CORNERSTONE THERAPEUTICS INC
Form 10-K
March 06, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

OR

¨ **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: 000-50767

CORNERSTONE THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*

1255 Crescent Green Drive, Suite 250

Cary, North Carolina	**27518**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant s telephone number, including area code:

(919) 678-6611

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	**The NASDAQ Stock Market LLC**

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

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ 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 ¨ 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 ¨

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 ¨	Accelerated filer ¨	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant as of June 30, 2011 was approximately $73,777,025 based on a price per share of $8.96, the last reported sale price of the registrant s common stock on the NASDAQ Stock Market on that date.

As of February 29, 2012, the registrant had 26,020,338 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2012 annual meeting of stockholders currently expected to be held on May 22, 2012, which is currently expected to be filed pursuant to Regulation 14A within 120 days after the end of the registrant s fiscal year ended December 31, 2011, are incorporated by reference into Part III of this report.

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CORNERSTONE THERAPEUTICS INC.

ANNUAL REPORT

ON FORM 10-K

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PART I

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, will, would or other words that convey uncertainty of future events or outcome 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 our critical accounting estimates ; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; our ability to replace the revenues from our marketed unapproved products, which we ceased manufacturing and distributing at the end of 2010, and from our propoxyphene products, which we voluntarily withdrew from the U.S. market in November 2010 at the request of the U.S. Food and Drug Administration, or FDA; the adverse impact of returns of previously sold inventory; patient, physician and third-party payer acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products; our ability to obtain FDA approval to market and sell our products under development; our ability to enter into additional strategic licensing, product acquisition, collaboration or co-promotion transactions on favorable terms, if at all; our ability to manage and control unknown liabilities in connection with any acquisitions; our ability to successfully manage growth or integrate acquired businesses and operations; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail 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, except as may be required by law. 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. ***BUSINESS***

Background

Cornerstone Therapeutics Inc. is a specialty pharmaceutical company focused on commercializing products for the hospital, niche respiratory and related specialty markets. Prior to our October 31, 2008 merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma (which we refer to herein as the Merger), we were known as Critical Therapeutics, Inc., or Critical Therapeutics. Following the closing of the Merger, we changed our name to Cornerstone Therapeutics Inc. Cornerstone BioPharma was deemed to be the acquiring

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company for accounting purposes. Our financial statements for periods prior to the Merger reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and our financial statements for all subsequent periods reflect the results of the combined company.

Unless specifically noted otherwise, as used herein, the terms we, us and our refer to the combined company after the Merger and acquisition and, as applicable, Critical Therapeutics and Cornerstone BioPharma prior to the Merger.

Strategy

We are a specialty pharmaceutical company focused on commercializing products for the hospital, niche respiratory and related specialty markets. We are actively seeking to expand our portfolio of products for these markets through the acquisition of companies and/or products and internal development.

Our strategy is to:

- Focus our commercial and internal development efforts in the hospital and related specialty product sector within the U.S. pharmaceutical marketplace;
- Acquire companies and marketed and/or registration-stage products that fit within our focus areas; and
- Market approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc., or Aristos.

We believe this strategy will allow us to improve our revenue growth rate, margins, and profitability and enhance stockholder value.

Our management team has broad experience in the acquisition, commercialization, development, and integration of pharmaceutical companies and products. During the last two years, we have made an intentional, strategic shift to focus on the branded approved products identified as Branded Products below and building an effective hospital sales force around our lead product, CUROSURF®, which we believe we can deploy to promote additional hospital-based products that we develop or acquire. We intend to leverage our management expertise and our sales infrastructure to grow our branded products, launch our product candidates and position ourselves as an ideal partner to acquire, develop and commercialize additional products.

We currently do not devote resources to early stage pharmaceutical research or captive manufacturing.

In March 2011, the FDA announced that it intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011 (this announcement is referred to as the March 2011 FDA Announcement). We expected this action, and all of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010. However, as a result of the March 2011 FDA Announcement, in August 2011 our distribution partners began returning substantial amounts of products that were in the distribution channel. Because we have historically derived significant revenues and income from these products, our net product sales, gross margin and income from operations declined in 2011 when compared to 2010. Going forward, we anticipate replacing these revenues and income with increased revenues and income from our branded products, particularly CUROSURF, ZYFLO CR® and any products we acquire, and, if approved, our product candidates CRTX 067, a generic product, and CRTX 080, the lixivaptan development program we acquired through our December 2011 acquisition of Cardiokine, Inc., or Cardiokine, a specialty pharmaceutical company focused on developing hospital products for cardiovascular indications.

In 2012, we will focus on the following priorities:

- growing revenues from our existing product portfolio;
- gaining regulatory approval of and launching CRTX 067;

advancing our product pipeline, in particular CRTX 080;

evaluating and executing upon strategic alternatives for our anti-infective products; and

evaluating inorganic opportunities.

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Branded Products

CUROSURF

Overview. CUROSURF is a porcine-derived natural lung surfactant with the active pharmaceutical ingredient, or API, poractant alfa. It is a world-leading treatment that was approved by the FDA in 1999 and launched in the United States in 2000 for the treatment of Respiratory Distress Syndrome, or RDS, in premature infants. CUROSURF is currently available in 1.5mL and 3.0mL vials in over 60 countries, including the United States and most of Europe, and has been administered to over one million infants since 1992. RDS can lead to serious complications and is one of the most common causes of neonatal mortality.

Our net sales of CUROSURF were $34.9 million, $33.6 million and $10.5 million in 2011, 2010 and 2009, respectively. Net sales in 2009 represent sales made from our launch in September 2009 until the end of 2009. We acquired the CUROSURF product rights in the United States from Chiesi Farmaceutici S.p.A., or Chiesi, during the third quarter of 2009 and began promoting and selling CUROSURF in September 2009.

Market Opportunity. Approximately one out of every 10, or 50,000, premature infants require surfactant treatment in the United States each year. Surfactants are typically dispensed in over 2,000 hospital neonatal intensive care units annually. According to IMS Health s NPA (National Prescription Audit Family of Services), or NPA, a third-party provider of prescription data, the surfactant market generated approximately $70 million, $75 million, $74 million in sales in 2011, 2010, and 2009, respectively and is relatively stable because the number of premature infants requiring treatment does not vary significantly from year to year.

Benefits of CUROSURF. CUROSURF has a higher concentration of phospholipids and lower volume per dose as compared to other surfactant products used to treat RDS. We believe that these characteristics provide efficient RDS treatment by shortening the drug s administration time, reducing the required manipulation of the infant and potentially lowering the rate of reflux and endotracheal tube blockage.

In a prospective, randomized clinical trial comparing CUROSURF and Survanta® (a surfactant marketed by Abbott Nutrition to treat RDS) in 293 infants, CUROSURF produced a significantly faster reduction in infant oxygen requirement, as reflected in the lower fraction of inspired oxygen, or FiO_2 over the first six hours. In this same study, 73% of infants required only one dose of CUROSURF, while only 51% of Survanta-treated infants required one dose of Survanta.

In another randomized controlled clinical study comparing CUROSURF and Survanta, CUROSURF produced a faster and more substantial reduction in FiO_2 and sustained results over the first 48 hours, while in the Survanta group infants required a higher need for redosing of surfactant. In another study in very premature infants with RDS, infants treated with CUROSURF required a lower level of respiratory support for the first 72 hours and were significantly more likely to be extubated at 48 and 72 hours than infants treated with Survanta.

It has been suggested that a rapid onset of action and a faster reduction in oxygen requirement may allow for faster weaning from mechanical ventilation and may lower the risk of oxygen toxicity for infants with RDS. Additionally, these features may facilitate the use of less invasive ventilation techniques, which is a key trend in the treatment of premature infants with RDS in the United States.

CUROSURF has been studied in conjunction with techniques such as nasal continuous positive airway pressure and nasal intermittent positive pressure ventilation, and has demonstrated a reduction in the rate of reintubation and surfactant redosing when used in combination with these advanced treatment methods versus conventional mechanical ventilation.

CUROSURF has demonstrated a consistent trend towards survival advantage compared to Survanta in trials that measure mortality as a secondary endpoint. In a prospective, randomized trial, a 3% mortality rate at 36 weeks post-conceptional age in the group of infants born at 32 weeks or less gestational age was demonstrated with CUROSURF compared with an 11% mortality rate for infants of the same subgroup who were treated with Survanta. Three other published studies demonstrated trends toward a survival advantage with CUROSURF treatment versus Survanta.

Most recently, a retrospective study compared all-cause, in-hospital mortality in more than 14,000 preterm infants with RDS. This analysis found that the group receiving a 200 mg/kg initial dose of CUROSURF was

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associated with a significantly reduced likelihood of death compared to Infasurf® (a surfactant marketed by ONY, Inc., or ONY), and a trend toward reduced mortality when compared with Survanta. Additionally, a new meta-analysis published in *Pediatrics*® showed lower mortality rates and less need for re-dosing when treating RDS with CUROSURF versus Survanta.

Proprietary Rights. We have an exclusive license from Chiesi under its CUROSURF know-how and the CUROSURF trademark to import, store, handle, promote, market, offer to sell and sell CUROSURF for RDS in the United States and its territories and possessions.

ZYFLO CR

Overview. ZYFLO CR and ZYFLO®, which contain the API zileuton, are leukotriene synthesis inhibitor drugs. ZYFLO was approved by the FDA in 1996 as an immediate-release, four-times-a-day tablet for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO was first launched in the United States in 1997; we began selling ZYFLO in the United States in October 2005. The FDA approved our new drug application, or NDA, for ZYFLO CR in May 2007, and we launched ZYFLO CR in October 2007. We believe ZYFLO CR offers a more convenient regimen for patients, which we believe may increase patient drug compliance because of its twice-daily, two tablets per dose dosing regimen, as compared to ZYFLO s four-times daily dosing regimen.

Net product sales of ZYFLO CR and ZYFLO combined were $30.7 million, $30.6 million and $18.0 million in 2011, 2010 and 2009, respectively.

Market Opportunity. Asthma is a chronic respiratory disease characterized by the narrowing of the lung airways, making breathing difficult. An asthma attack leaves the victim short of breath as the airways become constricted and inflamed. The National Center for Health Statistics estimated that in 2009 in the United States approximately 8.2% of the population, or approximately 24.6 million people, had asthma and approximately 4.2% of the population, or 12.8 million people, had asthma attacks.

Benefits of ZYFLO CR. We believe that many patients with asthma may benefit from therapy with ZYFLO CR or ZYFLO. ZYFLO CR and ZYFLO actively inhibit the main enzyme responsible for the production of a broad spectrum of lipids responsible for the symptoms associated with asthma, including all leukotrienes.

The full clinical development program for ZYFLO consisted of 21 safety and efficacy trials in an aggregate of approximately 3,000 patients with asthma. FDA approval was based on pivotal three-month and six-month safety and efficacy clinical trials in 774 asthma patients. The pivotal trials compared patients taking ZYFLO and their rescue bronchodilators as needed to patients taking placebo and rescue bronchodilators as needed. The results of the group taking ZYFLO and their rescue bronchodilators showed:

- rapid and sustained improvement for patients over a six-month period in objective and subjective measures of asthma control;
- reduction of exacerbations and need for either bronchodilatory or steroid rescue medications; and
- acute bronchodilatory effect within two hours after the first dose.

In these placebo-controlled clinical trials, 1.9% of patients taking ZYFLO experienced an increase in a liver enzyme called alanine transaminase, or ALT, greater than three times the level normally seen in the bloodstream compared to 0.2% of patients receiving placebo. These enzyme levels resolved or returned towards normal in approximately 50% of the patients who continued therapy and all of the patients who discontinued the therapy.

In addition, prior to FDA approval, a long-term, safety surveillance trial was conducted in 2,947 patients. In this safety trial, 4.6% of patients taking ZYFLO experienced ALT levels greater than three times the level normally seen in the bloodstream compared to 1.1% of patients receiving placebo, with 61.0% of the patients experiencing such elevated ALT levels in the first two months of dosing. After two months of treatment, the rate of ALT levels greater than three times the level normally seen in the bloodstream stabilized at an average of 0.3% per month for patients taking a combination of ZYFLO and their usual asthma medications compared to 0.11% per month for patients taking a combination of placebo and their usual asthma medications. This trial also

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demonstrated that ALT levels returned to below two times the level normally seen in the bloodstream in both the patients who continued and those who discontinued the therapy. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin.

After reviewing the data from these trials, the FDA approved ZYFLO in 1996 on the basis of the data submitted, and we are not aware of any reports of ZYFLO being directly associated with serious irreversible liver damage in patients treated with ZYFLO since its approval. We submitted an NDA for the ZYFLO CR formulation in asthma to the FDA based on safety and efficacy data generated from two completed Phase III clinical trials, a three-month efficacy trial and a six-month safety trial, each of which was completed by Abbott Laboratories, or Abbott.

Proprietary Rights. We licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. The U.S. patent covering the composition of matter of zileuton that we licensed from Abbott expired in December 2010. One U.S. patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the bioavailability of zileuton over time. Another U.S. patent for ZYFLO CR, which we added to the Orange Book in December 2011, will expire in September 2013 and also relates only to the controlled-release technology. ZYFLO CR and ZYFLO are the only leukotriene synthesis inhibitor drugs approved for marketing by the FDA. We believe ZYFLO CR is a difficult formulation to manufacture and such difficulty may create barriers for generic competitors looking to enter the market.

Anti-Infective Franchise

Our anti-infective products include FACTIVE® and SPECTRACEF®. During 2011, we began to further deemphasize these products as we migrated away from our focus on primary care. The migration is due to the increased presence of generic products in this sector of the market. We are currently evaluating strategic options with respect to these products and expect that they will continue to become less significant as we execute on our plan to focus on the hospital market.

FACTIVE

Overview. FACTIVE is a fluoroquinolone antibiotic with the API gemifloxacin mesylate. FACTIVE is currently available in 320 mg, once daily tablets packaged in five-day and seven-day dose packs. FACTIVE is approved for the treatment of acute bacterial exacerbation of chronic bronchitis, or ABECB, and community-acquired pneumonia, or CAP, of mild to moderate severity, caused by *Streptococcus pneumoniae* (including MDRSP), *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae*, or *Klebsiella pneumoniae*. FACTIVE was launched in the United States in September 2004 and is the only fluoroquinolone approved in the United States for the five-day treatment of both ABECB and CAP.

Our net sales of FACTIVE were $6.3 million, $5.1 million and $1.2 million in 2011, 2010 and 2009, respectively. Net sales in 2009 include sales made following our launch in September 2009. We acquired the FACTIVE product rights and related inventory from Oscient Pharmaceuticals Corporation, or Oscient, on September 9, 2009. We began earning revenues from FACTIVE in September 2009; however, we did not begin marketing and promoting FACTIVE until October 2009.

Market Opportunity. The U.S. oral solid antibiotic market is fairly fragmented, with approximately 35 branded products and more than 45 generic products. Pharmacists typically fill prescriptions for antibiotics with generic products when available. According to NPA, in 2011, the U.S. oral solid antibiotic market generated approximately 224 million prescriptions, of which the U.S. oral solid fluoroquinolone market generated approximately 34 million prescriptions. Approximately 1.9 million prescriptions have been dispensed in the United States for FACTIVE since it was first launched. In 2010 and 2011, FACTIVE generated approximately 65,000 and 74,000 prescriptions respectively.

Fluoroquinolones generally are considered safe and efficacious overall and have convenient dosing regimens. Fluoroquinolones, however, have multiple interactions with commonly prescribed drugs, cannot be used in children and have been associated with tendon rupture and photosensitivity adverse reactions.

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Benefits of FACTIVE. We believe FACTIVE is well positioned to meet the needs of health care providers for the treatment of ABECB and CAP. FACTIVE has demonstrated high clinical cure rates in multiple prospective, randomized clinical trials, rates that seem to resonate well with prescribers. FACTIVE is the only fluoroquinolone that has an indication for five-day treatment for both CAP and ABECB.

FACTIVE targets the infection site with high lung tissue penetration. In a clinical study, FACTIVE produced a concentration in bronchoalveolar tissue which is 3,567 times the MIC90 requirement to eradicate *Streptococcus pneumoniae* in critical lung tissue, cells and fluids (bronchoalveolar macrophages, epithelial lining fluid and bronchial mucosa). In another clinical study of 310 patients with CAP, five-day treatment with FACTIVE produced a 100% eradication of *Streptococcus pneumoniae*, 95.5% eradication of *Haemophilus influenzae*, 94.4% eradication of *Chlamydia pneumoniae* and 88.8% eradication of *Mycoplasma pneumoniae*. In a study of five-day treatment for ABECB, FACTIVE demonstrated clinical success rate was 94% (247 of 264 patients). In a separate study, five-day treatment with FACTIVE for CAP produced a clinical success rate of 95% (230 of 242 patients). These findings are in line with longer treatment regimens of other fluoroquinolone antibiotics.

Proprietary Rights. We have an exclusive license from LG Life Sciences, Ltd., or LGLS, to market FACTIVE in the United States, under nine issued U.S. patents with claims to the composition of matter of the API in FACTIVE, gemifloxacin mesylate, and to the formulation of FACTIVE. The FACTIVE patents extend through September 2019. FACTIVE has composition of matter patent protection that extends into 2017, longer than the composition of matter patent protection for any currently marketed oral fluoroquinolone or other oral antibiotic widely used to treat respiratory tract infections. We have also licensed from LGLS the U.S. trademark rights to FACTIVE.

SPECTRACEF

Overview. SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the API cefditoren pivoxil. The SPECTRACEF product line currently includes SPECTRACEF 200 mg and SPECTRACEF 400 mg, cefditoren pivoxil 200 mg and cefditoren pivoxil 400 mg. We sometimes refer to these products collectively as SPECTRACEF. SPECTRACEF 200 mg is currently available in a 10 day Dose Pack. SPECTRACEF 200 mg, two tablets twice daily, is indicated for the treatment of the same respiratory tract infections as SPECTRACEF 400 mg. Additionally, SPECTRACEF 200 mg, one tablet twice daily, is indicated for pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections. In 2010, Aristos introduced cefditoren pivoxil 200 mg and 400 mg authorized generic products to prepare to compete more effectively with potential generic market entrants. At this time, there are no competing generic cefditoren pivoxil products that have been approved by the FDA.

SPECTRACEF 400 mg and its generic equivalent, cefditoren pivoxil 400 mg, are single 400 mg tablets, twice-daily dosages of SPECTRACEF, which are indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated with particular respiratory tract infections, including CAP and ABECB. SPECTRACEF 400 mg is currently available in a 10-day Dose Pack and a 14-day Dose Pack. The generic equivalent is currently only available in a 10-day Dose Pack. We received approval for SPECTRACEF 400 mg in July 2008 and launched it in October 2008. We launched cefditoren pivoxil 400 mg in February 2010. We believe that patients find taking one 400 mg tablet twice daily to be more convenient than taking two 200 mg tablets twice daily. Our net sales of the SPECTRACEF product family were $8.1 million, $5.3 million and $9.4 million in 2011, 2010 and 2009, respectively.

Market Opportunity. Like FACTIVE, SPECTRACEF competes in the fragmented U.S. oral solid antibiotic market and is subject to competition from other branded and generic products. According to NPA, there were approximately 8.6 million prescriptions written in the United States for second and third generation oral solid cephalosporins in 2011.

Cephalosporins, including SPECTRACEF, generally cause few side effects. Common side effects are gastrointestinal in nature and are mild and transient.

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Benefits of SPECTRACEF. SPECTRACEF is effective against several common respiratory pathogens, including *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*. In two previously conducted and published clinical trials, cefditoren, present in SPECTRACEF as cefditoren pivoxil, demonstrated superior potency against community-acquired *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* as compared to cefdinir, cefuroxime and cefprozil, other second or third generation oral solid cephalosporins.

Proprietary Rights. We have an exclusive license from Meiji Seika Kaisha, Ltd., or Meiji, to market SPECTRACEF and related product candidates in the United States under an issued U.S. patent with claims to the formulation of products like SPECTRACEF that contain a mixture of cefditoren pivoxil with a water soluble casein salt. The composition of matter patent for cefditoren pivoxil expired in April 2009 and the formulation patent expires in October 2016. We have also licensed the U.S. trademark rights to SPECTRACEF from Meiji.

Other Products

Through the end of 2010, we marketed certain of our products, including ALLERX® (combinations of methscopolamine nitrate, pseudoephedrine hydrochloride, phenylephrine hydrochloride and chlorpheniramine maleate) tablets and HYOMAX® (hyoscyamine sulfate) tablets without them having FDA-approved marketing applications. In late 2010, we notified the FDA of our intention to cease manufacturing and distribution of all of our marketed unapproved products by the end of 2010, which included ALLERX Dose Pack products and the HYOMAX product family, and in August 2010, we publicly announced our plan. In December 2010, we sold our remaining inventory of our marketed unapproved products to distributors, wholesalers and retailers. Revenue related to these sales was deferred due to our inability to reasonably estimate returns as a result of large channel inventory levels and extended payment terms given related to certain sales. Revenue from the sales of these products was recorded when the risk of product returns was substantially eliminated, primarily when the product was sold to the end-user based upon prescriptions filled.

As discussed above, in March 2011, the FDA announced that it intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011. In 2010, we discontinued manufacturing and distribution of all of our marketed unapproved products. Our decision did not limit the FDA s enforcement authority. All of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010, and although this action did not require the recall or withdrawal of any products, it has resulted in the return of substantial amounts of products that were in the distribution channel.

Our net sales of our ALLERX Dose Pack and HYOMAX families of products were $25.4 million, $37.4 million and $59.9 million in 2011, 2010 and 2009, respectively. For a more complete discussion regarding FDA drug approval requirements, please see Item 1. Business Regulatory Matters in this annual report on Form 10-K and Item 1A. Risk Factors Some of our specialty pharmaceutical products have been marketed without approved NDAs or ANDAs in this annual report on Form 10-K.

Product Development Pipeline

Overview. We are committed to the expansion of our product portfolio with particular focus in the hospital pharmaceutical product sector. Our development pipeline consists of product candidates that are strategically aligned with our current products and customer focus. The following table sets forth additional information regarding our product candidates:

Therapeutic Class	Developmental Stage	Regulatory Status
Hyponatremia		
CRTX 080	Under FDA Review	Regulatory application submitted in December 2011
Anti-Asthma		
CRTX 073	Preclinical	Investigational new drug submission targeted in 2012
Cough/Cold		
CRTX 067	Under FDA Review	Regulatory application submitted in July 2009

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During 2011, 2010 and 2009, our research and development expenses were $1.6 million, $4.5 million and $3.6 million, respectively. Our development priorities may change from time to time, and the actual dates of regulatory submissions may differ from the target dates referenced above. For example, during 2011, management realigned its product development pipeline with its new focus on hospital and niche respiratory and related specialty markets. As a result, we ceased work on our allergy product candidates CRTX 058 and CRTX 070, as well as on our cough/cold product candidates CRTX 069, CRTX 072 and CRTX 074.

Hyponatremia Product Candidate CRTX 080

Overview and Development Status. On December 30, 2011, we acquired Cardiokine, a specialty pharmaceutical company focused on developing hospital products for cardiovascular indications. Prior to the acquisition, Cardiokine completed a series of phase III clinical trials for its lead compound, lixivaptan for treatment of hyponatremia, and filed an NDA with the FDA on December 29, 2011. CRTX 080 is the investigational, orally-active, vasopressin receptor 2 antagonist, lixivaptan targeting the treatment of hyponatremia. Hyponatremia is a metabolic condition that occurs when there is not enough sodium (salt) in the blood.

Market Opportunity. Hyponatremia is the most common electrolyte disorder among hospitalized patients affecting up to six million people in the United States and is often diagnosed in patients with congestive heart failure, or CHF. In the United States alone, there are five million heart failure patients, and each year one fourth of them develop hyponatremia. Other causes of hyponatremia include burns, diuretic medications, kidney disease, liver cirrhosis, and syndrome of inappropriate antidiuretic hormone secretion, or SIADH. According to NPA, in 2011, the hyponatremia market was valued at $60 million.

Benefits of Hyponatremia Product Candidate. CRTX 080 is an orally active, selective vasopressin 2 receptor antagonist developed for the treatment of hyponatremia and, if approved, has the potential to address an unmet medical need as some of the current treatment options have significant limitations that have impeded adoption by many hospitals. Three phase III, randomized controlled studies were performed with lixivaptan to demonstrate the efficacy and safety of the drug in symptomatic patients with euvolemic and hypervolaemic hyponatremia associated with SIADH and CHF, respectively. Differently from competitors of the same class, CRTX 080 has the potential not to require in-hospital treatment initiation, and its efficacy and safety have been studied in both hospitalized and non-hospitalized settings, including long-term care facilities, where the increasing incidence of hyponatremia and its associated risks (e.g. impaired balance, falls, hip fractures, disruption of cognitive function, and increased mortality) are well recognized.

Proprietary Rights. We have exclusively licensed from Pfizer Inc. its worldwide patent portfolio covering CRTX 080, which includes two issued U.S. patents with claims to the composition of matter and uses of the API, lixivaptan, and one issued patent for the formulation of the lixivaptan product candidate. The U.S. lixivaptan product candidate patents extend through September 2020. We have issued patents with claims to the composition of matter and uses of the API, lixivaptan, in Europe and Japan that extend through July 2013 and July 2014, respectively. Additionally, we have trademark applications and registered trademarks in the United States, Europe and the United Kingdom for the lixivaptan product candidate.

Anti-Asthma Product Candidate CRTX 073

Overview and Development Status. ZYFLO CR is an important asset to us; therefore, we have implemented a life cycle management strategy to improve the dosing regimen for this product. We believe that offering more convenient dosing for ZYFLO CR may improve patient compliance and overall quality of life as it relates to their asthma condition. We plan to file an investigational new drug application, or IND, with the FDA for CRTX 073 in 2012.

Market Opportunity. Please see Branded Products ZYFLO CR *Market Opportunity* above for a discussion of the competitive conditions and markets for CRTX 073.

Benefits of Anti-Asthma Product Candidate. Please see Branded Products ZYFLO CR *Benefits of ZYFLO CR* above for a discussion of the benefits of CRTX 073.

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Proprietary Rights. We have licensed from Abbott the rights to CRTX 073. Please see Branded Products ZYFLO CR Proprietary Rights above and License and Collaboration Agreements Abbott Zileuton License Agreements below for a discussions of our licensing arrangements related to CRTX 073.

Cough/Cold Product Candidate CRTX 067

Overview and Development Status. CRTX 067 is a cough/cold product candidate which was submitted for marketing approval in July 2009. We are targeting approval in the first half of 2012.

Market Opportunity. Cough can adversely affect quality of life, leading patients to seek medical attention. According to NPA, in 2011, there were approximately 36 million prescriptions generated for antitussive products. Over 8 million of these prescriptions were for products that only contained a narcotic antitussive and an antihistamine.

Benefits of Cough/Cold Product Candidate. Most cough/cold products that are currently marketed are in an immediate-release formulation, meaning they must be dosed every four to six hours, which can be inconvenient. For example, patients may not be able to sleep through the night because their antitussive is not effective for more than four hours. We believe that our cough/cold product candidate could improve patients compliance and quality of life by providing more convenient twice-daily, longer lasting dosing.

Proprietary Rights. We have licensed the rights to Neos Therapeutics, L.P. s, or Neos, Dynamic Time Release Suspension®, or DTRS®, technology and Coating Place, Inc. s, or Coating Place, drug resin complex technology. These licensed technologies allowed us to formulate CRTX 067 such that a portion of its API is immediately activated followed by a sustained timed release of the remaining API over a 12-hour period. Neos s DTRS technology is covered under a pending U.S. patent application that if issued would expire in 2025. Coating Place s drug resin complex technology is covered under an issued U.S. patent application that will expire in 2025.

Sales and Marketing; Co-promotion Agreements

Sales and Marketing

We have built a commercial organization comprised of sales professionals in a variety of sales and sales management positions supported by marketing, market research and commercial operations professionals who are responsible for developing our brands, implementing strategies and tactical plans for sales force execution, performing business analytics, leveraging commercial technology, overseeing sales operations and training our sales representatives.

The sales representatives in our hospital sales force promote CUROSURF in neonatal intensive care units. These representatives call on neonatologists, neonatal nurse practitioners, respiratory therapists and hospital pharmacists and administrators.

The sales representatives in our respiratory sales force call on high-prescribing, respiratory-focused physicians and key retail pharmacies.

We believe that the current market opportunity for our products and the future opportunity for certain of our product candidates, if approved, will likely warrant the need for expansion of our hospital sales force. We expect to commence this expansion following the successful execution of business development transactions and/or FDA approval of CRTX 080.

We seek to differentiate our products from our competitors by emphasizing their clinical and pharmacoeconomic advantages and favorable side effect profile for patients who are suffering from respiratory diseases and infections. Our marketing programs to support our products include patient co-payment assistance, health care provider education, pharmacoeconomic advantages, information to further support patient compliance and participation in national medical conventions. In addition, we use a respiratory advisory board with varying specialties to assist in developing our corporate strategy for both our products and product candidates.

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Co-promotion Agreement

We may seek to enter into co-promotion arrangements to enhance our promotional efforts and sales of our products. We may enter into co-promotion agreements when we lack sufficient sales force representation in a particular geographic area. Our material co-promotion arrangement is described below.

DEY Co-Promotion and Marketing Services Agreement for ZYFLO CR. On March 13, 2007, we entered into an agreement, as amended, with DEY, under which we agreed to jointly promote ZYFLO CR. Under the co-promotion and marketing services agreement, we granted DEY an exclusive right to promote and detail ZYFLO CR in the United States, together with us.

From January 1, 2009 through the expiration or termination of the co-promotion agreement, DEY is responsible for the costs associated with its sales representatives and the product samples distributed by its sales representatives, and we are responsible for all other promotional expenses related to the products. Prior to January 1, 2009, we paid DEY a co-promotion fee equal to 35% of the quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million. Beginning January 1, 2009 through December 31, 2013, we agreed to pay DEY a co-promotion fee equal to the ratio of total prescriptions written by certain pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by DEY and us.

Beginning on March 31, 2012, either party may terminate the co-promotion agreement with six-months prior written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if certain supply requirements are not met or if ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $20 million. ZYFLO CR cumulative net sales for the four consecutive calendar quarters ended December 31, 2011 were greater than $20 million.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement or March 31, 2012. However, if a third-party AB-rated generic product for ZYFLO CR is introduced, DEY would not be subject to these non-competition obligations; in such cases or if we decide to launch an authorized generic for ZYFLO CR, DEY will have the exclusive first right to market such product. DEY also will not be subject to these non-competition obligations if DEY terminates the co-promotion agreement either because ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $20 million or upon the occurrence of a material uncured breach by us.

Trade and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, hospitals, mass merchandisers and grocery store pharmacies. Our top three customers, which represented 94% of gross product sales in 2011, are all drug wholesalers and are listed below:

Customer	2011	2010
Cardinal Health	39%	43%
McKesson Corporation	34%	29%
AmerisourceBergen Corporation	21%	22%

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.

Our trade distribution group actively markets our products to authorized distributors through regular sales calls. This group has many years of experience working with various industry distribution channels. We believe that our trade distribution group enhances our commercial performance by ensuring product stocking in major

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channels across the country, continually following up with accounts and monitoring of product performance, developing successful product launch strategies and partnering with customers on other value-added programs.

We 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 United States and its territories as orders are placed through our customer service center.

Manufacturing

We currently outsource the manufacturing of all of our commercially available products and the formulation development of our product candidates for use in clinical trials to third parties. We intend to continue to rely on third parties for our manufacturing requirements. We provide regular product forecasts to assist our third-party manufacturers with efficient production planning.

We place orders pursuant to supply agreements or purchase order arrangements with third-party manufacturers and packagers for each of our marketed products. Depending on the finished product presentation, some of our manufacturers also package the product. In other cases, the manufacturer supplies the bulk form of the product and we package the product through a separate third party. Information about our manufacturing and packaging agreements related to our branded and anti-infective products is summarized in the following table.

Product	**Manufacturer/Packager**
CUROSURF	Chiesi
ZYFLO/ZYFLO CR	
API (zileuton)	Shasun Pharma Solutions Ltd. (or Shasun)
ZYFLO tablets	Patheon Pharmaceuticals Inc. (or Patheon)
ZYFLO CR tablet cores	Jagotec AG (or Jagotec)
ZYFLO CR tablet coating and packaging	Patheon
FACTIVE 5 and 7	
API (gemifloxacin mesylate)	LGLS
FACTIVE tablets	Patheon
FACTIVE packaging	Patheon
SPECTRACEF	
API (cefditoren pivoxil), tablets and packaging	Tedec-Meiji

We and our manufacturers and packagers are subject to the FDA s current Good Manufacturing Practice, or cGMP, requirements and other applicable laws and regulations administered by the FDA, the Drug Enforcement Administration, or DEA, and other regulatory authorities, including requirements related to controlled substances. Risks related to our arrangements with our manufacturers and packagers are described in greater detail below in Item 1A. Risk Factors.

While none of our products has alternative manufacturers qualified due to exclusivity provisions in the respective licensing agreements or based on other commercial considerations, we believe there are other suppliers that could serve as replacements for the current manufacturers if the need arose. However, qualifying such a replacement manufacturer with the FDA could take a significant amount of time, and, as a result, we would not be able to guarantee an uninterrupted supply of the affected product to our customers.

Chiesi License and Distribution Agreement

This agreement is described below under the caption License and Collaboration Agreements in this Item 1 of this annual report on Form 10-K.

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Shasun Agreement for Manufacturing and Supply of Zileuton API

Shasun manufactures all of our commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005, as amended. The API purchased from Shasun currently has a shelf-life of 36 months. The agreement will expire on the earlier of the date on which we have purchased a specified amount of the API for zileuton or December 31, 2012. The agreement automatically extends for successive one-year periods after December 31, 2012 unless Shasun provides us with 18-months prior written notice of cancellation. We have not received written notice of cancellation.

Jagotec Manufacture and Supply Agreement for ZYFLO CR

Jagotec, a subsidiary of SkyePharma PLC, manufactures all of our bulk, uncoated tablets of ZYFLO CR pursuant to a manufacture and supply agreement dated August 20, 2007, as amended. We have agreed to purchase from Jagotec a minimum of 20 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The agreement s initial term extends to May 22, 2012, and automatically continues thereafter unless we provide Jagotec with 24-months prior written notice of termination or Jagotec provides us with 36-months prior written notice of termination. We have not given or received written notice of cancellation.

LGLS License and Option Agreement

This agreement is described below under the caption License and Collaboration Agreements in this Item 1 of this annual report on Form 10-K.

Meiji SPECTRACEF License and Supply Agreement

This agreement is described below under the caption License and Collaboration Agreements in this Item 1 of this annual report on Form 10-K.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to acquire the rights to products that are covered by U.S. and foreign patents or patent applications, trade secrets and know-how and offer the opportunity for continuing technological innovation.

Patents

Our patents and patent applications include patents and patent applications that we own or exclusively license with claims directed to composition of matter, formulations of our products and product candidates and methods of use of our products and product candidates to treat particular indications.

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The following table shows our U.S. patents relating to our products and product candidates as of February 29, 2012:

Number	Issued Patents	Product(s)	Expiration
Licensed Patents			
5,422,123	Tablets with controlled-rate release of active substances	ZYFLO CR	06/06/2012
6,183,778	Tablets with controlled-rate release of active substances	ZYFLO CR	09/21/2013
5,633,262	Quinoline carboxylic acid derivatives having 7-(4-amino-methyl-3-oxime) pyrrolidine substituent and processes for preparing thereof	FACTIVE	06/15/2015
5,962,468	7-(4-aminomethyl-3- methyloxyiminopyrroplidin-1-yl)-1-cyclopropyl-6-flu oro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof	FACTIVE	06/15/2015
5,958,915	Antibacterial composition for oral administration	SPECTRACEF	10/14/2016
5,776,944	7-(4-aminomethyl-3- methyloxyiminopyrroplidin-1-yl)-1-cyclopropyl-6-flu oro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof	FACTIVE	04/04/2017
6,723,734	Salt of naphthyridine carboxylic acid derivative	FACTIVE	03/20/2018
6,340,689	Methods of use of quinolone compounds against atypical upper respiratory pathogenic bacteria	FACTIVE	09/14/2019
6,262,071	Methods of use of antimicrobial compounds against pathogenic amycoplasma bacteria	FACTIVE	09/21/2019
6,331,550	Methods of use of quinolone compounds against anaerobic pathogenic bacteria	FACTIVE	09/21/2019
6,455,540	Methods of use of quinolone compounds against anaerobic pathogenic bacteria	FACTIVE	09/21/2019
6,803,376	Method of use of quinolone compounds against pneumococcal and haemophilus bacteria	FACTIVE	09/21/2019
Patents for Product Candidates			
5,516,774	Vasopressin antagonists and oxytocin antagonists	CRTX 080	07/29/2013
5,624,923	Vasopressin antagonists and oxytocin antagonists	CRTX 080	07/29/2013
6,352,718	Vasopressin antagonist formulation and process	CRTX 080	09/25/2020

All of the above patents were filed with and subsequently issued by the United States Patent and Trademark Office, or USPTO. Additionally we have filed patents, which have been subsequently issued, in foreign countries for CRTX 080.

Other than FACTIVE and CRTX 080, patent protection is not available for composition of matter claims directed to the APIs of our current products and product candidates. As a result, we primarily rely on the protections afforded by our formulation and method of use patents. Method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. Our success depends, in part, on our ability to protect proprietary products, methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. If any parties should successfully claim that our proprietary products, methods and technologies infringe upon their intellectual property rights, we might be forced to pay damages, and a court

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could require us to stop the infringing activity. We do not know if our pending patent applications will result in issued patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

For information about the patents and patent applications that we own or exclusively license that we consider to be most important to the protection of our products and product candidates, see Proprietary Rights under each of the products and product candidates described above under Branded Products and Product Development Pipeline.

Trade Secrets

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, scientific advisors and consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how or inventions.

Trademarks

We use trademarks on many of our products, and believe that having distinctive marks is an important factor in marketing these products. We have U.S. and/or foreign trademark registrations and filings for certain of our corporate names, products (including ZYFLO CR and ZYFLO) and product candidates. CUROSURF is owned by Chiesi and is licensed to us for sales and marketing purposes in the United States. FACTIVE is owned by LGLS and is licensed to us for sales and marketing purposes in North America and many European countries. SPECTRACEF is owned by Meiji and licensed to us for sales and marketing purposes in the United States. Other trademarks or service marks appearing in this annual report are the property of their respective holders.

License and Collaboration Agreements

We have entered into a number of license agreements under which we have licensed intellectual property and other rights needed to develop our products or under which we have licensed intellectual property and other rights to third parties, including the license and collaboration agreements summarized below.

Chiesi CUROSURF License and Distribution Agreement

Overview. On May 6, 2009, we entered into a series of agreements with Chiesi pursuant to which we obtained an exclusive, 10-year license to the U.S. commercial rights to Chiesi s CUROSURF product and a two-year right of first offer on all drugs Chiesi intends to market in the United States, which has lapsed without renewal.

Fees, Milestones and Royalties. Under the license and distribution agreement, we pay Chiesi the greater of a percentage of the net sales price for CUROSURF or the applicable floor price as set forth in the license and distribution agreement.

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Exclusive Supplier. Under the license and distribution agreement, Chiesi is our exclusive supplier of CUROSURF.

Term and Termination. Our license agreement with Chiesi is for a 10-year initial term and thereafter will be automatically renewed for successive one-year renewal terms, unless earlier terminated by either party upon six months prior written notice.

Abbott Zileuton License Agreements

Overview. In December 2003, we acquired an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell controlled-release and injectable formulations of zileuton for all clinical indications, except for the treatment of children under age seven and use in cardiovascular and vascular devices. This license included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec. The agreement was amended in January 2010 to expand the patent rights to additional zileuton products. In March 2004, we acquired from Abbott the U.S. trademark ZYFLO and an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell the immediate-release formulation of zileuton for all clinical indications.

Fees and Royalty Payments. In consideration for the December 2003 license, we paid Abbott an initial license fee and agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including the specified minimum net sales of licensed products. We have made all of the required milestone payments under the December 2003 license agreement, although additional milestone payments would be due and payable upon any future FDA approval of CRTX 073. In addition, under each of the December 2003 and March 2004 license agreements, as amended, we agreed to pay royalties to Abbott based on the net sales of licensed products by us, our affiliates and our sublicensees. Our obligation to pay royalties continues on a country-by-country basis for a period of 10 years from the first commercial sale of a licensed product in each country. Upon the expiration of our obligation to pay royalties for licensed products in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. If we decide to sublicense rights under the license, we must first enter into good faith negotiations with Abbott for the commercialization rights to the licensed product. Abbott waived its right of first negotiation with respect to our co-promotion arrangement with DEY for ZYFLO CR.

Term and Termination. Except for a termination right provided to a party in connection with a breach by the other party, the term of the December 2003 license agreement is perpetual although we have the right to terminate the license at any time upon 60-days notice to Abbott and payment of a termination fee. Except for a termination right provided to a party in connection with a breach by the other party or a force majeure event that prevents the performance of a party for six months or more, the term of the March 2004 license agreement also is perpetual.

Jagotec Consent to Abbott Sublicense of Zileuton

In December 2003, we entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to us of rights to make, use and sell ZYFLO CR covered by Jagotec s patent rights and know-how. In addition to an upfront fee, we agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. We have made all of the required milestone payments. In addition, we agreed to pay royalties to Jagotec based on the net sales of the product by us and our affiliates. We also agreed to pay royalties to Jagotec under the license agreement between Jagotec and Abbott based on the net sales of the product by us and our affiliates. In addition, we agreed to pay Jagotec fees if we sublicense our rights under the licensed patent rights and know-how. Except for a termination right provided to a party in connection with a breach by the other party, the term of this agreement is perpetual.

LG Life Sciences FACTIVE License and Option Agreement

Overview. On September 9, 2009, we acquired the commercial rights to the anti-infective FACTIVE in North America and certain countries in Europe, certain inventory and related assets and specific product-related

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liabilities through an asset purchase agreement with Oscient, for $8.1 million and quarterly royalty payments based on net sales through September 9, 2014, adjusted for royalties we pay to LGLS with respect to those net sales.

Fees, Milestones and Royalties. Under the license and option agreement, as amended, we are obligated to pay a royalty on net sales of FACTIVE in the licensed territories. These royalty obligations expire with respect to each country covered by the agreement on the later of (1) the expiration of the patents covering FACTIVE in each country or (2) the expiration of data exclusivity in Mexico, Canada and the European Union, respectively, or 2014 in the United States. We are also obligated to make milestone payments upon achievement of additional regulatory approvals and sales thresholds.

Exclusive Supplier. Under the license and option agreement, LGLS is the exclusive supplier of all our requirements for the FACTIVE API.

Term and Termination. The term of the license and option agreement with respect to each country extends at least through the life of the patents covering gemifloxacin in such country. The patent term could extend further in countries outside the United States depending upon several factors, including whether we obtain patent extensions and the timing of our commercial sale of product in a particular country.

Meiji SPECTRACEF License and Supply Agreement

Overview. On October 12, 2006, we entered into a license and supply agreement, as subsequently amended and supplemented, with Meiji that grants us an exclusive, nonassignable U.S. license to manufacture and sell SPECTRACEF, using cefditoren pivoxil supplied by Meiji, for our currently approved therapeutic indications and to use Meiji s SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for our currently approved therapeutic indications.

Fees, Milestones and Royalties. In consideration for the licenses Meiji granted to us, we agreed to pay Meiji a nonrefundable license fee of $6 million in six installments over a period of five years from the date of the agreement. As of December 31, 2011, we have made all required license payments to Meiji. The license and supply agreement also requires us to make quarterly royalty payments based on the net sales of the products covered by the agreement for a period of 10 years from the date the particular product is launched by us.

Exclusive Supplier and Minimum Purchase Obligation. Under the license and supply agreement, Meiji is our exclusive supplier of cefditoren pivoxil for both our branded and authorized generic products and, through October 2018, of SPECTRACEF 400 mg so long as Meiji is able to supply 100% of our requirements for SPECTRACEF 400 mg. Additionally, we have agreed with Meiji for it to be a non-exclusive supplier of SPECTRACEF 200 mg through October 2018. We are required to purchase from Meiji combined amounts of the API cefditoren pivoxil, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg exceeding $15.0 million for the first year beginning October 2008, $20.0 million for year two, $25.0 million for year three, $30.0 million for year four and $35.0 million for year five. If we do not meet our minimum purchase requirement in a given year, we must pay Meiji an amount equal to 50% of the shortfall in that year. We expect to exceed the minimum purchase requirements. If we are unable to meet the minimum purchase requirements, the parties will discuss in good faith measures they can take to address the situation.

Term and Termination. The term of the license and supply agreement continues on a product-by-product basis until the expiration of 10 years from the launch date of each product. In addition, the term, on a product-by-product basis, shall automatically renew for subsequent one-year periods unless either party gives the other party six-months prior written notice of its intention not to renew. Meiji may immediately terminate the agreement if we undergo a change in control as defined in the agreement without Meiji s consent, which may not be unreasonably withheld; cease selling SPECTRACEF for a period of 60 days, unless the cessation is due to a force majeure event or a failure or delay by Meiji in supplying cefditoren pivoxil; or promote, market or sell, either directly or indirectly through a third party, any pharmaceutical products in the United States of the same therapeutic class as cefditoren pivoxil. On or after April 1, 2012, we may terminate the agreement with 270-days prior written notice if a generic cefditoren product is launched in the United States that substantially lessens our sales of SPECTRACEF.

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Competition

The pharmaceutical industry and hospital market in which we principally compete are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Our current products compete, and any product candidates that we successfully develop and commercialize will compete, with a wide range of products for the same therapeutic indications and new therapies that may become available in the future.

Upon loss of regulatory marketing exclusivity or patent protection or as a result of design-around strategies that allow for generic product introduction prior to the expiration of key product patents, we are potentially subject to competition from generic versions of our branded products. Generics are typically priced at lower levels than branded products and may substantially erode prescription demand and sales of our branded products. Our generic products are subject to competition from equivalent products introduced by other pharmaceutical companies. Such competition may adversely impact the sales volume and pricing of these products and our ability to profitably market these products.

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. Our ability to successfully market and sell the products in our pipeline will depend on the extent to which our newly formulated product candidates have the benefit of patent protection or some other form of regulatory marketing exclusivity or are meaningfully differentiated from these existing drugs or new competitive formulations of these drugs offered by third parties.

Our products compete, and our product candidates, if approved, will compete, principally with the following products or with new drugs that may be developed for the same indication:

CUROSURF Abbott s Survanta and ONY s Infasurf.

ZYFLO CR, CRTX 073 or any anti-asthma product candidate IgE blockers, such as Genentech USA, Inc s and Novartis Pharmaceutical Corporation s Xolair®, bronchodilatory drugs, such as Teva Respiratory LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering Corporation s, or Schering, Proventil® HFA (albuterol sulfate) Inhalation Aerosol; Leukotriene Receptor Agonists, such as Merck Sharp and Dohme Corporation s Singulair® (montelukast sodium); inhaled corticosteroids, such as GlaxoSmithKline s, or GSK, Flovent® Diskus® (fluticasone propionate inhalation powder); and combination products, such as GSK s Advair Diskus® (fluticasone propionate and salmeterol inhalation powder) and AstraZeneca LP s Symbicort® (budesonide/formoterol fumarate dehydrate) Inhalation Solution.

FACTIVE or any anti-infective product candidate Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Levaquin® (levofloxacin), Bayer Healthcare Pharmaceutical Inc. s Avelox® (moxifloxacin) and generic formulations of Bayer Schering Pharma s Cipro® (ciprofloxacin).

SPECTRACEF or any anti-infective product candidate second and third generation cephalosporins, such as Pernix Therapeutics LLC s Cedax® (ceftibuten), Lupin Pharmaceuticals, Inc. s, Suprax® and generic formulations of cefdinir and GSK s Ceftin® (cefuroxime).

CRTX 067 or any cough/cold product candidate various narcotic and non-narcotic antitussives, such as King Pharmaceuticals, Inc. s Tussigon® (hydrocodone and homatropine), Mallinckrodt, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), UCB, Inc. s, or UCB, Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) generic formulations of Tussionex marketed by UCB and Par Pharmaceuticals Companies, Inc., or Par Pharmaceuticals, generic formulations of promethazine hydrochloride and codeine phosphate oral syrup and Wyeth LLC s Tessalon® (benzonatate); over-the-counter antitussives, such as Reckitt Benckiser Inc. s Delsym® (dextromethorphan polistirex) and Schering-Plough s HealthCare Products Inc. s Coricidin HBP® Cough & Cold (dextromethorphan and chlorpheniramine).

CRTX 080 or any hyponatremia product candidate Otsuka Pharmaceutical Co., Ltd s Samsca® (tolvaptan) and Astellas Pharma Inc. s Vaprisol® (conivaptan).

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Regulatory Matters

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our products. In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Failure to comply with applicable regulatory requirements may subject us and our products to administrative or judicial sanctions, such as a refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

FDA Regulation of Drug Product

Before a new drug may be marketed in the United States, it must be approved by the FDA. Depending on the drug for which approval is sought, FDA marketing approval can be issued either as approval of an NDA or an abbreviated new drug application, or ANDA.

New Drug Applications. The steps required for approval of an NDA include:

pre-clinical laboratory tests, animal studies and formulation studies;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

submission to the FDA of an NDA;

satisfactory completion of an the FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and

FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies. The results of these pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the safety and effectiveness criteria, or endpoints, to be evaluated. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board, or IRB, or ethics committee before it can begin. Phase I usually involves the initial administration of the investigational drug to people to evaluate its safety, dosage, tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population afflicted with the disease or condition for which the drug is being developed, to evaluate dosage tolerance and appropriate dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate the effectiveness of the drug for specific indications. Phase III trials usually further evaluate effectiveness and test further for safety by administering the drug in its final form in an expanded patient population. Any Phase I, Phase II or Phase III clinical trials we initiate may not be completed successfully within any specified period of time, if at all. Further, we, third parties assisting in our product development efforts or the FDA may suspend

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clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or are obtaining no medical benefit from the product being studied.

Assuming successful completion of the required clinical testing, the results of the pre-clinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or facilities at which the product is manufactured, and will not approve the product unless cGMP compliance is satisfactory.

If the FDA determines the NDA is acceptable, it will approve it. If the FDA determines the NDA is not acceptable, it will issue a complete response letter outlining the deficiencies in the NDA and often requesting additional data and information. Even if the sponsor provides the requested or other information or data, the FDA may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

Supplemental New Drug Applications. If we plan line extensions of certain of our products with approved NDAs, such as new formulations including extended release formulations, new labeling claims and new indications, before we may market these products, we must submit for FDA review a supplemental new drug application, or sNDA, and receive FDA approval. The sNDA must include any additional testing, data and information necessary to demonstrate that the changed product is safe, effective and properly manufactured. Approved sNDAs are also required for certain other product changes, such as significant changes to the manufacturing process or changes in the manufacturing site.

The testing and approval process for NDAs and sNDAs requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis or at all.

In certain circumstances, product candidates may be eligible for submission of applications for approval that require less information than the NDAs discussed above. There are two such pathways to approval: ANDA and 505(b)(2) NDAs.

Abbreviated New Drug Applications. The FDA may approve an ANDA if the product is the same in important respects as a listed drug, or a drug with the FDA approval, or the FDA has declared it suitable for an ANDA submission. ANDAs for such drugs, often called generic drugs, must generally contain the same manufacturing and composition information as NDAs, but applicants do not need to submit pre-clinical and usually do not need to submit clinical safety and effectiveness data. Instead, they must demonstrate, among other things, that the product has the same active ingredient as the listed drug, that the product is bioequivalent to the listed drug, and that the drug is properly manufactured. Drugs are bioequivalent if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical trials necessary to support an NDA.

The FDCA provides that ANDA reviews and/or approvals will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity, during which the FDA will not approve, and may not even review, the ANDA. If the listed drug is claimed to be covered by an unexpired patent that the NDA holder has listed with the FDA, the ANDA applicant may certify in a so-called paragraph IV certification that the patent is invalid, unenforceable or not infringed by the product that is the subject of the ANDA. If the holder of the NDA sues the ANDA applicant within 45 days of being notified of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of a court decision favorable to the ANDA applicant or the expiration of 30 months. Also, in circumstances in which the listed drug is claimed to be covered by an unexpired patent and the patent s validity, enforceability or applicability to the generic drug has been challenged by more than one generic applicant, ANDA approvals of later generic drugs may be delayed until the first applicant has received a 180-day period of market exclusivity. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances until the FDA acts on one or more ANDA applications.

Section 505(b)(2) New Drug Applications. Some product candidates may be eligible for approval under the Section 505(b)(2) approval process. Section 505(b)(2) applications may be submitted for drugs that represent

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a modification of a listed drug, such as a new indication or a new dosage form, for which an ANDA is not available. Section 505(b)(2) applications may rely on the FDA s previous determinations of safety and effectiveness for the listed drug as well as information provided by the 505(b)(2) applicant to support the modification of the listed drug. Preparing Section 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information. Like ANDAs, approval of Section 505(b)(2) applications may be delayed because of market exclusivity awarded to the listed drug or because patent rights are being adjudicated.

In addition to the FDA s responsibilities with respect to drug approvals, both before and after approval of drugs for which approved NDAs and ANDAs have been obtained or will be sought, and in connection with marketed drugs that do not have approved NDAs or ANDAs, we and our manufacturers and other partners are required to comply with many FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising, promotion and sampling. Also, quality control and manufacturing procedures must conform to cGMP, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, sponsors, marketers and manufacturers must continue to expend time, effort and money in all areas of regulatory compliance, including production and quality control, to comply with these requirements. Also, discovery of problems such as safety problems may result in changes in labeling, restrictions on the product manufacturer and NDA/ANDA holder, imposition of risk evaluation and mitigation strategies and/or removal of the product from the market.

Foreign Regulation

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

Regulation of Controlled Substances

We, our contract manufacturers and packagers and our products and product candidates (in particular, CRTX 067, which contains hydrocodone) are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturer and packager for CRTX 067 must adhere to a number of requirements, including registration, recordkeeping and reporting requirements; security controls; and, assuming regulatory approval is received, labeling and packaging requirements and certain restrictions on prescription refills.

In addition, a DEA quota system controls and limits the availability and production of certain controlled substances, including hydrocodone, which are or may be used in our products or product candidates. The DEA annually establishes aggregate quotas for how much of each controlled substance may be produced based on the DEA s estimate of the quantity needed to meet legitimate scientific and medical needs. The limited aggregate amounts of this substance that the DEA allows to be produced in the United States each year are allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. A manufacturer or packager must receive an annual quota from the DEA in order to produce or procure any controlled substance product or product candidate. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, and it has substantial discretion over whether to make such adjustments. Our contract manufacturers and packagers quotas may not be sufficient for us to complete clinical trials of our product candidates. Any delay or refusal by the DEA in establishing our contract manufacturers or packagers quotas for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

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The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure by us or our contract manufacturers or packagers to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. 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.

Individual states also regulate controlled substances, and we and our contract manufacturers and packagers are subject to state regulation on distribution of these products.

Hazardous Materials

We rely on third parties to assist us in developing and manufacturing all of our products and do not directly handle, store or transport hazardous materials or waste products. We rely on third parties to comply with 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 expect the cost of complying with these laws and regulations to be material to us.

Pharmaceutical Pricing and Reimbursement

Our ability to commercialize our products successfully depends in significant part on the availability of adequate coverage and reimbursement to patients from third-party payers, including governmental payers such as the Medicare and Medicaid programs, managed care organizations, or MCOs, and private health insurers.

We participate in a number of governmental programs that require us to provide rebates or discounts or otherwise limit reimbursement for our products. Under the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class and to negotiate the prices to be paid for those drugs. Some Medicare Part D plans cover some or all of our products, but the amount and level of coverage vary from plan to plan. In addition, effective January 1, 2011, we were required to begin offering a 50% discount off of the plans negotiated prices on certain of our products to Medicare Part D beneficiaries during their coverage gap period. Our products may be excluded from private plans formularies and may be subject to significant price competition that depresses the prices we are able to charge. We believe that it is likely that private insurers will pattern their coverage and reimbursement policies on Medicare coverage and reimbursement policies with respect to prescription drug benefits.

In addition, we participate in the Medicaid Drug Rebate Program, or MDRP, with the Centers for Medicare and Medicaid Services in order for our products to be reimbursable under government health care programs. The MDRP requires us to pay rebates to the state Medicaid programs based on either a specified percentage of the average manufacturer price or the difference between the average manufacturer price and the best price. In addition, in order to participate in the MDRP, we are required to enter into a similar agreement with the U.S. Department of Veterans Affairs. Furthermore, some states currently require (and more states may begin to require) manufacturers to enter into supplemental rebate agreements, and we have entered into such agreements with some states.

We also participate in the Public Health Service s 340B Drug Pricing Program and some of our products are purchased under the program. As a participant in the program, we are required to charge a discounted price for our products to certain types of covered entities, such as qualified disproportionate share hospitals.

All of our products are generally covered by managed care and private insurance plans. Coverage by such plans for ZYFLO CR, FACTIVE and SPECTRACEF is similar to other products within the same class of drugs, but the status or tier of our products within each plan varies. A product s placement within a plan s status or tier structure can affect the out-of-pocket expense to the plan s beneficiaries. For example, the position of FACTIVE as a branded product often requires a higher patient copayment, which may make it more difficult to expand the current market share for this product.

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Third-party payers are increasingly challenging the prices charged for medicines and examining their cost-effectiveness, in addition to their safety and efficacy. 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 SPECTRACEF. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate 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 safe, less effective or less cost-effective than existing products, and third-party payers may decide not to provide coverage and reimbursement for our products, in whole or in part. Even if third-party payers approve coverage and reimbursement for our products, the resulting payment rates may not be sufficient for us to sell our products at a profit.

Moreover, political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes with respect to pricing and reimbursement. In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, which contain cost-containment measures and health care reforms to be implemented over the next decade, were signed into law. We refer to the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 as Health Care Reform. The provisions of Health Care Reform that are likely to impact our pricing and reimbursement for our products include the requirement to provide a 50% discount off negotiated prices to applicable brand-name drugs for Medicare Part D beneficiaries during their coverage gap period; an increase in the Medicaid rebates that we must pay to state Medicaid programs under the MDRP; the inclusion of Medicaid MCO enrollees in the calculation of rebates owed under the MDRP; the revised definition of average manufacturer price for rebate reporting purposes; and an increase in the number of entities eligible for discounted pricing under the 340B Drug Pricing Program. In addition, proposed regulations implementing the calculation and reporting requirements for average manufacturer price and best price were published in the Federal Register on February 2, 2012; we cannot predict whether and in what form these regulations will be made final, and what effect these regulations may have on our pricing and reimbursement. Furthermore, Health Care Reform includes initiatives to study and implement payment reforms and cost-containment measures, the results of which could reduce reimbursement for our products and reduce our profits.

We anticipate that Congress, state legislatures and the private sector will continue to consider and may adopt further health care policies intended to curb rising health care costs. These cost-containment measures could include, for example:

- controls on government-funded reimbursement for drugs;
- controls on payments to health care providers that affect demand for drug products;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- weakening of restrictions on imports of drugs; and
- expansion of the use of managed care systems in which health care providers contract to provide comprehensive health care for a fixed cost per person.

We may also face competition for our products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Although not implemented by Health Care Reform, potential future federal legislation may expand consumers ability to import lower-priced versions of competing products from Canada and other countries. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

We are unable to predict how all or portions of Health Care Reform will be implemented, what additional legislation, regulations or policies, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures, including those listed above, or other health care system reforms that are adopted could impair our ability to set prices that cover our costs, constrain our ability to generate revenue from government-funded or private third-party payers, limit the revenue and profitability of our potential customers, suppliers and collaborators and impede our access to capital needed to operate and grow. Any of these circumstances could significantly limit our ability to operate profitably.

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Fraud and Abuse Regulation

A number of federal and state laws and related 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 health programs, such as Medicare and Medicaid, or private insurers. These laws are extremely complicated, apply broadly and may constrain our business and the financial arrangements through which we market, sell and distribute our products. Examples of these laws and regulations include:

Federal Anti-Kickback Law. 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 willfully to offer or pay, or to solicit or receive, remuneration in order to induce 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. Both the party offering or paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to induce purchases or referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exemptions and regulatory safe harbors, but many legitimate transactions fall outside of the scope of any exemption or safe harbor, although that does not necessarily mean the arrangement will be subject to penalties under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate 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. Health Care Reform amended the intent requirement of the federal anti-kickback statute so that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Violations of the federal anti-kickback statute may now also be treated as a false or fraudulent claim for purposes of the federal false claims act or a violation of the criminal health care fraud law.

Federal False Claims Law. The federal false claims act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false or fraudulent claim for payment of government funds or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Penalties include three times the government s damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the federal false claims act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff or whistleblower, to file a lawsuit on behalf of the government against the person or entity that committed the fraud. If the government determines to intervene in the lawsuit and the government prevails, the *qui tam* plaintiff is rewarded with a percentage of the recovery.

Federal Health Insurance Portability and Accountability Act of 1996. The HIPAA statute imposes criminal liability for knowingly and willfully executing a scheme to defraud any health care benefit program. It also prohibits knowingly and willfully falsifying, concealing or covering up any material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Furthermore, HIPAA imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

Other Federal Criminal and Civil Health Care Laws. The Social Security Act contains numerous penalties for fraud and abuse in the health care industry, such as imposition of a civil monetary penalty, a monetary assessment, exclusion from participation in federal health care programs or a combination of these penalties.

State Laws. 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 payer, including private payers, commercial insurers and other payers. Moreover, these laws and regulations vary significantly from state to state and, in some cases, are broader than the federal laws

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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.

In addition, there is a trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Health Care Reform includes examples of this trend. Beginning in 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report of the drug samples requested by and provided to health care practitioners. Beginning in 2013, pharmaceutical manufacturers will be required to report information to the U.S. Department of Health and Human Services related to payments and other transfers of value to physicians during the preceding calendar year, which information will later be made publicly available. Pharmaceutical manufacturers will also be required to report and disclose physician ownership and investment interests in such manufacturers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Various states currently require or have proposed legislation that would require pharmaceutical companies to report expenses related to marketing and promotion of pharmaceutical products and gifts and payments to physicians within the states.

Employees

As of February 29, 2012, we had 116 full-time employees, 78 of whom were engaged in marketing and sales; 11 of whom were engaged in research, development and regulatory affairs; and 27 of whom were engaged in management, administration and finance. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages. We believe that relations with our employees are good.

Available Information

We maintain a web site with the address www.crtx.com. We are not including the information contained on our web site as part of, or incorporating it by reference into, this annual report. We make available, free of charge, on or through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with or furnished to the SEC.

In addition, a copy of any exhibit to this annual report on Form 10-K will be furnished free of charge upon written request by one of our stockholders directed as follows: Attn: Executive Vice President, General Counsel and Secretary, Cornerstone Therapeutics Inc., 1255 Crescent Green Drive, Suite 250, Cary, NC 27518.

ITEM 1A. *RISK FACTORS*

You should carefully consider the following risk factors, in addition to other information included in this annual report on Form 10-K and the other reports that we file with the SEC, in evaluating us and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected.

Risks Relating to Commercialization and Product Acquisitions

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 at an acceptable cost, which could delay, impair or prevent the clinical development and commercialization of our product candidates or our ability to meet commercial demands for our products.

We have no manufacturing facilities and rely on third parties to purchase raw materials for, manufacture, package and supply all of our products. Some of the agreements we have entered into are exclusive agreements in which the manufacturer is a single-source supplier, preventing us from using alternative sources. Similarly, many

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of our agreements may require us to make volume commitments or agree to long-term pricing arrangements that may affect our margins or constrain our ability to position our products optimally in the market. If we choose to cancel or are unable to meet our volume commitments, we may be subject to penalties or increased costs to manufacture our products. For a description of the manufacturing and packaging agreements related to our more important products, please see Item 1. Business Manufacturing.

If any of the third-party manufacturers with whom we contract fails to perform its obligations, we may be adversely affected in a number of ways, including the following:

We may not be able to meet commercial demands for our products;

We may be required to cease distribution or issue recalls;

We may not be able to initiate or continue clinical trials of product candidates that are under development; and

We may be delayed in submitting applications for regulatory approvals for product candidates.

We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If we were required to change manufacturers, we would be required to obtain FDA approval of an sNDA covering the new manufacturing site. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that the products manufactured by the new manufacturer are equivalent to the products manufactured by the current manufacturer, which could take 12 to 18 months or possibly longer. The technical transfer of manufacturing capabilities can be difficult. Any delays associated with the approval of a new manufacturer could adversely affect the production schedule or increase our production costs and could ultimately lead to a shortage of supply in the market.

Additionally, FDA regulations restrict the manufacture of penicillin products in the same facility that manufactures a cephalosporin such as the SPECTRACEF products. These restrictions reduce the number of cGMP FDA-approved facilities that are able to manufacture cephalosporins, which could complicate our ability to quickly qualify a new manufacturer for the SPECTRACEF products.

We also rely on third-party manufacturers that, in some instances, have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. In addition, supply interruptions or delays could occur that require us or our manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in our raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operation.

In addition, we import the API, tablet cores and/or finished product for all of our products from third parties that manufacture such items outside the United States, and we expect to do so in the future. This may give rise to difficulties in obtaining API, tablet cores or finished product 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, tablet cores and finished product 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 or finished product, the importation of the API or finished product could be delayed. While in transit from outside the United States or while stored with our third-party logistics provider, DDN, our API, tablet cores or finished product 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.

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The commercial success of our currently marketed products and any additional products that we successfully develop or bring to market depends on the degree of market acceptance by physicians, patients, health care payers and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, health care payers and others in the medical community. The degree of market acceptance of our products, including our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of the products side effects;
- the efficacy and potential advantages of the products over alternative treatments;
- the ability to offer the products for sale at competitive prices, including in relation to any generic or re-imported products or competing treatments;
- the relative convenience and ease of administration of the products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the perception by physicians and other members of the health care community of the safety and efficacy of the products and competing products;
- the availability and level of third-party reimbursement for sales of the products;
- the continued availability of adequate supplies of the products to meet demand;
- the strength of marketing and distribution support;
- any unfavorable publicity concerning us, our products or the markets for these products, such as information concerning product contamination or other safety issues in the markets for our products, whether or not directly involving our products;
- regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products; and
- changes in intellectual property protection available for the products or competing treatments.

If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be able to return to profitability.

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.

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.

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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 not successful in identifying and acquiring rights to products, or if we are not successful in developing product candidates, 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.

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, our current product candidates 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 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, CRTX 073, which is a modified formulation of an existing product, may not demonstrate sufficient additional clinical benefits to health care providers to justify a higher price compared to generic equivalents within the same therapeutic class. 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.

Our patents will not protect our products if competitors devise ways of making products that compete with our products without legally infringing our patents. The FDCA and FDA regulations and policies provide certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of ANDAs for generic substitutes. These same types of exclusivity incentives encourage manufacturers to submit 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 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. The FDCA provides a five-year period of exclusivity for a drug approved under the first NDA covering an API, and the drug approval for any of our product candidates may be blocked by such a period of marketing exclusivity. Similarly, the FDCA provides a three-year period of exclusivity for a drug approved under the first NDA covering a new indication or formulation of a drug that includes a previously approved API. These provisions may delay approval of our product candidates.

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Even if we are not excluded from obtaining marketing approval for our product candidates, it may adversely affect the revenue potential of those product candidates if our competitors succeed in commercializing similar products more rapidly or effectively than we are able to. For instance, in October 2010, one of our competitors, Par Pharmaceuticals, with its licensing partner, Tris Pharma, Inc., launched an FDA-approved generic hydrocodone polistirex and chlorpheniramine polistirex extended-release oral suspension product, which, like our CRTX 067 product candidate, is a generic version of UCB s, Tussionex. In addition, UCB launched its own generic version of Tussionex, through its generic subsidiary, Kremers Urban Pharmaceuticals Inc., which would make us the third entrant into the Tussionex generic market. While we continue to expect that CRTX 067 will receive marketing approval by the FDA in 2012, the presence of competing products in the market may adversely affect both the price we can charge for our product and the portion of the market for that product that may be available to us.

The principal competitors to our products and potential competitors to our product candidates are more fully described under the caption Competition in Item 1 above.

Many of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in 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 scientific and management personnel, establishing clinical trial sites, registering patients for clinical trials 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 currently marketed products and product candidates 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, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products noncompetitive. If our product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those product candidates.

If we are unable to identify and acquire products and/or companies, and if we cannot integrate them efficiently, our business and ability to realize the value of completed acquisitions, or ability to develop our product candidates and expand our product pipeline may be harmed.

Our plan to grow our existing product portfolio is based upon our ability to acquire or in-license products and to acquire companies that fit with our strategic focus. These acquisitions and licenses involve risks. For example:

- We may not be able to identify suitable companies to acquire or to acquire such companies on favorable terms. We compete with others in the pharmaceutical industry to acquire companies. We believe that this competition may increase and could result in decreased availability or increased prices for suitable acquisition candidates.

- During the acquisition process, we may fail or be unable to discover some of the liabilities of companies or products that we acquire.

- We may overuse our cash resources.

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We may experience higher than anticipated acquisition costs and expenses.

We may not be able to obtain the necessary financing, on favorable terms or at all, to finance any of our potential acquisitions.

We may fail to integrate acquired companies or products into our business successfully.

Acquired businesses or products may not perform as we expect or we may not be able to obtain the financial improvements and results we anticipate. In addition, the development and integration of new companies or products could disrupt our business and occupy our management s time and attention.

We face the risk that our existing financial controls, information systems, management resources and human resources will need to grow to support future growth.

We may be unable to preserve key suppliers or distributors of any acquired products.

We may issue equity securities to acquire companies or products, which may result in dilution.

Any acquisition could substantially increase our amortization expenses.

For example, we entered into a license and distribution agreement with Chiesi for CUROSURF that extends to 2019. There is no assurance that the net sales of CUROSURF will be sufficient to offset the net income per share impact of increased amortization expense and the dilutive effect of the shares issued to Chiesi.

If we fail to address adequately the financial, operational or legal risks of our acquisitions or licensing arrangements, or if we are unable to integrate our acquisitions successfully, our results of operations and financial condition could be materially and adversely affected.

As our competitors introduce their own pharmaceutical and/or therapeutic equivalents of our products, our net revenues from such products are expected to decline.

Product sales of pharmaceutical and/or therapeutic equivalents often follow a particular pattern over time based on regulatory and competitive factors. The first company to introduce an equivalent of a branded product is often able to capture a substantial share of the market. However, as other companies introduce competing equivalent products, the first entrant s market share, and the price of its equivalent 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 or a manufacturer contracted to market an authorized generic to the brand 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.

Our inability to introduce generic equivalents to our branded products or our withdrawal of existing products from the market due to increased competition would have a material adverse effect on our financial condition and results of operations.

Fluoroquinolone products have been associated with the risk of tendonitis and tendon ruptures. FACTIVE is a fluoroquinolone product and must comply with the FDA directives on prescribing information for fluoroquinolones.

In July 2008, the FDA notified manufacturers of fluoroquinolones that it was directing the prescribing information for all fluoroquinolone products, including FACTIVE (gemifloxacin mesylate), be revised to include a boxed warning relating to the risk of tendonitis and tendon rupture associated with the use of fluoroquinolone

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products. Warnings regarding the risk of tendon-related adverse events were already included in the prescribing information, as part of a class labeling, for all fluoroquinolones. The FDA has cautioned that such risk is increased in patients over the age of 60 and in those on concomitant corticosteroid therapy, as well as kidney, heart and lung transplant recipients. The FDA also required a medication guide to be included in each FACTIVE package. In April 2009, the FDA approved changes to the FACTIVE package insert and its medication guide as part of its approval of the Risk Evaluation and Mitigation Strategy, or REMS, for FACTIVE. We began using the package insert and medication guide when we began earning revenues from FACTIVE in September 2009. We submitted our initial REMS assessment in May 2011. The FDA responded to this submission in August 2011 advising us to implement changes to our medication guide and that we could cancel our remaining REMS program assessments. The recommended changes to our medication guide were implemented in August 2011.

We cannot predict what further action, if any, the FDA may take, including, among others things, further label restrictions in the fluoroquinolone class or even the removal of indications or products from the market. Any of these events could prevent us from achieving or maintaining market acceptance of FACTIVE or could substantially increase the costs and expenses of commercialization, which in turn could delay or prevent us from generating significant revenues from sales of this product.

Concerns regarding the safety profile of ZYFLO CR and ZYFLO may limit market acceptance of ZYFLO CR.

Market perceptions about the safety of ZYFLO CR and ZYFLO may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of ALT of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO CR can elevate liver enzyme levels, its product labeling, which was approved by the FDA in May 2007, contains the recommendation that periodic liver function tests be performed on patients taking ZYFLO CR. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO CR, ZYFLO or any other zileuton product candidates that we successfully develop and commercialize, which could limit their commercial acceptance.

In March 2008, the FDA issued an early communication regarding an ongoing safety review of the leukotriene montelukast relating to suicide and other behavior-related adverse events. In that communication, the FDA stated that it was also reviewing the safety of other leukotriene medications. On May 27, 2008, we received a request from the FDA that we gather and provide to the FDA data from the clinical trial database to evaluate behavior-related adverse events for ZYFLO and ZYFLO CR. On January 13, 2009, the FDA announced that the company studies it reviewed do not show any association between these drugs that act through the leukotriene pathway (for example, montelukast, zafirlukast and zileuton) and suicide, although the FDA noted that these studies were not designed to detect those events. The FDA also reviewed clinical trial data to assess other mood-related and behavior-related adverse events related to such drugs. On April 23, 2009, the FDA requested that we add wording to the precaution section of the ZYFLO CR and ZYFLO labeling to include post-marketing reports of sleep disorders and neuropsychiatric events. It is our understanding that other leukotriene modulator manufacturers were asked to make similar changes. There is a risk that this labeling change may cause physicians and other members of the health care community to prefer competing products without such labeling over ZYFLO CR and ZYFLO, which would cause sales of these products to suffer.

Safety concerns regarding ZYFLO CR and ZYFLO, actual or perceived, may adversely impact the market for ZYFLO CR and ZYFLO, and could have a material adverse effect on our financial condition and results of operations.

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Product liability lawsuits against us could cause us to incur substantial liabilities and to 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, previously marketed products that have been withdrawn or discontinued, any other products that we successfully develop and the testing of our product candidates in human clinical trials. If we cannot successfully defend against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

injury to our reputation;

the withdrawal of clinical trial participants;

the recall and/or withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary damages awards to clinical trial participants or plaintiffs, whether through settlement or trial;

diversion of management time and attention;

loss of revenue; and

inability to commercialize the products that we may develop.

As discussed in the risk factors above, there are concerns regarding the safety of the products containing the APIs gemifloxacin or zileuton. In addition, in November 2010, the FDA requested that all products containing the API propoxyphene be voluntarily withdrawn from the market due to safety concerns. All of our products containing propoxyphene have been removed from the market. We are aware of various pending product liability claims which have been asserted in lawsuits against numerous developers, manufacturers and distributors of propoxyphene products. A large number of those lawsuits have been consolidated into multidistrict litigation, or MDL, proceedings in the United States District Court, Eastern District of Kentucky (Northern Division), and we expect that the large majority of future lawsuits that are filed will continue to be consolidated in these MDL proceedings or in a complex litigation department in California state court. We have been named in a small number of those lawsuits, and, to date, we have been served with legal process in five such suits. For a more complete discussion regarding these lawsuits, please see Item 3. Legal Proceedings in this annual report on Form 10-K.

We had a less than 1% share of the market for propoxyphene products, and we believe that the probability that a party alleging injury could definitively link that injury to our products is low based on current facts known to us. In light of recent case law, we believe that plaintiffs will have difficulty explaining why their claims are not preempted by federal regulatory laws. Accordingly, we do not believe that we are likely to face significant liability in connection with the claims asserted against developers, manufacturers and distributors of propoxyphene products based on current facts known to us at this stage of this litigation.

Our contracts with wholesalers and other customers require us to carry product liability insurance. We have primary and excess product liability insurance coverage to meet these obligations. Our primary coverage offers a $10 million per claim and annual aggregate limit. The excess policy offers an additional $10 million per claim and annual aggregate limit. The annual cost of our product liability insurance was approximately

$303,000 for the policy year beginning September 13, 2011. In addition, our products liability insurance coverage for 2012 specifically excludes liability related to propoxyphene products.

In the event that we are found liable for injuries caused by our products, if defenses are unsuccessful, or if adverse facts are learned, we could face significant liability that may adversely affect our financial condition and results of operations. We may not be able to maintain insurance coverage at a reasonable cost and the amount of insurance that we currently hold may not be adequate cover all liabilities that we may incur.

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We may rely on third parties to market and promote some products, and these third parties may not successfully commercialize these products.

We may seek to enter into co-promotion arrangements to enhance our promotional efforts and, therefore, sales of our products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management support, we can reach health care providers in areas where we have limited or no sales force representation, thus expanding the reach of our sales and marketing programs. Without co-promotion arrangements, we may not be able to devote sufficient financial resources or capabilities to independently promote and market products which could limit our sales to certain specialties or in certain geographical areas. However, we might not be able to enter into such an arrangement on favorable terms, if at all.

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

We have built a commercial organization, consisting at February 29, 2012 of 63 sales professionals in a variety of sales and management positions. Our sales organization is divided into a hospital sales force and a respiratory sales force. Our sales teams are supported by marketing, market research and commercial operations professionals. We may not be able to attract, hire, train and retain qualified sales and marketing personnel to augment our existing capabilities in the manner or on the timeframe that we plan. If we are unsuccessful in our efforts to expand our sales force and marketing capabilities, our ability to independently market and promote our products and any product candidates that we successfully bring to market will 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 our products and 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 and hospital pharmacies, which ultimately dispense our products to the end consumers. Consolidation within the wholesale drug distribution industry has occurred and may continue to occur. As a result, a small number of large wholesale distributors control a significant share of the market. Sales to our three primary wholesale distributors, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, collectively accounted for approximately 94% of our gross product sales during 2011.

The loss of any of these wholesale distributors or a material reduction in their purchases could harm our business, financial condition and results of operations if we are unable to enter into agreements with replacement wholesale distributors on commercially reasonable terms.

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

We do not have our own warehouse or distribution capabilities, we lack the resources and experience to establish any of these functions, and we do not intend to establish these functions in the foreseeable future.

We rely on third parties to distribute our products to pharmacies. We have contracted with DDN, a third-party logistics company, for the distribution of our products to wholesalers, retail drug stores, mass merchandisers and grocery stores in the United States.

We also depend on the distribution abilities of our wholesale customers to ensure that products are effectively distributed throughout 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 fourth quarter of 2007 and 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.

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Our distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. 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. In addition, failure to maintain our third-party contracts or a third party s inability or failure to adequately perform as agreed under its contract with us could negatively impact us.

If any of the third parties that we rely upon for assistance in researching, developing, manufacturing, promoting and distributing our products and product candidates experience financial distress and are unable to provide this assistance, our operating performance would be adversely affected.

Economic unpredictability could adversely affect the third parties upon whom we rely for researching, developing, manufacturing, promoting and distributing our products and product candidates. We believe that some of the third parties upon which we rely depend on financing from banks, financial institutions and other third-party financing sources in order to finance their operations. The current economic environment may make it more difficult or impossible for these third parties to obtain additional financing or extend the terms of their current financing. Some of these third parties may be highly leveraged, and if they are unable to service their indebtedness, such failure could adversely affect their ability to maintain their operations and to meet their contractual obligations to us, which may have an adverse effect on our financial condition, results of operations and cash flows.

A failure to maintain optimal inventory levels could harm our reputation and subject us to financial losses.

Because accurate product planning is necessary to ensure that we maintain optimal inventory levels, significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If we are required to recognize charges for excess inventories, such charges could have a material adverse effect on our financial condition and results of operations.

We are obligated to make aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg exceeding specified dollar amounts annually over a five-year period under our supply agreement with Meiji. Under the agreement, the required annual aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg are $25.0 million for the sales year ending October 2011, $30.0 million for the sales year ending October 2012 and $35.0 million for the sales year ending October 2013. If we do not meet our minimum purchase requirement in a given year, we must pay Meiji an amount equal to 50% of the shortfall in that year.

We are also subject to minimum purchase obligations under supply agreements, which require us to purchase inventory of the tablet cores for ZYFLO CR. We have committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 30, 2008. If ZYFLO CR does not achieve the level of demand we anticipate, we are required to pay a penalty of 20% of the cost of the minimum inventory requirements we do not purchase. During the year ended December 31, 2011, we incurred a penalty of $413,964. Based on our current expectations regarding demand for ZYFLO CR, we expect that we will pay penalties under the supply agreement which could have a material adverse effect on our financial condition, results of operations and cash flows.

Product acquisitions typically include the purchase of existing inventory. If the previous company has distributed product to the wholesalers and distributors that exceeds current demand, such inventory levels could affect our ability to sell product to the wholesalers. Until the inventory levels decline, revenues for the acquired product could be minimal. For example, when we acquired FACTIVE, the wholesaler and distributor levels of inventory exceeded demand, which prevented us from selling significant amounts of product for the first three months following the acquisition.

Our ability to maintain optimal inventory levels also depends on the performance of third-party contract manufacturers. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations and because of the limited

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number of suppliers of certain APIs. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. 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 financial condition, results of operations and cash flows.

If our third-party manufacturers and packagers do not obtain the necessary quota for controlled substances needed to supply us with our product candidates or products or the quotas are not sufficient, our product launches may be delayed or we may be unable to meet commercial demand for our products following launch.

CRTX 067 contains hydrocodone, a controlled substance which is regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer may manufacture, the amount of API it may use to manufacture those products and the amount of controlled substance drug products a packager may package. We rely on the third-party manufacturer and packager of this product candidate, Neos and Coating Place, respectively, to request and obtain from the DEA the annual quota allocation needed to meet our production requirements for CRTX 067, and we will continue to rely on Neos and Coating Place to obtain necessary quotas following launch. If Neos and Coating Place are unsuccessful in obtaining quotas, CRTX 067 could be at risk of a delayed launch or we may be unable to meet commercial demand following launch.

If we or our contract manufacturers or packagers fail to comply with regulatory requirements for any controlled substance products and product candidates, 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 contract manufacturers and packagers and our products and product candidates (in particular, CRTX 067) are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturer and packager for CRTX 067 must adhere to a number of requirements with respect to CRTX 067, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls; procurement and manufacturing quotas; and certain restrictions on prescription refills. 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.

Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to Product Development and Regulatory Matters

If we fail to comply with regulatory requirements for our products or if we experience unanticipated problems with them, the FDA 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 products, our contract manufacturers and our other partners are subject to comprehensive regulation by the FDA. These requirements include submissions of safety and other post-marketing information; record-keeping and reporting; annual registration of manufacturing facilities and listing of products with the FDA; ongoing compliance with cGMP regulations; and requirements regarding advertising, promotion and the distribution of samples to physicians and related recordkeeping. For example, we received a warning letter from the FDA s Division of Drug Marketing, Advertising and Communications on June 22, 2010 relating to certain promotional and labeling material for our ZYFLO CR extended release tablets. The FDA asserted that our ZYFLO CR webpage was false and misleading because it presented efficacy claims for ZYFLO CR, but failed to contain certain risk information associated with the product, and that certain promotional material was false or

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misleading because it omitted important information about the risks associated with the use of ZYFLO CR, made unsubstantiated superiority claims and omitted material facts. Additionally, the FDA stated that the web page and promotional material were disseminated with an outdated version of the FDA-approved product labeling for ZYFLO CR. Although we did not admit and in fact denied some of FDA s allegations, as part of our response and in connection with the close out of this matter, we ceased dissemination of the relevant promotional materials, disabled and revised the web page, retrieved and destroyed the relevant promotional materials and updated our procedures regarding promotional material and labeling. We disseminated updated messaging to the recipients of the aforementioned promotional materials and updated our website to include corrective messaging consistent with the FDA s observations. The corrective messaging was required to remain on our website for 12 months from implementation, or February 2, 2012. We will seek formal FDA closure of this matter in early 2012. Going forward, if our promotional activities fail to comply with the FDA s regulations and guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions and other penalties, and, if so, our business and reputation could be harmed.

Under the Food and Drug Administration Amendments Act of 2007, or FDAAA, the FDA is also authorized, among other things, to require the submission of REMS with NDAs, or post-approval upon the discovery of new safety information, to monitor and address potential product safety issues. The FDAAA also grants the FDA the authority to mandate labeling changes in certain circumstances and establishes requirements for registering and disclosing the results of clinical trials.

The manufacturers and the manufacturing facilities used to make our products and product candidates are also subject to comprehensive regulatory requirements. While we generally negotiate for the right under our long-term manufacturing contracts to periodically audit our third-party manufacturers performance, we do not have control over our third-party manufacturers compliance with applicable regulations. Our current quality assurance program may not be reasonably designed to, or may not, discover all instances of non-compliance by our third-party manufacturers with these regulations. For instance, in 2004, the FDA inspected the predecessor company to one of our current development partners and, as a result of alleged failure of the manufacturer to comply with cGMPs, the FDA issued a warning letter to the manufacturer. Subsequent action by the FDA related to the 2004 warning letter resulted in a permanent injunction, or consent decree, in 2007 against the manufacturer. The manufacturer is working closely with their FDA district office to satisfy the conditions of the injunction; however, the manufacturer remains under the auspices of the consent decree at this point in time.

The FDA periodically inspects sponsors, marketers and manufacturers for compliance with these requirements. On March 24, 2010, the FDA issued us a Notice of Inspectional Observations, or Form 483, in connection with a March 2010 inspection of our cGMPs. The Form 483 stated that the following were areas of possible non-compliance with FDA regulations: our processes related to the review of batch specific documentation, analytical information, deviations and investigations prior to releasing finished product for distribution; our validation assessment procedure; and our documentation related to product complaints, the resultant investigations and close out. We responded to the FDA on May 5, 2010 and took actions to address each of the observations identified by the FDA in the Form 483 as quickly as practicable. The FDA agreed with and accepted our corrective response.

If the FDA makes additional inspectional observations in other inspections or is not satisfied with the corrective actions we take in response to the Form 483, we could be subject to further FDA action, including sanctions. We may also be subject to sanctions as a result of discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with applicable regulatory requirements. Possible sanctions include the following:

- 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;

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recalls;

fines;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

Any of these actions could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to develop safe and efficacious formulations of our product candidates, or our clinical trials for our product candidates are not successful, we may not be able to develop, obtain regulatory approval for and commercialize our product candidates successfully.

Although it is our strategy to focus our development efforts on late-stage product candidates, some of our product candidates may be in the preclinical stage of development and require clinical testing necessary to obtain the regulatory approvals or clearances required for commercial sale. Depending on the nature of the product candidate, to demonstrate a product candidate s safety and efficacy, we and our collaborators generally must either demonstrate bioequivalence with a drug already approved by the FDA or complete human clinical efficacy trials. We may not be able to obtain permission from the FDA, IRBs or other authorities to commence or complete necessary clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other characteristics that may delay or preclude submission and regulatory approval, or cause imposition of burdensome post-approval requirements or limit commercial use if approved.

Furthermore, we, one of our collaborators, IRBs or regulatory agencies may order a clinical hold or suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

Adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in failure to obtain approval or approval for a narrower indication. If clinical trials fail, our product candidates would not receive regulatory approval or achieve commercial viability.

If clinical trials for our product candidates are delayed, we would incur additional costs and delay the receipt of any revenues from product sales.

We currently expect to commence clinical trials with respect to CRTX 073 in 2012. We cannot predict whether we will encounter problems with any of our completed or planned clinical trials that will delay or cause regulatory authorities, IRBs or us to suspend those clinical trials or the analysis of data from such trials.

Any of the following could delay the completion of our planned clinical trials:

we, the FDA, a third party assisting us with product development or an IRB suspending or stopping a clinical trial;

discussions with the FDA regarding the scope or design of our clinical trials;

delay in obtaining, or the inability to obtain, required permissions from regulators, IRBs or other governing entities at clinical sites selected for participation in our clinical trials;

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;

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exposure of participants to unacceptable health risks;

our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, or we may abandon projects that had appeared to be promising;

we or our third-party contractors may fail to comply with regulatory requirements or contractual obligations in a timely manner;

insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct clinical trials; or

unfavorable FDA inspection and review of a clinical trial site or records of any clinical investigation.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the seasonality of the disease, the availability of effective treatments for the relevant disease, competing trials with other product candidates and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. In addition, subjects may drop out of clinical trials and thereby impair the validity or statistical significance of the trials.

Delays in patient enrollment and the related increase in costs also could cause us to decide to discontinue a clinical trial prior to completion. For example, in March 2008, we discontinued our Phase IV clinical trial for ZYFLO CR designed to generate data in the current patient treatment setting because patient enrollment was significantly slower than we had anticipated.

We have relied and expect to continue to rely on contract research organizations, clinical data management organizations, medical institutions, clinical investigators and academic institutions to conduct, supervise or monitor some or all aspects of the clinical trials for the product candidates we advance into clinical testing. Accordingly, we have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own, which could have an adverse impact on the conduct, timing and completion of our clinical trials and our ability to adhere to FDA regulations (commonly referred to as Good Clinical Practices) for conducting, recording and reporting the results of our clinical trials.

Although we have not previously experienced most of the foregoing risks with respect to our clinical trials, as a result of these risks, we or third parties upon whom we rely may not successfully begin or complete our clinical trials in the time periods forecasted, if at all. If the results of our planned clinical trials for our product candidates are not available when we expect or if we encounter any delays in the analysis of data from our clinical trials, we may be unable to submit results for regulatory approval or clearance or to conduct additional clinical trials on the schedule that we anticipate.

If clinical trials are delayed, the commercial viability of any of our current or future product candidates that require clinical trials may be reduced. If we incur costs and delays in our programs, or if we do not successfully develop and commercialize our products, our future operating and financial results will be materially affected.

If we are unable to obtain required regulatory approvals, we will be unable to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

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, and changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process, may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process and may require additional clinical or other data as a condition of reviewing or approving an application. 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.

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

Depending upon the nature of the product candidate, obtaining regulatory approval for the sale of our product candidates may require us and our collaborators to fund and conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, uncertain as to outcome and, depending upon the design of the trial, takes several years or more to complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. 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. One or more of our planned clinical trials could fail at any stage of testing.

If we are required to conduct additional clinical trials or other testing of our product candidates, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive, negative or inconclusive, or if there are safety concerns, we may be delayed in obtaining marketing approval for product candidates, not be able to obtain marketing approval, obtain approval for indications that are not as broad as intended or have the product removed from the market after obtaining marketing approval.

Delays in testing or obtaining approvals could cause our product development costs to increase, shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates, allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

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

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 products. Furthermore, private payers often implement reimbursement policies that are similar to those of government payers. For a discussion of the more important pharmaceutical pricing and reimbursement issues applicable to us, please see the Pharmaceutical Pricing and Reimbursement section of Item 1. Business and Risks Related to Financial Results below.

For example, in June 2011, we were informed by the Centers for Medicare and Medicaid Services that our two timed release dosage forms of HYOMAX would no longer be eligible for inclusion in the Medicaid Drug Rebate program. Since we have ceased manufacturing and distribution of these products, we did not exercise our right to contest this determination. We are unable to predict whether this action will affect sales of HYOMAX that remain in the distribution channel. Further legislative or administrative acts that reduce or discontinue reimbursement for our products could adversely impact our business. Any reduction or discontinuance 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.

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 Part D 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

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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. Because our product candidates are in the development stage, we do not know whether payers will cover the products and the level of reimbursement, if any, we will receive for these product candidates if they are successfully developed, and we are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of our products and product candidates. Moreover, Health Care Reform includes funding for comparative effectiveness research and the establishment of committees, such as the Independent Payment Advisory Board, to analyze different payment systems (including bundled payments) and recommend payment reform and other cost-containment measures, which all could reduce reimbursement for our products.

If the reimbursement we receive for any of our product candidates is inadequate in light of its development and other costs, our ability to realize profits from the affected product candidate would be limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

Some of our historical pharmaceutical products have been marketed without approved NDAs or ANDAs.

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has exercised its discretion to permit older legacy, unapproved drugs to remain on the market temporarily by employing a risk-based enforcement policy. Although the FDA considers all such drugs to require its approval, the FDA s enforcement policy prioritizes unapproved products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA is more likely to bring an enforcement action with respect to an unapproved drug if it finds that the marketer and its manufacturers are also allegedly in non-compliance with current Good Manufacturing Practices, or cGMPs, requirements.

In 2010, we discontinued manufacturing and distribution of all of our marketed unapproved products, including our ALLERX Dose Pack products and our HYOMAX line of products. Our decision did not limit the FDA s enforcement authority. In March 2011, the FDA announced that it intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011. All of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010, and this action did not require the recall or withdrawal of any products.

However, in connection with the March 2011 FDA Announcement, certain wholesalers indicated that they interpreted the Announcement to cover distribution of ALLERX Dose Pack products by wholesalers and that they intended to return product. During 2011, in connection with the anticipated returns, we reclassified $26.6 million of deferred revenue and related accrued expenses to accrued product returns. During 2011, actual returns of ALLERX Dose Pack products were $30.1 million, which exceeded our initial estimates.

For the years ended December 31, 2011 and 2010, our ALLERX Dose Pack products and our HYOMAX line of products generated in the aggregate $25.4 million and $37.4 million of net product sales, respectively. We may not be able to replace these revenues with revenues from our existing products. If we are not able to replace these product revenues, our discontinuance of these products could have a material adverse effect on our business, financial condition and results of operations and cash flows.

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We will spend considerable time and money complying with federal and state laws and regulations, and, if we are found not to be in compliance with such laws and regulations, we could face substantial penalties.

Health care providers play a primary role in the recommendation and prescribing of our products. Our arrangements with health care providers, third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. For a discussion of the more important laws and regulations applicable to us, please see the Regulatory Matters, Pharmaceutical Pricing and Reimbursement and Fraud and Abuse Regulation sections of Item 1. Business above.

We participate in the MDRP established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the MDRP, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law. We are also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. There have been enhanced political attention, governmental scrutiny and litigation at the federal and state levels regarding the prices paid or reimbursed for pharmaceutical products under Medicaid and other government programs. Although we estimate that less than 3% of our sales qualify for Medicaid rebates, any investigation of our rebate practices could be costly, could divert the attention of our management away from operations and could damage our reputation.

Health Care Reform includes a number of provisions aimed at strengthening the government s ability to pursue federal anti-kickback and federal false claims act cases against health care entities, such as increased funding for health care fraud enforcement activities, enhanced investigative powers and amendments to the federal false claims act to make it easier for the government and whistleblowers to pursue alleged violations. Recently, several pharmaceutical and other health care companies have been prosecuted under the federal fraud and abuse laws for allegedly providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company s products, allegedly misrepresenting the pricing data which the federal government uses to set reimbursement rates and calculate Medicaid rebates under the MDRP and allegedly causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. This new growth in litigation and enforcement action has increased the risk that a pharmaceutical company will have to defend a false claims action, which can be expensive, time consuming and distracting, and can potentially impact its financial performance.

Efforts to help ensure that our business arrangements comply with the extensive federal and state health care laws and regulations to which we are subject are costly. It is possible that governmental authorities may conclude that our business practices do not comply with current or future health care laws or regulations. If our past or present operations, including activities conducted by our sales teams or agents, are found to be in violation of any of these laws or regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from participation in federal health care programs, a corporate integrity agreement (which would require ongoing compliance and reporting obligations to the federal government) and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business is found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusion from federal health care programs.

Many aspects of the health care laws and regulations to which we are subject 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 the action, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation, business operations and financial results.

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Risks Relating to Intellectual Property and Licenses

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 depends in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products, whether such technology is owned by us or licensed to us by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. We and our licensors may not be able to obtain additional issued patents relating to our respective technology or products. Even if issued, patents issued to us or our licensors 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 longevity of the patent protection we may have for our products. Additionally, 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 owned or licensed patents also may not afford 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, we cannot be certain that we or our licensors were the first to make the inventions claimed in our or our licensors issued patents or pending patent applications, or that we or our licensors 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 USPTO to determine priority of invention in the United States. These proceedings are costly and time-consuming, and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent protection. In addition, U.S. patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-provisional filing date. Because the timing for submission of our applications to the FDA for regulatory approval of our product candidates is uncertain and, once submitted, the FDA regulatory process and timing for regulatory approval with respect to our product candidates is unpredictable, our estimates regarding the commercialization dates of our product candidates are subject to change. Accordingly, the length of time, if any, our product candidates, once commercialized, will remain subject to patent protection is uncertain.

Our collaborators and licensors may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, under our license arrangement with LGLS for FACTIVE, LGLS generally is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if LGLS fails to do so. In addition, each of LGLS and us has the right to pursue claims against third parties for infringement of the patent rights.

We may not have sufficient resources to bring these actions or to bring such actions to a successful conclusion. Even if we are successful in these proceedings, we may incur substantial cost and divert the time and attention of our management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on our business.

None of our current products or current product candidates except for FACTIVE and CRTX 080 have, or will have, composition of matter patent protection.

Some of our currently marketed products do not have patent protection and in most cases such products face generic competition. In addition, although we exclusively license United States patents and patent applications with claims directed to the pharmaceutical formulations of our product candidates, methods of use of our product candidates to treat particular conditions, delivery systems for our product candidates, delivery profiles of our product candidates and methods for producing our product candidates, patent protection is not available for composition of matter claims directed to the APIs of any of our products or product candidates except for FACTIVE and CRTX 080. The composition of matter United States patent for gemifloxacin mesylate that is used

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in FACTIVE will expire in April 2017. The composition of matter United States patents for lixivaptan that are used in CRTX 080 will expire in July 2013.

When the composition of matter patents for the API in FACTIVE and CRTX 080 expire, competitors will be able to offer and sell products with the same API so long as these competitors do not infringe any other patents that we or third parties hold, including formulation and method of use patents. However, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product s labeling. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit our ability to generate revenue from the sale of our product candidates, if approved for commercial sale. In addition, if a third party were able to design around our formulation and process patents and create a different formulation using a different production process not covered by our patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Our patents may be challenged by ANDA applicants.

If a drug is claimed to be covered by an unexpired patent that the NDA holder has listed with the FDA, an ANDA applicant must certify in a so-called paragraph IV certification that the patent is invalid, unenforceable or not infringed by the product that is the subject of the ANDA. If the holder of the NDA sues the ANDA applicant within 45 days of being notified of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of a court decision favorable to the ANDA applicant or the expiration of 30 months.

For example, on May 30, 2008, Orchid Healthcare, a Division of Orchid Chemicals & Pharmaceuticals Ltd., or Orchid, filed an ANDA seeking approval for a generic version of FACTIVE. In the application, Orchid certified that certain of the FDA-listed patents covering FACTIVE are invalid and/or will not be infringed by Orchid s manufacture, importation, use or sale of the product for which Orchid submitted its ANDA. The certification did not include a certification with respect to U.S. Patent No. 5,633,262, which is listed in the Orange Book as covering FACTIVE and expires in June 2015. We are evaluating whether to commence litigation in response to Orchid s Paragraph IV certification.

While Orchid received tentative approval by the FDA for its ANDA on July 2, 2010, because its paragraph IV certification did not extend to all the patents protecting FACTIVE, it will not be permitted to launch its generic version of FACTIVE until expiry of U.S. Patent No. 5,633,262 in June 2015.

Jagotec, the licensed manufacturer and supplier of ZYFLO CR cores, determined a patent that it owned was applicable to ZYFLO CR, and we subsequently listed this patent in the Orange Book in December 2011. Any ANDAs already on file with the FDA at the time of December 2011 patent addition may be approved without having to certify to the new Jagotec patent. Although we would not have the benefit of the 30-month stay associated with such certifications, we would nonetheless be able to assert this patent by filing suit and seeking an injunction. If we initiate legal proceedings to seek to protect our ZYFLO CR brand, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

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. 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 payers are, and are likely to continue to be, more important factors in the commercial success of our products and, if approved, our product candidates. For example, physicians and patients may not readily associate our trademark with the applicable product or API. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy if an approved generic

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is available, 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 or seek to cancel our similar trademarks based on the competitor s prior use. 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 intellectual property rights relating to most of our products and product candidates under license agreements with third parties and expect to enter into additional licenses in the future. These licenses provide us with rights to intellectual property that is necessary for our business. Our existing licenses impose, and we expect that future licenses will impose, various obligations related to development and commercialization activities, milestone and royalty payments, sublicensing, patent protection and maintenance, insurance and other similar obligations common in these types of agreements. If we fail to comply with our obligations under these agreements, the licensors may have the right to terminate the license in its entirety, 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 develop or market any product candidate or product, respectively, that is covered by the licensed patents. Even if we contest any such termination or claim and are ultimately successful, we could suffer adverse consequences to our operations and business interests. For a description of the licenses covering our more important products, please see Item 1. Business License and Collaboration Agreements.

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 current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets may otherwise become known or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, our competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

For example, while CUROSURF does not enjoy patent protection, CUROSURF requires a unique and intricate manufacturing process for production. If a competitor obtains the know-how needed to develop its own version of CUROSURF and successfully gains FDA approval for such, our business could be adversely impacted.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business will be adversely affected.

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 subsequently issue 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 such claims are successful, 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.

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As a result of patent infringement or other similar claims or to avoid potential claims, we or our potential future collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. 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.

There have 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, including interference proceedings declared by the USPTO, regarding intellectual property rights with respect to our products and technology. The cost 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 or biotechnology companies, including 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 our employees have inadvertently or otherwise used or disclosed the intellectual property, trade secrets or other proprietary information of any such employee s former employer. We may be required to engage in litigation to defend against these claims. Even if we are successful in such litigation, the litigation could result in substantial costs to us and/or be distracting to our management. If we fail to defend or are unsuccessful in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Risks Relating to Financial Results

Legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.

The implementation of Health Care Reform is expected to result in a transformation of the delivery of and payment for health care services in the United States. The combination of these measures will continue to 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 health care insurance and these additional market reforms should result in greater access to our products; however, the substantial increase in the number of Americans with health insurance will not occur until 2014.

Moreover, a number of provisions contained in Health Care Reform may adversely affect reimbursement for our products. Effective January 2, 2010, Health Care Reform retroactively increased the minimum basic Medicaid rebate for brand-name prescription drugs from 15.1% to 23.1% and for generic drugs from 11% to 13%, potentially 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 remove certain classes of trade. In addition, in March 2010, pharmaceutical manufacturers were required to pay states rebates on prescription drugs dispensed to Medicaid MCO enrollees.

Beginning on January 1, 2011, Health Care Reform required drug manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap, also known as the donut hole. The legislation 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.

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Beginning in 2011, Health Care Reform imposed a significant annual fee (which is not tax deductible) payable to the federal government on all companies that manufacture or import branded prescription drug products, which annual fee will increase through 2019. The total annual fee payable by the industry will be allocated based on a company s market share of all branded prescription drug sales to certain government programs during a certain period. Substantial new provisions affecting compliance are also included, which may require us to modify the manner in which we advertise, promote and distribute product samples to health care practitioners. Furthermore, Health Care Reform created the Independent Payment Advisory Board to recommend and implement proposals to limit Medicare spending, which could impact reimbursement for prescription drugs.

We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of Health Care Reform or legal and legislative challenges to all or portions of Health Care Reform. The financial impact of Health Care Reform may be affected by certain additional factors over the next few years, including pending implementation guidance, certain proposed reforms, repeals and legal challenges and state legislatures reactions stemming from state budget deficits. Health Care Reform and further changes in the law or regulatory framework that reduce our net product sales or increase our costs could also have a material adverse effect on our business, financial condition and results of operations.

We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our product development, commercialization or acquisition efforts.

We have incurred and expect to continue to incur significant development expenses in connection with our ongoing activities, particularly if and when we conduct clinical trials for product candidates. In addition, we incur significant commercialization expenses related to our currently marketed products for sales, marketing, manufacturing and distribution. We expect these commercialization expenses to increase in future periods if we are successful in obtaining FDA approval to market our product candidates or any newly acquired products. We have used, and expect to continue to use, revenue from sales of our marketed products to fund a significant portion of the development costs of our product candidates and to expand our sales and marketing infrastructure. However, we may need substantial additional funding for these purposes and may be unable to raise capital when needed or on acceptable terms, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

As of December 31, 2011, we had $74.0 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and revenue from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

the extent to which we 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 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 us.

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The terms of any additional capital funding that we require may not be favorable to us or our stockholders.

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, as we did in our transaction with Chiesi, our stockholders will experience dilution. Debt financing requires that payments of principal and interest be made at specified times and such payments may represent a significant portion of or our revenues. Additionally such 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 agreements governing debt or equity financing may also contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

We may incur losses in the future.

We experienced a net loss in 2011, and we may be unable to return to profitability, even if we are able to commercialize additional products. Prior to 2011, we had been profitable every year since 2007. To date, we have financed our operations primarily with revenue from product sales and debt and equity financings. We have devoted substantially all of our efforts to:

establishing a sales and marketing infrastructure;

acquiring marketed products, product candidates and related technologies;

commercializing marketed products; and

developing product candidates, including conducting clinical trials.

We expect to continue to incur significant development and commercialization expenses as we:

advance the development of our product candidates; and

seek regulatory approvals for product candidates that successfully complete clinical testing.

We also expect to incur additional expenses to add operational, financial and management information systems and personnel.

For us to return to profitability, we believe that we must succeed in commercializing additional drugs with significant market potential. This will require us to be successful in a range of challenging activities, including:

successfully completing any necessary clinical trials of our product candidates;

obtaining and maintaining regulatory approval for these product candidates;

manufacturing, marketing and selling those products for which we may obtain regulatory approval; and

obtaining, through product acquisitions and in-licenses, rights to products and product candidates.

We may never succeed in these activities and may never generate revenue that is sufficient to return to and then sustain or increase profitability on a quarterly or annual basis. Any failure to return to and then sustain and increase profitability could impair our ability to raise capital, expand our business, diversify our product offerings and continue operations.

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and

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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 chargebacks, 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. Our estimates, or the assumptions underlying them, may prove to be incorrect.

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:

- acquisition activity;
- new product launches, which could increase revenues but also increase sales and marketing expenses;
- charges for inventory expiration or product quality issues;
- changes in the amount and timing of sales of our products due to changes in product pricing, changes in the prevalence of disease conditions or generic competition from period to period or other factors;
- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;
- changes in research and development expenses resulting from the acquisition of product candidates or from general and industry-specific economic conditions;
- changes in the competitive, regulatory or reimbursement environment, including the amounts of rebates, discounts, holdbacks, chargebacks and returns, which could decrease revenues or increase sales and marketing, product development or compliance costs;
- unexpected product liability or intellectual property claims and lawsuits;
- significant payments, such as milestones, required under collaboration, licensing and development agreements before the related product candidate has received FDA approval;
- seasonality of the respiratory ailment season, which historically results in higher sales of our respiratory products during the first and fourth quarters of the calendar year;
- marketing exclusivity, if any, which may be obtained on certain new products;

the dependence on a small number of products for a significant portion of net revenues and net income;

price erosion and customer consolidation;

the results of ongoing and planned clinical trials of our product candidates;

the results of regulatory reviews relating to the development or approval of our product candidates; and

production problems occurring at our third-party manufacturers.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our business and operating results could be harmed. The Sarbanes-Oxley Act of 2002, as well as related rules and regulations implemented by the SEC, NASDAQ and the

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Public Company Accounting Oversight Board, have required changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act of 2002, have increased our legal and financial compliance costs and made many activities more time-consuming and more burdensome. These laws, rules and regulations are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time as regulatory and governing bodies provide new guidance, which could result in continuing uncertainty regarding compliance matters. The costs of compliance with these laws, rules and regulations have adversely affected our financial results. Moreover, we run the risk of non-compliance, which could adversely affect our financial condition or results of operations or the trading price of our stock.

We have in the past discovered, and may in the future discover, areas of our internal control over financial reporting that need improvement. We have devoted significant resources to remediate our deficiencies and improve our internal control over financial reporting. Although we believe that these efforts have strengthened our internal control over financial reporting, we are continuing to work to improve our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

Risks Relating 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.

Recruiting and retaining highly qualified scientific, technical and managerial personnel and research partners is critical to our success. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals and contract manufacturing, will place additional requirements on our management, operational and financial resources. These demands may require us to hire additional personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the development, regulatory approval and commercialization of our product candidates. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. We also experience competition for the hiring of scientific personnel from universities and research institutions. 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 third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to us.

We depend to a great extent on the principal members of our management. The loss of the services of any of our key personnel, in particular, Craig Collard, our Chief Executive Officer, might significantly delay or prevent the achievement of our business objectives and could cause us to incur additional costs to recruit replacements. Each member of our executive management team may terminate his employment at any time. We do not maintain key person life insurance with respect to any of our executives. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs. We may not be able to replace key personnel internally or without additional costs in the future. Our inability to attract and retain the executive talent necessary to manage and grow our company could have an adverse effect on our business, financial condition and results of operations.

Risks Relating to 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

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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.

Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to the following, as they relate to us and (as applicable) our competitors:

- the results of discovery, preclinical studies and clinical trials;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments.
- the entry into, amendment or termination of key agreements, including licensing and collaboration agreements;
- the results and timing of regulatory reviews relating to the approval of product candidates;
- the initiation of material developments in or conclusion of litigation to enforce or defend intellectual property rights;
- failure of any product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect research and development expenditures;
- issues in manufacturing products or product candidates;
- recall or withdrawal of a product or products;
- the loss of key employees;
- the acquisition, development or introduction of technologies, product candidates or products;
- changes in the structure of health care payment systems;
- regulatory actions with respect to products;
- our financial results, including period-to-period fluctuations in those results;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock; and

future sales 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.

Chiesi has substantial control over us and could delay or prevent a change in corporate control, including a transaction in which our stockholders could sell or exchange their shares for a premium.

As a result of our July 28, 2009 strategic transaction with Chiesi, Chiesi acquired a majority of our common stock and assumed substantial control over our company. The governance agreement with Chiesi that we entered into in connection with the Chiesi transaction terminated on July 28, 2011. Since Chiesi continues to own a majority of our common stock and the governance agreement was not renewed or replaced by a similar arrangement, Chiesi has the ability to exercise significant control over our company. Delaware law provides that directors, including those appointed by Chiesi, have fiduciary duties to all stockholders and also provides safeguards in certain situations to ensure that all stockholders are treated fairly. As a majority stockholder, Chiesi may nonetheless be able, without a meeting or prior notice to our other stockholders, to (1) remove our directors with or without cause; (2) approve or disapprove significant corporate actions, such as a sale of our company; (3) cause the removal of our management, including our executive officers; and (4) take or cause to be taken or not take or cause not to be taken other significant corporate actions.

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As a result of Chiesi s ownership and control over our company, we consider ourselves to be a Controlled Company under NASDAQ rules, which means, among other things, that NASDAQ does not require us to maintain a majority of independent directors or nominating and compensation committees comprised solely of independent directors. We cannot be certain that the interests of Chiesi will be consistent with the interests of our other stockholders. In addition, Chiesi s majority ownership of and control over our company may have the effect of delaying or preventing a change in control, merger or tender offer, which could deprive our stockholders of an opportunity to receive a premium for their shares of common stock and may negatively affect the market price of our common stock. Moreover, Chiesi, either alone or with other existing stockholders (including members of our management), could effectively receive a premium for transferring ownership to third parties that would not inure to the benefit of other stockholders.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

We lease approximately 21,000 square feet of office space in Cary, North Carolina. The lease expires on March 31, 2016, and we have an option to extend the term of the lease for an additional five years through March 2021. We believe our existing facilities are sufficient to meet our needs for the foreseeable future.

ITEM 3. ***LEGAL PROCEEDINGS***

ONY Litigation

On December 2, 2011, ONY, the maker of Infasurf, filed suit in United States District Court for the Western District of New York against us, Chiesi, and various other individuals and entities in connection with an article appearing in the September 2011 issue of the *Journal of Perinatology*, based on a retrospective study sponsored by Chiesi, that concluded that Infasurf was associated with significantly higher mortality rates than CUROSURF. ONY alleged that the article was false and misleading because it did not discuss all of the relevant data and literature and the underlying study was based on manipulated data. ONY asserted a claim under federal law against us for false advertising based on our dissemination of and references to the article in our promotional activities, as well as state law claims for tortious interference with existing and prospective contracts, injurious falsehood and violation of New York s deceptive trade practices statute.

On January 17, 2012, we filed a motion to dismiss the action for failure to state a claim on which relief could be granted and are awaiting a decision from the court on our motion.

Propoxyphene Litigation

On January 11, 2012, we were served with a complaint in the California Superior Court for the County of San Francisco by Mary and George Keene and 30 other individual plaintiffs. The suit names numerous pharmaceutical companies, including Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc., which are two of our subsidiaries. The plaintiffs allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The plaintiffs seek compensatory and exemplary damages, together with interest, costs of suit, attorneys fees, leave to amend as additional facts are gathered, and any other relief that the court deems just, equitable, and proper. The suit was removed to the United States District Court for the Northern District of California on January 23, 2012, the suit was stayed in the Northern District on February 1, 2012, and was transferred to the pending MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division) on March 2, 2012. We expect that the suit will remain consolidated with the pending MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division) (*MDL 2226 IN RE: Darvocet, Darvon and Propoxyphene Products Liability Litigation*) or that it will be remanded and consolidated in a complex litigation department in California state court.

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In February 2012, we were served with complaints in four additional cases: one in Tennessee (*Anderson, et al. v. Eli Lilly and Company, et al*., U.S. District Court, Eastern District of Tennessee (Greeneville), filed November 18, 2011); another in Tennessee (*Holland. individually and as Administrator of the Estate of Mary Taylor v. Eli Lilly and Company, et al*., U.S. District Court, Western District of Tennessee (Jackson), filed November 18, 2011); one in Mississippi (*McAlpine v. Eli Lilly and Company, et al*., U.S. District Court, Northern District of Mississippi (Western Division), filed November 18, 2011); and one in Louisiana (*Reynolds v. Eli Lilly and Company, et al*., U.S. District Court, Eastern District of Louisiana (New Orleans), filed November 17, 2011). The suits name numerous pharmaceutical companies, including Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc., and one suit names Aristos. The plaintiffs in the lawsuits generally allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene, marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The plaintiffs seek compensatory and exemplary damages, together with interest, costs of suit, attorneys fees, leave to amend as additional facts are gathered, and any other relief that the court deems just, equitable, and proper. All four cases have been consolidated with the MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division).

On November 15, 2011, a motion was filed to dismiss plaintiffs complaints in multiple other cases pending in the MDL proceedings on the basis of preemption. Oral argument was heard on the motion in the MDL proceedings on February 27, 2012. We await a decision from the court on the motion as the Court s ruling will significantly impact the plaintiffs other cases pending in the MDL proceedings.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and their positions as of February 29, 2012 are as follows:

Name	Age	Position
Craig A. Collard	45	Chief Executive Officer
Ken McBean	46	President
Vincent T. Morgus	46	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Andrew K. W. Powell	54	Executive Vice President, General Counsel and Secretary
Alan T. Roberts	45	Vice President, Scientific Affairs

Craig A. Collard has served as our Chief Executive Officer and the chairman of our Board of Directors since our merger with Cornerstone BioPharma in October 2008. Mr. Collard also served as our Interim Chief Financial Officer from July 2010 through January 2011 and our President from October 2008 to September 2011. In March 2004, Mr. Collard founded Cornerstone BioPharma Holdings, Ltd. (the assets and operations of which were restructured as Cornerstone BioPharma in May 2005), and served as its President and Chief Executive Officer and a director from March 2004 to October 2008. Before founding Cornerstone BioPharma, Mr. Collard s principal occupation was serving as President and Chief Executive Officer of Carolina Pharmaceuticals, Inc., a specialty pharmaceutical company he founded in May 2003. From August 2002 to February 2003, Mr. Collard served as Vice President of Sales for Verum Pharmaceuticals, Inc., a specialty pharmaceutical company in Research Triangle Park, North Carolina. From 1998 to 2002, Mr. Collard worked as Director of National Accounts at DJ Pharma, Inc., a specialty pharmaceutical company which was eventually purchased by Biovail Pharmaceuticals, Inc., or Biovail. His pharmaceutical career began in 1992 as a field sales representative at Dura Pharmaceuticals, Inc., or Dura. He was later promoted to several other sales and marketing positions within Dura. Mr. Collard is a member of the Board of Directors of Hilltop Home Foundation, a Raleigh, North Carolina, non-profit corporation as well as the Triangle Chapter of the Cystic Fibrosis Foundation in addition to our Board of Directors. Mr. Collard holds a B.S. in Engineering from the Southern College of Technology (now Southern Polytechnic State University) in Marietta, Georgia. As our founder and Chief Executive Officer, and as a former sales representative and/or executive at several other specialty pharmaceutical companies, Mr. Collard brings to our management team and Board of Directors a depth of sales and executive experience both in the specialty pharmaceutical industry in general and at our company in particular.

Kenneth McBean assumed the title of President from Craig Collard in September 2011. Mr. McBean joined us from Covidien plc, or Covidien, where he held the position of Vice President and General Manager of Specialty Pharmaceuticals from March 2009 until May 2011. At Covidien, Mr. McBean was responsible for executing a successful turnaround of Covidien s branded pharmaceutical products division. In 2006, Mr. McBean co-founded Tribute Pharmaceuticals Ltd., a Canadian-based pharmaceutical company, and served as its Senior Vice President of Commercial Affairs and Business Development from January 2006 through March 2009. In 2004, Mr. McBean co-founded Legacy Pharmaceuticals, Inc., a specialty pharmaceutical company, and served as its Senior Vice President of Commercial Affairs from July 2004 until October 2005. Prior to founding Legacy Pharmaceuticals, Inc., Mr. McBean was the Vice President of Marketing and Commercial Development for Biovail Pharmaceuticals, Inc., or Biovail, and its predecessor company, DJ Pharma, Inc., in the United States. His earlier career involved various U.S. and global positions at Glaxo Wellcome and Marion Merrell Dow in commercial strategy, product management, market research, and sales. Mr. McBean holds a B.S. in Business from Kansas State University.

Vincent T. Morgus was appointed as our Executive Vice President, Finance, Chief Financial Officer on February 1, 2011 and was appointed our Treasurer on November 9, 2011. Mr. Morgus joined us from Quintiles Transnational Corp., a global fully integrated biopharmaceutical services company, or Quintiles, where he had been Senior Vice President, Corporate Development since September 2003. He joined Quintiles in June 1994 and progressed through a variety of financial management positions within the Quintiles organization, including Vice President, Finance of Quintiles Americas and Chief Financial Officer of Quintiles Informatics. Prior to working

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at Quintiles, Mr. Morgus held Controller positions at Q+E Software, Inc. and DaVinci Systems Corporation. Mr. Morgus started his career as an auditor for Arthur Andersen in Northern California and is licensed as a certified public accountant in North Carolina and Pennsylvania. Mr. Morgus earned his Master s degree in Business Administration from the University of North Carolina s Kenan-Flagler Business School and his Bachelor of Science from the Pennsylvania State University s Smeal College of Business.

Andrew K. W. Powell, Esq. has served as our Executive Vice President, General Counsel and Secretary since November 2009. Mr. Powell has practiced law for more than 25 years. He began his career at the firm of Gibson, Dunn & Crutcher in 1985, before joining Baxter International, or Baxter. From 1989 to 2004 he held positions at Baxter of increasing responsibility, playing key roles in a series of transactions that established the company throughout Asia, and heading up the global law function at Baxter Bioscience. From September 2004 to June 2008 he was a leader in the management team that successfully developed CollaGenex Pharmaceuticals into a publicly traded commercial company that was sold to Galderma Laboratories. From July 2008 until January 2009 he was Senior Vice President and General Counsel at ImClone Systems, Inc. where he managed the sale of that company to Eli Lilly & Co. Mr. Powell holds a B.A. from the University of North Carolina at Chapel Hill and a J.D. from Stanford Law School.

Alan T. Roberts has served as our Vice President, Scientific Affairs since May 2009. In December 2007, Mr. Roberts founded Tybeam Pharma Consulting, LLC, or Tybeam, and serves as its President. Prior to founding Tybeam, Mr. Roberts served as Senior Vice President and Chief Scientific Officer for Auriga Laboratories, Inc., or Auriga, from February 2006 to December 2007. In January 2006, Mr. Roberts was named Vice President, Global Manufacturing and Development. He had served as Vice President, Scientific Affairs for First Horizon Pharmaceutical Corporation, or First Horizon since January 2005. Prior to becoming Vice President, Mr. Roberts was First Horizon s Director of Regulatory, Quality and Manufacturing from June 2000 to June 2002, and Senior Director, Regulatory and Technical Affairs through 2004. From June 1999 to February 2000, Mr. Roberts was Vice President, Research and Development for Mikart, Inc., a private pharmaceutical contract manufacturer. Prior positions with Mikart were Research and Development Manager and Director of Research and Development from July 1993 to June 1999. Additional experience also includes key management positions in regulatory and development with Solvay Pharmaceuticals, Inc. and the Medical University of South Carolina s Pharmaceutical Development Center, respectively. Mr. Roberts holds a B.S. in Microbiology from Clemson University.

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NON-EMPLOYEE DIRECTORS OF THE REGISTRANT

Our non-employee directors, their ages, principal occupation and name of their employer as of February 29, 2012 are as follows:

Name	Age	Principal Occupation and Employer
Alessandro Chiesi	45	Head of International Division, Chiesi Farmaceutici S.p.A.
Christopher Codeanne	44	Executive Vice President, Finance, Chief Financial Officer and Director, Premier Research Group Limited
Michael Enright	49	President, OckhamCRO, Ockham Development Group, Inc.
Anton Giorgio Failla	46	Head of Business Development, Chiesi Farmaceutici S.p.A.
James Harper	64	Board Member
Michael Heffernan	47	Co-Founder, President and Chief Executive Officer, Collegium Pharmaceuticals, Inc.
Robert M. Stephan	69	Attorney at Law, Law Office of Robert M. Stephan
Marco Vecchia	51	Head of Legal and Corporate Affairs, Chiesi Farmaceutici S.p.A.

Alessandro Chiesi has served on our Board of Directors since the closing of the Chiesi Transaction in July 2009. Mr. Chiesi has been employed by Chiesi, a research, development, production and sales pharmaceutical company, holding various positions. Since September 2010, he has served as Head of the International Division. From May 2005 to September 2010, he served as the Affiliates Coordinator of the International Division. From May 2002 through November 2004, he was the Managing Director of Asche-Chiesi GmbH. Between 1995 and 2002, he held positions including assistant to the CEO and project leader for various mergers and acquisitions. Mr. Chiesi has served on the Boards of Directors of the following companies: Master Pharma S.r.l. since July 1990, Chiesi Hellas Pharmaceuticals S.A. since April 1998, Chiesi S.A. since September 1999, Promedica S.r.l. since May 2001, Chiesi Farmaceutici, S.p.A. since January 2004, Valline S.r.l. since May 2004, Chiesi Pharmaceuticals B.V. since February 2007 and DOC Generici S.r.l. since November 2008. He brings to our Board of Directors a depth of experience in global business development, strategic business planning and risk assessment and the integration and management of transnational joint ventures.

Christopher Codeanne has served on our Board of Directors since the consummation of the Merger in October 2008. Since December 2010, Mr. Codeanne has served as the Executive Vice President, Finance, Chief Financial Officer and Director of Premier Research Group Limited, an international pharmaceutical and medical device services company. From April 2008 through November 2010, Mr. Codeanne served as Chief Operating Officer and Chief Financial Officer of Oncology Development Partners, LLC (d/b/a Oncopartners), a specialized international oncology contract research organization. During 2010, Mr. Codeanne also served as an advisor for private equity firm Warburg Pincus. From December 2006 through April 2008, Mr. Codeanne served as the Chief Financial Officer of Averion International Corp., or Averion, a publicly traded international contract research organization. Prior to Averion, from 2002 through July 2006, Mr. Codeanne was the Chief Financial Officer of SCIREX Corporation (which was acquired by Premier Research Group plc in 2006), or SCIREX, an international, full-service clinical research organization. From 1999 to 2002, Mr. Codeanne served as Director of Finance of SCIREX. Mr. Codeanne is a member of the American Institute of Certified Public Accountants. Mr. Codeanne holds a B.A. in Accounting from Fairfield University and an MBA from the University of Connecticut. He brings to our Board of Directors a depth of experience in financial, operational and public company matters and knowledge regarding pharmaceutical development and working with contract research organizations.

Michael Enright has served on our Board of Directors since the consummation of the Merger in October 2008. Since February 2011, Mr. Enright has served as the President of OckhamCRO, a division of Ockham Development Group Inc., or Ockham, a global contract research organization. Prior to becoming President of OckhamCRO, Mr. Enright had served as the Chief Financial Officer for Ockham since its merger with Atlantic Search Group, Inc., a staff augmentation and functional outsourcing services organization serving pharmaceutical companies and contract research organizations in the United States and India, where he held the same position

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since 1995. Prior to 1995, Mr. Enright held positions in employee benefits administration with Hauser Insurance Group and The Prudential Insurance Company, and in financial management with General Electric Company s aerospace business group. Mr. Enright holds a B.A. in Finance from Villanova University and an MBA from the Kenan-Flagler School of Business of the University of North Carolina at Chapel Hill. He brings to our Board of Directors a depth of experience in strategic planning and organizational development and human resources.

Anton Giorgio Failla has served on our Board of Directors since the closing of the Chiesi Transaction in July 2009. Since July 2008, Dr. Failla has served as Head of Business Development of Chiesi. Prior to his employment at Chiesi, from 2004 to 2008, Dr. Failla served as the CFO of Sorin Group, a medical device company, based in Milan, Italy and as its Senior Vice President of Operations based in Denver, Colorado. From 2000 to 2004, Dr. Failla served as Vice President, Business Development and Strategic Planning at Novartis Consumer Health, or Novartis, at its Headquarters in Switzerland. Prior to Novartis, Dr. Failla held various positions in business development at Medtronic Inc., both in the U.S. and in Europe. Dr. Failla has served on the boards of directors of several private companies in Europe and the United States: Bellco S.r.l. (April 2004-January 2007), Sorin Biomedica Cardio S.r.l. (April 2004-April 2005), Biofin Holding International N.V. (July 2004 -June 2006), Ela Medical S.a.s. (April 2004-June 2006), Sorin Biomedica CRM S.r.l. (April 2007-July 2008), Sorin Group International S.A. (December 2005-June 2006), Casino Municipale Campione d Italia (August 2007-June 2009), and Phenomix Corporation Inc. (February 2010 September 2010). Dr. Failla holds a Master in Business Administration from SDA Bocconi and a doctorate in Electronic Engineering from Polytechnic of Turin. He brings to our Board of Directors a depth of experience in the areas of strategic planning, finance, business development and operations management.

James Harper has served on our Board of Directors since December 2011. Mr. Harper has over 30 years of experience in the pharmaceutical and medical device industries. He has also served on multiple corporate and not-for-profit boards of directors. He is currently Chair of Phenomix Corporation (Chair December 2009-present and director July 2007-present), and an advisor to Nomura Phase4 Ventures (July 2007-present). Prior to his retirement, Mr. Harper held a number of management and senior executive positions at Eli Lilly (January 1974 April 2004), including Group Vice President of Global Marketing and Sales and Chief Marketing Officer (January 2001-April 2004), President of Diabetes and Growth Disorders Product Group (January 1994-January 2001), and President and CEO of Advanced Cardiovascular Systems, a Lilly subsidiary (December 1990-December 1992). In addition, Mr. Harper has served on the boards of directors of Anesiva, Inc. (May 2007-December 2008), Corcept Therapeutics (October 2004-May 2011), Inoveon Corporation (June 2002-April 2004) and Zymogenetics, Inc (July 2004-October 2010). On these boards, he served on various committees including compensation, governance, and audit committees. Mr. Harper was a member of the National Board of Directors of the American Diabetes Association (July 1993-June 1997), where he was a member of the Research Policy Committee (July 2000-June 2001) and Vice Chair of the Research Foundation Board (2003-2006). He was also on the National Osteoporosis Foundation Corporate Advisory Board (July 1995-June 1997). Mr. Harper is a member of the National Association of Corporate Directors (March 2006-present). A veteran Navy flight officer, he holds a B.A. in Biology from Vanderbilt University and an MBA in Marketing/Finance from The Wharton School. He brings to our Board of Directors a depth of operational and P&L experience.

Michael Heffernan has served on our Board of Directors since the consummation of the Merger in October 2008. Since 2002, Mr. Heffernan has served as President and Chief Executive Officer of Collegium Pharmaceutical, Inc., a specialty pharmaceutical company that develops and commercializes products to treat central nervous system, respiratory and skin-related disorders. From 1999 to 2001, Mr. Heffernan served as President and Chief Executive Officer of PhyMatrix Corp., an integrated health care services company. From 1995 to 1999, Mr. Heffernan served as President and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical clinical development company. From 1987 to 1994, Mr. Heffernan served in a variety of sales and marketing positions with Eli Lilly and Company, a pharmaceutical company. Mr. Heffernan has also served on the Board of Directors of TyRx Pharma, Inc. since 2002 and the Board of Directors of PreCision Dermatology since 2010. Mr. Heffernan holds a B.S. in Pharmacy from the University of Connecticut and is a Registered Pharmacist. He brings to our Board of Directors a depth of experience in sales, marketing, and licensing and knowledge regarding pharmaceutical development and working with contract research organizations.

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Robert M. Stephan has served on our Board of Directors since the closing of the Chiesi Transaction in July 2009. Mr. Stephan is an experienced business attorney currently in private practice in New Canaan, Connecticut. With over 40 years experience, Mr. Stephan concentrates his law practice on domestic and international business transactions and serves as chief counsel to small and mid-sized companies and local counsel to foreign companies with operations in the United States. Mr. Stephan has served as Vice President and Secretary since 1997 and as a director since April 2009, of Chiesi Pharmaceuticals Inc., USA, a subsidiary of Chiesi. Prior to opening his private practice in 1997 and after initial training with the Office of the General Counsel of the U.S. Securities and Exchange Commission in Washington D.C. and the law firm of Day, Berry & Howard in Hartford, Connecticut, Mr. Stephan embarked on a career as in-house counsel with publicly traded corporations. He served as Vice President and Group General Counsel for General Mills Inc; Vice President and Associate General Counsel for US Surgical Corporation; Vice President, General Counsel and Secretary for Erbamont N.V. (Montedison Group); and Vice President, General Counsel and Secretary for American Maize Products Corporation. Mr. Stephan has advised boards of directors on corporate governance matters and is a former member of the National Association of Corporate Directors. Mr. Stephan is a former Captain/Judge Advocate in the United States Marine Corps and an Assistant Attorney General for the State of Wisconsin. Mr. Stephan holds a Bachelor of Arts in economics and political science from Lawrence University and a Juris Doctor from the University of Wisconsin Law School. He brings to our Board of Directors a depth of experience in all areas of corporate governance, with particular emphasis on the governance of transnational joint ventures.

Marco Vecchia has served on our Board of Directors since May 2010. Since 1987, Mr. Vecchia has served as Head of Legal and Corporate Affairs at Chiesi. Mr. Vecchia holds a degree in law from the University of Parma. Mr. Vecchia has also served on the boards of directors of the following companies: Chiesi S.A., Belgium, since June 2010; Chiesi Pharmaceuticals Shanghai Co. Ltd. (Wfoe), China, since June 2008; Cheshire Healthcare Limited, England, since January 2003; Chiesi Limited, England, since May 1999; Chiesi Healthcare Limited, England, since May 1999; Chiesi S.A., France, since April 2002; Chiesi Hellas Pharmaceuticals S.A., Greece, since April 1998; Chiesi Int. H. B.V., Holland, since April 2008; Chiesi Pharmaceuticals B.V., Holland, since February 2007; Opocrin S.P.A., Italy, since November 2008; Opocrin S.r.l., Italy, since November 2008; Novadynamics Healthcare S.r.l., Italy, since May 2007; Chiesi Pharmaceuticals Pvt Limited, Pakistan, since November 2001; Chiesi España S.A., Spain, since April 2000; Chiesi Pharmaceuticals Inc., USA, since April 1992. He brings to our Board of Directors a depth of experience in the areas of mergers and acquisitions and transnational joint ventures, pharmaceutical IP licensing, risk management and corporate governance.

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PART II

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

Market Price of and Dividends on Cornerstone Therapeutics Inc. s Common Stock and Related Stockholder Matters

Our common stock trades on the NASDAQ Capital Market under the symbol CRTX. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock on the NASDAQ Stock Market.

Year Ended December 31, 2011	High	Low
First Quarter (from January 1 to March 31)	$ 7.19	$ 5.06
Second Quarter (from April 1 to June 30)	$ 9.08	$ 6.28
Third Quarter (from July 1 to September 30)	$ 9.20	$ 6.29
Fourth Quarter (from October 1 to December 31)	$ 7.89	$ 4.45

Year Ended December 31, 2010	High	Low
First Quarter (from January 1 to March 31)	$ 6.54	$ 4.77
Second Quarter (from April 1 to June 30)	$ 7.57	$ 5.20
Third Quarter (from July 1 to September 30)	$ 7.12	$ 5.07
Fourth Quarter (from October 1 to December 31)	$ 7.10	$ 5.37

On February 29, 2012, the closing price per share of our common stock as reported on the NASDAQ Capital Market was $5.74, and we had approximately 138 stockholders of record. This number does not include beneficial owners for whom shares are held by nominees in street name.

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors.

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Performance Graph

The following information in this Item 5 of this annual report on Form 10-K is not deemed to be soliciting material or to be filed with the SEC or subject to Regulation 14A or 14C under the Exchange Act or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

The following graph compares our cumulative total stockholder return from December 31, 2006 with those of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes that U.S. $100 was invested on December 31, 2006 in (1) our common stock, (2) the NASDAQ Composite Index and (3) the NASDAQ Biotechnology Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of our respective fiscal year. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.

Comparison of 5-Year Cumulative Total Return

among Cornerstone Therapeutics Inc. (known as Critical Therapeutics, Inc. prior to October 31, 2008),

the NASDAQ Composite Index and the NASDAQ Biotechnology Index

	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11
CRTX	$ 100	$ 62	$ 13	$ 30	$ 28	$ 27
NASDAQ Composite Index	$ 100	$ 110	$ 65	$ 94	$ 110	$ 108
NASDAQ Biotech Index	$ 100	$ 105	$ 91	$ 106	$ 122	$ 136

Recent Sales of Unregistered Securities; Uses of Proceeds From Registered Securities

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

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ITEM 6. ***SELECTED FINANCIAL DATA***

The selected statement of (loss) income and balance sheet data with respect to the years ended December 31, 2011, 2010, 2009, 2008 and 2007 set forth below are derived from our financial statements. As discussed elsewhere in this annual report, our financial statements for periods prior to October 31, 2008 reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and our financial statements for all subsequent periods reflect the results of the combined company. The selected financial data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 below, and our financial statements and the notes contained in Item 8 below. Historical results are not necessarily indicative of our future results.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(In thousands, except per share and share amounts)				
Statement of (Loss) Income Data:					
Net revenues	$ 101,422	$ 125,317	$ 109,564	64,867	28,071
Costs and expenses:					
Cost of product sales(1)	37,823	45,015	38,232	22,144	6,709
Selling, general and administrative	46,344	53,198	45,731	27,082	15,205
Research and development	1,624	4,488	3,608	3,679	556
Amortization of product rights	16,868	14,728	6,115	1,334	3,160
Total costs and expenses	102,659	117,429	93,686	54,239	25,630
(Loss) income from operations	(1,237)	7,888	15,878	10,628	2,441
Other expense, net	(128)	(110)	(128)	(1,221)	(1,741)
(Loss) income before income taxes	(1,365)	7,778	15,750	9,407	700
Benefit from (provision for) income taxes	672	(1,609)	(5,547)	(414)	(130)
Net (loss) income	$ (693)	$ 6,169	$ 10,203	$ 8,993	$ 570
Net (loss) income per share, basic	$ (0.03)	$ 0.24	$ 0.58	$ 1.29	$ 0.10
Net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ 0.54	$ 1.14	$ 0.08
Weighted-average common shares, basic	25,684,593	25,412,636	17,651,668	6,951,896	5,934,496
Weighted-average common shares, diluted	25,684,593	26,036,544	18,776,588	7,861,119	6,751,127

(1) Excludes amortization of product rights.

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	2011	2010	December, 31 2009	2008	2007
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 73,968	$ 50,945	$ 18,853	$ 9,286	$ 241
Accounts receivable, net	11,894	76,476	16,548	12,987	3,505
Inventories, net	9,419	15,174	18,106	11,222	2,998
Working capital	58,393	54,610	28,312	3,157	(5,131)
Total assets	232,314	285,459	203,322	69,889	15,909
Deferred revenue	1,428	57,194			
Debt obligations, including current portion(1)	146	1,597	2,409	4,856	14,768
Acquisition-related contingent liability	8,800				
Total stockholders equity (deficit)	174,803	172,398	163,868	29,426	(12,295)
Shares of common stock outstanding	25,804	25,473	25,023	12,024	5,935

(1) Includes line of credit, license agreement liability, note payable and capital leases.

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

The following discussion is designed to provide a better understanding of our consolidated financial statements, including a brief discussion of our business and products, key factors that impacted our performance, and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related 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. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the Risk Factors section of this annual report on Form 10-K.

Executive Overview

Strategy

We are a specialty pharmaceutical company focused on commercializing products for the hospital, niche respiratory and related specialty markets. We are actively seeking to acquire or develop additional products for these markets.

Our strategy is to:

- Focus our commercial and internal development efforts in the hospital and related specialty product sector within the U.S. pharmaceutical marketplace;
- Acquire companies and marketed and/or registration-stage products that fit within our focus areas; and
- Market approved generic products through our wholly owned subsidiary, Aristos.

We believe this strategy will allow us to improve our revenue growth rate, margins, and profitability and enhance stockholder value.

2011 Highlights

In 2011, our management concentrated on executing four key initiatives:

realigning our respiratory sales force to respiratory specialist targets, which we completed in the third quarter;

harvesting our ALLERX pull-through revenue through the period permitted under the March 2011 FDA Announcement;

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focusing our existing development pipeline around CRTX 067 and CRTX 073; and

evaluating and executing upon strategic alternatives for our anti-infective products, which is still on-going.

In addition to the above initiatives, we directed our business development efforts on identifying products and companies that meet our strategic acquisition criteria. These efforts resulted in acquiring all of the outstanding shares of Cardiokine on December 30, 2011 and its pending NDA for lixivaptan to be used, if approved, to treat hyponatremia (CRTX 080). If approved, CRTX 080 will be marketed and sold by our hospital sales force.

The following summarizes certain key financial results for the year ended December 31, 2011:

Cash and cash equivalents increased $23.1 million or 45% to $74.0 million as of December 31, 2011 from $50.9 million as of December 31, 2010;

Net product sales from strategic products increased $5.2 million to $79.9 million in 2011 from $74.7 million in 2010, representing 7% year-over-year growth. The percentage of net product sales generated from strategic products increased to 79% in 2011 from 60% in 2010, exceeding our strategic plan target of 70%. Overall net product sales were $101.3 million and $123.7 million for the years ended December 31, 2011 and 2010, respectively.

Income from operations decreased $9.1 million, or 116%, to a loss of $1.2 million in 2011 from income from operations of $7.9 million in 2010 on a GAAP basis, and decreased $5.7 million, or 24%, to $18.3 million in 2011 from $24.0 million in 2010 on a non-GAAP basis; and

Net income decreased $6.9 million, or 111%, to a loss of $693,000 in 2011 from net income of $6.2 million in 2010 on a GAAP basis, and decreased $9.7 million, or 51%, to $9.2 million in 2011 from $18.9 million in 2010 on a non-GAAP basis.

In March 2011, the FDA announced that it intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011. We expected this action, and all of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010. However, as a result of the March 2011 FDA Announcement, in August 2011 our distribution partners began returning substantial amounts of products that were in the distribution channel. Because we have historically derived significant revenues and income from these products, our net product sales, gross margin and income from operations have declined in 2011 when compared to 2010. Going forward, we anticipate replacing these revenues and income with increased revenues from our branded products, particularly CUROSURF, ZYFLO CR and any products we acquire, and, if approved, our product candidates CRTX 067, a generic product, and CRTX 080, a branded product.

Opportunities and Trends

We continue to execute on our strategic plan, which calls for promoting our CUROSURF and ZYFLO franchises and transitioning away from our primary care-focused anti-infective franchise. Also, we are sharpening our focus on the hospital, niche respiratory and related specialty markets. In addition, we will continue our business development efforts to expand our product portfolio. Finally, we will continue to progress both CRTX 067 and CRTX 080 through the regulatory approval process. We believe these actions, combined with the experience and expertise of our management team, position us well to drive the future growth of our revenue and income.

We generate revenue by promoting our products to targeted health care professionals who are hospital-based or whose practices focus on the treatment of respiratory disorders. Primarily, these health care professionals are specialists. In 2011, we realigned our sales force to focus calls on neonatologists and respiratory specialists. As a result, our share of the hospital market for our lead product, CUROSURF, has continued to grow, and the percentage of our respiratory products prescribed by specialists continues to increase. We have also focused our development pipeline to concentrate on projects that may enhance the life cycle of our ZYFLO products.

As we continue to focus on the growth of our existing products and product candidates, we also continue to position ourselves to execute acquisitions that will drive our next phase of growth. We are systematically

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focusing our efforts on acquiring products or companies whose products will fit strategically with the focus and strengths of our sales force. We believe that we can continue to operate efficiently in challenging economic and industry environments and that we will find opportunities to invest our cash in ways that will drive future growth. We will need to continue to maintain our strategic focus, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships in order to execute our strategy successfully.

In 2012 we will focus on the following five key initiatives:

- growing revenues from our existing product portfolio;
- evaluating and executing upon strategic alternatives for our anti-infective products;
- gaining regulatory approval and launching CRTX 067;
- advancing our product pipeline, in particular CRTX 080; and
- acquiring specialty products and/or companies.

See Item 1. Business for a more complete description of our products, product candidates and more important agreements.

Results of Operations

Comparison of the Years Ended December 31, 2011 and 2010

The following table sets forth certain consolidated statements of operations data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Year Ended December 31,		Change	
	2011	2010	$	%
Net Product Sales				
CUROSURF	$ 34,852	$ 33,621	$ 1,231	4%
ZYFLO product family	30,674	30,619	55	0
FACTIVE	6,296	5,126	1,170	23
SPECTRACEF product family	8,091	5,327	2,764	52
ALLERX Dose Pack products	23,263	27,305	(4,042)	(15)
HYOMAX product family	2,128	10,071	(7,943)	(79)
Other products	(4,003)	11,675	(15,678)	(134)
Total net product sales	101,301	123,744	(22,443)	(18)
License and royalty agreement revenues	121	1,573	(1,452)	(92)
Net revenues	101,422	125,317	(23,895)	(19)
Cost of product sales (exclusive of amortization of product rights)	37,823	45,015	(7,192)	(16)
Selling, general and administrative	46,344	53,198	(6,854)	(13)
Research and development	1,624	4,488	(2,864)	(64)
Amortization of product rights	16,868	14,728	2,140	15
(Loss) income from operations	(1,237)	7,888	(9,125)	(116)

Total other expenses, net	(128)	(110)	(18)	(16)
(Loss) income before income taxes	(1,365)	7,778	(9,143)	(118)
Benefit from (provision for) income taxes	672	(1,609)	(2,281)	(142)
Net(loss) income	$ (693)	$ 6,169	$ (6,862)	(111)%
Net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ (0.27)	(113)%
Non-GAAP income from operations(1)	$ 18,305	$ 23,955	$ (5,650)	(24)%
Non-GAAP net income(1)	$ 9,228	$ 18,912	$ (9,684)	(51)%
Non-GAAP net income per share, diluted(1)	$ 0.35	$ 0.73	$ (0.38)	(52)%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP financial measures is included below.

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Net Revenues

Net Product Sales.

CUROSURF net product sales increased $1.2 million, or 4%, during 2011 compared to 2010 primarily due to an increase in price, partially offset by an increase in the estimated fees to be paid to our distributors.

ZYFLO CR and ZYFLO net product sales were relatively flat during 2011 compared to 2010. Excluding the impact of an additional reserve of $1.9 million recorded in 2010 to account for an increase in actual returns compared to management s initial estimate at the time of the Merger, net product sales decreased approximately $2.0 million, or 6%, during 2011. This decrease was primarily due to lower unit volume and increases in government rebates and the estimated fees to be paid to our distributors, partially offset by a price increase.

FACTIVE net product sales increased $1.2 million, or 23%, during 2011 compared to 2010. Excluding the impact of additional reserves of $1.6 million recorded in 2010 to account for an increase in our estimated rate of future returns, net product sales decreased approximately $400,000, or 6%, during 2011. This decrease was primarily due to relatively flat unit volume along with increased voucher redemption as a result of additional promotional efforts for our anti-infective products, partially offset by a price increase.

SPECTRACEF net product sales increased $2.8 million, or 52%, during 2011 compared to 2010. Excluding the impact of an additional reserve of $2.5 million for potential returns of discontinued product and increases in our estimated rates for product returns on net product sales during 2010, net product sales increased approximately $300,000, or 4%, during 2011. This increase was primarily due to increases in unit volume as a result of additional promotional efforts for our anti-infective products, increases in price and a reduction in Medicaid rebates, partially offset by increased voucher redemption.

ALLERX Dose Pack net product sales decreased $4.0 million, or 15%, during 2011 compared to 2010. Deferred revenue related to the 2010 sales was recognized in 2011 as revenue when prescriptions were filled. The decrease in product sales was primarily due to the March 2011 FDA Announcement, which caused a decline in prescriptions. In addition, we received approximately $30.1 million in returns related to product for which revenue had been deferred. As of December 31, 2011, $915,000 remains in deferred revenue.

HYOMAX net product sales decreased $7.9 million, or 79%, during 2011 compared to 2010. This decrease was primarily due to lower net prices and lower unit volume as a result of increased competition from other manufacturers. During 2011, revenue has been recognized as prescriptions were filled instead of our historic practice of recognizing revenue at the time of sale. This change was due to our inability to estimate product returns as a result of changes in market dynamics, large amounts of channel inventory and extended payment terms offered on certain sales. As of December 31, 2011, $513,000 remains in deferred revenue.

Net product sales from other products decreased $15.7 million, or 134%, during 2011 compared to 2010 primarily due to our November 2010 withdrawal from the market of our propoxyphene/acetaminophen products. Net product sales for propoxyphene/acetaminophen products during 2010 were $11.8 million, whereas we had no product sales from propoxyphene/acetaminophen products during 2011. During 2011, we also recorded returns in excess of our original estimates related to our propoxyphene/acetaminophen products resulting in an additional $4.6 million decrease in net product sales.

License and Royalty Agreement Revenues.

License and royalty agreement revenues decreased $1.5 million, or 92%, during 2011 compared to 2010 primarily due to the one-time, upfront nonrefundable payment of $1.5 million we received in August 2010 in accordance with our license agreement with Targacept, Inc., or Targacept, under which we out-licensed certain rights with respect to our alpha-7 receptor technology.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $16.9 million and $14.7 million in 2011 and 2010, respectively) decreased $7.2 million, or 16% during 2011 compared to 2010. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

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Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Year Ended December 31,		Change	
	2011	2010	$	%
Net product sales	$ 101,301	$ 123,744	$ (22,443)	(18)%
Cost of product sales (exclusive of amortization of product rights)	37,823	45,015	(7,192)	(16)
Gross profit	$ 63,478	$ 78,729	$ (15,251)	(19)%
Gross margin	63%	64%		(1%)

Based on our current product mix, we expect that gross margin will continue to decline primarily because our lead product, CUROSURF, has a lower gross margin than our other products. Unless we are able to commercialize or acquire products with similar gross margins to the marketed unapproved products that we previously sold and the anti-infective products that we are deemphasizing, our gross margins will not return to historic levels.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $6.9 million, or 13%, during 2011 compared to 2010. This decrease was primarily due to decrease in labor and benefits-related costs as a result of the realignment of our respiratory sales force; decrease in co-promotion expenses from the withdrawal of our propoxyphene/acetaminophen products; decreased sample usage for ZYFLO CR; and decreased advertising and promotional expenses. These decreases were partially offset by higher stock-based compensation, regulatory fees and marketed product support during 2011.

Research and Development Expenses. We designate development projects to which we have allocated or plan to allocate significant research and development resources with the term CRTX and a unique number. Costs related to discontinued products and product candidates that are in the early stages of development are included in Other Projects. The following table summarizes our research and development expenses for 2011 and 2010 and for current projects under development (other than CRTX 080, which we acquired through our acquisition of Cardiokine) from project inception through December 31, 2011 (dollars in thousands):

	Project Inception to December 31, 2011	Year Ended December 31, 2011	2010	Change $	Change %
CRTX 067	$ 6,186	$ 838	$ 2,290	$ (1,452)	(63)%
CRTX 073	2,012	708	1,057	(349)	(33)
Other projects		78	1,141	(1,063)	(93)
Total		$ 1,624	$ 4,488	$ (2,864)	(64)%

Research and development expenses decreased $2.9 million, or 64%, during 2011 compared to 2010. This decrease was driven by realignment of our development pipeline with our focus on hospital and niche respiratory-related specialty markets. As a result, we ceased work on our allergy product candidates as well as our cough/cold product candidates, CRTX 069, CRTX 072 and CRTX 074.

Our product development expenses for particular product candidates will continue to vary significantly from year to year depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given year. We expect to continue to incur significant development expenses as we seek to advance the development and FDA approval of our product candidates and seek regulatory approvals for our product candidates that successfully complete clinical testing.

Amortization of Product Rights. Amortization of product rights increased $2.1 million, or 15%, during 2011 compared to 2010. During 2011, we focused our product development projects to align with our strategic direction. This decision resulted in the write-off of $2.5 million of capitalized product rights that no longer align with our strategic direction.

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Benefit from (Provision for) Income Taxes

The benefit from income taxes was $672,000 during 2011, compared to a provision for $1.6 million in 2010. Our effective tax rates for 2011 and 2010 were 49.2% and 20.7%, respectively. The increase in the effective tax rate for 2011 compared to 2010 is due primarily to the fact that we recorded a benefit associated with our pre-tax book loss for the period as well as an additional tax benefit associated with the release of a portion of the valuation allowance.

Quarterly Results of Operations

See Note 16 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a presentation of our unaudited quarterly results of operations for 2011 and 2010.

Comparison of the Years Ended December 31, 2010 and 2009

The following table sets forth certain consolidated statements of operations data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Year Ended December 31,		Change	
	2010	2009	$	%
Net Product Sales				
CUROSURF	$ 33,621	$ 10,463	$ 23,158	221%
ZYFLO product family	30,619	17,959	12,660	70
FACTIVE	5,126	1,178	3,948	335
SPECTRACEF product family	5,327	9,390	(4,063)	(43)
ALLERX Dose Pack products	27,305	31,707	(4,402)	(14)
HYOMAX product family	10,071	28,148	(18,077)	(64)
Other products	11,675	10,443	1,232	12
Total net product sales	123,744	109,288	14,456	13
License and royalty agreement revenues	1,573	276	1,297	470
Net revenues	125,317	109,564	15,753	14
Cost of product sales (exclusive of amortization of product rights)	45,015	38,232	6,783	18
Selling, general and administrative	53,198	45,731	7,467	16
Research and development	4,488	3,608	880	24
Amortization of product rights	14,728	6,115	8,613	141
Income from operations	7,888	15,878	(7,990)	(50)
Total other expenses, net	(110)	(128)	(18)	(14)
Income before income taxes	7,778	15,750	(7,972)	(51)
Provision for income taxes	(1,609)	(5,547)	(3,938)	(71)
Net income	$ 6,169	$ 10,203	$ (4,034)	(40)%
Net income per share, diluted	$ 0.24	$ 0.54	$ (0.30)	(56)%
Non-GAAP income from operations(1)	$ 23,955	$ 27,034	$ (3,079)	(11)%
Non-GAAP net income(1)	$ 18,912	$ 17,432	$ 1,480	8%

Non-GAAP net income per share, diluted(1)	$ 0.73	$ 0.93	$ (0.20)	(22)%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP financial measures is included below.

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Net Revenues

Net Product Sales.

CUROSURF net product sales increased $23.2 million, or 221%, during 2010 compared to 2009. This increase was primarily due to the fact that we acquired the CUROSURF product rights from Chiesi during the third quarter of 2009 and began promoting and selling CUROSURF in September 2009. Accordingly, our 2010 net product sales for CUROSURF reflect a full year of marketing, promoting and selling the CUROSURF products, as opposed to a partial year in 2009.

ZYFLO CR and ZYFLO net product sales increased $12.7 million, or 70%, during 2010 compared to 2009, primarily due to the increase in our price and the steady prescription volume, which were partially offset by additional expense recorded for actual product returns related to sales made prior to the Merger.

FACTIVE net product sales increased $3.9 million, or 335%, during 2010 compared to 2009. This increase was primarily due to the fact that we acquired the FACTIVE product rights and related inventory from Oscient on September 9, 2009. We began earning revenues from FACTIVE in September 2009; however, we did not begin marketing and promoting FACTIVE until October 2009. Accordingly, our 2010 net product sales for FACTIVE reflect a full year of marketing, promoting and selling the FACTIVE products, as opposed to a partial year in 2009. This increase in net product sales was partially offset by an 8% increase in our estimated rate of product returns as a result of lower demand than expected and an increase in returns over our initial estimate at the acquisition date as well as an increase in rebates expected to be paid as a result of promotional activities.

SPECTRACEF net product sales decreased $4.1 million, or 43%, during 2010 compared to 2009, primarily due to lower sales volumes caused by some dilution of our sales promotion efforts as a result of the introduction of FACTIVE into our product portfolio. Net product sales in 2010 were also impacted by increases in our estimated rates for product returns for various SPECTRACEF products as well as an increase in rebates expected to be paid as a result of new healthcare regulations.

ALLERX Dose Pack net product sales decreased $4.4 million, or 14%, during 2010 compared to 2009. The decrease in product sales was primarily due to the deferral of revenue from sales made during 2010 and to additional expense recorded for an increase in actual returns of certain ALLERX products sold prior to 2010. At December 31, 2010, approximately $53.2 million of revenue from sales of ALLERX was deferred due to the inability to estimate returns. As a result of changes in market dynamics, large amounts of channel inventory and extended payment terms offered on certain sales, we were unable to estimate returns due to uncertainty regarding consumer demand and the level of competition. Deferred revenue related to these sales was recognized as revenue when prescriptions were filled.

HYOMAX net product sales decreased $18.1 million, or 64%, during 2010 compared to 2009. This decrease was primarily due to lower net prices and lower volume as a result of increased competition from other manufacturers as well as deferral of revenue from sales made during December 2010. At December 31, 2010, approximately $4.0 million of revenue from sales of HYOMAX products was deferred due to the inability to estimate returns. As a result of large amounts of channel inventory and extended payment terms offered on certain sales, we were unable to estimate returns. Deferred revenue related to these sales was recognized as revenue when prescriptions were filled.

Net product sales from other products increased $1.2 million, or 12%, during 2010 compared to 2009 primarily due to the increase in sales volume of our propoxyphene/acetaminophen products, which included BALACET 325, APAP 325, our generic formulation of BALACET 325, and APAP 500. These products were voluntarily withdrawn from the market in November 2010 in response to the FDA s actions requiring the withdrawal of the branded versions of propoxyphene, specifically Darvon®, Darvon-N® and Darvocet-N®. Net product sales from our three propoxyphene products were $11.8 million and $9.6 million in 2010 and 2009, respectively.

License and Royalty Agreement Revenues.

License and royalty agreement revenues increased $1.3 million, or 470%, during 2010 compared to 2009 primarily due to the one-time, upfront, nonrefundable payment of $1.5 million we received in August 2010 in

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accordance with our license agreement with Targacept, under which we out-licensed certain rights with respect to our alpha-7 receptor technology, partially offset by a reduction in unrelated royalty revenue.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $14.7 million and $6.1 million in 2010 and 2009, respectively) increased $6.8 million, or 18% during 2010 compared to 2009. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties, and inventory allowances.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Year Ended December 31,		Change	
	2010	2009	$	%
Net product sales	$ 123,744	$ 109,288	$ 14,456	13%
Cost of product sales (exclusive of amortization of product rights)	45,015	38,232	6,783	18
Gross profit	$ 78,729	$ 71,056	$ 7,673	11%
Gross margin	64%	65%		(1%)

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $7.5 million, or 16%, during 2010 compared to 2009. This increase was primarily due to an increase in labor and benefits-related costs as a result of the addition of our hospital sales force in September 2009; co-promotion expenses relating to ZYFLO CR; and increased sample usage for ZYFLO CR and FACTIVE. These increases were partially offset by lower stock-based compensation and legal and consulting fees during 2010 as compared to 2009 when we incurred significant expenses related to our transaction with Chiesi. Costs associated with the Chiesi transaction were $3.3 million, which included $1.5 million of additional stock-based compensation expense due to acceleration of certain stock options and shares of restricted stock and $1.8 million of legal, accounting and related fees.

Research and Development Expenses. The following table summarizes our research and development expenses for 2010 and 2009 and for projects under development from project inception through December 31, 2010 (dollars in thousands):

	Project Inception to December 31, 2010	Year Ended December 31,		Change	Change
		2010	2009	$	%
CRTX 067	$ 5,348	$ 2,290	$ 2,442	$ (152)	(6)%
CRTX 072	83	80	3	77	2567
CRTX 073	1,305	1,057	248	809	326
CRTX 809	263	260	3	257	8567
Other projects		801	912	(111)	(12)
Total		$ 4,488	$ 3,608	$ 880	24%

Research and development expenses increased $880,000, or 24%, during 2010 compared to 2009. This increase was driven by an increase in expenses related to our product candidates, CRTX 073 and CRTX 809, of $1.1 million, partially offset by a decrease in expenses related to CRTX 067 and other projects. CRTX 067 expenses were driven by work performed in support of our filing with the FDA and scale-up activities with our contract manufacturers. CRTX 072, CRTX 073, and CRTX 809 expenses related to various preclinical activities in accordance with each project s development plan.

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Amortization of Product Rights. Amortization of product rights increased $8.6 million, or 141%, during 2010 compared to 2009. This increase was primarily due to the CUROSURF and FACTIVE product rights. We added CUROSURF and FACTIVE to our product portfolio during the third quarter of 2009.

Provision for Income Taxes

The provision for income taxes was $1.6 million during 2010, compared to $5.5 million in 2009. Our effective tax rates for 2010 and 2009 were 20.7% and 35.2%, respectively. The decrease in the effective tax rate was due to the impact of the release of valuation allowances against our deferred tax assets during 2010 as well as changes in the estimated income tax provision related to the year ended December 31, 2009. The majority of the impact from changes in the estimated income tax provision related to a change in estimate regarding utilization of net operating losses resulting from additional analysis that we performed related to the amount of net operating loss carryforwards that can be used under the rules governing ownership changes in Section 382 of the Internal Revenue Code. We performed an in-depth analysis during the year that resulted in a larger amount of net operating loss carryforward to be available to offset taxable income for the 2010 tax year. Upon release of the valuation allowances, we fully utilized our net operating loss carryforwards that were not subject to limitations, thereby reducing total income tax expense in 2010 and significantly lowering our effective tax rate.

Reconciliation of Non-GAAP Financial Measures

To supplement the consolidated financial statements presented in accordance with GAAP, we use non-GAAP measures of certain components of financial performance. These non-GAAP measures include non-GAAP operating income, non-GAAP net income and non-GAAP net income per diluted share. Our management regularly uses supplemental non-GAAP financial measures to understand, manage and evaluate our business and make operating decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from similarly titled non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. The additional non-GAAP financial information presented herein should be considered in conjunction with, and not as a substitute for, or superior to, the financial information presented in accordance with GAAP (such as operating income (loss), net income (loss) and earnings (loss) per share) and should not be considered measures of our liquidity. These non-GAAP measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization of product rights and transaction-related expenses. Transaction-related expenses consist of (1) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (2) integration costs related to our completed transactions; and (3) transaction-related fees associated with transactions that are not consummated. We exclude these expenses from our non-GAAP measures because we believe that their exclusion provides an additional means to assess the extent to which our efforts and execution of our strategy are reflected in our operating results. In particular, stock-based compensation expense is excluded primarily because it is a non-cash expense that is determined based on subjective assumptions, product rights amortization is excluded because it is not reflective of the cash-settled expenses incurred related to product sales, and transaction-related expenses are excluded because management believes they have no direct correlation to current operating results. Our management believes that these non-GAAP measures, when shown in conjunction with the corresponding GAAP measures, enhance investors and management s overall understanding of our current financial performance and our prospects for the future.

The non-GAAP measures are subject to inherent limitations because (1) they do not reflect all of the expenses associated with the results of operations as determined in accordance with GAAP and (2) the exclusion of these expenses involved the exercise of judgment by management. Even though we have excluded stock-based compensation expense, amortization of product rights and transaction-related expenses from the non-GAAP

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financial measures, stock-based compensation is an integral part of our compensation structure, the acquisition of product rights is an important part of our business strategy and the transaction-related expenses, whether or not the transaction is successfully closed, may be significant cash expenses.

The following tables reconcile our non-GAAP measures to the most directly comparable GAAP financial measures (in thousands, except share and per share amounts):

	For the Year Ended December 31,		
	2011	2010	2009
GAAP (loss) income from operations	$ (1,237)	$ 7,888	$ 15,878
Add: stock-based compensation(1)	2,207	1,339	1,478
Add: amortization of product rights	16,868	14,728	6,115
Add: transaction-related expenses(2)	467		3,563
Non-GAAP income from operations	$ 18,305	$ 23,955	$ 27,034
GAAP (loss) net income	$ (693)	$ 6,169	$ 10,203
Add: stock-based compensation(1)	2,207	1,339	1,478
Add: amortization of product rights	16,868	14,728	6,115
Add: transaction-related expenses(2)	467		3,563
Less: tax effects related to above items(3)	(9,621)	(3,324)	(3,927)
Non-GAAP net income	$ 9,228	$ 18,912	$ 17,432
GAAP net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ 0.54
Non-GAAP net income per share, diluted	$ 0.35	$ 0.73	$ 0.93
Shares used in diluted net (loss) income per share calculation:			
GAAP net (loss) income	25,684,593	26,036,544	18,776,588
Non-GAAP net income	26,232,333	26,036,544	18,776,588

(1) Stock-based compensation for 2009 excludes stock-based compensation charges incurred in connection with the Chiesi transaction, which are included in transaction-related expenses.

(2) Transaction-related expenses include legal, accounting and related costs that were incurred in connection with our acquisition of Cardiokine of approximately $400,000 and other anticipated transactions. Transaction-related expenses may include stock-based compensation charges. During 2009, all transaction-related expenses were incurred in connection with the Chiesi transaction and included $1.8 million of stock-based compensation charges that were included in selling, general and administrative expenses.

(3) Tax effects for 2011, 2010 and 2009 are calculated using effective tax rates of 49.2%, 20.7%, and 35.2% respectively.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products. To date, we have funded our operations primarily from product sales, royalty agreement revenues, and the investment from Chiesi. As of December 31, 2011, we had $74.0 million in cash and cash equivalents.

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Cash Flows

The following table provides information regarding our cash flows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Cash provided by (used in):			
Operating activities	$ 24,172	$ 32,989	$ 450
Investing activities	(616)	(623)	(5,504)
Financing activities	(533)	(274)	14,621
Net increase in cash and cash equivalents	$ 23,023	$ 32,092	$ 9,567

Net Cash Provided By Operating Activities

Our primary sources of operating cash flows are product sales. Our primary uses of cash in our operations are for funding working capital, selling, general and administrative expenses and royalties.

Net cash provided by operating activities in 2011 reflected our net loss of $693,000, adjusted by non-cash expenses totaling $22.9 million and changes in accounts receivable, inventories, income tax receivable, accrued expenses and other operating assets and liabilities totaling $2.0 million. Non-cash items consisted primarily of amortization and depreciation of $14.9 million, changes in allowances for prompt payment discounts and inventory of $3.7 million, impairment of product rights of $2.5 million and stock-based compensation of $2.2 million, partially offset by changes in deferred income tax assets of $388,000. Accounts receivable decreased by $61.1 million primarily due to collections of receivables and expected returns of our 2010 sales of ALLERX Dose Pack and HYOMAX products. Inventories decreased by $5.5 million primarily due to the decrease in CUROSURF finished goods and ZYFLO CR and FACTIVE API, partially offset by a reduction in inventory allowances due to write-offs of ALLERX Dose Pack and ZYFLO CR sample inventory. Prepaid expenses, long-term accounts receivable and other assets decreased by $8.5 million, primarily due to the decrease of long-term accounts receivables and long-term deferred cost of sales. Accounts payable decreased by $627,000 primarily due to the timing of payments. Accrued expenses decreased by $15.1 million primarily due to a decrease in accrued price adjustments and chargebacks, product returns and accrued bonuses. Deferred revenue decreased $55.8 million primarily due to expected product returns and revenue that was recognized based on prescriptions filled for our ALLERX and HYOMAX products. Income tax receivable increased by $1.7 million primarily due to lower than estimated taxable income for the year ended December 31, 2011.

Net cash provided by operating activities in 2010 reflected our net income of $6.2 million, adjusted by non-cash expenses totaling $18.8 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $8.1 million. Non-cash items consisted primarily of amortization and depreciation of $14.8 million, changes in allowances for prompt payment discounts and inventory of $5.2 million, stock-based compensation of $1.3 million and changes in deferred income tax assets of $3.0 million. Accounts receivable increased by $63.8 million primarily due to the sale of remaining ALLERX and HYOMAX inventories during December 2010. Inventories decreased by $1.6 million primarily due to reductions in ALLERX, HYOMAX and ZYFLO CR finished goods and sample inventories, partially offset by purchases of CUROSURF finished product and inventory destroyed or donated. Prepaid expenses, long-term accounts receivable and other assets increased by $8.8 million, primarily due to an increase in long-term accounts receivables and deferred cost of sales related to the sale of remaining ALLERX and HYOMAX inventories during December 2010, partially offset by the amortization of regulatory fees. Accounts payable increased by $499,000 primarily due to the timing of payments. Accrued expenses increased by $23.2 million primarily due to increases in our estimated product return rates and rebates and price adjustments related to the sale of remaining ALLERX and HYOMAX inventories during December 2010 and new laws, specifically Health Care Reform, partially offset by a decrease in accrued royalties related to our product mix. Deferred revenue increased $57.2 million primarily because of sales that were deferred due to extended payment terms and the inability to estimate product returns. Income taxes payable decreased by $1.8 million primarily due to a lower effective tax rate for the year ended December 31, 2010.

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Net cash provided by operating activities in 2009 reflected our net income of $10.2 million, adjusted by non-cash expenses totaling $10.7 million offset by changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $20.4 million. Non-cash items included amortization and depreciation of $6.4 million, change in allowances for prompt payment discounts and inventory obsolescence of $4.6 million, stock-based compensation of $3.3 million and changes in deferred income tax of $3.6 million. Accounts receivable increased by $6.7 million primarily due to increased net product sales. Inventories increased by $8.2 million primarily due to the purchase of $2.8 million of FACTIVE API and finished goods and purchases of CUROSURF. Prepaid expenses, long-term accounts receivable and other assets increased by $3.1 million primarily due to voucher programs, prepayments on purchases of API not yet received into inventory, and increases in FDA regulatory fees and in insurance premiums. Accounts payable decreased by $3.1 million primarily due to the payment of accounts payable related to the Merger and a reduction in payables related to manufacturing, product development and marketing expenses. Accrued expenses increased by $2.1 million primarily due to increased returns, rebates and chargebacks resulting from increased product sales, partially offset by a decrease in accrued bonuses. Income taxes payable (exclusive of income taxes payable assumed in the Merger) decreased by $1.3 million due to the tax benefits we recognized in 2009 related to exercises of non-qualified stock options.

Net Cash Used in Investing Activities

Our primary uses of cash in investing activities are the purchase of property and equipment and the acquisition and licensing of product rights.

Net cash used in investing activities in 2011 reflected the purchase of property and equipment for $616,000.

Net cash used in investing activities in 2010 primarily reflected the purchase of property and equipment for $375,000 and the purchase of product rights for $250,000, partially offset by proceeds from the sale of equipment.

Net cash used in investing activities in 2009 primarily reflected the purchase of FACTIVE product rights for $5.2 million and property and equipment for $635,000, partially offset by net proceeds from the sale of marketable securities of $300,000.

Net Cash (Used in) Provided by Financing Activities

Our primary sources of historical cash flows from financing activities are the investment from Chiesi. Going forward, we expect our primary sources of cash flows from financing activities to be equity or debt issuances or arrangements we may make or enter into. Our primary uses of cash in financing activities are the SPECTRACEF license agreement liability and payments in connection with any debt or structured finance arrangements we may enter into.

Net cash used in financing activities in 2011 reflected $1.4 million in principal payments on our license agreement liability and capital leases, partially offset by proceeds of $369,000 from common stock option exercises and related tax benefits of $522,000.

Net cash used in financing activities in 2010 reflected $1.3 million in principal payments on our license agreement liability and capital leases, partially offset by proceeds of $544,000 from common stock option exercises and related tax benefits of $478,000.

Net cash provided by financing activities in 2009 reflected proceeds of $15.5 million from our issuance of shares of common stock to Chiesi and common stock option exercises of $437,000 and related tax benefits of $1.3 million, partially offset by $2.5 million in principal payments on our license agreement liability and capital leases.

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Funding Requirements

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

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the extent to which we acquire or invest in products, businesses and technologies;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;
- the extent to which we are required to make certain contingent payments in connection with our acquisition of Cardiokine;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our 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 us.

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. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of December 31, 2011, we had $74.0 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and 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, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2011 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 165	$ 100	$ 65	$	$
Operating leases(1)	2,461	570	1,140	751	
Purchase obligations(2)	26,074	22,037	3,969	68	
Total contractual obligations(3)	$ 28,700	$ 22,707	$ 5,174	$ 819	$

(1) Operating leases include minimum payments under leases for our facilities, automobiles and certain equipment. Our total minimum lease payments for our corporate headquarters are $492,000 in 2012, $536,000 in 2013, $584,000 in 2014, $599,000 in 2015 and $152,000 thereafter.

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(2) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $18.5 million; clinical trial and research agreements with contract research organizations and consultants of $3.1 million; agreements with providers of marketing analytical services of $4.2 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $215,000.

(3) Excluded from the contractual obligations table are potential payments of up to $156 million for contingent consideration that we may be required to pay in connection with our acquisition of Cardiokine and $38.4 million in potential future milestone payments as part of our licensing, distribution and development agreements. We have excluded these potential liabilities and milestone payments from the contractual obligations table because we are unable to precisely predict the timing or ultimate cash settlement amounts of these payments. See Note 10 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for more information regarding the potential payments related to our acquisition of Cardiokine and milestone payments related to our licensing, distribution and development agreements.

Off-Balance Sheet Arrangements

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

Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception. We expect our cost of product sales and other operating expenses will change in the future in line with periodic inflationary changes in price levels. Because we intend to retain and continue to use our property and equipment, we believe that the incremental inflation related to the replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources. While our management generally believes that we will be able to offset the effect of price-level changes by adjusting our product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse effect on our financial condition, results of operations and cash flows.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and other financial information. We base these estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and these estimates form the basis for our judgments concerning the carrying values of assets and liabilities that are not readily apparent from other sources. We periodically evaluate our estimates and judgments based on available information and experience. Actual results could differ from our estimates under different assumptions and conditions. If actual results significantly differ from our estimates, our financial condition and results of operations could be materially impacted.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that could have been used, or changes in the accounting estimate that are reasonably likely to occur periodically, could materially impact our consolidated financial statements. See Note 2 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a description of our significant accounting policies and method used in preparation of our consolidated financial statements.

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Revenue Recognition

We record revenue from product sales, license agreements and royalty 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.

Net Product Sales

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, and prompt payment and other discounts. When we cannot reasonably estimate the amount of future product returns, we record revenues when the risk of product return has been substantially eliminated. As of December 31, 2011, we had $1.4 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, we rely on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

When we implement a price increase, we generally offer our existing customers an opportunity to purchase a limited quantity of product at the previous list price. Shipments resulting from these programs generally are not materially in excess of ordinary levels; therefore, we recognize the related revenue when the product is received by the customers and include the shipments in estimating our various product related allowances. In the event we determine that these shipments represent purchases of inventory in excess of ordinary levels for a given wholesaler, the potential impact on product returns exposure is specifically evaluated and reflected as a reduction in revenue at the time of such shipments.

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 that begins six months prior to and ends twelve months subsequent to expiration of the products. Our products have an 18- to 48-month expiration period from the date of manufacture. In determining our return allowance, we consider various relevant factors, including:

Actual and historical return rates for expired lots. Our historical return rates for expired lots vary by product and approximate, on a product by product basis, our current return rates.

Historical and forecasted product sales and consumer consumption data reported by external information management companies. Management reviews sales forecasts and consumption data on a product by product basis to assist it in estimating whether product is expected to become short-dated and thus subject to return.

Estimated expiration dates or remaining shelf life of inventory in the distribution channel. Our products generally have remaining shelf lives of between 15 to 45 months at time of shipment.

Levels of inventory in the distribution channel and any significant changes to these levels. Levels of inventory in the distribution channel typically range from six to eight weeks of product demand.

Competitive issues such as new product entrants and other known changes in sales trends.

Based on the above factors, management determines an estimated return rate for each product and applies that rate to the quantity of units sold that is subject to future return. As of December 31, 2011, our estimated return rates for products currently subject to return ranged from 1% to 20% depending on the product.

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We routinely assess our experience with product returns and adjust our reserves accordingly. The amount of actual product returns could be either higher or lower than the amounts we have accrued. Changes in our returns estimates are charged to income in the period in which the information that gives rise to the change becomes known.

If our estimates of returns differ from our actual results, there could be a material impact on our financial statements. Based on historical experience, our average actual return rates vary based on our product mix. We consider a one-percentage point variation to be a reasonably possible change in the percentage of our product returns to related gross sales on a product by product basis. A one-percentage point increase or decrease in each of the individual products estimated product returns rate would have had an approximate $1.7 million, or 2%, effect on our net revenues recognized in 2011.

Expense recognized for product returns was $15.5 million, $20.1 million and $13.0 million in 2011, 2010 and 2009, respectively, representing 9%, 11% and 9% of gross product sales in 2011, 2010 and 2009, respectively. Expense recognized during 2011 for product returns related to current year sales was $8.1 million, or 5% of gross product sales. Expense recognized during 2011 for product returns related to sales made in prior years was $7.3 million, or 4% of gross product sales. The additional expense of $7.3 million consisted primarily of $4.6 million related to our propoxyphene/acetaminophen products and $2.7 million related to ALLERX Dose Pack products.

The additional expense recorded in 2011 for our propoxyphene/acetaminophen products related to actual returns in excess of our original estimates established in November 2010 when these products were voluntarily withdrawn from the market in response to the FDA s actions requiring the withdrawal of the branded versions of propoxyphene. The additional expense recorded in 2011 for ALLERX related to an increase in actual returns due to a continued decline in prescription demand influenced by the March 2011 FDA Announcement. Even though the majority of our 2010 sales of ALLERX were deferred due to our inability to estimate returns, the market decline has impacted the level of returns of products sold prior to December 2010.

Rebates. The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

Expense recognized for rebates was $4.5 million, $4.7 million and $1.4 million in 2011, 2010 and 2009, respectively, representing approximately 3%, 3% and 1% of gross product sales in 2011, 2010 and 2009, respectively.

Price Adjustments and Chargebacks. Our estimates of price adjustments and chargebacks are based on our estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the listed prices of our products. These estimates are also based on the contract fees we pay to certain group purchasing organizations, or GPOs, in connection with our sales of CUROSURF. We make these estimates based on the facts and circumstances known to us in accordance with GAAP. In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we have estimated.

From time to time, we offer certain promotional incentives to our customers for our products, and we expect that we will continue this practice in the future. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. We estimate our liability for each promotional program and record the liabilities as price adjustments. We estimate our liability for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to us by a third-party claims processing organization and actual redemption rates for our completed programs.

Expense recognized for price adjustments and chargebacks was $40.6 million, $34.5 million and $21.8 million in 2011, 2010 and 2009, respectively, representing approximately 25%, 18% and 15% of gross product sales in 2011, 2010 and 2009, respectively. The increase in the expense as a percentage of gross product sales during 2011 was primarily due to increased redemption of vouchers for our anti-infective products. There were no current period adjustments during 2011 related to prior period provisions for price adjustments and chargebacks. We do not expect future changes in our estimates for price adjustments and chargebacks to be material.

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Prompt Payment Discounts. We typically require our customers to remit payments within the first 30 to 90 days, depending on the customer and the products purchased. In addition, 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 or customer and/or industry expectations. Because our wholesale distributors typically take the prompt payment discount, we accrue 100% of the prompt payment 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. 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.

Expense recognized for prompt payment discounts was $3.4 million, $3.9 million and $3.1 million in 2011, 2010 and 2009, respectively, representing approximately 2% of gross product sales in each year.

See Schedule II Valuation and Qualifying Accounts included in Item 8. Financial Statements and Supplementary Data for a reconciliation of our sales allowances and related accrual balances.

License and Royalty Agreement Revenues

Payments from our licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. If we have continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by our licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

License agreement revenues were $75,000 and $1.5 million in 2011 and 2010, respectively. In August 2010, in accordance with a license agreement with Targacept under which we out-licensed certain rights with respect to our alpha-7 receptor technology, we received a one-time, upfront, nonrefundable payment of $1.5 million. We have no continuing performance obligations related to the agreement and are also eligible for success-based milestone payments of up to $74.9 million, depending on which compound is progressed by Targacept.

Royalty agreement revenues are earned under license agreements which provide for the payment of royalties based on sales of certain licensed products. These revenues are recognized based on product sales that occurred in the relevant period. Royalty agreement revenues were $46,000, $73,000 and $276,000 during 2011, 2010 and 2009, respectively.

Goodwill and Product Rights

Goodwill

At December 31, 2011, we had $15.2 million in goodwill related to our Merger on October 31, 2008 and our acquisition of Cardiokine on December 30, 2011. Excluding goodwill, we have no intangible assets with indefinite lives; however we do have capitalized product rights for development projects that are not amortizable until regulatory approval. We use judgment in assessing goodwill for impairment. Goodwill is reviewed for impairment annually, as of October 1, and more frequently if events or circumstances indicate that the carrying amount could exceed fair value. Examples of those events or circumstances that may be indicative of impairment include a significant adverse change in the business climate or changes in our cash flow projections or forecast that demonstrate losses. We have one operating segment which represents our sole reporting unit for evaluation of goodwill.

We elected to early adopt the Financial Accounting Standards Board s Accounting Standards Update No. 2011-08, or ASU No. 2011-08, which allows a company to first assess qualitative factors to determine if it is necessary to perform the two-step quantitative goodwill impairment test. Under ASU No. 2011-08, companies should assess qualitative factors to determine whether it is more likely than not that a reporting unit s fair value is

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less than its carrying value, including goodwill. In the event we determine that it is more likely than not that our sole reporting unit s fair value is less than its carrying amount, quantitative testing would be performed comparing recorded values to estimated fair values. As part of our goodwill qualitative testing process, we evaluate various factors to determine whether it is reasonably likely that management s assessment would indicate a material impact on the fair value of our reporting unit. Factors assessed in the qualitative approach are cash flow forecasts of our reporting unit, the strength of our balance sheet, changes in strategic outlook or organizational structure, industry and market changes and macroeconomic indicators.

Fair values are based on discounted cash flows using a discount rate determined by our management to be consistent with industry discount rates and the risks inherent in our current business model. Other assumptions include, but are not limited to, our estimation of the amount and timing of future cash flows from products and product candidates and the estimation of related costs that are dependent on the size of our sale forces and research and development activity. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, we calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded. There was no impairment of goodwill as of December 31, 2011. Due to uncertain market conditions and potential changes in our strategy, product portfolio or reportable segments, it is possible that the forecasts we use to support goodwill could change in the future, which could result in goodwill impairment charges that would adversely affect our results of operations and financial condition.

Product Rights

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins. We review our product rights for impairment and evaluate the associated useful lives on a periodic basis. Events or circumstances that may be indicative of impairment include a significant adverse change in the business climate that could affect the value of the rights or a change in the extent or manner in which the rights are used such as regulatory actions. Our periodic evaluation of product rights is based on our projection of the undiscounted future cash flows associated with the products. Our assumptions about future revenues and expenses require significant judgment associated with the forecast of the performance of our products. Actual revenues and costs could vary significantly from these forecasted amounts. If actual cash flows are significantly different than our forecasted amounts, we could determine that some or all of our capitalized product rights are impaired. In the event of impairment, we would record an impairment charge, which could have a material adverse effect on our results of operations.

As of December 31, 2011, we had an aggregate of $107.0 million in capitalized product rights, which we expect to amortize over remaining periods of six months to eight years.

Acquisitions

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Amounts allocated to acquired in-process research and development, or IPR&D, are recognized at fair value and initially characterized as indefinite-lived intangible assets, irrespective of whether the acquired IPR&D has an alternative future use. IPR&D is subsequently accounted for as an indefinite-lived intangible asset until completion or abandonment of the associated research and development efforts. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense at the acquisition date.

The judgments made in determining the estimated fair value assigned to each class of asset acquired and liability assumed can materially impact our results of operations. There are several methods that can be used to determine fair value. For intangible assets, including IPR&D, we typically use an income approach. This

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approach starts with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include:

- the amount and timing of projected future cash flows, adjusted for the probability of technical and marketing success;
- the amount and timing of projected costs to develop IPR&D into commercially viable products;
- the discount rate selected to measure the risks inherent in the future cash flows; and
- an assessment of the asset s life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry.

We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions; however, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors, such as legal, regulatory, or contractual provisions that may limit the useful life, and the effects of obsolescence, anticipated demand, existence or absence of competition, and other economic factors on useful life.

During the year ended December 31, 2011, we acquired IPR&D through the acquisition of Cardiokine. Prior to the acquisition, Cardiokine completed a series of phase III clinical trials for its lead compound, lixivaptan, for treatment of hyponatremia, and filed an NDA with the FDA on December 29, 2011. The IPR&D related to lixivaptan, or CRTX 080, had a fair value of $11.5 million on the acquisition date. The excess-earning method under the income approach was used to determine the fair value. The projected cash flows were adjusted for the probabilities of approval and commercialization of the product. A discount rate of 19.0% was used to present value the projected cash flows. We did not incur any post-acquisition costs during the year ended December 31, 2011; however, we estimate that additional investment of approximately $1.4 million in research and development expenses will be incurred prior to commercial launch of the product, which we expect would be during 2013, assuming the product receives FDA approval.

Inventory

Inventory consists of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and record allowances for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. As of December 31, 2011, we had $9.9 million in inventory and an inventory reserve of $0.5 million.

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Stock-Based Compensation

We measure stock-based compensation for share-based payment awards granted to employees and non-employee directors on the grant date at fair value. We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured. Stock-based compensation related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of our stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

We currently use the Black-Scholes-Merton option-pricing model to calculate the fair value of stock-based compensation awards. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, the expected term of the award, the risk-free interest rate and any expected dividends.

The expected stock price volatility was based on Critical Therapeutics (now our) historical volatility for the five year period preceding the grant date. 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 was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

We do not intend to pay dividends on our common stock in the foreseeable future and, accordingly, we use a dividend rate of zero in the option-pricing model. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards that vest based on service, including those with graded vesting schedules, are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. As of December 31, 2011, there was $3.6 million and $1.2 million of total unrecognized compensation cost related to stock options and unvested restricted stock, respectively. These costs are expected to be recognized over a weighted-average period of 2.52 and 2.45 years, respectively.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the stock-based compensation expense we recognize in future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and earnings per share. This may result in a lack of consistency in future periods and materially affect the fair value estimate of stock-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Income Taxes

We record income tax expense in our consolidated financial statements based on an estimated annual effective income tax rate. We had an effective tax rate of 49.2%, 20.7% and 35.2% in 2011, 2010 and 2009, respectively. In 2011, the increase in the effective tax rate was primarily attributable to the fact that we had a net loss and the impact of our release of the valuation allowances against our deferred tax assets created a tax benefit which increased the rate.

We account for income taxes under the asset and liability method, which requires that we recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. Our deferred tax assets and liabilities are recorded at an amount calculated using a U.S. federal income tax rate of 35% and appropriate statutory tax rates of each of the jurisdictions in which we operate. If our tax rates change in the future, we may adjust our deferred tax assets and liabilities to an amount reflecting those income tax rates. Any such adjustment would affect our provision for income taxes during the period in which the adjustment is made.

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We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determinations, we consider all available positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. We review deferred tax assets periodically for recoverability and make estimates and judgments in assessing the need for a valuation allowance.

As of December 31, 2011, we had approximately $73 million in deferred tax assets. We determined that a $65 million valuation allowance relating to deferred tax assets for net operating losses and tax credits from the Merger and our acquisition of Cardiokine was necessary. If the estimates and assumptions used in our determination change in the future, we could be required to revise our estimates of the valuation allowances against our deferred tax assets and adjust our provisions for additional income taxes. In the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the valuation allowance which would reduce the provision for income taxes.

We recognize a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. We had $382,000 of unrecognized tax benefits at December 31, 2011. We do not expect to have any additional unrecognized tax benefits during the next twelve months.

Recent Accounting Pronouncements

See Note 15 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a description of recent accounting pronouncements, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Interest Rate Risk

Our exposure to market risk is confined to our cash equivalents, all of which have maturities of less than three months and bear and pay interest in U.S. dollars. Since we invest in highly liquid, relatively low yield investments, we do not believe interest rate changes would have a material impact on us.

Our risk associated with fluctuating interest expense is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. The interest rates on our existing long-term debt borrowings are fixed and as a result, interest due on borrowings are not impacted by changes in market-based interest rates. We do not have any other instruments with interest rate exposure.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have two development agreements denominated in foreign currencies, Euros and Swiss francs. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of changes in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the years ended December 31, 2011, 2010 and 2009. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

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ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Cornerstone Therapeutics Inc.

We have audited the accompanying consolidated balance sheets of Cornerstone Therapeutics Inc. (a Delaware corporation) as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 8. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the 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 Cornerstone Therapeutics Inc. as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina

March 6, 2012

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2011	2010
Assets		
Current assets:		
Cash and cash equivalents	$ 73,968	$ 50,945
Accounts receivable, net	11,894	76,476
Inventories, net	9,419	15,174
Prepaid expenses	3,753	3,552
Income tax receivable	1,900	197
Deferred income tax asset	2	44
Other current assets	6,112	1,559
Total current assets	107,048	147,947
Property and equipment, net	1,574	1,486
Product rights, net	106,960	112,328
Goodwill	15,218	13,231
Amounts due from related parties	38	38
Long-term accounts receivable		7,866
Deferred income tax asset, less current portion	523	1,876
Other assets	953	687
Total assets	$ 232,314	$ 285,459
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 10,012	$ 7,671
Accrued expenses	37,125	46,599
Current portion of license agreement liability		1,368
Current portion of capital lease	90	83
Current portion of deferred revenue	1,428	37,616
Total current liabilities	48,655	93,337
Capital lease, less current portion	56	146
Deferred revenue, less current portion		19,578
Acquisition-related contingent liability	8,800	
Total liabilities	57,511	113,061
Commitments and contingencies, Note 10		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock $0.001 par value, 90,000,000 shares authorized; 25,803,864 and 25,472,963 shares issued and outstanding as of December 31, 2011 and December 31, 2010, respectively	26	25
Additional paid-in capital	163,203	160,106
Retained earnings	11,574	12,267

Total stockholders equity	174,803	172,398
Total liabilities and stockholders equity	$ 232,314	$ 285,459

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Year Ended December 31,		
	2011	2010	2009
Net revenues	$ 101,422	$ 125,317	$ 109,564
Costs and expenses:			
Cost of product sales (exclusive of amortization of product rights)	37,823	45,015	38,232
Selling, general and administrative	46,344	53,198	45,731
Research and development	1,624	4,488	3,608
Amortization of product rights	16,868	14,728	6,115
Total costs and expenses	102,659	117,429	93,686
(Loss) income from operations	(1,237)	7,888	15,878
Other expenses, net:			
Interest expense, net	(128)	(85)	(128)
Other expense, net		(25)	
Total other expenses	(128)	(110)	(128)
(Loss) income before income taxes	(1,365)	7,778	15,750
Benefit from (provision for) income taxes	672	(1,609)	(5,547)
Net (loss) income	$ (693)	$ 6,169	$ 10,203
Net (loss) income per share, basic	$ (0.03)	$ 0.24	$ 0.58
Net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ 0.54
Weighted-average common shares, basic	25,684,593	25,412,636	17,651,668
Weighted-average common shares, diluted	25,684,593	26,036,544	18,776,588

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders Equity
	Shares	Amount			
Balance as of December 31, 2008	12,023,747	$ 12	$ 33,519	$ (4,105)	$ 29,426
Issuance of shares for acquisition of product rights	12,172,425	12	119,271		119,283
Cash settlement of common stock warrants			(41)		(41)
Stock-based compensation			3,291		3,291
Issuance of common stock to employees under stock incentive plan	826,472	1	436		437
Tax effect of stock-based awards			1,269		1,269
Net income				10,203	10,203
Balance as of December 31, 2009	25,022,644	$ 25	$ 157,745	$ 6,098	$ 163,868
Stock-based compensation			1,339		1,339
Issuance of common stock to employees under stock incentive plan	450,319		544		544
Tax effect of stock-based awards			478		478
Net income				6,169	6,169
Balance as of December 31, 2010	25,472,963	$ 25	$ 160,106	$ 12,267	$ 172,398
Stock-based compensation			2,207		2,207
Issuance of common stock to employees under stock incentive plan	330,901	1	368		369
Tax effect of stock-based awards			522		522
Net loss				(693)	(693)
Balance as of December 31, 2011	25,803,864	$ 26	$ 163,203	$ 11,574	$ 174,803

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2011	**2010**	**2009**
Cash flows from operating activities			
Net (loss) income	$ (693)	$ 6,169	$ 10,203
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Amortization and depreciation	14,896	14,778	6,392
Provision for prompt payment discounts	3,448	3,903	3,157
Provision for inventory allowances	209	1,340	1,474
Loss on sale of property and equipment		25	
Impairment of product rights	2,500	350	
Stock-based compensation	2,207	1,339	3,291
Provision for deferred income taxes	(388)	(2,977)	(3,632)
Changes in operating assets and liabilities:			
Accounts receivable	61,134	(63,831)	(6,718)
Inventories	5,546	1,592	(8,202)
Prepaid expenses, long-term accounts receivable and other assets	8,528	(8,743)	(3,121)
Accounts payable	(627)	499	(3,116)
Accrued expenses and license agreement liability	(15,119)	23,154	2,053
Income taxes payable/receivable	(1,703)	(1,803)	(1,331)
Deferred revenue	(55,766)	57,194	
Net cash provided by operating activities	24,172	32,989	450
Cash flows from investing activities			
Proceeds from sale of marketable securities			300
Proceeds from sale of property and equipment		2	
Purchase of property and equipment	(616)	(375)	(635)
Purchase of product rights		(250)	(5,169)
Net cash used in investing activities	(616)	(623)	(5,504)
Cash flows from financing activities			
Proceeds from issuance of shares of common stock			15,465
Proceeds from exercise of common stock options	369	544	437
Payments for cancellation of warrants			(41)
Excess tax benefit from stock-based compensation	522	478	1,269
Principal payments on license agreement liability	(1,341)	(1,250)	(2,500)
Principal payments on capital lease obligation	(83)	(46)	(9)
Net cash (used in) provided by financing activities	(533)	(274)	14,621
Net increase in cash and cash equivalents	23,023	32,092	9,567
Cash and cash equivalents as of beginning of year	50,945	18,853	9,286
Cash and cash equivalents as of end of year	$ 73,968	$ 50,945	$ 18,853
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 177	$ 318	$ 531
Cash paid during the year for income taxes	$ 1,379	$ 6,780	$ 9,260

Supplemental schedule of non-cash investing and financing activities			
Purchase of property and equipment with capital leases	$	$ 226	$
Acquisition of product rights through equity issued and liabilities assumed	$	$	$ 110,050
In connection with the acquisition of Cardiokine, Inc., liabilities were assumed as follows:			
Fair value of assets acquired	$ 7,669	$	$
Acquired in-process research and development	$ 11,500	$	$
Acquisition-related contingent liability	$ (8,800)	$	$
Other liabilities assumed	$ (10,369)	$	$

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Nature of Operations

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on commercializing products for the hospital, niche respiratory and related specialty markets. Key elements of the Company s strategy are to focus its commercial and internal development efforts in the hospital and related specialty product sector within the U.S. pharmaceutical marketplace; continue to seek out opportunities to acquire companies and marketed and/or registration-stage products that fit within the Company s focus areas; and generate revenues by marketing approved generic products through the Company s wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc. and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

Royalties previously classified separately are included in cost of product sales in the accompanying consolidated statements of operations. This reclassification had no effect on net income as previously reported. Additionally, certain tax accounts for 2010 have been reclassified to conform to the 2011 presentation. Such reclassifications had no effect on net income or stockholders equity as previously reported.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States 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 reporting period. The more significant estimates reflected in the Company s consolidated financial statements include certain judgments regarding revenue recognition, goodwill, product rights, acquisitions, inventory and stock-based compensation. Actual results could differ from those estimates or assumptions.

Segment and Geographic Information

The Company operates in a single industry and operating segment which acquires, develops and commercializes prescription pharmaceutical drugs used in the treatment of a variety of respiratory-related diseases. Accordingly, our business is classified as a single reportable segment.

The majority of the Company s revenues are generated in the United States, with approximately $46,000 of royalty revenue originating internationally under the Company s royalty agreement with Pfizer, S.A. de C.V. As of December 31, 2011, 99% of the Company s total assets are located in the United States. The remaining 1% of the Company s assets consisted of inventory on hand at international locations.

Concentrations of Credit Risk and Limited Suppliers

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents and accounts receivable. The Company s cash and cash equivalents are maintained with four financial institutions.

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The Company relies on certain materials used in its development and third-party manufacturing processes, most of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from any of these sources could have a material adverse effect on the Company s business, financial position and results of operations. During 2011, one supplier individually represented 78% of the Company s total inventory purchases for the year. Amounts due to this supplier represented approximately 14% of total accounts payable as of December 31, 2011. During the year ended December 31, 2010, one supplier individually represented 71% of the Company s total inventory purchases for the year. Amounts due to this supplier represented approximately 28% of total accounts payable as of December 31, 2010.

The Company sells its products primarily to large national wholesalers, which in turn may resell the products to smaller or regional wholesalers, hospitals, retail pharmacies, chain drug stores, government agencies and other third parties. The following tables list the Company s customers that individually comprise greater than 10% of total gross product sales for the years ended December 31, 2011, 2010 and 2009 or 10% of total accounts receivable as of December 31, 2011 and 2010:

	Year Ended December 31,			December 31,	
	2011 Gross Product Sales	2010 Gross Product Sales	2009 Gross Product Sales	2011 Accounts Receivable	2010 Accounts Receivable
Cardinal Health	39%	43%	34%	52%	50%
McKesson Corporation	34%	29%	34%	22%	30%
Amerisource Bergen Corporation	21%	22%	20%	21%	15%
Total	94%	94%	88%	95%	95%

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains its cash deposits with federally insured banks. As of December 31, 2011, all cash deposits were federally insured.

Accounts Receivable

The Company typically requires its customers to remit payments within the first 30 to 90 days, depending on the customer and the products purchased. In addition, 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 or customer and/or industry expectations. 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 sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of December 31, 2011 or 2010. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs during the years ending December 31, 2011, 2010 or 2009.

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The following table represents accounts receivable, net as of December 31 (in thousands):

	2011	2010
Accounts receivable	$ 12,479	$ 78,491
Less allowance for prompt payment discounts	(585)	(2,015)
Accounts receivable, net	$ 11,894	$ 76,476

In December 2010, the Company sold its remaining inventories of its marketed unapproved products, which include ALLERX® and HYOMAX®, primarily to national wholesalers. In connection with certain of these sales, the Company offered various extended payment terms, some of which extended through June 2012. Accordingly, the Company had accounts receivable of $1.4 million and $70.1 million, of which $7.9 million was classified as long-term accounts receivable, relating to such sales in the accompanying consolidated balance sheets as of December 31, 2011 and 2010, respectively.

Inventories

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method and consist of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales.

The following table represents inventories, net as of December 31 (in thousands):

		2011	2010
Raw materials		$ 2,791	$ 5,542
Work in process		1,663	1,575
Finished goods:			
Pharmaceutical products	trade	4,566	8,635
Pharmaceutical products	samples	849	1,267
Total		9,869	17,019
Inventory allowances		(450)	(1,845)
Inventories, net		$ 9,419	$ 15,174

Property and Equipment

The Company records property and equipment at cost. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred. The Company depreciates its property and equipment over the estimated useful lives of the assets ranging from three to seven years using the straight-line method. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lives of the underlying leases, whichever is shorter. Amortization expense for leasehold improvements has been included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

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The following table represents property and equipment as of December 31 (in thousands):

	Useful Life (Years)	2011	2010
Computers and software	3	$ 1,568	$ 995
Machinery and equipment	5	287	287
Furniture and fixtures	5-7	919	905
Leasehold improvements	Lesser of lease term or 5	132	127
Construction in progress	n/a	24	
Total		2,930	2,314
Less accumulated depreciation		(1,356)	(828)
Property and equipment, net		$ 1,574	$ 1,486

Depreciation expense, including depreciation related to assets acquired by capital lease, for the years ended December 31, 2011, 2010 and 2009 was $528,000, $400,000 and $277,000, respectively, and is included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Product Rights

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once Food and Drug Administration (FDA) approval has been obtained and commercialization of the product begins, which is expected to be shortly after regulatory approval. The Company evaluates its product rights annually to determine whether a revision to their useful lives should be made. This evaluation is based on management s projection of the future cash flows associated with the products.

In-Process Research and Development (IPR&D)

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized. The fair value of an IPR&D intangible asset is determined using an income approach. This approach starts with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. The net cash flows reflect the asset s stage of completion, the probability of technical success, the projected costs to complete, expected market competition and an assessment of the asset s life cycle. The net cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. The Company s acquired IPR&D is classified as product rights on the accompanying consolidated balance sheets.

Impairment of Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets, including property and equipment and identifiable intangible assets on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any write-downs are recorded as permanent reductions in the carrying amount of the assets. During the year ended December 31, 2011, the Company focused its product development projects to align with its strategic direction. This decision resulted in the write-off $2.5 million of capitalized product rights that no longer align with its strategic direction. This write-off is included in amortization expense in the accompanying consolidated statements of operations. No portion of the impairment charge will result in future cash expenditures.

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The Company does not amortize goodwill or purchased intangible assets (if any) with indefinite lives. Goodwill and purchased intangibles with indefinite lives are reviewed periodically for impairment. The Company performs an annual evaluation of goodwill as of October 1 of each fiscal year to test for impairment and more frequently if events or circumstances indicate that goodwill may be impaired. The Company has one operating segment which represents the Company s sole reporting unit for evaluation of goodwill.

The Company elected to early adopt the Financial Accounting Standards Board s (FASB) Accounting Standards Update No. 2011-08 (ASU No. 2011-08), which allows a company to first assess qualitative factors to determine if it is necessary to perform the two-step quantitative goodwill impairment test. The Company assesses qualitative factors to determine if its sole reporting unit s fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit s fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. Quantitative testing compares the fair value of the reporting unit to its book value, including goodwill. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded. Other than the write-off of product rights discussed above, there was no impairment of goodwill or other intangible assets for the years ended December 31, 2011, 2010 and 2009.

Revenue Recognition

The Company s consolidated net revenues represent the Company s net product sales and license and royalty agreement revenues. The following table sets forth the categories of the Company s net revenues (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Gross product sales	$ 165,383	$ 187,856	$ 148,652
Sales allowances	(64,082)	(64,112)	(39,364)
Net product sales	101,301	123,744	109,288
License and royalty agreement revenues	121	1,573	276
Net revenues	$ 101,422	$ 125,317	$ 109,564

The Company records all of its revenue from product sales, license agreements and royalty 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.

Net Product Sales

Product Sales. The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated.

As of December 31, 2011 and 2010, the Company had $1.4 million and $57.2 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying consolidated balance sheets as of December 31, 2011 and 2010.

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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 that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company s products have an 18- to 48-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 actual and historical return rates for expired lots, historical and forecasted product sales and consumer consumption data reported by external information management companies, estimated expiration dates or remaining shelf life of inventory in the distribution channel, estimates of inventory levels of its products in the distribution channel and any significant changes to these levels, and competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve through charges to income in the period in which the information that gives rise to the adjustment becomes known.

Rebates. The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

Price Adjustments and Chargebacks. The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. These estimates are also based on the contract fees the Company pays to certain group purchasing organizations (GPOs) in connection with the Company s sales of CUROSURF®. In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from the Company s estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

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. The Company has initiated voucher programs for its branded products whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts. The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 90 days after the invoice date depending on the customer and the products purchased (see Accounts Receivable above).

License and Royalty Agreement Revenues

Payments from the Company s licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. If the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company s licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

License agreement revenues were $75,000 and $1.5 million in 2011 and 2010, respectively. There was no license agreement revenue in 2009. In August 2010, in accordance with a license agreement with Targacept, Inc. (Targacept) under which the Company out-licensed certain rights with respect to its alpha-7 receptor technology, the Company received a one-time, upfront, nonrefundable payment of $1.5 million. The Company does not have any continuing performance obligations related to the agreement and is also eligible for success-based milestone payments of up to $74.9 million, depending on which compound is progressed by Targacept.

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Royalty agreement revenues are earned under license agreements which provide for the payment of royalties based on sales of certain licensed products. These revenues are recognized based on product sales that occurred in the relevant period. Royalty agreement revenues were $46,000, $73,000 and $276,000 in 2011, 2010 and 2009, respectively.

Research and Development

Research and development expenses consist of product development expenses incurred in identifying, developing and testing product candidates. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; expenses incurred under joint development agreements; regulatory costs; costs of contract research and manufacturing; and the cost of facilities used by the Company s product development personnel.

Product development expenses are expensed as incurred and reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which the Company has discontinued development. Additionally, product development expenses include the cost of qualifying new current Good Manufacturing Practice (cGMP) third-party manufacturers for the Company s products, including expenses associated with any related technology transfer. All indirect costs (such as salaries, benefits or other costs related to the Company s accounting, legal, human resources, purchasing, information technology and other general corporate functions) associated with individual product candidates are included in general and administrative expenses.

Advertising

Advertising costs, which include promotional expenses and the cost of samples, are expensed as incurred. Advertising expenses were $4.2 million, $8.2 million and $5.6 million for the years ended December 31, 2011, 2010 and 2009, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Shipping and Handling Costs

The Company includes shipping and handling costs within cost of product sales. Shipping and handling costs were $1.1 million, $1.2 million and $1.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

Stock-Based Compensation

The Company measures compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes-Merton option-pricing model. Compensation expense is recognized on a straight-line basis over the service period for awards expected to vest. Stock-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of the Company s stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

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Net deferred tax assets are recognized to the extent the Company s management believes these assets will more likely than not be realized. In making such determination, management considers all positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management periodically reviews its deferred tax assets for recoverability and its estimates and judgments in assessing the need for a valuation allowance.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

Fair Value of Financial Instruments

The estimated fair values of the Company s financial instruments, including its cash and cash equivalents, receivables, accounts payable and license agreement liability, approximate the carrying values of these instruments because they approximate the amounts for which the assets could be sold and the liabilities could be settled.

NOTE 3: ACQUISITION OF CARDIOKINE, INC.

Description of Transaction

On December 30, 2011, the Company acquired Cardiokine, Inc. (Cardiokine), a specialty pharmaceutical company focused on developing hospital products for cardiovascular indications. The Company acquired Cardiokine primarily to obtain Cardiokine s pending new drug application (NDA) for a lixivaptan compound to be used, if approved, to treat hyponatremia. In connection with the transaction, Cardiokine s stockholders received Cardiokine s cash on hand at closing, less the amount of a $2.7 million escrow fund established by Cardiokine out of its cash on hand to secure the Company s indemnification rights pursuant to the merger agreement, and the Company assumed approximately $2.0 million of Cardiokine s current liabilities. In addition, the Company agreed to pay consideration consisting of each of the following: (1) $1.0 million paid shortly following closing; (2) either $7.0 million or $8.5 million if Cardiokine s pending NDA for its lixivaptan compound, CRTX 080, is approved for sale by the FDA; (3) up to $147.5 million based on the achievement of certain sales related milestones ($7.5 million at $75 million, $15 million at $150 million, $25 million at $250 million and $100 million at $500 million, each payable at the first time the annual sales reach the relevant milestone); (4) quarterly earnout payments of 8% or 12% of net sales of the approved product, with such rate being dependent upon the scope of the labeling which the FDA may approve for the product; and (5) one-half of any proceeds realized from the license of the approved product outside the United States (collectively, the Purchase Consideration). The Purchase Consideration will be paid first to a subsidiary of Pfizer Inc. (Pfizer), the licensor of certain rights to the lixivaptan compound, in satisfaction of Cardiokine s payment obligations to Pfizer, until Pfizer has been paid a total of $20,000,000. Thereafter, any further Purchase Consideration will be paid in accordance with the merger agreement to certain other parties for which obligations existed and then directly to Cardiokine s former stockholders.

Basis of Presentation

The transaction has been accounted for as a business combination under the acquisition method of accounting, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred.

Fair Value of Consideration Transferred

A summary of the purchase price is as follows (in thousands):

Cash consideration payable	$ 1,000
Contingent consideration	8,800
Total fair value of consideration	$ 9,800

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Assets Acquired and Liabilities Assumed

The total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of Cardiokine based on their estimated fair values as of December 30, 2011. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

The allocation of the total fair value of consideration transferred, as shown above, to the acquired tangible and intangible assets and assumed liabilities of Cardiokine based on their estimated fair values as of the closing date of the transaction is as follows (in thousands):

Prepaid and other assets	5,682
Acquired in-process research and development	11,500
Contingent liability	(8,800)
Assumed liabilities	(9,369)
Total identifiable net assets	$ (987)
Goodwill	1,987
Total cash consideration payable	$ 1,000

Prepaid and other assets consist primarily of an anticipated income tax refund of $5.6 million related to NOL carryback claims and Cardiokine s 2011 final tax return. The refund is classified in other current assets offset by a liability to Cardiokine s former stockholders classified in accrued expenses on the accompanying consolidated balance sheet as of December 31, 2011.

The estimated fair value of in-process research and development related to the development program for lixivaptan, or CRTX 080, was determined using the excess-earning method under the income approach. Projected cash flows from the anticipated sales of the product were adjusted for the probabilities of approved labeling and commercialization of the product. A discount rate of 19.0% was used to determine the present value of the projected cash flows.

At the closing of the acquisition, the Company recorded an $8.8 million contingent liability for contingent consideration potentially payable under the merger agreement. The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments. These cash flows were then discounted to present value using a discount rate of 21.5%. The liability will be periodically assessed based on events and circumstances related to the underlying milestones, and any change will be recorded in the Company s consolidated statement of operations. The carrying amount of the liability may fluctuate significantly and actual amounts paid to Pfizer may be materially different from the carrying value of the liability. The fair value of the liability at December 30, 2011 was $8.8 million.

Goodwill is calculated as the difference between the fair value of the consideration and the provisional values assigned to the assets acquired and liabilities assumed. None of the goodwill is expected to be deductible for tax purposes.

The Company incurred approximately $400,000 of transaction-related costs related to the acquisition of Cardiokine, which include legal, valuation and accounting services. These costs were expensed as incurred and are included in selling, general and administrative expenses on the accompanying consolidated statements of operations.

Actual and Pro Forma Impact of the Transaction (Unaudited)

The results of operations of Cardiokine are included in the Company s consolidated financial statements from the closing date of December 30, 2011. The following table presents pro forma results of operations and gives effect to the transaction as if the transaction had been consummated at the beginning of the period presented (in thousands, except per share data). The unaudited pro forma results of operations are not necessarily

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indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies.

	Year Ended December 31,	
	2011	2010
	(Unaudited)	
Net revenues	$ 101,422	$ 224,445
Net (loss) income	$ (16,988)	$ 51,190
Net (loss) income per share, basic	$ (0.66)	$ 2.01
Net (loss) income per share, diluted	$ (0.66)	$ 1.97

NOTE 4: GOODWILL AND PRODUCT RIGHTS

Goodwill

The Company s goodwill balance was $15.2 million and $13.2 million as of December 31, 2011 and 2010, respectively. Of the goodwill balance at December 31, 2011, $13.2 million related to the October 31, 2008 merger whereby the Company, which was then known as Critical Therapeutics, Inc. (Critical Therapeutics), merged (through a transitory subsidiary) with Cornerstone BioPharma Holdings, Inc., which was deemed to be the acquiring company for accounting purposes (the Merger) and the remaining $2.0 million related to the December 30, 2011 acquisition of Cardiokine. No amount of the goodwill balance at December 31, 2011 will be deductible for income tax purposes.

Product Rights

The following tables represent product rights, net as of December 31 (in thousands):

	December 31, 2011			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 25,109	$ 82,497	10.0
FACTIVE®	7,613	3,636	3,977	0.5
SPECTRACEF®	4,505	2,437	2,068	0.5
ZYFLO®	11,500	5,082	6,418	7.1
CRTX 080	11,500		11,500	n/a
CRTX 067	500		500	n/a
Other	75	75		n/a
Total	$ 143,299	$ 36,339	$ 106,960	8.9

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	December 31, 2010			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 14,347	$ 93,259	10.0
FACTIVE	7,613	2,061	5,552	4.8
SPECTRACEF	4,505	2,017	2,488	10.0
ZYFLO	11,500	3,477	8,023	7.1
Products under development	3,000		3,000	n/a
Other	75	69	6	4.3
Total	$ 134,299	$ 21,971	$ 112,328	9.5

During 2011, the market for branded anti-infectives continued to decline due to the increased presence of generic products. As such, the Company reevaluated its forecast for its anti-infective products, FACTIVE and SPECTRACEF, and projected that sales of these products would decline significantly as the Company continues to deemphasize these products in connection with its transition away from a primary-care focus. The Company reviewed the product rights associated with FACTIVE and SPECTRACEF for impairment as of December 31, 2011 and determined that no impairment was necessary. However, the Company reduced the useful lives of these product rights to six months as of December 31, 2011 based on its estimate of the period during which it expects to continue to benefit from these rights pending its evaluation and execution of strategic options for its anti-infective products.

During the second quarter of 2011, the Company focused its product development projects to align with its strategic direction. This decision resulted in the write-off $2.5 million of capitalized product rights that no longer align with its strategic direction. This write-off is included in amortization expense in the accompanying consolidated statements of operations for the year ended December 31, 2011.

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which range from six months to ten years. As of December 31, 2011, the Company had $12.0 million of product rights related to its product candidates, CRTX 067 and CRTX 080, which it expects to launch in the future. The Company expects to begin amortization upon the commercial launch of these products, which is expected to be shortly after regulatory approval. The rights will be amortized over the product candidates estimated useful lives.

During the fourth quarter of 2010, the Company wrote off fully amortized product rights of $7.6 million related to its propoxyphene/acetaminophen products in connection with the removal of these products from market. In addition, the Company wrote-off $350,000 of capitalized product rights related to a product it no longer expects to launch in the future. The write-off of $350,000 is included in amortization expense in the accompanying consolidated statement of operations for the year ended December 31, 2010.

Amortization expense for the years ended December 31, 2011, 2010 and 2009 was $16.9 million, $14.7 million and $6.1 million, respectively.

Future estimated amortization expense (excluding the rights related to products expected to be launched) subsequent to December 31, 2011 is as follows (in thousands):

2012	$ 18,410
2013	12,365
2014	12,365
2015	12,365
2016	10,761
Thereafter	28,694
	$ 94,960

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NOTE 5: ACCRUED EXPENSES

The following table represents accrued expenses as of December 31 (in thousands):

	2011	2010
Accrued product returns	$ 13,211	$ 15,025
Accrued rebates	2,634	3,034
Accrued price adjustments and chargebacks	9,159	21,520
Accrued compensation and benefits	2,559	2,760
Accrued royalties	3,046	3,303
Accrued taxes	5,668	32
Accrued expenses, other	848	925
Total accrued expenses	$ 37,125	$ 46,599

In December 2010, the Company sold its remaining inventories of its marketed unapproved products, which include ALLERX and HYOMAX, primarily to national wholesalers. As of December 31, 2011 and 2010, the Company had $1.4 million and $57.2 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. Deferred revenue was recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances on these deferred sales were recorded and classified as accrued expenses as of December 31, 2011 and 2010.

NOTE 6: LICENSE AGREEMENT LIABILITY

Meiji

On October 12, 2006, the Company entered into a license and supply agreement with Meiji Seika Kaisha, Ltd. (Meiji) granting the Company an exclusive, nonassignable U.S. license to manufacture and sell a 200 mg dosage of SPECTRACEF, using cefditoren pivoxil supplied by Meiji (SPECTRACEF 200 mg). In consideration for the license, the Company agreed to pay Meiji a nonrefundable license fee of $6.0 million in six installments over a period of five years from the date of the agreement. The agreement provided that if a generic cefditoren product was launched in the United States prior to October 12, 2011, the Company would be released from its obligation to make any further license fee payments due after the date of launch. In the year ended December 31, 2006, the Company estimated that a generic cefditoren product would be available in two and a half years, which would limit the total installment payments to $2.25 million.

On July 27, 2007, the Company entered into an amendment to the license and supply agreement and a letter agreement supplementing the Meiji license and supply agreement. The amendment to the license and supply agreement extended the Company s rights under the agreement to additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are jointly developed by Meiji and the Company and which Meiji and the Company agree to have covered by the agreement. The letter agreement provides that if the Company successfully launches a 400 mg product (SPECTRACEF 400 mg), a once-daily product and/or a pediatric product and sales of these products substantially lessen a generic product s adverse effect on SPECTRACEF sales, the Company will be required to continue paying Meiji a reasonable amount of the license fee as mutually agreed by the parties. Therefore in the year ended December 31, 2007, the Company revised its estimate of payments to include the full $6.0 million in installments over five years commencing in October 2006. As of December 31, 2011, the Company has made all such license payments to Meiji.

The license and supply agreement also requires the Company to make quarterly royalty payments based on the net sales of the cefditoren pivoxil products covered by the agreement. The Company is required to make these payments for a period of ten years from the date it launches a particular product.

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The license agreement liability (excluding royalties) related to the above agreements consisted of the following as of December 31 (in thousands):

	2011	2010
License agreement liability to Meiji; imputed interest at 12% per annum; principal and interest payable		1,368
Less current portion		(1,368)
Long-term	$	$

The remaining principal of the license agreement liability of $1.3 million matured and was paid in October 2011.

NOTE 7: STOCKHOLDERS EQUITY

Authorized Capital

As of December 31, 2011, the authorized capital stock of the Company consisted of 90,000,000 shares of voting common stock with a par value of $0.001 per share and 5,000,000 shares of undesignated preferred stock with a par value of $0.001 per share. The common stock holders are entitled to one vote per share. The rights and preferences of the preferred stock may be established from time to time by the Company s Board of Directors.

Warrants to Purchase Common Stock

In June 2005, the Company issued two warrants to purchase 2,380 shares each of common stock at $0.43 per share in exchange for services. The warrants were valued at $2,000 and were exercisable for a ten-year period from the date of grant. The fair value of the warrants granted was estimated on the date of grant using the Black-Scholes-Merton pricing model with the following assumptions: dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 3.91% and expected life of ten years. These warrants were settled in cash for approximately $42,000 during the year ended December 31, 2009.

In connection with the Merger, the Company assumed, for financial reporting purposes, warrants to purchase the Company s common stock from Critical Therapeutics. These warrants were originally issued by Critical Therapeutics in June 2005 and October 2006, and were fully vested prior to the closing of the Merger. The warrants issued in June 2005 were exercisable for up to 348,084 shares of the Company s common stock, had an exercise price of $65.80 per share, contained a cashless exercise feature and expired in June 2010. None of these warrants were exercised. The warrants issued in October 2006 were exercisable for up to 372,787 shares of the Company s common stock, had an exercise price of $26.20 per share and expired in October 2011. None of these warrants were exercised.

NOTE 8: STOCK-BASED COMPENSATION

Overview of Stock-Based Compensation Plans

2000 Equity Plan and 2003 Stock Incentive Plan Assumed from Critical Therapeutics in the Merger

In connection with the Merger, the Company assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2000 Equity Incentive Plan (the 2000 Equity Plan) and the Critical Therapeutics, Inc. 2003 Stock Incentive Plan (the 2003 Stock Incentive Plan). The Company terminated the 2000 Equity Plan on March 3, 2010, as there were no outstanding awards or shares available for issuance under that plan. As of December 31, 2011, there were 159,066 shares of common stock authorized and no shares of common stock available for award under the 2003 Stock Incentive Plan.

2004 Stock Incentive Plan Assumed from Critical Therapeutics in the Merger

In connection with the Merger, the Company also assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2004 Stock Incentive Plan, as amended (the 2004 Stock Incentive Plan). The 2004 Stock

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Incentive Plan provides for the award to the Company s employees, directors and consultants of shares of common stock to be granted through incentive and nonstatutory stock options, restricted stock and other stock-based awards.

The exercise price of stock options granted under the 2004 Stock Incentive Plan is determined by the compensation committee of the Company s Board of Directors and may be equal to or greater than the fair market value of the Company s common stock on the date the option is granted. Equity awards granted under the 2004 Stock Incentive Plan generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date. As of December 31, 2011, there were 3,233,922 shares of common stock authorized, and 1,052,209 shares available for award, under the 2004 Stock Incentive Plan.

The 2004 Stock Incentive Plan provides for an annual increase in the number of shares authorized for award under the plan, if approved by the Company s Board of Directors. This increase, if approved, is effective on January 1 of each year and may not exceed the lesser of 4% of the Company s outstanding shares on the effective date of the increase or 133,333 shares. The Company s Board of Directors authorized an annual increase to be effective as of January 1, 2012.

2005 Stock Option Plan and 2005 Stock Incentive Plan

In May 2005, the Company adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (the 2005 Stock Option Plan), which provided for the award to the Company s employees, directors and consultants of up to 2,380,778 shares of common stock through incentive and nonstatutory stock options. In December 2005, the Company adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (the 2005 Stock Incentive Plan, and together with the 2005 Stock Option Plan, the 2005 Plans), which provided for the award to the Company s employees, directors and consultants of up to 2,380,778 shares of common stock through incentive and nonstatutory stock options, restricted stock and other stock-based awards. Following the adoption of the 2005 Stock Incentive Plan, no further awards were made under the 2005 Stock Option Plan.

Cornerstone BioPharma s Board of Directors determined the terms and grant dates of all equity awards issued under the 2005 Plans and the underlying fair market value of Cornerstone BioPharma s common stock covered by such awards. Under the 2005 Plans, equity awards generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date.

Prior to the closing of the Merger, the Company made equity awards totaling 88,949 and 2,380,778 shares under the 2005 Stock Option Plan and the 2005 Stock Incentive Plan, respectively, that had not been returned to the applicable plan.

On October 31, 2008, in connection with the Merger, Cornerstone BioPharma s Board of Directors amended and restated the 2005 Stock Option Plan to reduce the number of awards available for issuance under the plan to 88,949, which equaled the number of awards previously granted under and not returned to the plan. In addition, Cornerstone BioPharma s board also amended each of the 2005 Plans to provide that no shares of common stock corresponding to terminated awards will be returned to the 2005 Plans. Accordingly, as of December 31, 2011, there were no shares available for award under the 2005 Plans.

Stock Options

The Company 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.

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

	Year Ended December 31,		
	2011	2010	2009
Estimated dividend yield	0.0%	0.0%	0.0%
Expected stock price volatility	80%	80-85%	75%
Risk-free interest rate	0.79% - 2.24%	1.73% - 2.60%	2.31% - 2.85%
Expected life of option (in years)	5.00	5.00	4.84
Weighted-average grant date fair value per share	$ 3.87	$ 3.57	$ 4.85

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. The expected stock price volatility was based on the Company s historical volatility for the five year period preceding the grant date. 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 was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

The following table summarizes the Company s stock option activity during 2011 under all of the Company s stock-based compensation plans:

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2011	2,198,541	$ 4.15		
Granted	809,597	$ 5.99		
Exercised	(273,181)	$ 1.35		
Forfeited	(146,841)	$ 5.41		
Expired	(35,269)	$ 13.88		
Outstanding at December 31, 2011	2,552,847	$ 4.82	6.89	$ 3,275
Vested or expected to vest at December 31, 2011	2,495,788	$ 4.80	6.84	$ 3,264
Exercisable December 31, 2011	1,441,197	$ 3.91	5.41	$ 3,054

The total intrinsic value of options exercised during 2011, 2010 and 2009 was $1.6 million, $1.7 million and $2.6 million, respectively. As of December 31, 2011, there was approximately $3.6 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.52 years.

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The following table summarizes information about the Company s stock options outstanding as of December 31, 2011:

	Outstanding			Exercisable	
Exercise Price	Number of Options Outstanding	Weighted-Average Contractual Life Outstanding (In Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
$0.43-$1.77	599,014	3.34	$ 1.56	599,014	$ 1.56
$2.02-$5.25	667,610	7.71	4.51	289,625	3.62
$5.26-$5.88	513,659	8.02	5.39	190,556	5.28
$5.97-$7.88	651,322	8.28	6.86	297,434	6.84
$7.89-$55.20	121,242	7.79	9.32	64,568	9.52
	2,552,847	6.89	4.82	1,441,197	3.91

Restricted Stock

The Company also made restricted stock grants to certain employees under the 2004 Stock Incentive Plan during 2011 and 2009.

The following table summarizes the Company s restricted stock activity during 2011:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested January 1, 2011	172,500	$ 6.38
Granted	105,000	6.47
Vested	(57,720)	6.37
Forfeited		
Unvested December 31, 2011	219,780	$ 6.42

The fair value of restricted stock that vested during the year ended December 31, 2011, 2010 and 2009 was $417,000, $242,000, and $3.1 million respectively. As of December 31, 2011, there was approximately $1.2 million of total unrecognized compensation cost related to unvested restricted stock issued under the Company s equity compensation plans, which is expected to be recognized over a weighted-average period of 2.45 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately $2.2 million, $1.3 million and $3.3 million for the years ended December 31, 2011, 2010 and 2009, respectively. As a result of the strategic transaction with Chiesi Farmaceutici S.p.A. (Chiesi) in 2009, the vesting of 1,145,145 stock options and 342,633 shares of restricted stock accelerated. During the year ended December 31, 2009, the Company incurred additional stock-based compensation expense of approximately $1.8 million related to the acceleration of these stock options and shares of restricted stock, which is included in the total stock-based compensation expense of $3.3 million.

NOTE 9: EMPLOYEE BENEFIT PLANS

The Company established a qualified 401(k) plan (the Cornerstone Plan), effective January 1, 2005, covering all employees who are at least 21 years of age. The Company s employees may elect to make contributions to the plan within statutory and plan limits, and the Company may

elect to make matching or voluntary contributions. The Company began contributing to the 401(k) Plan during 2011 and made a total of $85,000 in contributions for the year ended December 31, 2011. The Company s contributions vest in four equal

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installments on each of the four anniversaries following the later of the start date of the match or the employee s date of participation in the Cornerstone Plan. Expenses related to the plan were insignificant during the years ended December 31, 2011, 2010 and 2009.

NOTE 10: COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes lease expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Lease expense was $1.1 million, $1.4 million and $1.0 million for the years ended December 31, 2011, 2010 and 2009, respectively.

Future minimum aggregate payments under non-cancelable lease obligations as of December 31, 2011 are as follows (in thousands):

Year Ending	Operating Leases
2012	$ 570
2013	556
2014	584
2015	599
2016	152
Thereafter	
Total minimum lease payments	$ 2,461

Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $3.2 million as of December 31, 2011, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management s estimates. As of December 31, 2011, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $15.3 million.

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or current licensors of certain product rights that have been acquired by or licensed to the Company. These royalties are typically based on a percentage of net sales of the particular licensed product and are included in cost of product sales in the consolidated statements of operations. For the years ended December 31, 2011, 2010 and 2009, total royalty expenses were $7.5 million, $12.7 million and $18.8 million, respectively.

Collaboration Agreements

The Company is committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. The Company may be required to make $38.4 million in additional payments to various parties if all milestones under the agreements are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on the accompanying consolidated balance sheets. The Company is also

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obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

In addition, upon closing of our acquisition of Cardiokine, we recorded an $8.8 million contingent liability for contingent consideration potentially payable under the merger agreement. The merger agreement stipulates that amounts payable of either $7.0 million or $8.5 million will be payable if Cardiokine s pending NDA for its lixivaptan compound, CRTX 080, is approved for sale by the FDA and up to an additional $147.5 million based on the achievement of certain sales related milestones ($7.5 million at $75 million, $15 million at $150 million, $25 million at $250 million and $100 million at $500 million, each payable at the first time the annual sales reach the relevant milestone). The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments discounted to present value using a discount rate of 21.5%. The liability will be periodically assessed based on events and circumstances related to the underlying milestones, and any change in fair value will be recorded in the Company s consolidated statement of operations. The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

As of December 31, 2011, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $3.1 million.

Co-Promotion and Marketing Services Agreements

The Company has entered into a co-promotion and marketing service agreement and a co-promotion agreement that grant third parties the exclusive rights to promote and sell certain products in conjunction with the Company. Under these agreements, the third parties are responsible for the costs associated with their sales representatives and the product samples distributed by their sales representatives, as well as certain other promotional expenses related to the products. Under one agreement, the Company pays the third party co-promotion fees equal to the ratio of total prescriptions written by pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of the products covered by the agreement, after third-party royalties. Under the other agreement, the Company pays the third parties fees based on a percentage of the net profits from sales of the product above a specified baseline within assigned sales territories. The co-promotion agreement is also subject to sunset fees that require the Company to pay additional fees for up to three months in the event of certain defined terminations of this agreement.

As of December 31, 2011, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.2 million.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. As of December 31, 2011, the Company had $14,000 recorded as accrued severance related to the departure of one of its executive officers.

Legal Proceedings

The Company is involved in lawsuits, claims, investigations and proceedings related to its business. There are no matters pending that the Company currently believes are reasonably possible of having a material impact to our business, consolidated financial condition, results of operations or cash flows.

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NOTE 11: INCOME TAXES

The components of the (benefit from) provision for income taxes are as follows for the years ending December 31, (in thousands):

	2011	2010	2009
Current:			
Federal	$ (278)	$ 4,340	$ 8,400
State	(6)	246	779
Total	(284)	4,586	9,179
Deferred:			
Federal	(398)	(2,793)	(3,164)
State	10	(184)	(468)
Total	(388)	(2,977)	(3,632)
Total tax (benefit) provision	$ (672)	$ 1,609	$ 5,547

The significant components of the Company s deferred tax assets and liabilities consisted of the following as of December 31 (in thousands):

	2011	2010
Current:		
Deferred tax assets:		
Accounts receivable, net	$ 216	$ 752
Inventories, net	301	1,223
Accrued expenses	5,051	5,605
Valuation allowance	(4,959)	(6,555)
Total current deferred tax assets	609	1,025
Deferred tax liabilities:		
Acquired intellectual property	(607)	(981)
Net current deferred tax assets	$ 2	$ 44
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	$ 61,154	$ 60,966
Tax credits	4,643	1,900
Stock-based compensation	1,276	974
Product license rights, net	359	1,263
Valuation allowance	(60,005)	(56,311)
Total noncurrent deferred tax assets	7,427	8,792
Deferred tax liabilities:		
Acquired intellectual property	(6,433)	(6,500)
Property and equipment, net	(471)	(416)
Total noncurrent deferred tax liabilities	(6,904)	(6,916)

Net deferred tax asset noncurrent	523	1,876
Total net deferred tax asset	$ 525	$ 1,920

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As of December 31, 2011 and 2010, the Company has provided a valuation allowance for its gross deferred tax assets acquired as a result of the Merger that relate to federal net operating loss carryforwards (NOLs), state net economic loss carryforwards (NELs) and federal tax credits due to uncertainty regarding the Company s ability to fully realize these assets. In addition, during December 2011, the Company completed its acquisition of Cardiokine. As a result of the acquisition, the Company acquired various gross deferred tax assets including federal tax credits and NOLs. Due to uncertainty regarding the Company s ability to fully realize the tax credits and NOLs, a valuation allowance has been provided. This determination considered the limitations on the utilization of NOLs and tax credits imposed by Section 382 and 383, respectively, of the Internal Revenue Code (the Code).

The valuation allowance increased by approximately $2.1 million during the year ended December 31, 2011 and decreased by approximately $644,000 for the year ended December 31, 2010. The increase during the year ended December 31, 2011 primarily relates to an additional valuation allowance recorded in connection with the Cardiokine acquisition, partially offset by the utilization of loss carryforwards. The decrease during the year ended December 31, 2010 was due to utilization and/or release of loss carryforwards and the reduction in the Company s valuation allowance related to its deferred tax assets that existed prior to the Merger.

As of December 31, 2011, the Company had federal NOLs of approximately $159.5 million that begin to expire in the year 2021, state NELs of approximately $154.0 million that begin to expire in 2011 and federal tax credits of approximately $4.6 million that begin to expire in 2021. Because of the limitations discussed above, the Company has concluded that it is not more likely than not that it will be able to utilize the majority of these federal or state loss carryforwards or federal tax credit carryforwards. Accordingly, the Company has established a valuation allowance with respect to the majority of these loss carryforwards and tax credit carryforwards. The Company recognized approximately $1.9 million in tax benefits in both 2011 and 2010 related to NOL carryforwards, of which $644,000 were recorded as a reduction of tax expense in each year.

A reconciliation of the statutory income tax rate to the effective income tax rate is as follows:

	2011	2010	2009
Federal statutory taxes	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	2.3	2.3	2.3
Permanent differences	(37.3)	1.3	2.6
Change in estimated federal and state NOL utilization		(7.4)	
Change in valuation allowance	47.3	(8.3)	(1.8)
Other	1.9	(2.2)	(2.9)
	49.2%	20.7%	35.2%

The changes in the permanent differences and the valuation allowance that are included in the rate reconciliation are the result of the change in each of these items as a relative percentage of the income (loss) before taxes.

The 2008 through 2010 tax years of the Company are open to examination by federal and state tax authorities. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years are under examination.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon adoption of these principles and in subsequent periods. As of December 31, 2011 and 2010, the Company has $382,000 and $0 of unrecognized tax benefits. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next 12 months.

The Company had no tax-related accrued interest or interest expense in the consolidated financial statements as of and for the years ended December 31, 2011, 2010 and 2009. The Company had no tax-related penalties or accrued penalties included in the consolidated financial statements as of and for the years ending December 31, 2011, 2010 and 2009.

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NOTE 12: RELATED PARTY TRANSACTIONS

Chiesi, the Company s majority stockholder, manufactures all of the Company s requirements for CUROSURF pursuant to a license and distribution agreement that became effective on July 28, 2009. The Company began promoting and selling CUROSURF in September 2009. Inventory purchases from Chiesi aggregated $18.3 million for the year ended December 31, 2011. As of December 31, 2011, the Company had accounts payable of $1.4 million due to Chiesi.

NOTE 13: NET (LOSS) INCOME PER SHARE

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of common shares outstanding during each period. Diluted net (loss) income per share is computed by dividing net (loss) income by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants and the impact of non-vested restricted stock grants.

The following table sets forth the computation of basic and diluted net (loss) income per share (in thousands, except share and per share data):

	Year Ended December 31,		
	2011	2010	2009
Numerator:			
Net (loss) income	$ (693)	$ 6,169	$ 10,203
Denominator:			
Weighted-average common shares, basic	25,684,593	25,412,636	17,651,668
Dilutive effect of stock options, warrants and restricted stock		623,908	1,124,920
Weighted-average common shares, diluted	25,684,593	26,036,544	18,776,588
Net (loss) income per share, basic	$ (0.03)	$ 0.24	$ 0.58
Net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ 0.54
Anti-dilutive weighted-average shares	3,000,613	1,489,258	1,136,792

As of December 31, 2011 and 2010, there were 219,780 and 172,500 shares of unvested restricted stock outstanding that contain non-forfeitable rights to dividends. These securities are considered to be participating securities under the two-class method for determining basic and fully diluted net income per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net income in each of the periods presented, only the treasury stock method has been disclosed.

NOTE 14: SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2011. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements.

NOTE 15: RECENT ACCOUNTING PRONOUNCEMENTS

In September 2011, the FASB issued ASU 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment* (ASU 2011-08), which amends current guidance to allow a company to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment also improves previous guidance by expanding upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. ASU 2011-08 is

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effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted ASU 2011-08 during the fourth quarter of 2011, and it did not have any impact upon its financial position and results of operations.

NOTE 16: QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following is a summary of the Company s consolidated quarterly results of operations for each of the years ended December 31, 2011 and 2010 (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2011					
Net product sales	$ 29,975	$ 27,964	$ 25,178	$ 18,184	$ 101,301
Cost of product sales (exclusive of amortization of product rights)	10,034	9,189	9,960	8,640	37,823
Income (loss) from operations	2,540	540	191	(4,508)	(1,237)
Net income (loss)	1,742	197	117	(2,749)	(693)
Net income (loss) per share, basic	0.07	0.01	0.00	(0.11)	(0.03)
Net income (loss) per share, diluted	0.07	0.01	0.00	(0.11)	(0.03)
2010					
Net product sales	$ 36,392	$ 28,460	$ 26,410	$ 32,482	$ 123,744
Cost of product sales (exclusive of amortization of product rights)	11,417	10,801	10,342	12,455	45,015
Income (loss) from operations	8,063	(540)	98	267	7,888
Net income (loss)	5,013	(400)	764	792	6,169
Net income (loss) per share, basic	0.20	(0.02)	0.03	0.03	0.24
Net income (loss) per share, diluted	0.19	(0.02)	0.03	0.03	0.24

The sum of the quarterly earnings per share amounts will not necessarily equal the annual earnings per share amount due to the weighting of common shares outstanding during each of the respective periods.

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SCHEDULE

CORNERSTONE THERAPEUTICS INC.

VALUATION AND QUALIFYING ACCOUNTS

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(In thousands)

	Beginning Balance	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts(1)	Deductions	Ending Balance
Year Ended December 31, 2011					
Reserves:					
Allowance for product returns	$ 15,025	$	$ 42,021(2)	$ 43,835	$ 13,211
Allowance for rebates	3,034		4,067(3)	4,467	2,634
Allowance for price adjustments and chargebacks	21,520		24,266(4)	36,627	9,159
Deducted from asset accounts:					
Allowance for prompt payment discounts	2,015		2,153	3,583	585
Inventory allowance	1,845	209		1,604	450
Year Ended December 31, 2010					
Reserves:					
Allowance for product returns	$ 10,962	$	$ 20,131(5)	$ 16,068	$ 15,025
Allowance for rebates	1,013		5,230(6)	3,209	3,034
Allowance for price adjustments and chargebacks	3,503		51,235(7)	33,218	21,520
Deducted from asset accounts:					
Allowance for prompt payment discounts	384		5,665(8)	4,034	2,015
Inventory allowance	1,802	1,340		1,297	1,845
Year Ended December 31, 2009					
Reserves:					
Allowance for product returns	$ 5,043	$	$ 15,417(9)	$ 9,498	$ 10,962
Allowance for rebates	884		1,407	1,278	1,013
Allowance for price adjustments and chargebacks	4,307		21,838	22,642	3,503
Deducted from asset accounts:					
Allowance for prompt payment discounts	302		3,157	3,075	384
Inventory allowance	677	1,474	234(10)	583	1,802

(1) All activity is netted against gross product sales unless otherwise stated.

(2) Includes a provision of $7,291 relating to sales made in prior periods and $26,632 for anticipated returns of product for which revenue had been previously deferred.

(3) Includes $82 relating to sales made during 2010 for which revenue had been previously deferred.

(4) Includes $884 relating to sales made during 2010 for which revenue had been previously deferred.

(5) Includes a provision of $8,865 relating to sales made in prior periods.

(6) Includes a deferred provision of $493 relating to sales made during 2010 for which revenue has been deferred.

(7) Includes a deferred provision of $16,731 relating to sales made during 2010 for which revenue has been deferred.

(8) Includes a deferred provision of $1,763 relating to sales made during 2010 for which revenue has been deferred.

(9) Includes a provision of $2,333 relating to sales made in prior periods and $2,455 which was recorded in connection with the acquisition of FACTIVE product rights.

(10) Represents an allowance of $234 recorded in connection with the Company s acquisition of FACTIVE product rights and related inventory.

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ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***
Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***
Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2011, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of December 31, 2011, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system is designed to provide reasonable assurance to our management and the Board of Directors regarding the preparation and fair presentation 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. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (the COSO criteria). Based on its assessment, our management determined that, as of December 31, 2011, our internal control over financial reporting was effective.

ITEM 9B. ***OTHER INFORMATION***
Not applicable.

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PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Directors and Executive Officers

Information regarding our directors may be found under the captions Proposal One Election of Directors and Corporate Governance Board Committees in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Information regarding our executive officers and directors may be found under the caption Executive Officers of the Registrant and Non-Employee Directors of the Registrant, respectively, in Part I of this annual report on Form 10-K. Such information is incorporated herein by reference.

Compliance With Section 16(a) of the Exchange Act

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption Stock Ownership Information Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and other employees. A copy of our code of business conduct and ethics is available on our website at www.crtx.com under Investors Corporate Governance. We intend to post on our website and file on Form 8-K, if required, all disclosures that are required by applicable law, the rules of the SEC or NASDAQ listing standards concerning any amendment to, or waiver from, our code of business conduct and ethics.

Director Nominees

Information regarding procedures for recommending nominees to the Board of Directors may be found under the caption Corporate Governance Director Nomination Process in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee, including our audit committee financial expert, may be found under the captions Corporate Governance Board Committees Audit Committee and Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Audit Committee Report in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

Information with respect to this item may be found under the caption Information About Executive and Director Compensation in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Stock Ownership Information and Information About Executive and Director Compensation Securities Authorized for Issuance Under Equity Compensation Plans in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Chiesi Transaction and Corporate Governance in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information with respect to this item may be found under the captions Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Independent Registered Public Accounting Firm s Fees and Corporate Governance Pre-Approval Policy and Procedures in the Proxy Statement for our 2012 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

(a) (1) *Financial Statements.*

For a list of the financial information included herein, see Index to Consolidated Financial Statements on page 81 of this annual report on Form 10-K.

(a) (2) *Financial Statement Schedules*

Schedule II Valuation and Qualifying Accounts is included in Item 8 of this Annual Report on Form 10-K. All other schedules are omitted because they are not applicable or the required information is shown in our consolidated financial statements or the related notes thereto.

(a) (3) *Exhibits.*

The list of exhibits filed as a part of this annual report on Form 10-K is set forth on the Exhibit Index immediately preceding the exhibits hereto and is incorporated herein by reference.

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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.

CORNERSTONE THERAPEUTICS INC.

By: /s/ Craig A. Collard
Craig A. Collard
Chief Executive Officer
March 6, 2012

Date: March 6, 2012

We, the undersigned officers and directors of Cornerstone Therapeutics Inc., hereby severally constitute and appoint Craig A. Collard and Vincent T. Morgus, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable Cornerstone Therapeutics Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

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/ Craig A. Collard	Chief Executive Officer and	March 6, 2012
Craig A. Collard	Director (Principal Executive Officer)	
/s/ Vincent T. Morgus	Executive Vice President,	March 6, 2012
Vincent T. Morgus	Finance, Chief Financial Officer and Treasurer	
	(Principal Financial Officer)	
/s/ Ira Duarte	Director, Accounting and Financial Planning and Analysis (Principal Accounting Officer)	March 6, 2012
Ira Duarte		
/s/ Alessandro Chiesi	Director	March 6, 2012
Alessandro Chiesi		
/s/ Christopher Codeanne	Director	March 6, 2012
Christopher Codeanne		
/s/ Michael Enright	Director	March 6, 2012
Michael Enright		

/s/ Anton Giorgio Failla	Director	March 6, 2012
Anton Giorgio Failla		

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Signature	Title	Date
/s/ James Harper	Director	March 6, 2012
James Harper		
/s/ Michael Heffernan	Director	March 6, 2012
Michael Heffernan		
/s/ Robert Stephan	Director	March 6, 2012
Robert Stephan		
/s/ Marco Vecchia	Director	March 6, 2012
Marco Vecchia		

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Exhibit Index

Exhibit No	Description
2.1	Agreement and Plan of Merger among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated May 1, 2008).
2.2	Amendment No. 1, dated August 7, 2008, to Agreement and Plan of Merger among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 2.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
2.3	Agreement and Plan of Merger among the Registrant, Cohesion Merger Sub, Inc., Cardiokine, Inc. and Shareholder Representative Services LLC dated December 28, 2011 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated December 28, 2011).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004).
3.2	Amendment to the Registrant s Certificate of Incorporation, effecting a 10-to-1 reverse stock split of the Registrant s common stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
3.3	Amendment to the Registrant s Certificate of Incorporation, changing the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
3.4	Amendment to the Registrant s Certificate of Incorporation, effecting certain changes pursuant to the Governance Agreement among Chiesi Farmaceutici S.p.A., the Registrant and certain other stockholders of the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated August 27, 2009).
3.5	Fourth Amended and Restated Bylaws of the Registrant dated July 28, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated July 27, 2009).
4.1	Form of the Registrant s Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.1+	Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007).
10.2+	Amendment No. 1, dated June 25, 2007, to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007).
10.3+	Amendment No. 2, dated May 4, 2009, to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009).
10.4+	License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.5	Amendment No. 1, dated July 27, 2007, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.7 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.6	Amendment No. 2, dated January 28, 2010 and effective November 16, 2009, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010).

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10.7+	Letter Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated July 27, 2007 (incorporated by reference to Exhibit 10.8 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.8+	Addendum, dated August 14, 2008, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.10 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.9+	Agreement for Manufacturing and Supply of Zileuton between Shasun Pharma Solutions Limited (formerly known as Rhodia Pharma Solutions Ltd.) and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004).
10.10+	Amendment No. 1, dated May 9, 2007, to Agreement for Manufacturing and Supply of Zileuton, between Shasun Pharma Solutions Limited (formerly known as Rhodia Pharma Solutions Ltd.) and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007).
10.11+	Manufacturing and Supply Agreement among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007).
10.12+	Letter Amendment, dated June 12, 2009, to Manufacturing and Supply Agreement among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.13+	License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.10 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.14	Amendment No. 1, dated April 13, 2005, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006).
10.15+	Amendment No. 2, dated January 28, 2010, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010).
10.16+	License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.17	Amendment No. 1, dated September 15, 2004, to License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (incorporated by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006).
10.18+	Agreement between the Registrant and Jagotec AG dated December 3, 2003 (incorporated by reference to Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.19+	Development and Scale-Up Agreement between the Registrant and Jagotec AG dated May 5, 2004 (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.20+	Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.16 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.21+	Amendment No. 1, dated June 16, 2009, to Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 16, 2009).

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10.22	Stock Purchase Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 6, 2009; Exhibits A, B, C, D and E thereto incorporated by reference to Exhibits 10.9-10.14, 10.4, 10.3, 10.5 and 10.6, respectively, to the Registrant s Current Report on Form 8-K dated May 6, 2009; and Exhibit H thereto incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.23+	License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.24	Governance Agreement among the Registrant, Chiesi Farmaceutici S.p.A. and, solely with respect to the sections identified therein, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.25	Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.26	Amendment, dated June 26, 2009, to Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated June 26, 2009).
10.27	Registration Rights Agreement between the Registrant and Chiesi Farmaceutici S.p.A. dated May 6, 2009 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.28	Registration Rights Agreement among the Registrant, Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.29	Stock Purchase Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd. and Lutz Family Limited Partnership dated December 16, 2010 (incorporated by reference to Exhibit 10.45 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2010).
10.30+	License and Option Agreement between LG Life Sciences, Ltd. and Cornerstone BioPharma, Inc. (as assignee of Oscient Pharmaceuticals Corporation) dated October 22, 2002, as amended by Amendment No. 1 dated November 21, 2002, Amendment No. 2 dated December 6, 2002, Amendment No. 3 dated October 16, 2003, Amendment No. 4 dated March 31, 2005, Amendment No. 5 dated February 3, 2006, Amendment No. 6 dated February 3, 2006 and Amendment No. 7 dated December 27, 2006 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.31	Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.26 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.32	Lease Modification Agreement No. 1, dated October 31, 2008, to Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.33	Lease Modification Agreement No. 2, dated October 2, 2009, to Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).

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10.34#	2004 Stock Incentive Plan of the Registrant (as Amended and Restated May 20, 2010) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 20, 2010).
10.35#	Form of Incentive Stock Option Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.68 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.36#	Form of Nonstatutory Stock Option Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.70 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.37#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted before May 20, 2010) (incorporated by reference to Exhibit 10.72 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.38#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted from May 20, 2010 to May 18, 2011) (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010).
10.39#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted on or after May 19, 2011) (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011).
10.40#	Form of Restricted Stock Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.75 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009).
10.41#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.37 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.42#	Form of Nonstatutory Stock Option Agreement granted under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (incorporated by reference to Exhibit 10.39 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.43#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.38 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.44#	Form of Nonstatutory Employee Stock Option Agreement granted under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.40 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.45#	Amended and Restated Non-Employee Director Compensation and Reimbursement Policy of the Registrant effective October 31, 2008 (incorporated by reference to Exhibit 10.80 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.46#	Amended and Restated Non-Employee Director Compensation and Reimbursement Policy of the Registrant effective May 18, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011).
10.47#	Amended and Restated Executive Employment Agreement between the Registrant and Craig A. Collard dated May 6, 2009 (incorporated by reference to Exhibit 10.9 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.48#	Amended and Restated Executive Employment Agreement between the Registrant and Joshua B. Franklin dated May 6, 2009 (incorporated by reference to Exhibit 10.13 to the Registrant s Current Report on Form 8-K dated May 6, 2009).

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10.49#	Amended and Restated Executive Employment Agreement between the Registrant and Steven M. Lutz dated May 6, 2009 (incorporated by reference to Exhibit 10.10 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.50#	Separation Letter Agreement and General Release between the Registrant and Steven M. Lutz dated October 21, 2011 and effective October 26, 2011.
10.51#	Executive Employment Agreement between the Registrant and Kenneth R. McBean dated September 6, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated August 30, 2011).
10.52#	Executive Employment Agreement between the Registrant and Vincent T. Morgus dated February 1, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated February 1, 2011).
10.53#	Executive Employment Agreement between the Registrant and Andrew K. W. Powell dated October 30, 2009 (incorporated by reference to Exhibit 10.96 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009).
10.54#	Executive Employment Agreement between the Registrant and Alan Roberts dated May 6, 2009 (incorporated by reference to Exhibit 10.14 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.55#	Form of Indemnification Agreement, entered into between Cornerstone BioPharma Holdings, Inc. and each of Craig A. Collard and certain other directors of Cornerstone BioPharma Holdings, Inc. on April 12, 2005 (incorporated by reference to Exhibit 10.36 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
21.1	Subsidiaries of the Registrant.
23.1	Consent of Grant Thornton LLP.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Cornerstone Therapeutics Inc. s Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

\# Management contract or compensatory plan or arrangement.

\+ Portions of the exhibit have been omitted pursuant to a request for confidential treatment, which portions have been separately filed with the Securities and Exchange Commission.