customer discounts	(305,917)	(127,573)
Total trade receivables	13,077,104	3,836,279
Receivables from third parties – collaboration arrangements	1,681,136	297,078
Total account receivables	$14,758,240	$4,133,357

The Company typically requires our customers to remit payments within the first 30 (for brand purchases) or 60 days (for generic purchases), depending on the customer and the products purchased. The Company offers wholesale distributors a prompt payment discount as an incentive to remit payment within these deadlines. This discount is generally between 2% and 7%. Because the Company's wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of the sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Accounts receivable is stated net of estimated discounts. The Company's management evaluates accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. As of December 31, 2010 and 2009, no receivables were outstanding for longer than 90 days. The net amount of accounts receivable was considered collectible and no allowance for doubtful accounts has been recorded.

Note 6. Inventory

Inventories consist of the following:

	December 31,	
	2010	2009
Purchased finished goods	$ 4,145,734	$ 1,081,970
Purchased samples	743,092	591,880
	4,888,826	1,673,850
Less allowance for samples inventory	(743,092)	(591,880)
	$ 4,145,734	$ 1,081,970

Note 7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2010	2009
Prepaid expenses	$ 795,559	$ 119,123
Deposits on inventory and prepaid royalties	1,020,541	506,596
Current unamortized research and development fees related to Macoven agreement (see Note 16)	—	1,000,000
Total	$ 1,816,100	$ 1,625,719

Note 8. Property, Plant & Equipment

	December 31,	
	2010	2009
Land	$ 952,342	$ —
Buildings	25,485	—
Equipment	319,016	182,185
Furniture and fixtures	52,998	24,596
Computer software and website	88,500	88,500
	1,438,341	295,281
Less accumulated depreciation	(224,491)	(155,825)
	$ 1,213,850	$ 139,456

Depreciation expense amounted to approximately $61,000 and $32,000 for the years ended December 31, 2010 and 2009, respectively.

In March 2010, the Company acquired land and furniture and fixtures valued at approximately $952,000 and $12,000, in the merger with GTA, respectively. The $952,000 represents the estimated fair value of 118.67 acres of undeveloped land in Charleston County, South Carolina.

Note 9. Investment in Joint Venture

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% voting interest and approximately 46% of the total economic power 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 with SEEK. Under its license arrangement, Pernix may fund the development costs to seek approval for a new drug application from the United States Food and Drug Administration (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.

The JV intends to commence a single phase III trial of BC 1036 in the second half of 2011 in order to obtain regulatory approval in Europe. With respect to United States regulatory approval, the JV has initiated preliminary discussions with the FDA and has met with the FDA to discuss a regulatory approval program in the United States.

Condensed Balance Sheet as of December 31, 2010 (unaudited) (in thousands)	
Cash	$1,332
Intellectual property and other rights	1,676
Total assets	$3,008
Total equity	$3,008

See Note 20 for further discussion.

Note 10. Intangible Assets

Intangible assets consist of the following:

		December 31,	
	Life	2010	2009
Patents	12 - 15 years	$ 1,442,000	$ 1,200,000
Brand – CEDAX	8 years	3,887,000	—
Non-compete and supplier contract – Macoven	3 years	5,194,571	—

Non-compete – Ubiquinone	2 years	250,000	250,000
Trademark rights – BROVEX	Indefinite	238,758	238,758
Goodwill	Indefinite	1,406,591	—
		12,418,920	1,688,758
Accumulated amortization		(1,457,020)	(279,421)
		$ 10,961,900	$ 1,409,337

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

	Amount
2011	$ 2,799,000
2012	2,185,000
2013	1,534,000
2014	602,000
2015	602,000
Thereafter	1,594,000
	$ 9,316,000

Amortization expense is approximately $1,178,000 and $179,000 for the years ended December 31, 2010 and 2009, respectively.

Patents

Gaine entered into a patent assignment with the original owners of a U.S. patent for an active pharmaceutical ingredient that the Company intends to use for certain of its antitussive product candidates. Gaine paid $500,000 for the ownership of this patent.

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, Pediatex and Z-Cof 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. The Company incurred royalty expense to Kiel of approximately $112,000 and $1,224,000 for the years ended December 31, 2010 and 2009, respectively, for products manufactured with the TCT technology. The 2010 royalties represent the amortization of prepaid royalties paid upon receipt of the products and amortized as the products are sold.

Product Licenses

The Company acquired rights to certain products incorporating a patented drug delivery technology owned by Kiel pursuant to a development agreement dated November 2006. Pursuant to the 2006 development agreement, Kiel agreed to develop certain products using the Kiel technology, including ALDEX AN and PEDIATEX TD, and granted Gaine an exclusive, worldwide license to manufacture and market these products at its expense. Gaine, in turn, licensed these products to Pernix. The term of this license was 15 years. As consideration for the license and development of these products, Gaine paid Kiel an aggregate fee of $800,000. The value originally paid for these rights was considered in the purchase of the patent on August 24, 2010 and was, therefore, combined to derive the total value of the TCT Technology.

On October 27, 2009, the Company executed a cancellation and settlement agreement related to a license agreement for the Company’s QUINZYME line. Pursuant to the agreement, the Company paid a one-time settlement fee of $250,000. In consideration for this amount, the licensor agreed not to sell, develop or cause to be developed any ubiquinone products (the active ingredient in Pernix’s QUINZYME line) for a period of two years. No further payments will be due under the agreement.

On June 1, 2009, the Company completed an acquisition of all rights to the BROVEX product lines including related trademarks for $239,000 and inventory for $211,000 in cash paid at closing.

See Note 4 for discussion regarding the acquisition of the Macoven intangible assets and the CEDAX brand and sublicense rights.

Note 11. Accrued Allowances

Accrued allowances consist of the following:

	December 31,	
	2010	2009
Accrued returns allowance	$ 4,313,000	$ 3,975,000
Accrued customer rebates and chargebacks allowance	1,122,500	—
Accrued contracted vendor discounts	621,174	519,542
Accrued Medicaid rebates	4,432,000	2,301,000
Total	$ 10,488,674	$ 6,795,542

Note 12. Contracts Payable

Contracts payable consist of the following:

	December 31, 2010	December 31, 2009
Stock repurchase contract with related party (see Note 14)	$ 1,200,000	$ —
Gaine acquisition	1,000,000	—
Other	—	42,382
Total contracts payable – short term	$ 2,200,000	$ 42,382
Stock repurchase contract with related party (see Note 14) – long term	$ 1,800,000	$ —

Note 13. Lines of Credit

On September 8, 2010, the Company entered into a Loan Agreement (the "Loan Agreement") with Regions Bank ("Regions"). 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 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%.

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, 2010, the Company was in compliance with all 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 currently 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 as of December 31, 2010 were $5,000,000 and $0, respectively.

Note 14. Stockholders' Equity

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 the next 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 in open market purchases for an aggregate price of approximately $250,000. As of December 31, 2010, after consideration of the repurchase of 2,000,000 shares discussed, there remained $1,150,000 of the authorized amount to repurchase shares of the Company's outstanding common stock under the repurchase program.

In 2009, the Board declared and paid total distributions of approximately $9,456,000.

Note 15. Major Customers

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, 2010 and 2009, 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, 2010 and 2009:

Gross Product Sales	For the years ended December 31,	
	2010	2009
Cardinal Health, Inc.	43%	37%
McKesson Corporation	29%	32%
Morris & Dickson	13%	13%
Total	85%	82%

Accounts Receivable	As of December 31,	
	2010	2009
Cardinal Health, Inc.	50%	17%
McKesson Corporation	27%	62%
Morris & Dickson	11%	10%
Total	88%	89%

Note 16. Collaboration Agreements

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, as well as expense reimbursements or payments to the third party. Revenues related to products sold by the Company pursuant to these arrangements are included in product sales, while other sources of revenue (e.g., royalties and profit share payments) are included in collaboration and other revenue. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item.

Macoven Pharmaceuticals, LLC

On July 27, 2009, the Company and Macoven entered into an agreement whereby the Company granted Macoven a non-exclusive license to develop, market and sell generic products based on the Company's branded products. The initial term of the agreement was 18 months, and was automatically renewable for successive 12- month terms unless terminated by either party. Pursuant to the terms of the agreement, the Company paid Macoven a one-time development fee of $1,500,000. Prior to the acquisition of Macoven on September 8, 2010, this fee was being amortized over the 18-month term of the agreement. As discussed in Note 4, effective September 8, 2010, Macoven became a wholly-owned subsidiary of Pernix. Prior to the acquisition, the unamortized balance of the fee was included in current assets. Subsequent to September 8, 2010, the revenue/expense and unamortized balance from the

collaborative agreement is eliminated in consolidation.

Co-promotion agreements

The Company seeks to enter into co-promotion agreements to enhance its promotional efforts and sales of its 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 that are not aligned with its product focus or when Pernix lacks sufficient sales force representation in a particular geographic area. See Note 4 for further discussion. With the acquisition of Macoven, the Company assumed two additional co-promotion agreements, one of which expired at December 31, 2010. The total revenue from co-promotion agreements is approximately $2,490,000 and $292,000 for the years ended December 31, 2010 and 2009, and is recorded as collaboration revenue included in net sales. The total expense from co-promotion agreements for the years ended December 31, 2010 and 2009, is approximately $458,000 and $0, respectively. Expense from co-promotion agreements is included in cost of goods sold.

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 $209,000 and $226,000 for the years ended December 31, 2010 and 2009, respectively.

Stock Options

The Company's 2009 Stock Incentive Plan was approved concurrent with its merger with GTA on March 9, 2010. The maximum number of shares offered under this plan is 3,683,787 (following the reverse stock split). Incentives may be granted under the Plan to eligible participants in the forms 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, 2010, approximately 250,000 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 two years.

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.

From March 10, 2010 to December 31, 2010, 790,000 options were issued to employees and non-employee board members from the Company's 2009 Stock Incentive Plan at an average exercise price of $3.74 based on the most recent closing price of our common stock on the NYSE Amex as of the date of the grant. These options vest ratably over three years and expire ten years from the date of the grant.

During the year ended December 31, 2010, 40,000 options previously granted to non-employee former board members of GTA were exercised, all in the second quarter. The exercise price of these options was $1.94. Additionally, 60,000 options previously granted to non-employee former board members expired and 24,000 options previously granted to former employees were cancelled during the year ended December 31, 2010.

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

	Year Ended December 31, 2010
Expected stock price volatility - range	69.3 - 76.3%
Estimated dividend yield	0.00%
Risk-free interest rate	2.51%

Expected life of option (in years)		6.00
Weighted-average fair value per share	$	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 during the year ended December 31, 2010.

Option Shares	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2009	—	$ 0.00
Assumed in reverse merger with GTA on March 10, 2010	360,000	3.73
Granted	790,000	3.74
Exercised	(40,000)	1.94
Cancelled	(24,000)	3.73
Expired	(60,000)	8.25
Outstanding at December 31, 2010	1,026,000	$ 3.81
Vested and exercisable, end of the period	260,000	$ 4.02

The following table shows the details by range of exercise price for the total options outstanding:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Shares	Remaining Contractual life (years)	Shares	Price	
$ 1.94 – 2.20	67,500	2.2	67,500	$	2.12
$ 3.31	75,000	9.7	—		—
$ 3.64	20,000	2.2	20,000		3.64
$ 3.73	516,000	9.4	—		—
$ 3.80	25,000	2.2	25,000		3.80
$ 3.94	75,000	9.9	—		—
$ 3.98	100,000	9.2	—		—
$ 4.20	137,500	2.2	137,500		4.20
$ 15.70	10,000	0.1	10,000		15.70
	1,026,000	7.6	260,000	$	4.02

As of December 31, 2010, the aggregate intrinsic value of 260,000 options outstanding and exercisable was approximately $623,900.

As of December 31, 2010, there was approximately $1,374,000 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized ratably over a weighted-average period of 2.45 years.

Restricted Stock

As of December 31, 2010, there were 100,000 restricted common shares outstanding that will vest ratably over three years beginning on March 10, 2011. Approximately $290,000 of total unrecognized compensation cost related to unvested restricted stock is expected to be recognized over a weighted-average period of 2.19 years.

Stock-Based Compensation Expense

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

	Years Ended December 31,	
	2010	2009
Employee	$ 287,000	$ 681,000
Non-employees/Directors	177,000	—
Total	$ 464,000	$ 681,000

The stock compensation in the year ended December 31, 2009 of $681,000 is related to a stock transaction in January 2009, representing the difference in the fair value and the transaction price, between one outside stockholder and certain officers of Pernix.

Equity Awards Related to Macoven Acquisition

As previously disclosed, we entered into an employment agreement with an officer of Macoven concurrent with the closing of the Macoven acquisition on September 8, 2010. The agreement provided the opportunity for this individual to receive equity grants based on Macoven's performance over six fiscal quarters, beginning with the quarter ending December 31, 2010. For the quarter ended December 31, 2010, no equity award was earned, and on March 14, 2011, the parties amended and restated this agreement. See Note 20, Subsequent Events for further discussion.

Note 18. 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 Pernix's shareholders. 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, 2010 and 2009, 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. For the year ended December 31, 2009, the components of the income tax benefit related primarily to the operations of Gaine and the state income taxes relating to Pernix.

The components of the provision for income taxes are as follows for the years ending December 31, 2010 and 2009:

	Year Ended December 31,	
	2010	2009
Current:		
Federal	$ 3,765,000	$ (37,900)
State	776,000	95,500
	4,541,000	57,600
Deferred Provision:		
Federal	(2,807,000)	(16,600)
State	(248,000)	(2,000)
	(3,055,000)	(18,600)
	$ 1,486,000	$ 39,000

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,	
	2010	2009
Deferred tax assets:		
Accounts receivable	$ 118,000	$ —
Accruals	2,268,000	
Restricted stock	42,000	
NOL carryovers	649,000	44,000
Other	—	17,000
Gross deferred tax assets	3,077,000	61,000
Deferred tax liabilities:		
Differences in carrying value of property and equipment	$ (33,000)	$ —
Other	(90,000)	—
Intangibles	(1,535,000)	—
Gross deferred tax liability	(1,658,000)	—
Net deferred tax asset/(liability)	1,419,000	61,000
Included in consolidated balance sheet:		
Deferred income tax assets/deferred income tax liabilities–current	2,494,000	61,000
Deferred income tax assets/deferred income tax liabilities–long-term	(1,075,000)	—
Net deferred tax asset	$ 1,419,000	$ 61,000

For the year ended December 31, 2009, the rate reconciliation reflects only the operations of Gaine as Pernix was an S-Corporation until January 1, 2010.

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, 2010 and 2009 for the following reasons:

	December 31,	
	2010	2009
Expected taxes at statutory rates	35.0%	(34.0%)
State taxes	3.2%	(4.0%)
Establishment of deferred tax asset due to tax status change	(17.0%)	—
Incentive stock options	1.2%	—
Nondeductible expenses, including merger related expenses	1.6%	86.0
Non-taxable gain upon merger	(2.9%)	—
Release of valuation allowance	(7.2%)	—
Other	(0.1%)	—
	13.8%	48.0%

Note. 19. Commitments and Contingencies

Letter of Credit

During the three months ended June 30, 2010, 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. At December 31, 2010, the Company has $501,906 in a certificate of deposit to secure this letter of credit. The letter of credit expires on April 30, 2011.

Consulting Agreement

On April 13, 2010, Pernix entered into a consulting agreement with Kiel whereby it paid Kiel an aggregate fee of $200,000 to assist it in the development of two of its Theobromine antitussive product candidates incorporating the invention claimed in the patent owned by Gaine and the preparation and filing of an investigational new drug application with the FDA. This fee is being amortized over the term of this agreement which expires on April 13, 2011.

Leases

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 $5,000 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. See Note 20 for further discussion.

The Company leases it office facilities in South Carolina under a lease with an unrelated third party. The term of the lease is two years and the initial term expires on April 1, 2012. Pursuant to this lease, the Company pays rent of approximately $1,050 per month with annual escalators of 10%.

The Company leases certain equipment under operating leases pursuant to which future expected payments are approximately $29,000 in 2011, $8,000 in 2012, and $9,000 thereafter.

Purchase Commitments

As of December 31, 2010, the Company has commitments for the purchase of goods and services of approximately $563,000.

Other Commitments

From time to time in the ordinary course of business, the Company enters into agreements that require royalty payments. The royalty expense recognized in the year ended December 31, 2010 related to such agreements was approximately $739,000.

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.

Note 20. Subsequent Events

Approval of Natroba

The Company and ParaPRO, LLC ("ParaPRO") announced on January 19, 2011 that the U.S. Food and Drug Administration (FDA) approved Natroba™ (spinosad) Topical Suspension, 0.9%, to eliminate head lice (pediculosis capitis). Natroba™ received approval as a prescription medication and is indicated for the topical treatment of head lice infestations in patients four (4) years of age and older. Pursuant to an agreement for support services entered into between the Company and ParaPRO on August 27, 2010, 460,000 stock options will be issued to ParaPRO upon formal approval of Natroba's packaging and labeling, which is expected to occur in the second quarter of 2011. The options have an exercise price of $3.65 which is the closing price of the Company's stock as of the date of this agreement, August 27, 2010. When issued, the options will become exercisable in seven installments in the following amounts: (i) 30,000 on August 1, 2011; (ii) 40,000 on August 1, 2012; (iii) 50,000 on August 1, 2013; (iv) 60,000 on August 1, 2014; (v) 70,000 on August 1, 2015; (iv) 90,000 on August 1, 2016; and (vii) 120,000 on August 1, 2017. The options are exercisable for a period of five years from the date each becomes exercisable. These options will be issued in a private offering under Rule 4(2) of the Securities Act of 1933.

The Company's co-promotion agreement for Natroba requires that Pernix meet certain annual sales targets. In the event the Company is unable to meet these requirements, ParaPRO may revoke Pernix's exclusivity to market Natroba and/or terminate the co-promotion agreement.

Grant of Equity Incentives to Director of Investor Relations and Corporate Communications

On January 19, 2011, 20,000 shares of restricted stock and 40,000 stock options were granted from the 2009 Stock Incentive Plan to the Director of Investor Relations and Corporate Communications as an inducement for employment. The exercise price of the options is $7.90 and is based on the most recent closing price of our common stock on NYSE Amex as of the date of the grant. These options vest ratably over three years and expire ten years from the date of the grant.

$1,000,000 Under Secured Credit Facility

On January 31, 2011, the Company increased its borrowings under its credit facility with Regions Bank by $1,000,000 for an outstanding balance of $6,000,000, of which $5,000,000 is under the GLOC and $1,000,000 is under the RLOC.

Amended and Restated Employment Agreement with Vice President of Sales of Macoven

On March 14, 2011, the Company entered into an amended and restated employment and non-compete agreement with the vice president of sales of Macoven. Under the terms of the amended and restated agreement, this individual continues to be employed by Macoven as Vice President of Sales at a base salary of $208,000. Macoven paid this officer a one-time cash bonus of $200,000 upon execution of the amended and restated agreement, and he is eligible to earn annual cash bonuses based on his performance beginning with the fiscal year 2011 up to a maximum 100% of his base salary.

Beginning with the quarter ended June 30, 2011 and continuing for the next nineteen quarterly periods thereafter, if Macoven generates $1 million in quarterly net income, this officer is entitled to a payment of $200,000 (the “Employee Quarterly Bonus”). In addition, if the annual net income for a given calendar year exceeds $4 million, and this officer did not earn an Employee Quarterly Bonus for the second and/or third quarter of that year, then he will be entitled to an Employee Quarterly Bonus for the missed quarter(s) in addition to any Employee Quarterly Bonus earned based on net income for the fourth quarter of that calendar year.

In each quarter for which an Employee Quarterly Bonus is payable, the amended and restated agreement also provides for the establishment of a "Quarterly Bonus Pool." For each quarter beginning with the quarter ended June 30, 2011 and continuing for the next nineteen quarterly periods thereafter, if Macoven generates $1 million in quarterly net income, a "Quarterly Bonus Pool" of $200,000 is set aside. In addition, if the annual net income for a given calendar year exceeds $4 million, and no Quarterly Bonus Pool was established for the second and/or third quarter, then a Quarterly Bonus Pool will be established for such quarter(s) in addition to any Quarterly Bonus Pool established based on net income for the fourth quarter of that calendar year. The compensation committee of the Company's board of directors must approve the list of participants and allocate the entirety of the Quarterly Bonus Pool among those participants.

The committee, in its discretion, may elect to pay any Employee Quarterly Bonus or Quarterly Bonus Pool payment in cash, shares of common stock, or a combination of the two. Any shares of common stock so issued must be issued from, and subject to the general terms and conditions of, the Company's equity incentive plans.

Lease of Woodlands Office

On January 7, 2011, the Company entered into a 62-month lease, which became effective March 15, 2011, for additional corporate office space in The Woodlands, Texas. The total obligation over the lease term is approximately $503,000.

Engagement of JP Morgan Cassenove by our U.K. Joint Venture

With respect to our investment in the joint venture with SEEK, on March 24, 2011, we announced the appointment of JP Morgan Cassenove as financial advisor in connection with an auction of the Theobromine assets of the joint venture. The auction will be for the global commercialization rights (excluding Korea) of Theobromine. We continue to explore all strategic alternatives available with respect to the Theobromine assets, and continue to fund the development of these product candidates through our joint venture with SEEK. Our decision to sell or otherwise transfer the Theobromine assets in an auction will depend on the terms of any offers we may receive. We make no guarantee that we will receive any offers in an auction of these assets, or that such offers will be made on terms acceptable to us.

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 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, 2010. Pursuant to our certificate of incorporation and bylaws, our officers are appointed annually by the Board of Directors ("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	49	Chairman of the Board
Cooper C. Collins	31	President, Chief Executive Officer and Director
Tracy S. Clifford	42	Chief Financial Officer, Treasurer and Secretary
Anthem Hayek Blanchard	29	Director
Jan H. Loeb	52	Director
James E. Smith, Jr.	58	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.

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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

Tracy S. Clifford currently serves as Chief Financial Officer, Secretary and Treasurer. Ms. Clifford previously was appointed Chief Financial Officer of GTA on January 18, 2008, a position she continues to hold following the merger between GTA and Pernix on March 9, 2010. Ms. Clifford has served as GTA's Principal Accounting Officer, Corporate Secretary and Treasurer since February 2007. Ms. Clifford served as GTA's Controller from September 1999 to February 2007. Before joining GTA, Ms. Clifford served as a Director of Finance (February 1999 to September 1999) and Manager of Accounting and Financial Reporting (May 1995 to February 1999) at United Healthcare of Georgia. From June 1993 to May 1995, Ms. Clifford served as Manager of Accounting (January 1994 to May 1995) and Senior Accountant (June 1993 to January 1994) at North Broward Hospital District in Fort Lauderdale, Florida. Ms. Clifford began her career at Deloitte & Touche in Miami, Florida, where she was an auditor primarily for clients in the healthcare industry from September 1991 to June 1993. Ms. Clifford holds a Bachelors of Science in Accounting from the College of Charleston and a Masters in Business Administration with a concentration in Finance from Georgia State University. Ms. Clifford is a member of the South Carolina Association of CPAs and the American Institute of CPAs and serves as an adjunct faculty member in the School of Business and Economics at the College of Charleston.

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 currently the CEO and a director of nuMetra, Inc., a software manufacturer enabling network carriers to offer IPTV service to consumers via delivery of broadband across the Internet. Prior to joining the nuMetra team as its CEO in September 2008, Mr. Blanchard served as a key strategic advisor to that company since December 2002. 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 in the precious metal industry, including Robert Kiyosaki's Rich Dad Precious Metals Expert, 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

Jan H. Loeb 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. Prior to the merger between Pernix and GTA on March 9, 2010, Mr. Loeb served as an independent director of GTA since November 17, 2006 and Chairman of the Company's Audit Committee and financial expert since October 10, 2007. Mr. Loeb is currently a portfolio manager for Leap Tide Capital Management, Inc., a position he has held since February 2005. From February 2004 through January 2005, Mr. Loeb was a portfolio manager for Chesapeake Partners. From January 2002 through December 2004, Mr. Loeb was a Managing Director of Jefferies & Company, Inc., an investment banking firm based in New York City. From 1994 through 2001, Mr. Loeb was a Managing Director of Dresdner Kleinwort and Wasserstein, Inc., an investment banking firm based in New York City, which was formerly known as Wasserstein Perella & Co., Inc. Mr. Loeb also serves on the board of directors of American Pacific Corporation, a chemical and aerospace corporation, and TAT Technologies, LTD, which provides services and products to the military and commercial aerospace and ground defense industries. In addition, Mr. Loeb serves on the boards of numerous charitable organizations. Mr. Loeb holds a Bachelor of Business Administration from Bernard M. Baruch College.

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.

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.

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.

- 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.

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- 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.

- 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. Loeb 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. Loeb was appointed Chairman of the Audit Committee on October 10, 2007, and continued in that capacity following the merger of GTA and Pernix on March 9, 2010. 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. Loeb 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.

- 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.

- Conducting an annual performance evaluation of the Compensation Committee.

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

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.

- 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 25, 2011, 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 2010.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

As of December 31, 2010, Pernix had two executive officers, Mr. Collins and Ms. Clifford. Mr. Venters was an executive officer of Pernix until September 30, 2010, and Mr. Pearce was an executive officer until March 9, 2010. The following table sets forth 2010 and 2009 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 Collins	2010	290,000	300,000	—	40,155	(4)	630,155
President and Chief Executive Officer	2009	270,500	395,000	—	151,530	(4)	817,030
Tracy Clifford	2010	143,060	100,000	181,392	34,187	(5)	458,639
Chief Financial Officer, Secretary and Treasurer	2009	112,747	7,100	5,350	16,418	(5)	141,615
Michael Venters	2010	208,000	180,000	362,784	40,559	(6)	791,343
Vice President of Corporate Development	2009	200,000	200,000	—	20,496	(6)	420,496
Michael C. Pearce	2010	37,500	—	—	130,623	(7)	168,123
Former President and CEO of GTA; Current Chairman of the Board of Directors	2009	180,000	—	45,474	22,005	(7)	247,479

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(1) The individuals listed in this table were named executive officers of Pernix as of December 31, 2010 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 2010 for Mr. Collins includes (i) auto allowance, (ii) medical and dental insurance coverage, and (iii) our contributions to his 401(k) account. "All Other Compensation" in 2009 for Mr. Collins includes (i) auto allowance, (ii) medical and dental insurance coverage, (iii) Company contributions to his 401(k) account, (iv) a cash bonus of $25,000 paid to him in December 2009 for his service as a director, and (v) imputed income of $90,015, representing the difference between the purchase price and fair market value of Pernix shares purchased by Mr. Collins in January 2009.

(5) "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. "All Other Compensation" in 2009 for Ms. Clifford includes medical and dental coverage.

(6) "All Other Compensation" in 2010 for Mr. Venters includes (i) auto allowance, (ii) medical and dental insurance coverage, and our contributions to his 401(k) account. "All Other Compensation" in 2009 for Mr. Venters includes medical and dental insurance coverage and Company contributions to his 401(k) account.

(7) Effective March 9, 2010, Mr. Pearce resigned as President and Chief Executive Officer of GTA upon the reverse merger between Pernix and GTA on March 9, 2010. Mr. Pearce continues to serve as the non-executive Chairman of our Board. Mr. Pearce's compensation information for 2010 reflects compensation paid by GTA during the period January 1, 2010 – March 9, 2010 and all of 2009. "All Other Compensation" for Mr. Pearce for 2010 includes (i) auto allowance, (ii) medical and dental insurance coverage, (iii) the pay-out of accrued vacation from GTA, and (iv) severance of $92,400. "All Other Compensation" for Mr. Pearce for 2009 includes auto allowance and medical and dental insurance coverage.

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 receives an annual base salary of $264,000 (which was subsequently increased to $290,000), and is eligible to receive bonus payments in such amounts as our Board may determine. In the event Mr. Collins terminates this agreement prior to May 31, 2011, or we terminate the agreement for cause, Mr. Collins is required to pay us a termination fee equal to 10% of his annual base salary, plus 10% of the aggregate amount of bonus payments received by him under the terms of the agreement. Mr. Collins is entitled to an amount equal to the unpaid portion of his annual base salary, less all required deductions, if we terminate his employment without cause. The agreement prohibits Mr. Collins from competing with our Company for two years after termination of his employment.

Ms. Clifford. Ms. Clifford is not subject to a written employment agreement with us.

Mr. Venters. In December 2008, Pernix entered into an employment agreement with Mr. Venters that continued through December 31, 2009, and automatically renews for one year terms thereafter unless otherwise terminated by either party pursuant to the terms of the agreement. Under the agreement, Mr. Venters receives an annual base salary of $200,000 (which was subsequently increased to $208,000 effective January 1, 2010). Mr. Venters is entitled to one year's base salary, as well as health insurance for one year, if his employment is terminated without cause.

Mr. Pearce. As a result of the merger between Pernix and GTA on March 9, 2010, Mr. Pearce's employment with GTA terminated and he received severance compensation equal to 50% of his annual base salary (or approximately $92,000), as well as continued health benefits for six months. In addition, all of Mr. Pearce's outstanding unvested stock options vested.

Change in Control.

Our 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 the 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.

Awards of Equity Compensation

On February 27, 2009, GTA's Board awarded Mr. Pearce 85,000 and Ms. Clifford 10,000 options to purchase shares of our common stock. All of Mr. Pearce's and Ms. Clifford's then-outstanding options vested following the closing of the merger between Pernix and GTA on March 9, 2010. With regard to equity awards granted by Pernix, Messrs. Collins and Venters were not granted any such awards during fiscal 2009 nor did they have any outstanding equity awards at December 31, 2009.

On March 10, 2010, our Board awarded 25,000 stock options to each current Board member with the exception of Mr. Collins. On May 12, 2010, our Board awarded Mr. Venters 150,000 and Ms. Clifford 75,000 stock options to purchase shares of our common stock.

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, 2010. The value of unexercised in-the-money options at December 31, 2010 (the last business day of the year) is based on a value of $6.05 per share, the closing price of our common stock on the NYSE Amex on December 31, 2010.

	Outstanding Equity Awards at December 31, 2010				
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					
Tracy Clifford	25,000	—		3.80	3/9/2013
Chief Financial Officer, Secretary and Treasurer	5,000	—		2.20	3/9/2013
	—	75,000	(3)	3.73	5/12/2020
Michael Venters(1)		150,000	(4)	3.73	5/12/2020
Vice President of Corporate Development					
Michael C. Pearce(2)	137,500	—		4.20	3/9/2013
Former President and	42,500	—		2.20	3/9/2013
CEO; Current Chairman of the Board of Directors	—	25,000	(5)	3.98	3/10/2020

(1) 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.

(2) Mr. Pearce was the former President and Chief Executive Officer of GTA. Effective March 9, 2010, Mr. Pearce resigned as President and Chief Executive Officer but continues to serve as the non-executive Chairman of our Board.

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

(4) Mr. Venters was awarded 150,000 options on May 12, 2010 which vest ratably over three years and expire ten years from the date of issuance.

(5) Mr. Pearce, as a component of his board compensation, was awarded 25,000 options on March 10, 2010 which vest ratably over three years and expire ten years from the date of issuance.

Director Compensation

As of December 31, 2010, Pernix had five directors, Mr. Pearce, Mr. Collins, Mr. Blanchard, Mr. Loeb and Mr. Smith. The following table sets forth compensation for our directors for fiscal year 2010.

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	52,903	99,500	63,311	—	—	7,815	215,714
Cooper C. Collins	—	—	—	—	—	—	—
Anthem H. Blanchard	43,950	99,500	63,311	—	—	—	206,761
Jan H. Loeb	47,630	99,500	63,311	—	—	—	210,441
James E. Smith, Jr.	38,253	99,500	63,311	—	—	—	201,064

(1) Reflects the aggregate grant date fair value of equity awards granted in 2010 and calculated in accordance with FASB ASC 718, excluding effect of estimated forfeitures.

On March 10, 2010, following the merger of GTA and Pernix, each non-executive director received a grant of options to purchase 25,000 shares of our common stock and a grant of 25,000 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 consolidated, reverse-split-adjusted closing price of $3.98 per share on March 9, 2010, the date of the most recently-completed trading session preceding the grant date. In addition, our Board approved the following new compensation program for our non-management directors:

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Annual Cash Compensation:

- $30,000 per director;
- additional $35,000 for the non-executive Chairman of the Board;
- 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 25,000 shares of restricted stock, vesting over a three-year period; and
- annual grant of options to purchase 25,000 shares of common stock, vesting over a three-year period.

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, 2010. Pernix did 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)	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)
Equity Compensation Plans Approved by Security Holders(1)	1,026,000	$3.81	2,817,787
Equity Compensation Plans Not Approved by Security Holders	---	---	---
Total	1,026,000	3.81	2,817,787

(1) Includes 260,000 options, in the aggregate, issued under GTA's 2007 Stock Incentive Plan and GTA's 1997 Non-Employee Directors' 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 $4.02. All other outstanding options were issued from our 2009 Stock Incentive Plan.

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Security Ownership of Directors and Executive Officers

The following table describes, as of March 25, 2011, 2011, 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 25, 2011, 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 25, 2011. 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 22,687,727 shares outstanding as of March 25, 2011. Addresses of the named beneficial owners below are in care of Pernix Therapeutics Holdings, Inc., 33219 Forest West Street, Magnolia, TX 77354.

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 C. Pearce	188,333	35,000	223,333	.98	%
Cooper C. Collins(4)	---	---	9,405,000	41.45	%
Anthem Blanchard	8,333	35,000	43,333	.19	%
Jan H. Loeb	48,333	35,000	516,883	2.27	%
James E. Smith, Jr.	8,333	35,000	5,284,284	23.28	%
Named Executive Officers					
Tracy S. Clifford	55,000	---	55,000	.24	%
Michael Venters	50,000	---	50,000	.22	%
All Current Directors and Officers as a Group (7 Persons)	358,332	140,000	15,577,833	67.59	%

(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 22,687,727 shares of our common stock outstanding on March 25, 2011.

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

The following table describes, as of March 25, 2011, 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.

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class(1)
Common Stock	Brandon Belanger 33219 Forest West Street	2,090,000 (2)	9.21%
Common Stock	Emily E. Bonner Deville 33219 Forest West Street Magnolia, Texas 77354	2,090,000 (3)	9.21%

(1) Based on 22,687,727 shares of our common stock outstanding on March 25, 2011.

(2) Based on a Schedule 13D filed on March 19, 2010 with the SEC by Mr. Belanger, who has sole voting and investment power over all shares reported. Mr. Belanger is employed as our Western United States Director of Sales.

(3) Based on a Schedule 13D filed on March 19, 2010 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 and Marketing.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, 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.

Acquisition of Macoven Pharmaceuticals

On September 8, 2010, Pernix purchased 100% of the outstanding membership interests of Macoven Pharmaceuticals, L.L.C. for an aggregate purchase price of $2,200,000 (which includes inventory of approximately $1,200,000). Upon the effectiveness of the acquisition, Macoven became a wholly-owned subsidiary of Pernix.

The acquisition of Macoven was unanimously approved by a special committee comprised solely of independent directors of Pernix. Prior to the acquisition, Macoven was owned 59.4% by ZInterests (a limited liability company owned by Cooper Collins, Pernix's Chief Executive Officer and President, James Smith, a director of Pernix and two officers of Pernix), 19.8% by Mike Venters, an officer of Pernix, 19.8% by John McMahon, an officer of Macoven, and 1% by Robert Cline, Vice President of Supply Chain Management of Pernix.

Repurchase of 2,000,000 Shares of Pernix Common Stock for $1.80 Per Share

On September 10, 2010, Pernix entered into an agreement to purchase 2,000,000 shares of its common stock from David Waguespack, 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 the next three years. The repurchase was made pursuant to Pernix's previously disclosed $5 million stock repurchase program and was approved by Pernix's Audit Committee.

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. Loeb, 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 2010 and 2009.

	2010	2009
Audit Fees(1)	$ 221,907	$ 74,700
Audit-Related Fees(2)	103,674	3,000
Tax Fees(3)	44,250	1,560
All Other Fees	—	—
Total	$ 382,808	$ 79,260

(1) "Audit Fees" represent fees for professional services rendered by Cherry, Bekaert & Holland, L.L.P for fiscal years 2010 and 2009 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 2010 and 2009 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 2010 and 2009 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 AND 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 refference 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.

March 30, 2011	By:	/s/ Cooper C. Collins Cooper C. Collins

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 30, 2011
/s/ Cooper C. Collins Cooper C. Collins	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2011
/s/ Tracy S. Clifford Tracy S. Clifford	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 30, 2011
/s/ Anthem Blanchard Anthem Blanchard	Director	March 30, 2011
/s/ Jan H. Loeb Jan H. Loeb	Director	March 30, 2011
/s/ James E. Smith James E. Smith, Jr	Director	March 30, 2011

INDEX TO EXHIBITS

No.	Description	Filed or Furnished with this Form 10-K	Incorporated by Reference Form	Date Filed
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	03/10/2010
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.		8-K	03/15/2010
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 Non-Compete Agreement, dated March 14, 2011, by and between Pernix Therapeutics Holdings, Inc. and John McMahon	ü		
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	Stock Purchase Agreement by and among Pernix Therapeutics Holdings, Inc., Pernix Therapeutics, LLC and the sellers named therein dated June 18, 2010	ü		
10.13	2007 Stock Option Plan		Def14A	11/16/2007
10.14	1997 Non-Employee Director's Plan		S-11/A†	11/15/1997
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 Tracy S. Clifford 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 Tracy S. Clifford pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	ü

* Indicates a management contract or compensatory plan or arrangement

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