CORNERSTONE THERAPEUTICS INC
Form 10-K
March 04, 2010

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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, 2009

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 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** *(Address of Principal Executive Offices)*	**27518** *(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 o No þ

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

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

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

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

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

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

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant as of June 30, 2009 was approximately $78,402,913 based on a price per share of $10.99, the last reported sale price of the registrant s common stock on the NASDAQ Stock Market on that date.

As of February 28, 2010, the registrant had 25,602,028 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2010 annual meeting of stockholders currently expected to be held on May 20, 2010, 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, 2009, are incorporated by reference into Part III of this report.

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, tar other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates ; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; the possibility that the Food and Drug Administration, or FDA, will take enforcement action against us or one or more of our marketed drugs that do not have FDA-approved marketing applications; patient, physician and third-party payor 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 with FDA-approved marketing applications; our ability to obtain FDA approval to market and sell our products under development; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; 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 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. 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 acquiring, developing and commercializing significant products primarily for the respiratory and related markets. Prior to our October 31, 2008 merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma, we were known as Critical Therapeutics, Inc., or Critical Therapeutics. Following the closing of the merger, former Cornerstone BioPharma

stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of our common stock. In connection with the completion of the merger, on October 31, 2008, we changed our name to Cornerstone Therapeutics Inc.

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Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with accounting principles generally accepted in the United States, or GAAP. Accordingly, for all purposes, including reporting with the Securities and Exchange Commission, or SEC, 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, as applicable, Critical Therapeutics and Cornerstone BioPharma prior to the merger. In addition, unless specifically noted otherwise, discussions of our financial results throughout this document do not include the historical financial results of Critical Therapeutics (including sales of ZYFLO CR® (zileuton) extended-release tablets and ZYFLO® (zileuton) tablets) prior to the completion of the merger.

On July 28, 2009, we closed a transaction with Chiesi Farmaceutici S.p.A., or Chiesi, whereby we issued Chiesi approximately 12.2 million shares of common stock in exchange for $15.5 million in cash, an exclusive license for the U.S. commercial rights to Chiesi s CUROSURF® (poractant alfa) Intratracheal Suspension product and a two-year right of first offer on all drugs Chiesi intends to market in the United States. As part of this transaction, our President and Chief Executive Officer and our Executive Vice President of Manufacturing and Trade agreed to sell to Chiesi an aggregate of 1.6 million of their shares of our common stock and enter into lockup, right of first refusal and option agreements with respect to their remaining shares. In addition, certain of our other executive officers entered into lockup agreements with Chiesi with respect to their shares of our common stock and are entitled to receive certain equity incentives from us. The transaction was considered a change of control as defined in certain employment arrangements between us and various employees, which caused the acceleration of vesting of 1.1 million stock options and 342,633 shares of restricted stock held by these employees.

On September 9, 2009, we acquired the commercial rights to the antibiotic FACTIVE® (gemifloxacin mesylate) tablets in North America and certain countries in Europe through an asset purchase agreement with Oscient Pharmaceuticals Corporation, or Oscient. We refer to the asset purchase agreement as the Oscient Agreement.

Overview

We are a specialty pharmaceutical company that:

- promotes products that address acute respiratory ailments to high prescribing respiratory physicians and key retail pharmacies through our respiratory sales force;
- promotes a respiratory product prescribed in hospitals to hospital-based healthcare professionals through our hospital sales force; and
- launches branded, unbranded and authorized generic versions of products (including our own products) through our wholly owned subsidiary Aristos Pharmaceuticals, Inc., or Aristos.

We seek to acquire rights to existing undervalued and/or poorly marketed established commercial products, which we then quickly re-launch to generate lasting high-value earnings streams. We also seek to acquire late-stage development products that we can shepherd through FDA approval and commercialization. We target products that fit within our existing product families, fill holes in our expanding portfolio and offer potential synergies once integrated into our portfolio.

We also seek to develop and commercialize variations on existing products for which we can pursue additional regulatory approvals, and to leverage our proprietary and licensed technology platforms to develop those products into significant sources of revenue.

We have assembled a management team with broad experience in the acquisition, marketing and distribution of branded medicines. This team has substantial experience in successfully bringing significant products to market, whether they are internally developed new products, recently acquired established products

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that have been under-marketed or variations of these types that expand already successful prescriptive applications of existing products.

At the same time we have built knowledgeable and effective sales forces. The strong relationships these sales forces have established with respiratory physicians, key retail pharmacies and hospitals enable us to efficiently commercialize acquired and developed products so they can quickly generate revenue.

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

We believe that our business model and the competencies we have developed position us to add additional products in the acute respiratory segment and can also be easily transferred to other specialty market segments.

In 2009, we have expanded the Cornerstone product portfolio in order to drive higher sales, and to change our product mix in order to generate longer lasting, higher quality revenue streams. We are undergoing an intentional, strategic shift in product mix from sales of opportunistic products to a sales mix that is focused on growing our portfolio of patent or trade secret protected medicines.

We currently derive the majority of our revenue from five key product families:

CUROSURF, an FDA-approved natural lung surfactant for the treatment of Respiratory Distress Syndrome, or RDS, in premature infants, for which we acquired rights in the United States in August 2009;

FACTIVE, a fluoroquinolone with a broad and powerful activity against certain microorganisms implicated in certain respiratory infections, including multi-drug resistant strains of *Streptococcus pneumoniae*, or MDRSP, for which we acquired rights in North America and certain European countries in September 2009;

SPECTRACEF® (cefditoren pivoxil) tablets, a third-generation cephalosporin indicated for the treatment of certain respiratory and skin infections, for which we acquired rights in the United States in October 2006;

ZYFLO CR, the only FDA-approved leukotriene synthesis inhibitor indicated for prophylaxis and chronic treatment of asthma, for which we acquired worldwide rights in December 2003 and March 2004; and

Our other products, of which the most significant are ALLERX® (combinations of methscopolamine nitrate, pseudoephedrine hydrochloride, phenylephrine hydrochloride and chlorpheniramine maleate) tablets and HYOMAX® (hyoscyamine sulfate) tablets. Our ALLERX Dose Pack products consist of various oral tablet dose packs prescribed for the treatment of symptoms of allergic rhinitis, for which we acquired U.S. rights to the current patent covering this product line in August 2006. Our HYOMAX family of products includes five antispasmodic medications containing an anticholinergic, which may be prescribed for functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries, diverticulitis and irritable bowel syndrome, or IBS, for which we acquired the rights in May 2008.

Revenues from some of our products fluctuate from quarter to quarter in-line with the seasonality of the cough/cold season, which primarily results in higher revenues in our first and fourth quarters of the year.

We have also built a significant pipeline of products that includes line extensions for ZYFLO CR and SPECTRACEF, as well as a portfolio of additional product candidates we are developing using controlled-release liquid technology licensed from Neos Therapeutics, L.P., or Neos. The controlled-release liquids are focused on the cough/cold segment of the acute respiratory marketplace, where we believe that the effectiveness of our sales force in selling the anti-infectives FACTIVE and SPECTRACEF provides us a competitive advantage. We believe our pipeline offers

significant opportunities for future growth because of the size of the cough/cold market and the relative lack of significant competition in this marketplace, particularly for antitussives, or medicines for the treatment of cough.

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We plan to build on this base going forward by focusing on the following priorities:

Remaining profitable and leveraging our established business to continue to generate cash;

Growing our lead products;

Acquiring additional products that complement our lead products;

Aggressively advancing our development initiatives; and

Identifying partners to maximize the value of our non-strategic assets.

Our Promoted Products

We promote CUROSURF, FACTIVE, SPECTRACEF and ZYFLO CR through our own direct sales forces because we believe these products are most responsive to promotional efforts.

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 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 during the period from our launch in September 2009 until the end of 2009 were $10.5 million. We acquired the CUROSURF product rights in the United States from Chiesi during the third quarter of 2009 and began promoting and selling CUROSURF in September 2009. There is no assurance that we will achieve the sales level for CUROSURF that was achieved by Chiesi s prior licensee of the U.S. rights to this product.

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. The surfactant market generated almost $100 million in sales in 2009 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, lower volume per dose and lower viscosity as compared to other surfactant products used to treat RDS. These characteristics help reduce the impact on the infant by shortening the drug s administration time, reducing the required manipulation of the infant, and lowering the rate of reflux and endotracheal tube blockage.

In a prospective, randomized clinical trial comparing CUROSURF and Survanta® (a surfactant marketed by Abbott Laboratories, or Abbott, to treat RDS) in 293 infants, CUROSURF produced a faster reduction in infant oxygen requirement, as reflected in the fraction of inspired oxygen (FiO_2). In this same study, 73% of infants required only one dose of CUROSURF, while 49% of Survanta-treated infants required a second dose. It is theorized that faster reduction in oxygen requirement generally allows for faster weaning from mechanical ventilation and may lower the risk of oxygen toxicity.

In a separate clinical study comparing CUROSURF and Survanta, CUROSURF produced a faster and more substantial reduction in oxygen requirement (FiO_2) and sustained results over the first 48 hours while certain infants in the Survanta group experienced a rebound in FiO_2 requiring a higher need for redosing of surfactant.

A rapid onset of action and faster reduction in infant oxygen requirement facilitates the use of less invasive ventilation techniques, which is a key trend in the treatment of premature infants in the United States.

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CUROSURF has additionally been extensively studied with techniques such as nasal continuous positive airway pressure and has demonstrated a reduction in the rate of reintubation and surfactant redosing when used in combination with this advanced treatment method.

CUROSURF has demonstrated favorable outcomes including a consistent survival advantage in trials that measure mortality as a secondary endpoint. For example, in a prospective, randomized trial in 293 infants, CUROSURF-treated infants demonstrated a 3% mortality rate at 36 weeks post-conceptional age in infants born at less than 33 weeks gestational age compared with 11% in Survanta-treated infants. Three other published studies demonstrate trends toward a survival advantage with CUROSURF treatment 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.

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 during the period from our launch in October 2009 until the end of 2009 were $1.2 million. 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.

Market Opportunity. The U.S. oral solid antibiotic market is fairly fragmented, with approximately 40 branded products and more than 50 generic products. Pharmacists typically fill prescriptions for antibiotics with generic products when available. According to Wolters Kluwer Health, a third-party provider of prescription data, in 2009, the U.S. oral solid antibiotic market generated approximately 226 million prescriptions, of which the U.S. oral solid fluoroquinolone market generated approximately 37 million prescriptions. Approximately 1.1 million prescriptions have been dispensed for FACTIVE since its launch. In 2008 and 2009, FACTIVE generated approximately 212,000 and 96,000, 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.

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 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

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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. We sometimes refer to these products collectively as the SPECTRACEF Dose Packs. 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.

SPECTRACEF 400 mg is a single 400 mg tablet, twice-daily dosage of SPECTRACEF, which is 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. We received approval for SPECTRACEF 400 mg in July 2008 and launched it in October 2008. We believe that patients will find taking one 400 mg tablet twice daily to be more convenient than taking two SPECTRACEF 200 mg tablets twice daily. Our net sales of SPECTRACEF were $9.4 million, $7.0 million and $6.9 million in 2009, 2008 and 2007, 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 Wolters Kluwer Health, there were approximately 7.9 million prescriptions written in the United States for second and third generation oral solid cephalosporins.

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

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 2016. We have also licensed the U.S. trademark rights to SPECTRACEF from Meiji.

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

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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 $18.0 million and $888,000 in 2009 and 2008. Our historical financial results for 2008 do not include sales of ZYFLO CR and ZYFLO by Critical Therapeutics prior to the completion of our October 31, 2008 merger.

We entered into an agreement in March 2007, as amended, with Dey, L.P., or DEY, a wholly owned subsidiary of Mylan Inc., or Mylan, under which we and DEY jointly co-promote ZYFLO CR.

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 2008 in the United States approximately 7.6% of the population, or approximately 23 million people, had asthma and approximately 3.9% of the population, or 12 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 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.

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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 expires in December 2010. The U.S. patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the release of zileuton.

Other Products

We market but do not promote the products described below. We market these products without their having FDA-approved marketing applications. 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 are now being marketed without approved NDAs or ANDAs in this annual report on Form 10-K.

ALLERX DOSE PACKS

Overview. Our ALLERX Dose Pack products are oral tablets prescribed for the temporary relief of symptoms associated with allergic rhinitis. We currently market ALLERX 10 Dose Pack/ALLERX 30 Dose Pack, ALLERX Dose Pack DF/ALLERX Dose Pack DF 30 and ALLERX Dose Pack PE/ALLERX Dose Pack PE 30. Each ALLERX Dose Pack product contains the antihistamine chlorpheniramine maleate, a choice of decongestant, including an option without a decongestant, and methscopolamine nitrate, an anticholinergic, which provides additional symptomatic relief by drying up the mucosal secretions associated with allergic rhinitis. Our net sales of ALLERX Dose Pack products were $31.7 million, $26.4 million and $14.2 million in 2009, 2008 and 2007, respectively.

Market Opportunity. Rhinitis is an inflammation of the mucous membranes of the nose with symptoms of sneezing, itching, nasal discharge and congestion. Rhinitis can be allergic, nonallergic or both. Seasonal allergic rhinitis is caused by substances that trigger allergies, called allergens, and is sometimes referred to as hay fever.

According to the Centers for Disease Control and Prevention, allergic rhinitis was estimated to be responsible for approximately 13.1 million ambulatory visits in 2006. According to a January 2006 Allergies in America survey, approximately 69% of patients with allergic rhinitis had taken medication for their nasal allergies in the prior four weeks, including 45% who took prescription medication. The survey also reported that 40% of patients surveyed indicated that nasal allergies had a lot or a moderate amount of impact on their daily life, compared with only 33% of patients who indicated that nasal allergies had little or no impact on their daily life.

Benefits of ALLERX Dose Packs. ALLERX Dose Pack products use a patented dosing regimen and are designed so that side effects, such as insomnia with decongestants and drowsiness with first generation antihistamines, to the extent they are experienced, are most likely to occur at times that these side effects do not inconvenience the patient.

Proprietary Rights. We have an exclusive license from Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations, to market ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 within the United States under an issued United States patent 6,843,372, or the 372 Patent, with claims, among other things, to a prepackaged, therapeutic dosing regimen that includes a less sedating first dose containing a nasal decongestant, and a second dose containing an antihistamine and an attenuated dosage of nasal decongestant. This patent expires in 2021. On June 13, 2008, the U.S. Patent and Trademark Office, or the USPTO, received a request from Vision Pharma, LLC, or Vision, to re-examine this patent. The re-examination proceedings before the USPTO are more fully discussed in Item 3. Legal Proceedings in this annual report on Form 10-K.

In addition, we have applied for a U.S. patent that, if issued, would include claims to ALLERX Dose Pack DF s and ALLERX Dose Pack DF 30 s AM and PM dosing regimen and method of treating a rhinitic

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condition using an antihistamine and an anticholinergic in both doses. This patent application has been published and is currently pending. If issued, this patent would expire in 2026.

HYOMAX

Overview. The HYOMAX line of products consists of five antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries, diverticulitis, urinary incontinence and IBS. Our net sales of HYOMAX products were $28.1 million and $23.0 million in 2009 and 2008, respectively.

Market Opportunity. Antispasmodics are often a first-line treatment for patients with IBS because they offer a safe, cost-effective method of relieving abdominal pain and diarrhea by preventing or slowing contractions in the bowel.

According to the American Gastroenterology Association, up to 15% of the U.S. population is affected by IBS. According to the American Physical Therapy Association, more than 17 million Americans have urinary incontinence, although only 15% seek treatment. Patients with urinary incontinence may find that antispasmodics relax the bladder muscle and relieve spasms.

Benefits of HYOMAX. The HYOMAX line of products offers patients a cost-effective treatment option for a variety of gastrointestinal problems, such as urinary incontinence or IBS, and may be preferred by physicians concerned about the potential serious side effects associated with newer products such as Prometheus Laboratories Inc. s Lotronex® (alosetron HCl) product, which is restricted to those patients for whom the benefit-to-risk balance is most favorable.

Proprietary Rights. We have an exclusive license from Sovereign Pharmaceuticals, Ltd., or Sovereign, to market and distribute five hyoscyamine sulfate products in the United States through April 2011.

Product Development Pipeline

Overview. We are committed to the expansion of our product portfolio with particular focus in the respiratory therapeutic area. Our development pipeline consists of product candidates that are strategically aligned with our current products and are based on marketed drug compounds. The following table sets forth additional information regarding our product candidates:

Therapeutic Class	Regulatory Status
Cough/Cold	
Product Candidate Submitted	
CRTX 067	Regulatory application submitted in July 2009
Other Product Candidates	
CRTX 069	Submission targeted in 2011
CRTX 072	Submission targeted in 2011
CRTX 074	Submission targeted in 2011
Allergy	
CRTX 058	Submission timeline under review by management
CRTX 070	Submission targeted in 2012
Anti-Asthma	
CRTX 073	Submission targeted in 2011
Anti-Infective	

CRTX 062	Submission timeline under review by management
CRTX 068	Submission timeline under review by management

During 2009, 2008 and 2007, our research and development expenses were $4.3 million, $3.8 million and $948,000, 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.

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Cough/Cold Product Candidates CRTX 067, CRTX 069, CRTX 072 and CRTX 074

Overview and Development Status. CRTX 067, CRTX 069, CRTX 072 and CRTX 074 are cough/cold product candidates currently in development. We submitted the application for marketing approval for CRTX 067 in July 2009. We are targeting submission of applications for marketing approval for the remaining product candidates in 2011.

Market Opportunity. Cough can adversely affect quality of life, leading patients to seek medical attention. According to Wolters Kluwer Health, in 2009, there were approximately 42 million prescriptions generated for antitussive products. Nearly 10 million of these prescriptions were for products that only contained a narcotic antitussive and an antihistamine.

Benefits of CRTX 067, CRTX 069, CRTX 072 and CRTX 074. 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 CRTX 067, CRTX 069, CRTX 072 and CRTX 074 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 market CRTX 067, CRTX 069 and CRTX 074 utilizing Neos s Dynamic Time Release Suspension®, or DTRS®, technology and Coating Place, Inc. s, or Coating Place, drug resin complex technology. We expect that these licensed technologies will allow us to formulate these product candidates with one or more APIs that require immediate activation followed by a sustained timed release of the remaining APIs 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 a pending U.S. patent application that if issued would expire in 2025. Suitable patented, drug delivery technologies are currently being evaluated for CRTX 072.

Allergy Product Candidates CRTX 058 and CRTX 070

Overview and Development Status. CRTX 058 and CRTX 070 are product candidates in development for the treatment of symptoms of allergic rhinitis. We plan to file an investigational new drug application, or IND, with the FDA and to commence the clinical program for CRTX 070 in 2010. If approved, we believe this anticholinergic therapy would be the first of its kind with an indication for the treatment of symptoms of allergic rhinitis. Because we are prioritizing the development of CRTX 070 over CRTX 058, our management is still reviewing the adjusted timeline for CRTX 058.

Market Opportunity. According to the American Academy of Allergy, Asthma & Immunology, or AAAAI, rhinitis is one of the most common illnesses, affecting more than 50 million people. Rhinitis has a strong link to other respiratory diseases including chronic sinusitis, middle ear infections, nasal polyps and bronchial asthma. The connection to bronchial asthma has caused great concern among allergists and immunologists. Additionally, asthmatics with rhinitis require more potent medications to control their symptoms. One potential explanation is that severe post-nasal drip triggers episodes of asthma. For example, researchers have found that inflammatory chemicals commonly found in the noses of people with allergic rhinitis drip into the lungs while they sleep, thus causing asthma to worsen.

According to Wolters Kluwer Health, oral solid anticholinergic combination products for the treatment of symptoms of respiratory diseases and allergies generated approximately 860,000 prescriptions in 2009, which was significantly less than in 2008 due to limited availability of the API methscopolamine. In addition, second and third generation antihistamine and antihistamine combination products generated a total of approximately 37.2 million prescriptions in

2009.

Benefits of CRTX 058 and CRTX 070. If approved, CRTX 058 and CRTX 070 will provide relief of symptoms of allergic rhinitis, such as itchy or watery eyes and runny nose, utilizing an active ingredient that has never been approved by FDA for this indication.

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We anticipate that, if approved based on the results of clinical trials that we plan to conduct, the FDA will grant CRTX 058 and/or CRTX 070 a three-year period of marketing exclusivity under the Hatch-Waxman Act. In addition, we believe that the FDA would require other unapproved products containing the ingredient in these product candidates to be removed from the market after a grace period.

Proprietary Rights. We have licensed from Neos the rights to market CRTX 058 utilizing Neos s Dynamic Variable Release® technology. Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. This licensed technology allows us to formulate CRTX 058 with one or more APIs that require immediate activation followed by extended release of the remaining APIs. Suitable patented drug delivery technologies are currently being evaluated for CRTX 070.

Anti-Asthma Product Candidate CRTX 073

Overview. ZYFLO CR remains 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.

Proprietary Rights. We have licensed from Abbott the rights to CRTX 073. Please see Our Promoted 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.

Anti-Infective Product Candidates CRTX 062 and CRTX 068

Overview. SPECTRACEF is an integral part of our current sales strategy. To protect and expand SPECTRACEF s market share, we are still considering developing CRTX 062, an oral suspension for the pediatric market, and CRTX 068, a once daily dosage tablet, for SPECTRACEF life cycle management purposes. Our development efforts on these two projects have been hampered by the closure of the Patheon Pharmaceuticals, Inc., or Patheon, facility in Puerto Rico that was authorized to handle cephalosporin products. While we believe market opportunity still exists with for these line extensions, we are evaluating the viability of these projects against the rest of our development pipeline.

Proprietary Rights. CRTX 062 and CRTX 068 are covered by the same U.S. patent as SPECTRACEF 200 mg and SPECTRACEF 400 mg. Meiji also has applied for a U.S. patent that, if issued, would include claims to enhanced oral absorptivity for these product candidates. This patent application has been published and is currently pending. If issued, this patent would expire in 2022. Our rights to market and develop SPECTRACEF 200 mg, SPECTRACEF 400 mg, CRTX 062 and CRTX 068 are subject to our license arrangements with Meiji.

Other Technology Assets

In connection with our merger with Cornerstone BioPharma, we completed a review of all former Critical Therapeutics early stage research projects and determined it is in our best interests to cease further significant expenditures on these projects so that we can focus our efforts and financial resources on opportunities that are consistent with our core strategies discussed above. In connection with our review, we also sought to identify any technologies that we believe are suitable for outlicensing to third parties. These former Critical Therapeutics early stage research projects include technology assets related to:

- the development of a small molecule product candidate targeting the alpha-7 receptor;

- the development, in collaboration with MedImmune, Inc., or MedImmune, a subsidiary of AstraZeneca PLC, of monoclonal antibodies directed toward a cytokine called HMGB1, which we believe may be an important

target for the development of products to treat diseases mediated by the body s inflammatory response;

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the development of an injectable form of zileuton initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma; and

the examination of the pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton to determine if there are potential dosing improvements for patients from this isomer.

Alpha-7 Program

Two of the former Critical Therapeutics early stage research projects, the alpha-7 program and the HMGB1 program, are directed towards reducing the potent inflammatory response that we believe is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. These programs center on controlling the production of potent inflammatory mediators that play a key role in regulating the body s immune system.

While we believe the technologies identified through our alpha-7 research have commercial potential, we have initiated a process to seek potential licensees that can commit greater resources to this program than we can given our principal focus on currently marketed products and late-stage product candidates.

HMGB1 Program

Our HMGB1 program is another early-stage pre-clinical program directed towards reducing the potent inflammatory response in many acute and chronic diseases. HMGB1 has been identified as a potential late mediator of inflammation-induced tissue damage. We have previously conducted research regarding mechanisms to prevent HMGB1 from effecting its role in inflammation-mediated diseases. Unlike other previously identified cytokines, such as interleukin-1 and TNF alpha, HMGB1 is expressed much later in the inflammatory response and persists at elevated levels in the bloodstream for a longer time period. We believe, therefore, that HMGB1 is a unique target for the development of products to treat inflammation-mediated diseases.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune to jointly develop and commercialize therapeutic products directed towards blocking the pro-inflammatory activity of HMGB1. In January 2005, we entered into a collaboration with Beckman Coulter, Inc., or Beckman Coulter, to develop a diagnostic assay that could be used to identify which patients have elevated levels of HMGB1 and would, therefore, be most likely to respond to anti-HMGB1 therapy.

As part of the MedImmune collaboration, the research programs are currently aimed at generating antibodies that can neutralize circulating HMGB1 prior to it binding to its receptor. Fully human antibodies directed towards HMGB1, including fully human antibodies identified as part of the MedImmune collaboration, are currently in preclinical development. In December 2005, MedImmune agreed that proof of concept had been achieved for two preclinical models with human anti-HMGB1 monoclonal antibodies. These antibodies are now undergoing further evaluation with the goal of selecting candidates for use in clinical testing. While we previously had research responsibilities under our collaboration agreement with MedImmune, MedImmune is responsible for conducting all future research activities necessary to advance potential product candidates into Phase I clinical trials. As of February 28, 2010, no decision to select a clinical candidate has been made.

Zileuton Injection

We believe zileuton injection is a promising adjunctive treatment for use in emergency room and urgent care centers for patients who suffer acute exacerbations of asthma. We believe acute exacerbations of asthma are a significant unmet medical need that occur in asthma patients who are poorly controlled on their existing medications. We believe

zileuton injection could offer a new treatment option for acute asthma patients in the emergency department that can be added to existing therapies in order to improve pulmonary function by controlling both bronchospasm and pulmonary inflammation.

We believe that these exploratory analyses and the tolerability of zileuton injection may support a clinical trial in an acute population as a potential next step in the development process. We have initiated a process to

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seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

R(+) Isomer of Zileuton

We have previously performed research regarding the pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton to determine if there are potential dosing improvements for patients from this isomer. In April 2008, we announced the results of a Phase I clinical trial to assess the safety and tolerability of an oral single dose of the R(+) isomer of zileuton. R(+) zileuton combined in equal proportion with its mirror image isomer, S(-) zileuton, comprise racemic zileuton. The trial was designed to examine the safety, tolerability, pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton in healthy subjects. Based on this Phase I clinical trial, we believe that certain features of the R(+) isomer of zileuton may offer the opportunity for the development of a product candidate with a reduced tablet size or less frequent dose administration.

Sales and Marketing; Co-promotion Agreements

Sales and Marketing

We have built a commercial organization, consisting at February 28, 2010 of 114 sales professionals in a variety of sales and sales management positions. Our sales organization is divided into a respiratory sales force and a hospital sales force. Our sales teams are 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 respiratory sales force currently call on high-prescribing, respiratory-focused physicians and key retail pharmacies. We believe this highly specialized approach provides us with the opportunity for greater access to this group of health care professionals. It also increases our market coverage and frequency of detailing visits to this target audience.

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.

We believe that the current market opportunity for our products and the future opportunity for our pipeline of product candidates, if approved, will likely warrant the need for sales force expansion. We expect to commence this expansion as FDA approval of a product candidate is obtained.

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, infections and symptoms associated with cough/cold or allergies. 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.

Co-promotion Agreements

We may seek to enter into additional co-promotion arrangements to enhance our promotional efforts and sales of our products. We may enter into co-promotion agreements with respect to our products that are not aligned with our respiratory focus or when we lack sufficient sales force representation in a particular geographic area. Our material

co-promotion arrangements are 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.

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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 thirty five percent (35%) of 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 advance 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, 2009 were less than $20 million, but we have not received any notice from DEY expressing DEY s intention to exercise its termination right.

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 15, 2012. However, if a third party AB-rated generic product to ZYFLO CR is introduced, DEY would not be subject to these non-competition obligations, and DEY will have the exclusive right to market the authorized generic version of ZYFLO CR. 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, Distribution and Reimbursement

Trade Sales 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 88% of gross product sales in 2009, are all drug wholesalers and are listed below:

Customer	2009	2008
Cardinal Health	34%	40%
McKesson Corporation	34%	31%
AmerisourceBergen Corporation	20%	15%

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

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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.

Reimbursement

In the U.S. market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care organizations, or MCOs, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. The status or tier within each plan varies, but coverage for FACTIVE, SPECTRACEF and ZYFLO CR is similar to other products within the same class of drugs. For example, the position of SPECTRACEF as a branded product often requiring a higher patient copayment may make it more difficult to expand the current market share for this product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for SPECTRACEF. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate Program with the Centers for Medicare & Medicaid Services. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, some of our products are purchased under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for our products.

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. Where possible and commercially reasonable, we qualify more than one source for manufacturing and packaging of our products to manage the risk of supply disruptions. In such circumstances, if one of our manufacturers or packagers were unable to supply our needs, we would have an alternative source available for those products.

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

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manufacturing and packaging agreements related to our more important products is summarized in the following table.

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

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 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 some of our products do not have an alternative manufacturer 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.

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.

Shasun Agreement for Manufacturing and Supply of Zileuton API

Shasun Pharma Solutions Ltd., or 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

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purchased a specified amount of the API for zileuton or December 31, 2011. The agreement will automatically extend for successive one-year periods after December 31, 2011, unless Shasun provides us with 18-months prior written notice of cancellation.

Jagotec Manufacture and Supply Agreement for ZYFLO CR

Jagotec AG or 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 will automatically continue 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.

Patheon Manufacturing Services Agreement for ZYFLO CR

Patheon coats, conducts quality control and quality assurance and stability testing and packages commercial supplies of ZYFLO CR for us using uncoated ZYFLO CR tablets we supply to Patheon. We have agreed to purchase from Patheon at least 50% of our requirements for such manufacturing services for ZYFLO CR for sale in the United States each year during the term of this agreement. The agreement s current term extends to May 9, 2011, and will automatically continue for successive one-year periods thereafter, unless we provide Patheon with 12-months prior written notice of termination or Patheon provides us with 18-months prior written notice of termination.

Patheon Commercial Manufacturing Agreement for ZYFLO Immediate-Release Tablets

Patheon also manufactures all of our ZYFLO immediate-release tablets pursuant to a commercial manufacturing agreement. We have agreed to purchase from Patheon at least 50% of our commercial supplies of ZYFLO immediate-release tablets for sale in the United States each year for the term of the agreement. The agreement s current term extends to September 15, 2011, and will automatically continue for successive one-year periods thereafter, unless we provide Patheon with 12-months prior written notice of termination or Patheon provides us with 18-months prior written notice of termination.

Sovereign Manufacturing of HYOMAX Product Line

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 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 seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business and obtaining, where possible, assignment of invention agreements from employees and consultants. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Patents

Our patents and patent applications include patents and patent applications 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.

The following table shows our U.S. patents and pending U.S. patent applications relating to FACTIVE, SPECTRACEF, ZYFLO CR and ALLERX as of February 28, 2010:

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Patents

Number	Issued Patents	Product(s)	Expiration
Licensed Patents			
4,873,259	Indole, Benzofuran, Benzothiophene Containing Lipoxygenase Inhibiting Compounds	ZYFLO CR and ZYFLO	12/10/2010
5,422,123	Tablets with controlled-rate release of active substances	ZYFLO CR	06/06/2012
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-fluoro-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-fluoro-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
6,843,372	Antihistamine/decongestant regimens for treating rhinitis	ALLERX Dose Pack PE, ALLERX 10 Dose Pack, ALLERX 30 Dose Pack	05/04/2021

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Patent Applications

Number	Pending Patents	Product	Expiration
20080015241	All day rhinitic condition treatment regimen	ALLERX Dose Pack DF	07/13/2026
20080311196	All day rhinitic condition treatment regimen	ALLERX Dose Pack DF	07/13/2026

All of the above patents were filed with and subsequently issued by the USPTO.

Other than FACTIVE, ZYFLO CR and ZYFLO, 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 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 Our Promoted Products, Other Products ALLERX Dose Packs 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. trademark registrations, issued by the USPTO, for our ZYFLO CR, ZYFLO, ALLERX, HYOMAX and BALACET trademarks, among others. CUROSURF is owned

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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.

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.

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.

LG Life Sciences FACTIVE License and Option Agreement

Overview. On September 9, 2009, we acquired the commercial rights to the antibiotic FACTIVE (gemifloxacin mesylate) in North America and certain countries in Europe, certain inventory and related assets and specific product-related liabilities through the Oscient Agreement 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. The agreement also extends these rights to

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additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are to be jointly developed by Meiji and us and which we and Meiji agree to have covered by the agreement. We and Meiji have agreed that the agreement will apply to CRTX 062 and CRTX 068 once we receive the necessary FDA approvals for these SPECTRACEF line extensions.

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. Under certain circumstances, we will be released from our obligation to make any further license fee payments if a third-party generic cefditoren product is launched in the United States prior to October 12, 2011. 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 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, Meiji will 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. These minimum purchase requirements cease to apply if a third party generic cefditoren product is launched in the United States prior to October 12, 2011.

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.

Joint Product Development. If either we or Meiji desires to develop new products or new therapeutic indications of an existing product under the license and supply agreement, that party must notify the other party, and both parties must then discuss in good faith the joint development of the new product or therapeutic indication and agree on whether the license and supply agreement will cover the new product or therapeutic indication and on the allocation of expenses between the parties related to the joint development.

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.

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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. As of December 31, 2009, we had made all of the required milestone payments. In addition, under each of the December 2003 and March 2004 license agreements, 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. As of December 31, 2009, we had made all 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.

Pharmaceutical Innovations ALLERX 372 Patent License Agreement

Overview. On August 31, 2006, we entered into a license agreement with Pharmaceutical Innovations that, as subsequently amended, provides for an exclusive license in the United States and Puerto Rico and a nonexclusive license in all other markets to manufacture, package, market, distribute and otherwise exploit ALLERX Dose Pack products that are covered by claims under the 372 Patent, by corresponding foreign patents and foreign patent applications and by certain Pharmaceutical Innovations know-how related to those ALLERX Dose Pack products. We also have the right to sublicense our rights under the license agreement to third parties. The 372 Patent expires May 4, 2021. On June 13, 2008, the USPTO received a request from Vision to re-examine the 372 Patent. On August 21, 2008, the USPTO ordered the re-examination of the 372 Patent. These re-examination proceedings are more fully discussed in Item 3, Legal Proceedings of this annual report on Form 10-K.

Royalties. We pay Pharmaceutical Innovations royalties based on the net sales per calendar year of each product covered by the licensed Pharmaceutical Innovations patents or know-how. We have agreed to a minimum annual royalty payment to Pharmaceutical Innovations throughout the term of the agreement. Royalties are payable with respect to the licensed patents until the earlier of the date all of the licensed patents expire or the date all of the licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Royalties are payable with respect to licensed know-how for a further period of seven years

after the expiration of our obligation to pay royalties with respect to the licensed patents.

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Term and Termination. The term of the agreement expires on the seventh anniversary of the earlier of the date that all the licensed patents expire or the date all licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Following expiration of the agreement, we have a fully paid, perpetual license to continue to make use of the Pharmaceutical Innovations know-how to manufacture, package, market, distribute and otherwise exploit the ALLERX Dose Pack products covered by claims under the 372 Patent.

Neos Development, License and Services Agreement Anticholinergic and Antihistamine Combination Product

Overview. In March 2008, we entered into a development, license and service agreement with Neos pursuant to which we obtained an exclusive license under Neos s patent-pending Dynamic Variable Release technology to develop, manufacture and commercialize an anticholinergic and antihistamine combination product in the United States, subject to obtaining necessary approvals from the FDA. Following successful formulation, Neos is responsible for manufacturing the licensed product for use in connection with our clinical trials and our regulatory submission to the FDA for the licensed product. Neos also has the exclusive right to manufacture the licensed product for commercial sale following FDA approval pursuant to a separate supply agreement that the parties agree to negotiate in good faith following FDA approval of the licensed product.

Fees, Milestones and Royalties. Under the agreement, we are obligated to pay Neos a minimum fee of approximately $1.8 million for its performance of the formulation and development work under the agreement, plus hourly fees related to development work performed by Neos personnel. In consideration for Neos s exclusive license to us of its patent-pending Dynamic Variable Release technology and related know-how in connection with the anticholinergic product, CRTX 058, we are obligated to pay Neos royalties determined as a percentage of the net sales of any licensed product.

Term and Termination. The agreement expires on the earlier of March 19, 2013 or FDA approval of an application for the licensed product. We may terminate the agreement with 90-days prior written notice if Neos fails to meet any milestones or quality targets determined in the development plan and may terminate the agreement immediately if Neos s manufacturing site is revoked as a cGMP manufacturing facility by the FDA. We also may immediately terminate the agreement if the product is unable to achieve a suitable pharmacokinetic profile as determined by the bioavailability study in the development plan or if we receive a complete response letter from the FDA with respect to the licensed product. If the regulatory submission is approved by the FDA, Neos s license of its Dynamic Variable Release technology and related know-how to us and Neos s exclusive manufacturing rights with respect to any licensed product will continue in full force and effect despite the expiration of the agreement generally. Additionally, our obligation to pay royalties with respect to any licensed product will continue until March 19, 2013 if no U.S. patent with a valid claim covering the licensed product has been issued or, if later, such date as there no longer exists a valid claim covering the licensed product under an issued U.S. patent or patent application.

Neos and Coating Place Development and Manufacturing Agreement Antitussive and Antihistamine Combination Product

Overview. In February 2008, we entered into a development and manufacturing agreement with Neos and Coating Place, as amended, pursuant to which we obtained an exclusive license under Neos s patent-pending DTRS technology and Coating Place s patent-pending drug resin complex technology to develop, manufacture and commercialize an antitussive and antihistamine combination product to compete directly in the U.S. narcotic antitussive market, subject to obtaining necessary approvals from the FDA.

Fees, Milestones and Profit Sharing. In consideration for our rights under the agreement, we paid Neos and Coating Place aggregate upfront fees of $500,000, and following product launch, we, Neos and Coating Place will share the

net profits from sales of the licensed product equally.

Product Development, Regulatory and Commercialization Expenses. Under the agreement, we are obligated to reimburse Neos and Coating Place for their respective costs of performing the development work

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related to the licensed product. The parties have agreed to share equally the Prescription Drug User Fee Act, or PDUFA, fees for licensed product.

Exclusivity. Under the agreement, Coating Place has the exclusive right to supply Neos with the drug resin complex needed to manufacture the licensed product. Neos is responsible for formulation development related to the licensed product and has the exclusive right to manufacture the licensed product for commercial sale. We are responsible for all regulatory activities with respect to licensed product in the United States, including preparation and regulatory submission to the FDA and, following FDA approval, have the exclusive right to sell, market and distribute the licensed product.

Term and Termination. The term of this agreement is 15 years from the date the first product is approved by the FDA, with the opportunity for one or more additional five-year successive terms, as mutually agreed by the parties. If we have failed to commercially launch the first product in the United States or Canada by the fifth anniversary of the agreement, any party may immediately terminate the agreement by written notice to the other parties. Additionally, upon the failure of clinical testing with respect to Neos s proposed formulation for the first product or our receipt of an FDA rejection of our drug approval application with respect to the first product, if we decide not to proceed with additional work or studies, then we have the right to immediately terminate the agreement by written notice to the other parties.

Neos Products Development Agreement

Overview. Pursuant to a products development agreement with Neos, as amended and restated in August 2008, we engaged Neos to develop various extended-release liquid products using Neos s patent-pending DTRS technology. Following successful formulation, Neos is responsible for manufacturing the licensed product for use in connection with our clinical trials and a regulatory submission to the FDA for the licensed product. Neos also has the exclusive right to manufacture the licensed product for commercial sale following FDA approval pursuant to a separate manufacturing agreement that the parties would enter into following FDA approval of the licensed product.

Fees, Milestones and Royalties. Under the agreement, we forgave debt owed by Neos to us totaling $500,000. Neos, at its own expense, is obligated to develop the first product up to and including completion of the first clinical study in humans. We are obligated to pay Neos hourly fees related to all other development work performed by Neos personnel under the agreement. In addition, we are obligated to pay certain milestone payments for additional work by Neos, including work performed in connection with regulatory approval and patent issuance. In connection with a manufacturing agreement, we will be obligated to pay royalties determined as a percentage of the net sales of any licensed product.

Term and Termination. The agreement expires on December 31, 2026. This agreement may be terminated upon written notice by either party to the other that federal or state regulatory authorities with jurisdiction over a party and the products has effected, or will effect at a time certain, changes to the regulations or have instituted one or more enforcement actions that can, in the determination of the relevant party, be reasonably expected to result in the commercial infeasibility of the objectives of the agreement. The agreement may also be terminated upon written notice by us to Neos if we determine that continued investment in the development or commercialization of the products is not commercially advisable.

Sovereign Supply and Marketing Agreement for Sovereign s Hyoscyamine Products

In May 2008, Aristos entered into a supply and marketing agreement, as amended, with Sovereign pursuant to which Aristos obtained the exclusive right to market, sell and distribute in the United States five of Sovereign s antispasmodic products, each containing the API hyoscyamine, in return for a share of the net profits realized from the

sale of the products. The initial term of the agreement expires April 30, 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination.

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The Feinstein Institute HMGB1 License Agreement and Alpha-7 License Agreement

Overview. In July 2001, we acquired from The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute), or The Feinstein Institute, an exclusive worldwide license, under patent rights and know-how controlled by The Feinstein Institute relating to HMGB1, to make, use and sell products covered by the licensed patent rights and know-how.

Fees and Royalty Payments Under License Agreement. In consideration for the license, in addition to an initial license fee, we agreed to make payments to The Feinstein Institute ranging from $50,000 to $275,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how, in each case upon the achievement of specified development and regulatory milestones for the applicable licensed product. In addition, we agreed to pay The Feinstein Institute royalties based on the net sales of licensed products by us and our affiliates until the later of 10 years from the first commercial sale of each licensed product in a given country and the expiration of the patent rights covering the licensed product in that country. We agreed to pay minimum annual royalties to The Feinstein Institute beginning in July 2007 regardless of whether we sell any licensed products. For the year July 2008 to June 2009, the agreement provided for minimum royalties of $15,000. We also agreed to pay The Feinstein Institute fees if we sublicense our rights under the licensed patent rights and know-how.

Related Sponsored Research Agreements. We also have entered into two sponsored research and license agreements with The Feinstein Institute in July 2001 related to identifying identify inhibitors and antagonists of HMGB1 and related proteins and in January 2003 in the field of cholinergic anti-inflammatory technology, including alpha-7. Under the terms of these agreements, we acquired an exclusive worldwide license to make, use and sell products covered by the patent rights and know-how arising from the sponsored research.

Fees and Royalty Payments Under Sponsored Research Agreements. In connection with the July 2001 sponsored research and license agreement, we agreed to make payments to The Feinstein Institute ranging from $50,000 to $200,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how. In connection with the January 2003 sponsored research and license agreement, we agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. We also agreed to make aggregate milestone payments to The Feinstein Institute of up to $1.5 million in both cash and shares of our common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. In addition, under each of these agreements, we agreed to pay The Feinstein Institute royalties based on the net sales of a licensed product by us and our affiliates until the later of 10 years from the first commercial sale of licensed products in a given country and the expiration of the patent rights covering the licensed product in that country. Under the January 2003 sponsored research and license agreement, we agreed to pay minimum annual royalties beginning in 2008 to The Feinstein Institute, regardless of whether we sell any licensed products, of $100,000 in 2008, which minimum annual royalties amount will increase by $50,000 annually to a maximum of $400,000 in 2014, with a minimum annual royalty payment of $400,000 thereafter payable through the expiration of the patent in 2024. We also agreed to pay The Feinstein Institute certain fees if we sublicense our rights under the licensed patent rights and know-how under either agreement.

MedImmune License and Collaboration Agreement HMGB1 Pharmaceuticals

Overview. In July 2003, we entered into an exclusive license and collaboration agreement with MedImmune to jointly develop products directed towards HMGB1. This agreement was amended in December 2005. Under the terms of the agreement, we granted MedImmune an exclusive worldwide license, under patent rights and know-how controlled by us, to make, use and sell products, including antibodies, that bind to, inhibit or inactivate HMGB1 and are used in the

treatment or prevention, but not the diagnosis, of diseases, disorders and medical conditions.

We and MedImmune determine the extent of the collaboration on research and development matters each year upon the renewal of a rolling three-year research plan. We are currently working with MedImmune to evaluate the potential of a series of fully human monoclonal antibodies as agents for development as

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therapeutic antibodies to enable them to enter clinical development. Under the terms of the agreement, MedImmune agreed to fund and expend efforts to research and develop at least one HMGB1-inhibiting product for two indications through specified clinical phases.

Milestones and Royalties. Subject to the terms and conditions of the agreement, we may receive other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124.0 million, after taking into account payments that we are obligated to make to The Feinstein Institute. We have not recorded and will not record these future development and commercialization milestones until they are achieved. MedImmune also has agreed to pay royalties to us based on the net sales by MedImmune of licensed products resulting from the collaboration. MedImmune s obligation to pay us royalties continues on a product-by-product and country-by-country basis until the later of 10 years from the first commercial sale of a licensed product in each country and the expiration of the patent rights covering the product in that country. We are obligated to pay a portion of any milestone payments or royalties we receive from MedImmune to The Feinstein Institute.

Term and Termination. The term of the agreement expires on July 30, 2053 or the expiration of all royalty obligations, whichever is earlier. MedImmune has the right to terminate the agreement at any time on six-months written notice. Under specified conditions, we or MedImmune may have certain payment or royalty obligations after the termination of the agreement.

Beckman Coulter License Agreement HMGB1 Diagnostic Products

Overview. In January 2005, we entered into a license agreement with Beckman Coulter relating to the development of diagnostic products for measuring HMGB1. Under the terms of the agreement, we granted to Beckman Coulter and its affiliates an exclusive worldwide license, under patent rights and know-how controlled by us relating to the use of HMGB1 and its antibodies in diagnostics, to evaluate, develop, make, use and sell a kit or assemblage of reagents for measuring HMGB1 that utilizes one or more monoclonal antibodies to HMGB1 developed by us or on our behalf. In August 2009, we consented to Beckman Coulter s grant sublicenses under the terms of the license agreement.

Milestones and Royalties. In consideration for the license, among other things, we may receive additional aggregate license fees of $450,000 upon the achievement of the first commercial sale of a licensed product. Beckman Coulter also agreed to pay us royalties based on the net sales of licensed products by Beckman Coulter and its affiliates, and to pay us a percentage of any license fees, milestone payments or royalties Beckman Coulter receives from its sublicensees.

Term and Termination. The agreement expires on the later of either the last to expire of the patents included in this agreement or the cessation of Beckman Coulter using any of our monoclonal antibodies in the products. Beckman Coulter has the right to terminate the license agreement at any time on 90-days written notice.

SetPoint Vagus Nerve Technology License

Overview. In January 2007, we entered into an exclusive license agreement with SetPoint Medical Corporation (formerly known as Innovative Metabolics, Inc.), or SetPoint, under which we granted to SetPoint an exclusive worldwide license under patent rights and know-how controlled by us relating to the mechanical and electrical stimulation of the vagus nerve to make, use and sell products and methods covered by the licensed patent rights and know-how in the licensed field. Under this license agreement, SetPoint agreed to be responsible for specified obligations we owe to The Feinstein Institute pursuant to our January 2003 sponsored research and license agreement, under which this technology was developed. SetPoint agreed to financially support sponsored research under the sponsored research and license agreement to the extent that the sponsored research is in the licensed field under the SetPoint license agreement. SetPoint also agreed to reimburse us for a portion of:

amounts payable to The Feinstein Institute in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology; and

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minimum annual royalties payable to The Feinstein Institute beginning in the first year after termination of research activities under the sponsored research agreement.

Milestones and Royalties. Under this license agreement, SetPoint agreed to make a one-time milestone payment to us of $1.0 million upon receipt of all regulatory approvals needed to market and sell any product or method covered by the licensed patent rights in any country. Additionally, SetPoint is obligated to pay us royalties based on the net sales of licensed products and methods by SetPoint and a percentage of any royalties, fees and payments actually received from third parties, with limited exceptions, in connection with sublicenses by SetPoint of its rights under the licensed patent rights and know-how.

Term and Termination. The agreement expires on the date at which time there are no more valid claims under the patents covered by the agreement. SetPoint has the right to terminate the SetPoint license agreement at any time on 90-days prior written notice to us.

Competition

The pharmaceutical industry, including the respiratory market in which we principally compete, is 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.

Given that we are developing product candidates based on currently marketed drug compounds, some or all of the products in our product pipeline, if approved, may face competition from generic and branded formulations of these existing 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:

CUROSURF Abbott s Survanta and ONY, Inc. s Infasurf®

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

SPECTRACEF Dose Packs or any anti-infective product candidate second and third generation cephalosporins, such as Shionogi USA, Inc. s Cedax® (ceftibuten), Lupin Pharmaceuticals, Inc. s, Suprax® and generic formulations of Abbott s Omnicef® (cefdinir) and GlaxoSmithKline plc s, or GSK, Ceftin® (cefuroxime).

ZYFLO CR and ZYFLO or anti-asthma product candidate bronchodilatory drugs, such as Teva Specialty Pharmaceuticals LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering-Plough Corporation s, or Schering Plough, Proventil® HFA (albuterol sulfate) Inhalation Aerosol;

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LTRAs, such as Merck Sharp and Dohme s Singulair® (montelukast sodium); inhaled corticosteroids, such as GSK s 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. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market.

ALLERX Dose Pack Products or any allergy product candidate prescription products, including first generation antihistamine and antihistamine combination products, such as Capellon Pharmaceuticals, Ltd. s Rescon® (phenylephrine, chlorpheniramine and methscopolamine) and Laser Pharmaceuticals, LLC s Dallergy® (phenylephrine, chlorpheniramine and methscopolamine); over-the-counter products, such as McNeil-PPC, Inc. s, or McNeil-PPC, Benadryl® (diphenhydramine), Schering-Plough s Chlor-Trimeton® (chlorpheniramine) and Claritin® (loratadine), McNeil-PPC s Zyrtec® (cetirizine); second generation antihistamines, such as Sanofi-Aventis U.S. LLC s, or Sanofi Aventis, Allegra® (fexofenadine); and third generation antihistamine branded families of products, such as UCB, Inc. and Sanofi-Aventis s Xyzal® (levocetirizine) and Schering-Plough s Clarinex® (desloratadine).

HYOMAX Products belladonna and derivative antispasmodics, such as the generic formulations of Alaven Pharmaceutical LLC s Levsin® (hyoscyamine sulfate) and Levbid® (hyoscyamine sulfate) and of PBM Pharmaceuticals, Inc. s Donnatal® (belladonna alkaloids/phenobarbital); IBS selective serotonin 5-HT3 antagonists, such as Lotronex®; urinary incontinence antispasmodics, such as Pfizer Inc. s Detrol® LA (tolterodine tartrate), Astellas Pharmaceuticals, Inc. and GSK s VESIcare® (solifenacin) and the generic formulations of Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Ditropan® and Ditropan XL® (oxybutynin); and synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma Inc. s Bentyl® (dicyclomine) and Bradley Pharmaceuticals, Inc. s Pamine® (methscopolamine bromide).

Cough/cold product candidates various narcotic and non-narcotic antitussives, such as King Pharmaceuticals, Inc. s Tussigon® (hydrocodone and homatropine), Mallinckrodt Brand Pharmaceuticals, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), UCB, Inc. s Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) and generic formulations of promethazine hydrochloride and codeine phosphate oral syrup and Forest Laboratories, Inc. s Tessalon® (benzonatate); over-the-counter antitussives, such as Reckitt Benckiser Inc. s Delsym® (dextromethorphan polistirex), Schering-Plough s Coricidin HBP® Cough & Cold (dextromethorphan and chlorpheniramine).

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 the applicable United States 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 Products

Before a new drug may be marketed in the United States, it must be approved by the FDA. Certain of our drugs, including ALLERX and HYOMAX, do not have such approval and are subject to the risk that the FDA will take enforcement action against us, which could preclude our marketing these products until we have obtained FDA approval for them. As a matter of the FDA enforcement discretion, the FDA has tolerated some such drugs remaining

on the market without having first received FDA marketing approval, but the FDA is under no obligation to continue to refrain from enforcement action and can take enforcement action at any time.

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Depending on the drug for which approval is sought, FDA marketing approval can be issued either as approval of an NDA or an 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 investigational new drug application, or 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. There can be no assurance that submission of an IND will 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. We cannot be sure that any Phase I, Phase II, or Phase III clinical trials we initiate will 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 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

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additional data and information. Even though 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. 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 can 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.

Some of our 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: Abbreviated New Drug Applications, or 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 of our 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 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

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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 certain of our products and product candidates, including those containing propoxyphene, pseudoephedrine and hydrocodone, are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturers and packagers must adhere to a number of requirements with respect to our controlled substance products and product candidates, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls; and certain restrictions on prescription refills.

In addition, a DEA quota system controls and limits the availability and production of certain controlled substances, including propoxyphene, pseudoephedrine and hydrocodone that are used in our products and 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 these substances 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. 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 meet commercial demand for our products or 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.

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.

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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 from third-party payors, including governmental payors such as the Medicare and Medicaid programs, MCOs and private health insurers. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products, 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 payors may decide not to provide coverage and reimbursement for our products, in whole or in part. If third-party payors approve coverage and reimbursement, the resulting payment rates may not be sufficient for us to sell our products at a profit.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the health care system in ways that could significantly affect our business.

We anticipate that Congress, state legislatures and the private sector will continue to consider and may adopt 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.

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. Under this program, our products may be excluded from 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 managed care plans will follow Medicare coverage and reimbursement policies.

Outpatient pharmaceuticals sold to state administered Medicaid programs are subject to the national Medicaid Drug Rebate Program. In order to have their drugs covered by state Medicaid programs, pharmaceutical companies must enter into an agreement under which they agree to pay a rebate to the states that is determined on the basis of a specified percentage of the average manufacturer price or the difference between the average manufacturer price and the best price. Pharmaceutical companies must also enter into a similar agreement with the U.S. Department of Veterans Affairs to have their drugs covered by state Medicaid

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programs, and some states may impose supplemental rebate agreements. We are a party to these types of pricing agreements with respect to our currently marketed products.

We may also face competition for our products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes 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 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 payors, 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.

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. These laws apply broadly and may constrain our business and the financial arrangements through which we market, sell and distribute our products. 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, direct or indirect 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.

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 payor, including private, commercial insurers and other payors. Moreover, these laws and regulations vary significantly from state to state and, in some cases, are broader than the federal laws and regulations. These differences increase the costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

Employees

As of February 28, 2010, we had 162 full-time employees, 110 of whom were engaged in marketing and sales; seven of whom were engaged in research, development and regulatory affairs; and 45 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.

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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.

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

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 payors and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, health care payors and others in the medical community. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be able to sustain or increase our profitability. 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.

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Our strategy of obtaining, through product acquisitions and in-licenses, rights to products and product candidates for our development pipeline and to proprietary drug delivery and formulation technologies for our life cycle management of current products may not be successful.

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

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

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

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

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

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 of our currently marketed products do not have patent protection and in

many cases face competition from generics and other unbranded products. All of these products face significant price competition from a range of branded, unbranded and generic products for the same therapeutic indications.

Given that our product development approach is to develop new formulations of existing drugs, some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. For example, our CRTX 073 product candidate, which is a modified formulation of an existing product, may not demonstrate sufficient additional clinical benefits to physicians 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. If NDA approval is received for a new drug containing an API that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, a NDA approval for a new indication or formulation of the drug with the same API, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA for a generic version of such drug for a period of three years from the date of the NDA approval. This three-year exclusivity, however, only covers the innovation associated with the NDA to which it attaches.

The FDCA also provides a five-year period of exclusivity for a drug approved under the first NDA no API of which has previously been approved. If the drug approval for any of our product candidates were blocked by such a period of marketing exclusivity, we would not be able to receive FDA approval until the applicable exclusivity period expired.

The principal competitors to our products and potential competitors to our product candidates are more fully under the caption Competition in Item 1 of this annual report on Form 10-K.

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.

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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 fail to manage successfully our product acquisitions, our ability to develop our product candidates and expand our product pipeline may be harmed.

Our failure to address adequately the financial, operational or legal risks of our product acquisitions or in-license arrangements could harm our business. These risks include:

- the overuse of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses and/or restructuring charges;
- the assumption of or exposure to unknown liabilities;
- the development and integration of new products that could disrupt our business and occupy our management s time and attention;
- the inability to preserve key suppliers or distributors of any acquired products; and
- the acquisition of products that could substantially increase our amortization expenses.

If we are unable to successfully manage our product acquisitions, our ability to develop new products and expand our product pipeline may be limited, and we could suffer significant harm to our financial condition, results of operations and prospects.

For example, we entered into a license and distribution agreement with Chiesi for CUROSURF that extends to 2019. Even though CUROSURF was already marketed in the United States at the time we acquired the rights to market it, there can be no assurance that our pre-acquisition due diligence identified all possible issues that may arise with respect to this product. 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.

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. 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.

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

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

Certain of our products, including ALLERX 10 Dose Pack, ALLERX 30 Dose Pack and our propoxyphene/acetaminophen products (BALACET 325, APAP 325 and APAP 500), contain controlled substances, which are regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer can manufacture, the amount of API it can use to manufacture those products and the amount of controlled substance drug products a packager can package. We rely on the third-party manufacturers and packagers of these products to annually request and obtain from the DEA the quota allocation needed to meet our production requirements. If our manufacturers and packagers are unsuccessful in obtaining quotas, our supply chain for controlled substance products could be at risk.

If we or our contract manufacturers or packagers fail to comply with regulatory requirements for our 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 certain of our products and product candidates, including those containing propoxyphene, pseudoephedrine and hydrocodone, are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturers and packagers must adhere to a number of requirements with respect to our controlled substance products and product candidates, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on prescription refills. 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. 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.

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 that 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 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, and we are obligated to submit periodic REMS assessments for FACTIVE to the FDA 18 months and three years following the approval of the REMS.

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.

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Concerns regarding the potential toxicity and addictiveness of propoxyphene and the known liver toxicity of acetaminophen may limit market acceptance of our propoxyphene/acetaminophen products or cause the FDA to remove these products from the market.

Periodically, there is negative publicity related to the potential toxicity and addictiveness of propoxyphene. Propoxyphene is one of two APIs, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. For example, the consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. The FDA denied the citizen petition on July 7, 2009 stating, that despite serious concerns about propoxyphene, the benefits of using the medication for pain relief outweighed its safety risks. However, as part of the REMS for propoxyphene products, the FDA is also requiring our propoxyphene/acetaminophen products to include additional labeling in the boxed warning to address the risk of overdose and to be accompanied by an FDA-approved medication guide. 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 the propoxyphene/acetaminophen products, which would cause sales of these products to suffer.

In December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. The FDA convened a public advisory committee meeting to discuss acetaminophen risk management in June 2009 and resulted in a number of recommendations to the FDA, including changing the amount of acetaminophen per dosage unit from 500 to 325 mg and banning combinations of acetaminophen and narcotic analgesics such as propoxyphene. The FDA could act on these concerns by changing its policies with respect to acetaminophen as a single ingredient and in combination with opioid products. A change in the FDA s policy could adversely affect our ability to market our propoxyphene/acetaminophen products.

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 alanine transaminase, or 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

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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.

We 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.

We rely on DEY to jointly market and promote ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR in October 2007. If DEY were to terminate or breach the co-promotion agreement, and we were unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promote and market ZYFLO CR, then our sales of ZYFLO CR would be limited and we would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. 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. Because ZYFLO CR cumulative net sales for the four consecutive calendar quarters ended December 31, 2009 were less than $20 million, DEY has the right to terminate the co-promotion agreement.

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. Sales to our three primary wholesale distributors, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, collectively accounted for at least 88% of our gross product sales during 2009.

The loss of any of these wholesaler customers accounts 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. The risk of this occurring is exacerbated by the significant consolidation in the wholesale drug distribution industry and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

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

We rely on third parties to distribute our products 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.

Our distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. 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. 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. 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.

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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.

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 is unable to provide this assistance, our operating performance would be adversely affected.

The full impact of the credit crunch that is currently affecting the national and international credit markets has yet to be fully established and therefore the possibility remains that credit conditions, as well as a slowdown or recession in economic growth, 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.

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 28, 2010 of 114 sales professionals in a variety of sales and management positions. Our sales organization is divided into a respiratory sales force and a hospital 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. However, we might not be able to enter into such an arrangement on favorable terms, if at all. Even if we are able to effectively expand our sales force and marketing capabilities, our sales force and marketing teams may not be successful in commercializing and promoting our products.

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 Seika Kaisha, Ltd., or 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 $15.0 million for the sales year ended October 2009,

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$20.0 million for the sales year ended October 2010, $25.0 million for the sales year ended October 2011, $30.0 million for the sales year ended October 2012 and $35.0 million for the sales year ended 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 using our current inventory of cefditoren pivoxil for formulation, development and manufacture of the currently marketed SPECTRACEF products as well as the SPECTRACEF line extensions.

We are also subject to minimum purchase obligations under supply agreements, which require us to buy 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 may not be able to use the inventory we are required to purchase. Based on our current expectations regarding demand for ZYFLO CR, we expect that inventory levels could increase substantially in the future as a result of minimum purchase obligations under supply agreements with third-party manufacturers and orders we have submitted to date.

Product acquisitions typically include 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 current demand. We do not anticipate FACTIVE sales to wholesalers and distributors to increase until the current wholesaler inventories decrease.

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 products as a result of U.S. Drug Enforcement Administration regulations and because of the limited number of suppliers of pseudoephedrine, hyoscyamine sulfate and methscopolamine nitrate. 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.

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, 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 will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products or any products that we may develop;
- injury to our reputation;
- the withdrawal of clinical trial participants;
- the withdrawal of a product from the market;
- costs to defend the related litigation;

substantial monetary awards to clinical trial participants or patients;

diversion of management time and attention;

loss of revenue; and

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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 propoxyphene, acetaminophen, gemifloxacin or zileuton. While we are not aware of any pending or threatened product liability claims against us related to any of these APIs, we cannot assure you that such claims will not arise in the future.

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 products liability insurance was approximately $358,000 for the policy year beginning September 13, 2009. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Relating to Product Development and Regulatory Matters

Some of our specialty pharmaceutical products are now being 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 refrained from taking enforcement action against some marketed, unapproved new drugs. The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. 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 cGMP requirements. Also, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and the FDA could at any time ask or require that the products be removed from the market immediately. Although we may be given the benefit of a grace period to submit a marketing application before the agency would take enforcement action, we cannot guarantee this would be the case. Furthermore, the time it would take us to complete the necessary clinical trials and submit an NDA or ANDA to the FDA may exceed any grace period and would result in an interruption of sales of our products.

In November 2009, we reported that as a result of an inspection of one of our contract manufacturers facilities we had received a warning letter from the FDA alleging that Deconsal CT (phenylephrine hydrochloride, pyrilamine maleate) chewable tablets and Deconsal DM (phenylephrine hydrochloride, pyrilamine maleate, dextromethorphan hydrobromide) chewable tablets were new drugs lacking an approved application and as such should not be introduced into interstate commerce. We responded to the warning letter by advising the FDA that although we did not admit its allegations, we had not sold any Deconsal CT products since July 2009 and had not sold any Deconsal DM products since January 2009, and do not intend to manufacture, or have manufactured, any further lots of these products.

If the FDA required us to remove our unapproved products from the market, particularly our ALLERX Dose Pack products and our HYOMAX line of products, our revenue from product sales would be significantly reduced. Our net revenues from sales of our ALLERX Dose Pack products and our HYOMAX line of products were $31.7 million and

$28.1 million for 2009, respectively.

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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 these product candidates successfully.

Our product candidates are still in various stages of development. All of our product candidates other than CRTX 067 remain subject to pharmaceutical formulation development and 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 trials. We may not be able to obtain permission from the FDA, institutional review boards, or 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.

For example, Guidance for Industry issued by the FDA in 2007 regarding, among other things, the design of clinical trials of anti-infective drug candidates for the treatment of acute bacterial otitis media, noted that investigators or IRBs may consider a placebo-controlled study to be unethical where the trial would involve the withholding of known effective antimicrobial treatment to the placebo control group unless the investigators and IRBs determine that the withholding of known effective treatment would result in no more than a minor increase over minimal risk. The FDA suggested that the ethical dilemma might be bridged by using a superiority study of the investigational antimicrobial compared to a known effective antimicrobial treatment. While the FDA did not absolutely prohibit placebo-controlled trials, we believe this FDA guidance may make placebo-controlled trials more difficult to design and complete for antibiotics, especially in pediatric populations.

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 a number of our product candidates in 2010 and 2011. 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;

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- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;

- our 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 meet their contractual obligations in a timely manner;

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

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

- exposure of participants to unacceptable health risks.

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 our product candidates 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, 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

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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.

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 clinical trials could fail at any stage of testing.

We expect to submit an NDA to the FDA in 2012 for CRTX 070 for use of this product candidate by children 12 years of age and older and adults with seasonal and perennial allergic rhinitis. Failure of our clinical trials to achieve the desired efficacy endpoint, or issues such as incomplete, outdated or otherwise unacceptable data could cause this NDA to be delayed or rejected.

If we are required to conduct additional clinical trials or other testing of our product candidates in addition to those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, 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 payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of our products.

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs varies but coverage is similar to other products within the same class of drugs. For example, SPECTRACEF is covered by private insurance plans similar to other marketed, branded cephalosporins. However, the position of SPECTRACEF as a branded product often requiring a higher patient copayment may make it more difficult to expand the current market share for this product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for SPECTRACEF. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our

products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Additionally, some of our products are purchased under the 340B Drug Pricing Program,

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which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals.

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

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

If we succeed in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates are in the development stage, we do not know whether payors 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.

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.

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 and our products and our contract manufacturers and 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,

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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, or DDMAC, on May 4, 2009 relating to two sales aids that we formerly used to promote SPECTRACEF. The FDA asserted that the sales aids were misleading, and although we did not admit and in fact denied FDA s allegations, we no longer use the sales aids. In connection with the close out of this matter, we also disseminated corrective messages to the recipients of the deficient promotional materials and incorporated revisions into new SPECTRACEF promotional materials 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. For example, as part of the REMS for FACTIVE, the FDA required the packaging to be revised to include a boxed warning and a medication guide. The FDA also requires us to periodically submit a REMS assessment for FACTIVE to evaluate whether the REMS are sufficient to inform patients of the serious risks associated with their use. Completion of the REMS assessment could be costly and time consuming.

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. We cannot assure you that our current quality assurance program is reasonably designed to, or would, discover all instances of non-compliance by our third-party manufacturers with these regulations. For instance, the FDA inspected one of our contract manufacturer s facilities in 2009 and as a result of alleged failure of the manufacturer to comply with cGMP, the FDA issued a warning letter to the manufacturer. Companies, including us, whose products were cited in the manufacturer s warning letter were issued warning letters for separate allegations.

The FDA periodically inspects sponsors, marketers and manufacturers for compliance with these requirements. On April 28, 2009, the FDA issued us a Notice of Inspectional Observations, or Form 483, in connection with an inspection of our ZYFLO CR regulatory procedures it conducted during April 2009. The Form 483 stated that our processes related to ZYFLO CR for review of batch specific documentation, analytical information, deviations and investigations prior to releasing finished product for distribution; our staffing levels relating to quality assurance and controls; and our late filing of a ZYFLO CR Field Alert Report are areas of possible non-compliance with FDA regulations. We responded to the FDA on May 7, 2009 and have taken actions to address each of the observations identified by the FDA in the Form 483 as quickly as practicable.

If the FDA makes additional inspectional observations in other inspections or if the FDA 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;

recalls;

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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.

We will spend considerable time and money complying with federal and state laws and regulations, and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.

Health care providers, physicians and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other 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 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. Applicable federal and state health care laws and regulations, include, but are not limited to, the following:

The federal anti-kickback statute 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, direct or indirect 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 federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds. Penalties include three times the government s damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the False Claims Act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the *qui tam* plaintiff is rewarded with a percentage of the recovery;

HIPAA imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

The Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and

Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws. In some cases, these state laws impose more strict requirements than the federal laws. Some state laws also require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

We are a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the Medicaid rebate program, 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. Both the federal government and state governments have initiated investigations into the rebate practices of many pharmaceutical companies to ensure compliance with these rebate programs. Although we estimate that less than 1% of our sales qualify for Medicaid rebates, any

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investigation of our rebate practices could be costly, could divert the attention of our management and could damage our reputation.

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 team 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 government health care programs 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 exclusions from government 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.

Risks Relating to Our Dependence on Third Parties

We use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates at an acceptable cost, which could result in clinical development and commercialization of product candidates being delayed, prevented or impaired.

We have no manufacturing facilities and rely on third parties to manufacture and supply all of our products. We currently rely on these third parties for the purchase of raw materials and the manufacture and packaging of our products. Many 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 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 their 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.

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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 who, in some instances, have encountered difficulties obtaining raw materials needed to manufacture our products as a result of DEA regulations and because of the limited number of suppliers of pseudoephedrine, hyoscyamine sulfate, and methscopolamine nitrate. 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 finished product for certain of our products from third parties that manufacture such items outside the United States, and we expect to do so from outside the United States in the future. This may give rise to difficulties in obtaining API, 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.

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. For example, two United States patents exclusively licensed to us have been challenged by third parties in re-examination proceedings before the USPTO. While we no longer rely on one of the patents to protect any of our products, we believe that the other United States patent being re-examined, the 372 Patent, covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. If the USPTO finds that some or all of the claims under the 372 Patent are invalid, our sales of the ALLERX Dose Pack products and our future operating and financial results could be adversely affected. 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.

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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 United States 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 United States patent protection. In addition, United States 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.

The composition of matter patent for the API in ZYFLO CR and ZYFLO will expire in December 2010 and the composition of matter patent for the API in FACTIVE will expire in April 2017. None of our other current products or current product candidates 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 own or 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 other than ZYFLO CR, ZYFLO and FACTIVE. The composition of matter United States patent for zileuton that is used in ZYFLO CR and ZYFLO will expire in December 2010. The composition of matter United States patent for gemifloxacin mesylate that is used in FACTIVE will expire in April 2017.

When the composition of matter patent for the API in one of our products expires, 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

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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.

If Orchid successfully challenges all of the patents covering FACTIVE, it could result in the introduction of a generic product prior to the expiration of the patents covering FACTIVE, as well as in significant legal expenses and diversion of management s time.

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 payors 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 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. 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.

Competitors may also seek to cancel our similar trademarks based on the competitor s prior use. For example, on May 15, 2008, the USPTO sent written notice to us that Bausch & Lomb Incorporated, or Bausch & Lomb, filed a cancellation proceeding with respect to the ALLERX registration, 3,384,232 (serial number 77120121), seeking to cancel the ALLERX registration based on Bausch & Lomb s claims that such registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We responded to the Trademark Trial and Appeal Board, or TTAB, on June 24, 2008 opposing the claims by Bausch & Lomb. On February 2, 2010, the TTAB granted a motion to again suspend proceedings for 90 days until May 3, 2010 to allow the parties to negotiate a possible settlement of the cancellation proceeding. If the settlement

discussions do not provide a prior resolution, we could take numerous courses of action, including continuing to oppose the claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex® trademark, or entering into discovery. If the USPTO cancels the ALLERX registration, we will be required to cease marketing products under that brand,

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which could adversely affect sales of the ALLERX Dose Pack products and our future operating and financial results.

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.

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.

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.

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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

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 or commercialization efforts.

We have incurred and expect to continue to incur significant development expenses in connection with our ongoing activities, particularly as 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 newly acquired products or product candidates. 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, 2009, we had $18.9 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 from 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;

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the extent to which we chooses 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.

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, 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 have only been profitable since 2007, and we may be unable to sustain and increase our profitability, even if we are able to commercialize additional products. To date, we have financed our operations primarily with revenue from product sales and borrowings. 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;

seek regulatory approvals for product candidates that successfully complete clinical testing; and

expand our sales force and marketing capabilities to prepare for the commercial launch of future products, subject to FDA approval.

We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts.

For us to sustain and increase our 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 clinical trials of our product candidates;
- obtaining and maintaining regulatory approval for these product candidates; and
- manufacturing, marketing and selling those products for which we may obtain regulatory approval.

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

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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. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated 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. We cannot assure you, therefore, that any of our estimates, or the assumptions underlying them, will be correct.

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:

seasonality of the cough/cold and allergy seasons, which historically results in higher sales of our respiratory products during the first and fourth quarters of the calendar year;

new product launches, which could increase revenues but also increase sales and marketing expenses;

acquisition activity;

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 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;

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.

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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 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, President and Chief Executive Officer, and David Price, Executive Vice President, Finance and Chief Financial Officer, might significantly delay or prevent the achievement of our

development and commercialization objectives and could cause us to incur additional costs to recruit replacements. Each member of our executive management team may terminate his or her 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. For example, Brian Dickson, M.D., our former Chief Medical Officer, retired during October 2009. Although Alan Roberts,

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Vice President, Scientific Affairs, assumed primary responsibility for coordinating all of our medical activities, there is no assurance that Dr. Dickson s departure will not adversely affect our ability to achieve our business objectives.

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 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;

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. In connection with the Chiesi transaction,

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we entered into a governance agreement with Chiesi and amended our certificate of incorporation and bylaws to, among other things, do the following:

- reconstitute our board of directors to be comprised of two classes of directors, with our Class A Directors consisting of our Chief Executive Officer and three independent directors and our Class B Directors consisting of four persons designated by Chiesi, or the Chiesi Designees (the number of Chiesi Designees will decrease depending on the level of Chiesi s and its affiliates ownership of our common stock);

- so long as Chiesi and its affiliates beneficially own at least 50% of our common stock, require board actions to be taken by a majority in voting power of the directors present, and further provide that the Class B Directors present at a meeting will collectively have the same voting power as the Class A Directors present at the meeting; and

- so long as Chiesi and its affiliates beneficially own at least 40% of our common stock, require Chiesi s or our full board of directors approval of certain corporate actions.

These provisions, among others, give Chiesi a strong ability to influence our business, policies and affairs. 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. 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 (subject to certain restrictions in the governance agreement while they remain in effect) effectively receive a premium for transferring ownership to third parties that would not inure to the benefit of other stockholders.

The governance agreement with Chiesi terminates on July 28, 2011, unless it earlier terminates due to (1) Chiesi and its affiliates acquiring all of our common stock, (2) Chiesi and its affiliates ceasing to own 10% or more of our common stock on a fully diluted basis (as defined in the agreement) or (3) our experiencing a change in control. If Chiesi continues to own a majority of our common stock at the time the governance agreement terminates, and if the governance agreement is not renewed or replaced by a similar arrangement, Chiesi would have the ability to exercise even greater control over our company. Delaware law provides that directors, including those appointed by Chiesi, have fiduciary duties to all stockholders. Delaware law 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 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 other significant corporate actions.

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***

Prior to March 2008, we used a different formulation for ALLERX 10 Dose Pack and ALLERX 30 Dose Pack that we believe was protected under claims in U.S. patent number 6,270,796, or the 796 Patent. In 2007, the USPTO ordered a re-examination of the 796 Patent as a result of a third-party request for ex parte re-examination by J-Med Pharmaceuticals, Inc., or J-Med.

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In proceedings before a re-examination examiner in the USPTO, the examiner rejected claims of the 796 Patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims. J-Med appealed to the USPTO Board of Patent Appeals and Interferences, or Board of Patent Appeals, on June 13, 2008, seeking reversal of the examiner s rejections. On the same date, J-Med filed additional documents with the USPTO for review by the examiner. The examiner responded with an advisory action, withdrawing several of the rejections, but maintaining other rejections. An appeal brief was filed on August 18, 2008, a supplemental appeal brief was filed on May 7, 2009 and a reply brief was filed on January 25, 2010. If the examiner does not reverse her prior rejections, then the Board of Patent Appeals will act on the case and can take various actions, including affirming or reversing the examiner s rejections in whole or part, or introducing new grounds of rejection of the 796 Patent claims. If the Board of Patent Appeals thereafter affirms the examiner s rejections, J-Med can take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 796 Patent with narrowed claims. The further proceedings involving the 796 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 796 Patent.

On June 13, 2008, counsel for Vision filed in the USPTO a request for re-examination of certain claims under U.S. patent number 6,843,372, or the 372 Patent, which we believe covers our current formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, as well as ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Our counsel reviewed the request for re-examination and the patents and publications cited by counsel for Vision, and our counsel have concluded that valid arguments exist for distinguishing the claims of the 372 Patent over the references cited in the request for re-examination. On June 18, 2009, the USPTO examiner issued an office action, rejecting claims of the 372 Patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims, in view of the patents and publications cited by Vision. On August 18, 2009, the patent owner, Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations, filed an amendment to the claims and request for reconsideration of the office action issued on June 18, 2009. If the USPTO re-examination examiner maintains one or more of the USPTO rejections of the claims of the 372 Patent, Pharmaceutical Innovations may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If the Board of Patent Appeals thereafter affirms the examiner s rejections, Pharmaceutical Innovations could take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 372 Patent with narrowed claims. The further proceedings involving the 372 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 372 Patent.

In February 2008, we filed a notice of opposition before the Trademark Trial and Appeal Board, or TTAB, in relation to Application No. 77/226,994 filed in the USPTO by Vision, seeking registration of the mark VisRx. The opposition proceeding is captioned *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, Opposition No. 91182604. In April 2008, Vision filed an answer and counterclaims in which it requested cancellation of our U.S. Registration Nos. 3,384,232 (covering the mark ALLERX for use in connection with anti-allergy, antihistamine and decongestant preparations) and 2,448,112 (covering the mark ALLERX for use in connection with dietary and nutritional supplements). Vision did not request monetary relief. On October 29, 2009, we reached an agreement with Vision to settle the opposition proceeding, which provided for dismissal with prejudice of our opposition to Vision s application for registration of the mark VisRx; dismissal without prejudice of Vision s counterclaim seeking cancellation of U.S. Registration No. 3,384,232; and voluntary cancellation of U.S. Registration No. 2,448,112. A stipulation memorializing the agreed resolution of the opposition proceeding and an application for voluntary cancellation of U.S. Reg. No. 2,448,112 were filed with the TTAB on October 29, 2009.

On May 15, 2008, the TTAB issued written notice to us indicating that Bausch & Lomb, Incorporated, or Bausch & Lomb, had initiated a cancellation proceeding (Cancellation No. 92049358) against U.S. Reg. No. 3,384,232. The petition for cancellation filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark, that the ALLERX mark so resembles Bausch & Lomb s Alrex® mark as to cause confusion as to the source of goods sold under ALLERX mark and that Bausch & Lomb is likely to be damaged by

the ALLERX registration. We timely filed an answer to

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Bausch & Lomb s petition for cancellation, disputing claims made in such petition and raising various defenses. Discovery requests were issued to Bausch & Lomb in January 2009, but cancellation proceedings were suspended by the TTAB on February 10, 2009 for six months and on July 29, 2009 for an additional three months upon indication that the parties were engaged in settlement negotiations. Motions for Suspension on Consent were filed by the parties on November 6, 2009 requesting 90 day suspension and on February 2, 2010 for an additional 90 days suspension. These motions were granted. The current suspension of cancellation proceedings will expire on May 3, 2010. We are currently engaged in settlement discussions with Bausch & Lomb to resolve the dispute on favorable terms. If settlement is not reached, then proceedings will resume, and a final decision by the TTAB could take several years.

ITEM 4. ***(REMOVED AND RESERVED)***

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EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and their positions as of February 28, 2010 are as follows:

Name	Age	Position
Craig A. Collard	43	President and Chief Executive Officer
Steven M. Lutz	43	Executive Vice President, Manufacturing and Trade
David Price	47	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Joshua B. Franklin	40	Vice President, Sales and Marketing
Alan Roberts	43	Vice President, Scientific Affairs
Andrew K. W. Powell	52	Executive Vice President, General Counsel and Secretary

Craig A. Collard has served as our President and Chief Executive Officer and the chairman of our board of directors since our merger with Cornerstone BioPharma in October 2008. 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., or Verum, 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, 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.

Steven M. Lutz has served as our Executive Vice President, Manufacturing and Trade since our merger with Cornerstone BioPharma. Mr. Lutz was a founding stockholder of Cornerstone BioPharma and served as its Executive Vice President of Commercial Operations from March 2004 to October 2008. Before joining Cornerstone BioPharma, Mr. Lutz s principal occupation was serving as Vice President of Corporate Accounts for Carolina Pharmaceuticals, Inc. from July 2003 to March 2004. In previous positions, Mr. Lutz was responsible for Trade Sales for Verum from September 2002 to February 2003 and was a National Account Manager for Biovail from February 2001 to September 2002 and Roberts Pharmaceutical Corporation (later acquired by Shire Pharmaceuticals Group plc) from January 1995 to February 2001. Mr. Lutz holds a B.A. in Political Science and Sociology from Moravian College in Bethlehem, Pennsylvania.

David Price has served as our Executive Vice President, Finance, Chief Financial Officer, Treasurer and Assistant Secretary since our merger with Cornerstone BioPharma. Mr. Price served as Executive Vice President, Finance, and Chief Financial Officer of Cornerstone BioPharma from September 2008 to October 2008. Before joining Cornerstone BioPharma, Mr. Price served as a Managing Director for Jefferies & Company, Inc, an investment banking firm, from April 2006 to September 2008 in the Specialty Pharmaceutical and Pharmaceutical Services investment banking practice. From September 2000 to March 2006, Mr. Price served as a Managing Director for Bear, Stearns & Co. Inc.,

an investment banking firm, in London and in New York. Mr. Price served as the Director of the Merger Integration Practice of PriceWaterhouseCoopers Consulting from 1997 to 2000. From 1993 to 1997, Mr. Price served as Mergers and Acquisitions Director for Lex Service PLC, an automotive services provider. He worked as an Audit Senior Manager and Corporate Finance Manager for Price Waterhouse, an accounting firm, in London and Los Angeles from 1987 to 1993. He worked for Arthur Andersen & Co., an accounting firm, as an Audit Assistant from 1984 to 1987. Mr. Price qualified as a Chartered Accountant in 1987 with the Institute of Chartered Accountants in England and Wales and holds an Honours degree in Accounting and Financial Management from Lancaster University, Lancaster, United Kingdom.

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Joshua B. Franklin has served as our Vice President, Sales and Marketing, since December 2008 and, before that, as Vice President of Marketing since our merger with Cornerstone BioPharma. Before joining Cornerstone, Mr. Franklin served in a variety of marketing positions at Ther-Rx Corporation (a subsidiary of K-V Pharmaceutical Company) from July 2003 to September 2008, including most recently as Vice President, Marketing. Prior to joining Ther-Rx Corporation, Mr. Franklin held various marketing roles with Biovail from January 2002 to July 2003 and the Ross Products Division of Abbott Laboratories from August 1999 to January 2002. Mr. Franklin is a U.S. Army veteran and holds a B.S. in Business Administration from Methodist University and M.H.A. and M.B.A. degrees from The Ohio State University.

Alan Roberts was appointed Vice President, Scientific Affairs in 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.

Andrew K. W. Powell, Esq. was appointed Executive Vice President, General Counsel and Secretary in November 2009. Mr. Powell has practiced law for more than 20 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., or Eli Lilly. Mr. Powell holds a B.A. from the University of North Carolina at Chapel Hill and a J.D. from Stanford Law School.

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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. Prior to July 2008, our common stock traded on the NASDAQ Global Market. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock on the NASDAQ Stock Market, as adjusted for the 10-to-1 reverse stock split effected on October 31, 2008.

Year Ended December 31, 2009	**High**	**Low**
First Quarter (from January 1 to March 31)	$ 4.70	$ 1.72
Second Quarter (from April 1 to June 30)	$ 12.29	$ 3.50
Third Quarter (from July 1 to September 30)	$ 11.23	$ 6.08
Fourth Quarter (from October 1 to December 31)	$ 6.76	$ 4.80

Year Ended December 31, 2008	**High**	**Low**
First Quarter (from January 1 to March 31)	$ 14.50	$ 6.70
Second Quarter (from April 1 to June 30)	$ 7.20	$ 2.60
Third Quarter (from July 1 to September 30)	$ 4.20	$ 1.20
Fourth Quarter (from October 1 to December 31)	$ 4.99	$ 1.30

On March 1, 2010, the closing price per share of our common stock as reported on the NASDAQ Capital Market was $5.06, and we had approximately 146 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.

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

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

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

Not required for smaller reporting companies.

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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 acquiring, developing and commercializing significant products for the respiratory and related markets.

Our long-term commercial strategy is to in-license or acquire rights to non-promoted or underperforming, patent or trade secret protected, branded pharmaceutical products that we can promote through our respiratory and hospital sales forces. Consistent with our respiratory-focused strategy, we are also developing late-stage cough/cold product candidates to enhance our presence in the respiratory market.

Although we have historically derived a large part of our revenues from branded, unbranded and authorized generic versions of products that have or had limited intellectual property protection, we consider these products to be non-strategic because we expect the sales of these products to show a downward trend in the future. We are therefore refocusing our efforts on growing our revenues from branded, patent or trade-secret protected, respiratory and related products, which we consider strategic specialty products. We believe that if we can successfully implement our refocused strategy we will be able to offset declines in other product sales and deliver more consistent long-term earnings growth for our stockholders.

In 2009 we believe we made significant progress towards these goals.

In the third quarter of 2009, we acquired an exclusive ten-year license to the U.S. commercial rights to Chiesi s CUROSURF (poractant alfa) Intratracheal Suspension product. In connection with the acquisition, we issued Chiesi approximately 12.2 million shares of our common stock, and we recorded product rights of $107.6 million, which we will amortize over the life of the agreement. With the addition of CUROSURF to our portfolio, in 2009 we invested in a hospital sales force to promote CUROSURF and any additional hospital products that we may acquire, and going forward we will continue to experience amortization expense related to the CUROSURF product rights and dilution related to the share issuance. Our challenges going forward will therefore include growing our sales of CUROSURF and acquiring other suitable hospital-delivered products that will allow us to generate growth and value from our transaction with Chiesi and our new hospital sales team. If we can grow our sales of CUROSURF and acquire one or more additional hospital-delivered products, we believe that the financial returns from hospital product sales (including CUROSURF) represent a key opportunity for future growth.

Also during the third quarter of 2009, we acquired the commercial rights to the antibiotic FACTIVE (gemifloxacin mesylate). We believe that FACTIVE offers significant opportunities for growth. By promoting FACTIVE along with

our products, SPECTRACEF and ZYFLO CR, we have the opportunity to leverage our respiratory sales force. Our ability to maximize the productivity of this team will be a key driver in the success of our strategy. We expect our prospects for future growth in the respiratory market to be affected by our ability to manage seasonal fluctuations of demand for these products, the uncertainty surrounding the likely entry of generic versions of competing products into this market and with respect to FACTIVE, our ability to overcome a recent downward trend in demand for quinolone antibiotics.

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During 2009 we also advanced our development pipeline, and in particular our four cough/cold product candidates (CRTX 067, CRTX 069, CRTX 072 and CRTX 074). We made a regulatory filing in July 2009 with the FDA for CRTX 067 and we anticipate this will be the first of these products to be approved by the FDA. We believe that successfully validating our licensed technology and obtaining regulatory approval for these products are critical for us to achieve a competitive advantage and to translate that advantage into growth. We plan to continue to invest in product development to realize the potential of these and other product candidates. If we are unable to validate our technology platforms or if others develop similar platforms, our competitive advantage and prospects for future growth could be diminished.

We also expect to incur additional expenses to expand our sales team and marketing capabilities when product candidates are approved and add operational, financial and management information systems and personnel, including personnel to support our product development efforts.

Although we are shifting our focus away from our non-strategic products, we will continue to generate revenues from sales of these products without investing further resources in promoting them. These products include the ALLERX Dose Pack products, the HYOMAX products and the propoxyphene/acetaminophen products. We expect sales of these products to trend downward, but in the near term we believe that they may generate significant cash, which we intend to use to fund future growth in our areas of strategic focus.

Since we contract with third parties to manufacture all of our products and product candidates, and we do not plan to engage in any manufacturing for ourselves, our business is also affected by third-party manufacturing and distribution costs and the cost of API. Changes in our mix of products sold will likely result in variations in our margins and cost of product sales. Managing relationships with our manufacturers and distributors will therefore continue to be a key area of focus for us.

2009 Highlights

The following is a summary of key financial results and certain non-financial results achieved for the year ended December 31, 2009:

Our net revenues for the year increased 69% to $109.6 million, of which the percentage of revenue derived from non-strategic products declined from 84.7% to 63.4%;

Cash and cash equivalents increased $9.6 million or 103% to $18.9 million at December 31, 2009 compared to $9.3 million at December 31, 2009;

We acquired an exclusive ten-year license to the commercial rights to Chiesi s lung surfactant CUROSURF in the United States;

We acquired the commercial rights to the antibiotic FACTIVE in North America and certain countries in Europe; and

We made a regulatory filing with the FDA in July 2009 for our product candidate CRTX 067.

Opportunities and Trends

In summary, during 2010, we plan to continue to implement our strategy of combining organic growth, strategic acquisitions and product development. As we do so, we will be evaluating our performance with particular reference to the following fiscal and management measures, which we believe will be drivers of our success:

Sales growth of our strategic specialty products through our respiratory and hospital sales forces;

Cash generation from continued sales of our non-strategic products;

Acquisition of rights to available and profitable new respiratory and related products with intellectual property protection;

Progress in the development of our product candidates;

Control of our manufacturing and general and administrative expenses; and

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Identification of partners and entry into value-maximizing transactions to divest our non-core technologies.

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, 2009 and 2008

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

	Year Ended December 31,		Change	Change
	2009	2008	$	%
Net Product Sales				
CUROSURF	$ 10,463	$	$ 10,463	NM
FACTIVE	1,178		1,178	NM
SPECTRACEF product family	9,390	6,981	2,409	35%
ZYFLO product family(1)	17,959	888	17,071	1922
ALLERX Dose Pack products	31,707	26,395	5,312	20
HYOMAX product family	28,148	22,962	5,186	23
Propoxyphene/acetaminophen products	9,608	5,548	4,060	73
Other currently marketed products	683	692	(9)	(1)
Discontinued products	152	(261)	413	158
Total net product sales	109,288	63,205	46,083	73
Royalty agreement revenues	276	1,662	(1,386)	(83)
Net Revenues	109,564	64,867	44,697	69
Cost of product sales (exclusive of amortization of product rights)	19,457	5,951	13,506	227
Sales and marketing	27,605	16,993	10,612	62
Royalties	18,775	16,193	2,582	16
General and administrative	17,422	9,930	7,492	75
Research and development	4,312	3,838	474	12
Amortization of product rights	6,115	1,334	4,781	358
Income from operations	15,878	10,628	5,250	49
Total other expenses, net	(128)	(1,221)	(1,093)	(90)
Income before income taxes	15,750	9,407	6,343	67
Provision for income taxes	(5,547)	(414)	5,133	1240
Net income	$ 10,203	$ 8,993	$ 1,210	13%

Net income per share, diluted	$ 0.54	$ 1.14	$ (0.60)	(53)%
Non-GAAP income from operations(2)	$ 27,034	$ 12,711	$ 14,323	113%
Non-GAAP net income(2)	$ 17,432	$ 10,984	$ 6,448	59%
Non-GAAP net income per share, diluted(2)	$ 0.93	$ 1.40	$ (0.47)	(34)%

(1) Does not include the historical sales of ZYFLO CR and ZYFLO made by Critical Therapeutics.

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

NM Not meaningful.

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Net Revenues

Net Product Sales.

CUROSURF net product sales were $10.5 million in 2009. We acquired the CUROSURF product rights from Chiesi during the third quarter of 2009 and began promoting and selling CUROSURF in September 2009.

FACTIVE net product sales were $1.2 million in 2009. 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.

SPECTRACEF net product sales increased during 2009 compared to 2008, primarily due to our introduction of SPECTRACEF 400 mg in late 2008 and promotional incentives we offered to patients during 2009.

ZYFLO CR and ZYFLO net product sales increased during 2009 compared to 2008, primarily because our historical financial results for 2008 do not include sales of ZYFLO CR and ZYFLO by Critical Therapeutics prior to the completion of our October 2008 merger.

ALLERX Dose Pack net product sales increased during 2009 compared to 2008. The increase in product sales was primarily due to limited competition for the ALLERX Dose Pack formulation, partially offset by greater competition for the ALLERX DF and ALLERX PE Dose Pack formulations.

HYOMAX net product sales increased during 2009 compared to 2008. This increase was primarily due to the fact that the HYOMAX line of products was launched during 2008; the first product of this line was launched in May 2008. This increase was partially offset by lower sales prices during 2009 as a result of increased competition.

Net product sales from our propoxyphene/acetaminophen products increased during 2009 compared to 2008 primarily due to the increase in sales of APAP 325, our generic formulation of BALACET 325, and APAP 500. Net product sales for APAP 325 were $3.9 million in 2009 compared to $1.2 million in 2008. We expect that APAP 325 will continue to challenge BALACET 325 for market share.

Royalty Agreement Revenues. Royalty agreement revenues decreased during 2009 due the expiration of our supply and marketing agreement with Pliva, Inc., or Pliva, for APAP 500 in December 2008, partially offset by the addition of FACTIVE royalty revenue. Subsequent to the expiration of the supply and marketing agreement with Pliva, we began marketing APAP 500 ourselves. Net product sales for APAP 500 were $2.0 million in 2009 and are included in propoxyphene/acetaminophen products.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $6.1 million and $1.3 million in 2009 and 2008, respectively) increased $13.5 million, or 227%.

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

	Year Ended December 31,		Change	Change

	2009	2008	$	%
Net product sales	$ 109,288	$ 63,205	$ 46,083	73%
Cost of product sales (exclusive of amortization of product rights)	19,457	5,951	13,506	227
Gross margin	$ 89,831	$ 57,254	$ 32,577	57%
% of net product sales	82%	91%		(9%)

Gross margin for 2009 decreased nine percentage points compared to 2008 due to a relatively higher portion of our net product sales in 2009 derived from products with lower gross margins, specifically

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CUROSURF. We also increased our provision for inventory obsolescence by $1.5 million and $599,000 in 2009 and 2008, respectively. These adjustments were necessary to adequately state reserves related to excess or obsolete inventory that, due to its expiration dating, will not be sold.

Sales and Marketing Expenses. Sales and marketing expenses increased $10.6 million, or 62%, during 2009 compared to 2008. This increase was primarily due to increases in labor and benefits-related costs as a result of the growth of our sales force and management team; marketing and promotional spending relating to the launch of ZYFLO CR, FACTIVE and CUROSURF; co-promotion expenses relating to ZYFLO CR; travel-related expenses due to the increased number of sales representatives; and consulting expenses relating to increased market research. These increases were partially offset by lower sample and co-promotion expenses for the ALLERX Dose Pack products.

Royalty Expenses. Royalty expenses increased $2.6 million, or 16%, during 2009 compared to 2008. This increase was primarily due to the full year effect of selling the HYOMAX line of products, ZYFLO CR and ZYFLO in 2009 as opposed to a partial year in 2008.

General and Administrative Expenses. General and administrative expenses increased $7.5 million, or 75%, during 2009 compared to 2008. This increase was primarily due to increases in labor and benefits-related employee expenses and travel-related expenses due to the expansion of our workforce; legal and accounting costs, most of which relate to increased regulatory requirements as a result of our becoming a public company and costs associated with the Chiesi transaction; FDA regulatory-related fees; and product liability and other insurance related costs. 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. 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. Marketed Products Support includes expenses related to stability and ongoing support for our existing products. Costs related to discontinued products and/or 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 the years ended December 31, 2009 and 2008 and for current projects under development from project inception through December 31, 2009 (dollars in thousands):

	Project Inception to December 31, 2009	Year Ended December 31, 2009	2008	Change $	Change %
CRTX 067	$ 3,058	$ 2,442	$ 616	$ 1,826	296%
CRTX 058	638	366	272	94	35
CRTX 068	593	72	521	(449)	(86)
CRTX 062	272	15	257	(242)	(94)
Marketed products support		704	159	545	343
Other projects		713	2,013	(1,300)	(65)
Total		$ 4,312	$ 3,838	$ 474	12%

Research and development expenses increased $474,000, or 12%, during 2009 compared to 2008. In 2008, we expensed acquired in-process research and development of $1.9 million, which is included in other projects in the table above. Excluding that expense, research and development expenses increased $2.4 million over 2008. This increase was driven by an increase in expenses related to our product candidate, CRTX 067, of $1.8 million and an increase in development expenses related to other projects of $587,000 compared to 2008. During 2009, we also spent an additional $545,000 on activities to support our currently marketed products. These increases were partially offset by reductions in spending related to CRTX 068 and CRTX 062.

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

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significant development and commercialization expenses as we seek to advance the development and seek 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 $4.8 million, or 358%, during 2009 compared to 2008. This increase was primarily due to the amortization of ZYFLO CR and CUROSURF product rights. We added ZYFLO CR to our product portfolio as a result of our merger. We added CUROSURF to our product portfolio in July 2009 upon the closing of our strategic transaction with Chiesi, and we began promoting and selling CUROSURF in September 2009. The increase in amortization was partially offset by a reduction in amortization expense related to BALACET 325 product rights which were fully amortized during 2008.

Other Expenses. Total other expenses decreased $1.1 million, or 90%, during 2009 compared to 2008. This decrease was primarily due to a decrease in net interest expense of $759,000 related to the conversion of our promissory note with Carolina Pharmaceuticals Ltd., an entity controlled by certain of our executive officers, or the Carolina Note, into common stock on October 31, 2008 in connection with our merger.

Provision for Income Taxes

The provision for income taxes was $5.5 million during 2009, compared to $414,000 in 2008. Our effective tax rates for the years ended December 31, 2009 and 2008 were 35.2% and 4.4%, respectively. The increase in effective tax rate was due primarily to the impact of the release of valuation allowances against our deferred tax assets during 2008. 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 2008 and significantly lowering our effective tax rate.

Quarterly Results of Operations

See Note 17 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a presentation of our quarterly results of operations for the years ended December 31, 2009 and 2008.

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Comparison of the Years Ended December 31, 2008 and 2007

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

	Year Ended December 31,		Change	Change
	2008	**2007**	**$**	**%**
Net Product Sales				
SPECTRACEF product family	$ 6,981	$ 6,886	$ 95	1%
ZYFLO product family(1)	888		888	NM
ALLERX Dose Pack products	26,395	14,180	12,215	86
HYOMAX product family	22,962		22,962	NM
Propoxyphene/acetaminophen products	5,548	4,403	1,145	26
Other currently marketed products	692	99	593	599
Discontinued products	(261)	679	(940)	(138)
Total net product sales	63,205	26,247	36,958	141
Royalty agreement revenues	1,662	1,824	(162)	(9)
Net Revenues	64,867	28,071	36,796	131
Cost of product sales (exclusive of amortization of product rights)	5,951	3,300	2,651	80
Sales and marketing	16,993	10,391	6,602	64
Royalties	16,193	3,409	12,784	375
General and administrative	9,930	4,422	5,508	125
Research and development	3,838	948	2,890	305
Amortization of product rights	1,334	3,160	(1,826)	(58)
Income from operations	10,628	2,441	8,187	335
Total other expenses, net	(1,221)	(1,741)	(520)	(30)
Income before income taxes	9,407	700	8,707	1244
Provision for income taxes	(414)	(130)	284	218
Net income	$ 8,993	$ 570	$ 8,423	1478%
Net income per share, diluted	$ 1.14	$ 0.08	$ 1.06	1325%
Non-GAAP income from operations(2)	$ 12,711	$ 6,402	$ 6,309	99%
Non-GAAP net income(2)	$ 10,984	$ 3,794	$ 7,190	190%
Non-GAAP net income per shares, diluted(2)	$ 1.40	$ 0.56	$ 0.84	150%

(1) Does not include the historical sales of ZYFLO CR and ZYFLO made by Critical Therapeutics.

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

NM Not meaningful.

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Net Revenues

Net Product Sales

ZYFLO CR and ZYFLO net product sales were $888,000 in 2008. Our historical financial results for 2008 do not include sales of ZYFLO CR and ZYFLO by Critical Therapeutics prior to the completion of our merger.

ALLERX Dose Pack products net product sales increased $12.2 million, or 86%, during 2008 compared to 2007. The increase in product sales was due primarily to increased sales volume including 2007 sales that were not shipped until 2008 due to packaging issues.

HYOMAX net product sales were $23.0 million in 2008. The HYOMAX line of products was launched during 2008, with the first product launched in May 2008.

Royalty Agreement Revenues. Royalty agreement revenues decreased in 2008 due to a net decrease in royalty agreement revenues based on the underlying volume of sales pursuant to our license agreements with third parties.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $1.3 million and $3.2 million in 2008 and 2007, respectively) increased $2.7 million, or 80%.

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

	Year Ended December 31,			
	2008	2007	Change $	Change %
Net product sales	$ 63,205	$ 26,247	$ 36,958	141%
Cost of product sales (exclusive of amortization of product rights)	5,951	3,300	2,651	80
Gross margin	$ 57,254	$ 22,947	$ 34,307	150%
% of net product sales	91%	87%		4%

Gross margin for 2008 increased four percentage points compared to 2007 due to a relatively higher portion of our net product sales in 2008 derived from products with higher gross margins, specifically our HYOMAX line of products, which we launched in 2008, as compared to our product mix in 2007. We increased our provision for inventory obsolescence by $599,000 and $169,000 in 2008 and 2007, respectively. These adjustments were necessary to adequately state reserves related to excess or obsolete inventory that, due to its expiration dating, would not be sold.

Sales and Marketing Expenses. Sales and marketing expenses increased $6.6 million, or 64%, during 2008 compared to 2007. This increase was primarily due to increases in labor, benefits, related employee expenses and travel-related expenses, primarily due to the reorganization of our sales force in May 2008, which resulted in a reduction in the total number of employees on our sales force, but an increase in pay, benefits and travel-reimbursement packages given to the former commission-based sales professionals who were retained following the reorganization; co-promotion

expenses relating to the ALLERX Dose Pack products and BALACET; and advertising and promotion expenses, primarily due to product launches and increased promotional efforts.

In addition, sales and marketing expenses in 2007 were reduced by $1.5 million of funding we received from Meiji in 2007 in connection with the 2007 expansion of our sales force that was promoting SPECTRACEF. We received this funding pursuant to a July 2007 letter agreement with Meiji, which supplemented the SPECTRACEF license and supply agreement. We did not receive any such payments from Meiji in 2008.

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Royalty Expenses. Royalty expenses increased $12.8 million, or 375%, during 2008 compared to 2007. This increase was primarily due to the launch of the HYOMAX line of products in 2008 and increased net product sales of the ALLERX Dose Pack products.

General and Administrative Expenses. General and administrative expenses increased $5.5 million, or 125%, during 2008 compared to 2007. This increase was primarily due to increases in labor, benefits, related employee expenses and travel-related expenses due to our growth during 2008; additional merger-related legal and accounting expenses not capitalized as direct costs of our merger; FDA regulatory related fees; product liability and other insurance related costs; facility lease related costs; and corporate advertising and promotional costs.

Research and Development Expenses. The following table summarizes our research and development expenses for the years ended December 31, 2008 and 2007 (dollars in thousands):

	Year Ended December 31,			
	2008	2007	Change $	Change %
CRTX 067	$ 616	$	$ 616	NM
CRTX 058	272		272	NM
CRTX 068	521		521	NM
CRTX 062	257		257	NM
Marketed products support	159	410	(251)	(61)%
Other projects	2,013	538	1,475	274
Total	$ 3,838	$ 948	$ 2,890	305%

NM Not meaningful.

Research and development expenses increased $2.9 million, or 305%, during 2008 compared to 2007. In 2008, we expensed acquired in-process research and development of $1.9 million, which is included in other projects in the table above. Excluding that expense, research and development expenses increased $1.0 million over 2007. This increase was primarily driven by an increase in our expenses related to our product candidates, CRTX 067 and CRTX 058 compared to 2007. We also spent approximately $778,000 on our SPECTRACEF projects, CRTX 068 and CRTX 062 for the formulation and manufacturing of batches that were used for a Phase II pharmacokinetic clinical study and manufacturing costs for clinical trial batches of the previous suspension formulation developed by TAP Pharmaceutical Products Inc. These increases were partially offset by reductions in spending related to marketed products.

Amortization of Product Rights. Amortization of product rights decreased $1.9 million, or 58%, during 2008 compared to 2007. This decrease was primarily due to the BALACET product rights becoming fully amortized as of March 31, 2008.

Other Expenses. Total other expenses decreased $520,000, or 30%, during 2008 compared to 2007. This decrease was due to a decrease in net interest expense of $199,000 related to the conversion of the Carolina Note, into common stock on October 31, 2008 in connection with our merger and the loss on our marketable security of $315,000 related to our investment in Auriga in 2007.

Provision for Income Taxes

The provision for income taxes was $414,000 in 2008 compared to $130,000 in 2007. Our effective tax rates for the years ended December 31, 2008 and 2007 were 4.4% and 18.6%, respectively. The decrease in the effective tax rate was driven by a decrease in nondeductible expenses as a relative percentage of income before taxes.

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-

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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, net income and earnings 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 acquisition-related expenses. Acquisition-related expenses consist of certain expenses that were incurred in connection with the 2009 transaction with Chiesi, including additional stock-based compensation due to the accelerated vesting of certain stock options and shares of restricted stock resulting from the closing of that transaction. 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 acquisition-related expenses are excluded because they arise from prior acquisitions and 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 acquisition-related expenses from the non-GAAP 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 with Chiesi resulted in significant cash expenses.

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

	For the Year Ended December 31,		
	2009	2008	2007
GAAP income from operations	$ 15,878	$ 10,628	$ 2,441
Add: stock-based compensation(1)	1,478	749	801
Add: amortization of product rights	6,115	1,334	3,160
Add: acquisition-related expenses(2)	3,563		
Non-GAAP income from operations	$ 27,034	$ 12,711	$ 6,402
GAAP net income	$ 10,203	$ 8,993	$ 570
Add: stock-based compensation(1)	1,478	749	801
Add: amortization of product rights	6,115	1,334	3,160
Add: acquisition-related expenses(2)	3,563		
Less: tax effects related to above items(3)	(3,927)	(92)	(737)
Non-GAAP net income	$ 17,432	$ 10,984	$ 3,794
GAAP net income per share, diluted	$ 0.54	$ 1.14	$ 0.08
Non-GAAP net income per share, diluted	$ 0.93	$ 1.40	$ 0.56
Shares used in diluted net income per share calculation:			
GAAP net income	18,776,588	7,861,119	6,751,127
Non-GAAP net income	18,776,588	7,861,119	6,751,127

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

(2) Acquisition-related expenses include stock-based compensation charges and legal, accounting and related costs that resulted from or were incurred in connection with the Chiesi transaction. For the year ended December 31, 2009, acquisition-related stock-based compensation charges include $1.5 million and $262,000 of charges that were included in general and administrative and sales and marketing expenses, respectively, in the Company s consolidated statement of income.

(3) Tax effects for the years ended December 31, 2009, 2008 and 2007 are calculated using effective tax rates of 35.2%, 4.4%, and 18.6% 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 and payments on our license agreement liability. To date, we have funded our operations primarily from product sales, royalty agreement revenues, the investment from Chiesi and borrowings under the Carolina Note and our previous line of credit, which we terminated in May 2009. We borrowed $13.0 million under the Carolina Note in April 2004. In connection with the closing of our merger, the outstanding principal amount of the Carolina Note of approximately $9.0 million was exchanged for 6,064,731 shares of Cornerstone BioPharma s common stock (which was exchanged for 1,443,913 shares of our common stock in the merger). In July 2009, in connection with the consummation of our strategic transaction with Chiesi, among other consideration, we received approximately $15.5 million in cash. As of December 31, 2009, we had $18.9 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,		
	2009	2008	2007
Cash provided by (used in):			
Operating activities	$ 450	$ 12,629	$ 1,563
Investing activities	(5,504)	(346)	(718)
Financing activities	14,621	(3,238)	(720)
Net increase in cash and cash equivalents	$ 9,567	$ 9,045	$ 125

Net Cash Provided By Operating Activities

Our primary sources of operating cash flows are product sales and royalty agreement revenues. Our primary uses of cash in our operations are for inventories and other costs of product sales, sales and marketing expenses, royalties, general and administrative expenses and interest.

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 and 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 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 our 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 our 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 provided by operating activities in 2008 reflected our net income of $9.0 million, adjusted by non-cash expenses totaling $3.3 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $322,000. Non-cash items primarily included amortization and depreciation of $1.4 million, change in allowances for prompt payment discounts and inventory obsolescence of $2.5 million, write-off of research and development costs acquired in our merger relating to the alpha-7 program of $1.9 million, stock-based compensation of $749,000 and change in deferred income tax of $3.3 million. Accounts receivable (exclusive of accounts receivable acquired in our merger) increased by $9.1 million from December 31, 2007 to December 31, 2008, primarily due to increased net product sales, including increased sales of Aristos products, which have longer payment terms. Inventories (exclusive of inventories acquired in our merger) increased by $2.5 million from December 31, 2007 to December 31, 2008, primarily due to the purchase of ZYFLO CR inventory in December 2008. Prepaid expenses and other assets (exclusive of prepaid expenses acquired in our

merger) decreased by $1.7 million, primarily due to a reduction in royalty receivables and receipt of $1.5 million from Meiji in connection with our sales force expansion. Accounts payable (exclusive of accounts payable assumed in our merger) increased by $2.6 million from December 31, 2007 to December 31, 2008, primarily due to increased payables for manufacturing, product development and marketing expenses. Accrued expenses (exclusive of accrued expenses assumed in our merger) increased by $4.5 million, primarily due to increased royalties, rebates and chargebacks resulting from increased product sales, partially offset by a decrease in accrued interest due to the conversion of the Carolina Note and payment of accrued interest in connection with our merger. Income taxes

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payable (exclusive of income taxes payable assumed in our merger) increased by $3.1 million due to an $8.7 million increase in income before income taxes during 2008.

Net cash provided by operating activities in 2007 reflected our net income of $570,000, adjusted by non-cash expenses totaling $5.2 million and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash items included amortization and depreciation of $3.2 million, change in allowances for prompt payment discounts and inventory obsolescence of $814,000, stock-based compensation of $801,000 and loss on our investment in Auriga common stock of $323,000. Accounts receivable increased $2.4 million in 2007 compared to 2006 primarily due to an increase in sales during the fourth quarter of 2007 compared to same period in 2006. Inventories increased $1.3 million from December 31, 2006, primarily due to stocking and lead time requirements related to the manufacturing of SPECTRACEF. Prepaid and other assets increased $2.5 million primarily due to an increase in royalty receivables and $1.5 million due from Meiji for our sales force expansion. Accrued expenses increased $1.0 million from December 31, 2006, primarily due to increased accruals for royalty expenses of $1.5 million and interest expense of $941,000, partially offset by a decrease in sales allowances of $475,000 and accrued settlement expenses of $1.1 million.

Net Cash Used in Investing Activities

Our primary sources of historical cash flows from investing activities are sales of marketable securities and cash acquired in connection with our merger, net of costs paid. Going forward, we do not expect to have significant proceeds from 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 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 investing activities in 2008 primarily reflected the purchase of product rights for $2.5 million and the purchase of property and equipment for $638,000, partially offset by net cash acquired in connection with our merger of $2.1 million and net proceeds from the collection of advances to related parties of $638,000.

Net cash used in investing activities in 2007 primarily reflected net advances to related parties of $614,000, the purchase of product rights for $75,000 and the purchase of property and equipment of $64,000, partially offset by net proceeds received from the net collection of deposits of $35,000.

Net Cash Provided by (Used in) Financing Activities

Our primary sources of historical cash flows from financing activities are the investment from Chiesi, borrowings under the Carolina Note and borrowings under our previous line of credit. 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 historical uses of cash in financing activities are the SPECTRACEF license agreement liability and principal payments on our previous line of credit and the Carolina Note. In connection with the closing of our merger, we paid off the Carolina Note through the issuance of 6,064,731 shares of Cornerstone BioPharma s common stock (which was exchanged for 1,443,913 shares of our common stock in our merger). Going forward, we expect our primary uses of cash in financing activities to be 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 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.

Net cash used in financing activities in 2008 reflected net payments on our previous line of credit of $1.8 million, a principal payment on the Carolina Note of $460,000, a principal payment on the

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SPECTRACEF license agreement liability of $576,000 and stock issuance costs in connection with our merger of $504,000.

Net cash used in financing activities in 2007 reflected a principal payment on the SPECTRACEF license agreement liability of $720,000.

Funding Requirements

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

- the level of product sales of our currently marketed products and any additional products that we may market in the future;
- the 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.

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. Our only committed external source of funds is borrowing availability under the line of credit we entered into in January 2010. We may borrow up to $5.0 million under our line of credit subject to certain conditions. 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, 2009, we had $18.9 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

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scientific, regulatory, or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2009 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 62	$ 15	$ 31	$ 16	$
Operating leases(1)	3,678	766	1,041	1,120	751
Purchase obligations(2)	46,753	26,791	16,969	2,993	
Royalty obligations(3)	7,500	500	1,150	1,050	4,800
Other long-term liabilities(4)	2,750	1,250	1,500		
Total contractual obligations	$ 60,743	$ 29,322	$ 20,691	$ 5,179	$ 5,551

(1) Operating leases include minimum payments under leases for our facilities, automobiles and certain equipment. In October 2009, we entered into a lease modification agreement for our corporate headquarters. Our total minimum lease payments for the corporate headquarters are $400,000 in 2010, $482,000 in 2011, $492,000 in 2012, $536,000 in 2013 and $1.3 million thereafter.

(2) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $29.5 million; clinical trial and research agreements with contract research organizations and consultants of $741,000; agreements with providers of marketing analytical services of $3.2 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $13.4 million.

(3) Royalty obligations include minimum royalty payments due in connection with our agreements with Pharmaceutical Innovations and The Feinstein Institute. See Note 11 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information.

(4) Other long-term liabilities include principal and interest due under our license agreement liability with Meiji. See Note 7 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a description of the amounts due under the license agreement.

In addition to the material contractual cash obligations included the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. We may be required to make additional payments of $42.2 million if all milestones are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets and have not been included in the table above.

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 affect on our financial condition, results of operations and cash flows.

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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.

Revenue Recognition

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 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 would be 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, from six months prior to and up to twelve months subsequent to the expiration date of the products. Our products, except for CUROSURF, have a 24 to 36 month expiration period from the date of manufacture. CUROSURF has an 18-month expiration period from the date of manufacture. We estimate our liability for product returns based on our estimate of inventory levels of our products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. We evaluate and adjust our estimate of product returns on a quarterly basis or as needed if we become aware of changes in such factors and if we believe they could significantly impact our expected returns.

Expense recognized for product returns was $13.0 million, $6.9 million and $2.9 million in 2009, 2008 and 2007, respectively, representing 9%, 8% and 9% of gross product sales in 2009, 2008 and 2007, respectively. Expense recognized during 2009 for product returns related to current year sales was $8.8 million, or 6% of gross product sales. Expense recognized during 2009 for product returns related to

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changes in our prior year estimates was $4.2 million and related primarily to an increase in our expected product returns of ALLERX DF and ALLERX PE Dose Packs, SPECTRACEF 200 mg and ZYFLO CR and ZYFLO. The increase in returns is primarily due to the expiration dating of these products that were sold prior to 2009. In September 2009, we also accrued $2.5 million for potential returns of FACTIVE sold prior to our acquisition of the product rights.

Rebates. The liability for commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial contract. The liability for Medicaid and Medicare rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state.

Expense recognized for rebates was $1.4 million, $1.6 million and $228,000 in 2009, 2008 and 2007, respectively, representing approximately 1%, 2% and 1% of gross product sales in 2009, 2008 and 2007, respectively.

Price Adjustments and Chargebacks. Our estimates of price adjustments and chargebacks are based on our estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the listed prices of our products. 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 judgments based on the facts and circumstances known to us in accordance with GAAP. In the event that the sales mix to third-party payors 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. As of December 31, 2009, we have three voucher programs whereby we offer a point-of-sale subsidy to retail customers. 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 $21.8 million, $8.9 million and $1.3 million in 2009, 2008 and 2007, respectively, representing approximately 15%, 11% and 4% of gross product sales in 2009, 2008 and 2007, respectively. The increase in the expense as a percentage of gross product sales during 2009 was primarily due to increased competition for HYOMAX and the addition of CUROSURF to our product portfolio, which caused higher levels of price adjustments and chargebacks.

Prompt Payment Discounts. We typically require our customers to remit payments within either 31 or 61 days, depending on 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 $3.1 million, $1.9 million and $645,000 in 2009, 2008 and 2007, 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.

Royalty Agreement Revenues

We receive royalties under a license agreement with a third party that sells products to which we have the rights. The license agreement provides for the payment of royalties based on sales of the licensed product.

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These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensee and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. We maintain regular communication with our licensee to gauge the reasonableness of our estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

Goodwill and Product Rights

At December 31, 2009, we had $13.2 million in goodwill related to our merger. Excluding goodwill, we have no intangible assets with indefinite lives. 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 operate in three segments: a prescription branded pharmaceuticals segment, a prescription generic pharmaceuticals segment and a hospital pharmaceuticals segment. Our segments have been aggregated into one segment for reporting purposes. For our evaluation of goodwill, each of the three operating segments represents a reporting unit. Our goodwill has been allocated in total to our prescription branded pharmaceuticals segment.

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, 2009. 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 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.

As of December 31, 2009, we had an aggregate of $126.8 million in capitalized product rights, which we expect to amortize over a period of five to ten years. As of December 31, 2009, the estimated undiscounted future cash flows expected from our products are sufficient to recover their carrying value. If actual cash flows are significantly different than our forecasted amounts, we could determine that some or all of capitalized product rights are impaired. In the event of impairment, we could record an impairment charge to earnings that could have a material adverse effect on our results of operations.

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

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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 write down 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 requirements based upon anticipated product revenues. As of December 31, 2009, we had $19.9 million in inventory and an inventory reserve of $1.8 million. The inventory reserve includes provisions for inventory that management believes will become short-dated before being sold. Short-dated inventory is inventory that has not expired yet, but which wholesalers or pharmacies refuse to purchase because of its near-term expiration date.

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 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.

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.

Prior to the completion of our merger, Cornerstone BioPharma s board of directors determined the underlying fair value of Cornerstone BioPharma s common stock (which was exchanged in our merger for shares of our common stock) based on Cornerstone BioPharma s results of operations; the book value of its stock; its available cash, assets and financial condition; its prospects for growth; the economic outlook in general and the condition and outlook of the pharmaceutical industry in particular; its competitive position in the market; the market price of stocks of corporations engaged in the same or similar line of business that are actively traded in a free and open market, either on an exchange or over-the-counter; positive or negative business developments since the board s last determination of fair value; and such additional factors that it deemed relevant at the time of the grant or issuance. With respect to the grants made on October 31, 2008, the date of the merger, Cornerstone BioPharma s board of directors considered the fair market value of Critical Therapeutics common stock. Following the completion of the merger, our board of directors determines the underlying fair value of our common stock based on the market price of our common stock as traded on the NASDAQ Capital Market.

The expected stock price volatility for stock option awards granted prior to our merger was based on the historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. For awards granted on the date of and subsequent to our merger, we used Critical Therapeutics (now our) historical volatility from July 1, 2004 through the month of grant and the historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. The expected term of our stock options is based on historical employee exercise patterns over the

option lives while considering employee exercise strategy and cancellation behavior. The approximate risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with remaining terms equivalent to the expected term on our options. 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

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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, 2009, there was $1.9 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 2.94 and 3.62 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 35.2%, 4.4% and 18.6% in 2009, 2008 and 2007, respectively. In 2009, the increase in the effective tax rate was primarily attributable to the impact of our release of the valuation allowances against our deferred tax assets during 2008. 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 2008 and significantly lowering our effective tax rate.

Significant judgment is required in determining the provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. 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.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, 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, 2009, we had approximately $70.5 million in deferred tax assets. We determined that a $63.5 million valuation allowance relating to deferred tax assets for net operating losses and tax credits from the merger 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

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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. We had no unrecognized tax benefits at December 31, 2009 and do not expect to have any unrecognized tax benefits during the next twelve months.

Recent Accounting Pronouncements

See Note 16 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 current long-term debt borrowings are fixed and as a result, interest due on borrowings are not impacted by changes in market-based interest rates. If amounts are drawn down on our line of credit during 2010, we will be exposed to interest rate risk. The line of credit bears a variable interest rate equal to the prime rate published by the Wall Street Journal with a floor of 5%. Given the amount of borrowing availability we have under the line of credit, we do not believe that interest rate changes would have a material impact on us.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have one supplier contract denominated in Euros which will expire during 2010. Unfavorable fluctuations in the dollar-to-Euro exchange rate could have a negative impact on our financial statements. The impact of change in the exchange rate related to this contract was immaterial to our consolidated financial statements for the years ended December 31, 2009, 2008, and 2007. We do not believe a fluctuation in the dollar-to-Euro exchange rate 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, 2009 and 2008, and the related consolidated statements of income, stockholders equity (deficit) and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2009. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 financial statements referred to above present fairly, in all material respects, the financial position of Cornerstone Therapeutics Inc. as of December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cornerstone Therapeutics Inc. s internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 4, 2010 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina
March 4, 2010

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2009	2008
Assets		
Current assets:		
Cash and cash equivalents	$ 18,853	$ 9,286
Marketable securities		300
Accounts receivable, net	16,548	12,987
Inventories, net	18,106	11,222
Prepaid and other current assets	4,808	1,754
Deferred income tax asset	3,507	2,428
Total current assets	61,822	37,977
Property and equipment, net	1,312	895
Product rights, net	126,806	17,702
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Other assets	113	46
Total assets	$ 203,322	$ 69,889
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 7,172	$ 10,288
Accrued expenses	23,703	19,052
Current portion of license agreement liability	1,019	2,543
Current portion of capital lease	10	
Income taxes payable	1,606	2,937
Total current liabilities	33,510	34,820
License agreement liability, less current portion	1,341	2,313
Capital lease, less current portion	39	
Deferred income tax liability	4,564	3,330
Total liabilities	39,454	40,463
Commitments and contingencies, Note 11		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
	25	12

Common stock $0.001 par value, 90,000,000 shares authorized; 25,022,644 and 12,023,747 shares issued and outstanding as of December 31, 2009 and December 31, 2008, respectively		
Additional paid-in capital	157,745	33,519
Retained earnings (accumulated deficit)	6,098	(4,105)
Total stockholders equity	163,868	29,426
Total liabilities and stockholders equity	$ 203,322	$ 69,889

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

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except share and per share data)

	Year Ended December 31,		
	2009	**2008**	**2007**
Net revenues	$ 109,564	$ 64,867	$ 28,071
Costs and expenses:			
Cost of product sales (exclusive of amortization of product rights)	19,457	5,951	3,300
Sales and marketing	27,605	16,993	10,391
Royalties	18,775	16,193	3,409
General and administrative	17,422	9,930	4,422
Research and development	4,312	3,838	948
Amortization of product rights	6,115	1,334	3,160
Total costs and expenses	93,686	54,239	25,630
Income from operations	15,878	10,628	2,441
Other expenses, net:			
Interest expense, net	(128)	(1,211)	(1,410)
Loss on marketable security		(8)	(323)
Other expenses		(2)	(8)
Total other expenses, net	(128)	(1,221)	(1,741)
Income before income taxes	15,750	9,407	700
Provision for income taxes	(5,547)	(414)	(130)
Net income	$ 10,203	$ 8,993	$ 570
Net income per share, basic	$ 0.58	$ 1.29	$ 0.10
Net income per share, diluted	$ 0.54	$ 1.14	$ 0.08
Weighted-average common shares, basic	17,651,668	6,951,896	5,934,496
Weighted-average common shares, diluted	18,776,588	7,861,119	6,751,127

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

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) AND COMPREHENSIVE INCOME
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders Equity (Deficit)	Total Comprehensive Income
	Shares	Amount					
Balance as of December 31, 2006	5,934,496	$ 6	$ (4)	$ (178)	$ (13,668)	$ (13,844)	
Stock-based compensation			801			801	
Unrealized loss on investment				(145)		(145)	$ (145)
Reclassification adjustment for losses on investments included in net income (net of tax)				323		323	323
Net income					570	570	570
Total comprehensive income							$ 748
Balance as of December 31, 2007	5,934,496	$ 6	$ 797	$	$ (13,098)	$ (12,295)	
Issuance of shares in connection with the Merger (net of issuance costs of $504)	4,325,498	4	22,971			22,975	
Exercise of common stock warrants	316,101		52			52	
Stock-based compensation			749			749	
Conversion of related party note payable to common stock	1,443,913	2	8,950			8,952	
Issuance of common stock to employees under stock incentive plan	3,959						
Restricted stock buyback	(220)						
Net income					8,993	8,993	8,993
Total comprehensive income							$ 8,993

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	10,203
Total comprehensive income							$ 10,203
Balance as of December 31, 2009	25,022,644	$ 25	$ 157,745	$	$ 6,098	$ 163,868	

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,		
	2009	2008	2007
Cash flows from operating activities			
Net income	$ 10,203	$ 8,993	$ 570
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization and depreciation	6,392	1,425	3,231
Provision for prompt payment discounts	3,157	1,887	645
Provision for inventory obsolescence	1,474	599	169
Stock-based compensation	3,291	749	801
Loss on marketable security		8	323
Write-off of acquired in-process research and development		1,900	
Impairment of property and equipment		56	
Benefit from deferred income taxes	(3,632)	(3,310)	
Changes in operating assets and liabilities:			
Accounts receivable	(6,718)	(9,067)	(2,351)
Amounts due from related parties			18
Inventories	(8,202)	(2,523)	(1,320)
Prepaid and other assets	(3,121)	1,749	(2,456)
Accounts payable	(3,116)	2,573	783
Accrued expenses	2,053	4,505	1,020
Income taxes payable	(1,331)	3,085	130
Net cash provided by operating activities	450	12,629	1,563
Cash flows from investing activities			
Advances to related parties		(19)	(876)
Proceeds from collection of advances to related parties		657	262
Proceeds from sale of marketable securities	300		
Purchase of property and equipment	(635)	(638)	(64)
Purchase of product rights	(5,169)	(2,450)	(75)
Collection of deposits		223	50
Payment of deposits		(237)	(15)
Cash acquired in connection with the Merger, net of costs paid		2,118	
Net cash used in investing activities	(5,504)	(346)	(718)
Cash flows from financing activities			
Proceeds from issuance of shares of common stock	15,465		
Proceeds from exercise of common stock options and warrants	437	52	
Payments for cancellation of warrants	(41)		
Excess tax benefit from stock-based compensation	1,269		

Principal payments on license agreement liability	(2,500)	(576)	(720)
Principal payments on capital lease obligation	(9)		
Principal payments on notes payable		(460)	
Proceeds from line of credit		7,250	9,000
Principal payments on line of credit		(9,000)	(9,000)
Payment of stock issuance costs in connection with the Merger		(504)	
Net cash provided by (used in) financing activities	14,621	(3,238)	(720)
Net increase in cash and cash equivalents	9,567	9,045	125
Cash and cash equivalents as of beginning of year	9,286	241	116
Cash and cash equivalents as of end of year	$ 18,853	$ 9,286	$ 241
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 531	$ 2,734	$ 433
Cash paid during the year for income taxes	$ 9,260	$ 644	$
Supplemental schedule of non-cash investing and financing activities			
Product rights acquired through issuance of a license agreement	$	$	$ 2,565
Related party note payable converted to common stock in connection with the Merger	$	$ 8,952	$
Common stock issued in connection with the Merger	$	$ 23,479	$
Acquisition of product rights through equity issued and liabilities assumed	$ 110,050	$	$

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 acquiring, developing and commercializing significant products primarily for the respiratory and related markets. Key elements of the Company s strategy are to in-license or acquire rights to existing undervalued and/or poorly marketed established commercial branded respiratory or related pharmaceutical products, or late-stage product candidates; implement life cycle management strategies to maximize the potential value and competitive position of the Company s currently marketed products, newly acquired products and product candidates that are currently in development; grow product revenue through the Company s specialty sales forces, which are focused on the respiratory and hospital markets; and maintain and strengthen the intellectual property position of the Company s currently marketed products, newly acquired products and product candidates.

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.

Merger

On October 31, 2008, the Company completed a merger (the Merger) whereby the Company, which was then known as Critical Therapeutics, Inc. (Critical Therapeutics), merged (through a transitory subsidiary) with Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma). As a result of the Merger, Cornerstone BioPharma became a wholly owned subsidiary of the Company. Immediately following the closing of the Merger, the Company changed its name from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc.

Because former Cornerstone BioPharma stockholders owned, immediately following the Merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with accounting principles generally accepted in the United States (GAAP). Accordingly, the Company s financial statements for periods prior to the Merger reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and the Company s financial statements for all subsequent periods reflect the results of the combined company. Stockholders equity has been retroactively restated to reflect the number of shares of common stock received by former Cornerstone BioPharma stockholders in the Merger, after giving effect to the difference between the par values of the common stock of Cornerstone BioPharma and the Company, with the offset to additional paid-in capital. In addition, the pre-Merger financial information has been restated to reflect the 10-to-1 reverse split of Critical Therapeutics common stock that became effective immediately prior to the closing of the Merger and the related conversion of all of the common stock of Cornerstone BioPharma into common stock of the Company.

Unless specifically noted otherwise, as used throughout these consolidated financial statements, the term Company refers to the combined company after the Merger and the business of Cornerstone BioPharma before the Merger. The terms Cornerstone BioPharma and Critical Therapeutics refer to such entities standalone businesses prior to the Merger.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Reclassifications

Royalties and other receivables, which were previously included in accounts receivable, net, are included in prepaid and other current assets and other assets, respectively, in the accompanying consolidated balance sheets. Accrued interest on the license agreement liability, which was previously included in accrued expenses, is included in the current portion of the license agreement liability in the accompanying consolidated balance sheets. Depreciation expense, which was previously included in amortization and depreciation, is included in general and administrative expenses in the accompanying consolidated statements of income. Other charges, which were previously stated separately on the consolidated statements of income, are included in general and administrative expenses in the accompanying consolidated statements of income. These reclassifications had no effect on total assets, stockholders equity or net income as previously reported.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company s consolidated financial statements include certain judgments regarding revenue recognition, product rights, inventory valuation, accrued expenses and stock-based compensation. Actual results could differ from those estimates or assumptions.

Segment and Geographic Information

The Company operates in three segments: a prescription branded pharmaceuticals segment, a prescription generic pharmaceuticals segment and a hospital pharmaceuticals segment. The prescription branded pharmaceuticals segment is engaged in the development, licensing, manufacture, marketing and distribution of prescription branded pharmaceutical products promoted by the Company s respiratory sales force. The prescription generic pharmaceuticals segment is engaged in the development, licensing, manufacture, marketing and distribution of prescription generic and other non-promoted pharmaceutical products. The hospital pharmaceuticals segment is engaged in marketing and distribution of pharmaceuticals promoted by the Company s hospital sales force. For segment reporting purposes, the three segments are aggregated and reported as a single reportable segment. The financial information disclosed herein represents all of the material financial information related to the Company s three operating segments as so aggregated.

The majority of the Company s revenues are generated in the United States, with approximately $40,000 of royalty revenue originating internationally under the Company s royalty agreement with Pfizer, S.A. de C.V. related to sales made during the fourth quarter of 2009. As of December 31, 2009, 98% of the Company s total assets are located in the United States. The remaining 2% 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 one financial

institution and are monitored against the Company s investment policy, which limits concentrations of investments in individual securities and issuers.

The Company relies on certain materials used in its development and manufacturing processes, some 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

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 these sources could have a material adverse effect on the Company s business, financial position and results of operations. During 2009, two suppliers individually comprised greater than 10% of total inventory purchases and accounted for 53% of the Company s total inventory purchases for the year. Amounts due to these two suppliers represented approximately 25% of total accounts payable as of December 31, 2009. During the year ended December 31, 2008, no individual supplier exceeded 10% of total inventory purchases and during the year ended December 31, 2007, one supplier accounted for 23% of total inventory purchased for the year.

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 or chain drug stores. The following table lists the Company s customers that individually comprise greater than 10% of total gross product sales for the years ended December 31, 2009, 2008 and 2007 or 10% of total accounts receivable as of December 31, 2009 and 2008:

	Year Ended December 31,			December 31,	
	2009 Gross Product Sales	2008 Gross Product Sales	2007 Gross Product Sales	2009 Accounts Receivable	2008 Accounts Receivable
Cardinal Health	34%	40%	43%	26%	35%
McKesson Corporation	34%	31%	34%	37%	32%
Amerisource Bergen Corporation	20%	15%	14%	24%	16%
Total	88%	86%	91%	87%	83%

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 cash deposits with a federally insured bank that may at times exceed federally insured limits. The majority of funds in excess of the federally insured limits are held in sweep investment accounts collateralized by the securities in which the funds are invested. As of December 31, 2009 and 2008, the Company had balances of $15.0 and $1.3 million, respectively, in excess of federally insured limits held in non-investment accounts.

Marketable Securities

The Company records its investments in marketable securities at fair value. Unrealized gains or losses due to the change in fair value were recognized net of tax in other comprehensive income (loss). The classification of marketable securities is generally determined at the date of purchase. The Company s marketable securities are classified as

available-for-sale. Gains and losses on sales of investments in marketable securities, which are computed based on specific identification of the adjusted cost of each security, are included in investment income at the time of the sale.

During the years ended December 31, 2008 and 2007, the Company recorded losses of $8,000 and $323,000, respectively, for the other-than-temporary impairment of the investment in the common stock of a U.S. publicly traded company, as management does not believe the value of this security will be recovered. This common stock investment was still held by the Company as of December 31, 2009.

Marketable securities as of December 31, 2008 consisted of an auction rate security. The auction rate security was of investment-grade quality and had an original maturity date greater than 90 days and could be

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

sold within one year. In February 2009 the Company sold its investment in the auction rate security for $300,000, which was the carrying value of the security.

Accounts Receivable

The Company typically requires its customers to remit payments within 31 or 61 days, depending on the products purchased. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within the 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, 2009 or 2008. 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, 2009 or 2008.

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

	2009	2008
Accounts receivable	$ 16,932	$ 13,289
Less allowance for prompt payment discounts	(384)	(302)
Accounts receivable, net	$ 16,548	$ 12,987

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 writes down 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 requirements based upon anticipated product revenues.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2009	2008
Raw materials	$ 5,597	$ 6,393
Work in process	2,007	1,832
Finished goods:		
Pharmaceutical products trade	9,962	3,182
Pharmaceutical products samples	2,342	492
Total	19,908	11,899
Inventory allowances	(1,802)	(677)
Inventories, net	$ 18,106	$ 11,222

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 or the period of the benefit, whichever is shorter. Amortization expense for leasehold improvements has been included in general and administrative expenses in these consolidated financial statements.

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

	Useful Life (Years)	2009	2008
Computers and software	3-5	$ 535	$ 365
Machinery and equipment	3-7	236	113
Furniture and fixtures	5-7	906	523
Leasehold improvements	Lesser of lease term or 7	100	82
Total		1,777	1,083
Less accumulated depreciation		(465)	(188)
Property and equipment, net		$ 1,312	$ 895

Depreciation expense, including depreciation related to assets acquired by capital lease, for the years ended December 31, 2009, 2008 and 2007 was $277,000, $91,000 and $71,000, respectively, and is included in general and administrative expenses in the accompanying consolidated statements of income.

In connection with the abandonment of furniture, fixtures and leasehold improvements at the previously leased facility during the year ended December 31, 2008, the Company recorded a loss of $56,000 related to the impairment of fixed assets, which is included in general and administrative expenses in the accompanying consolidated statements of income.

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. The Company evaluates its product rights annually to determine

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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.

The Company does not amortize goodwill or purchased intangible assets 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 three operating segments, each of which represents a reporting unit for evaluation of goodwill. The fair value of the reporting unit is compared to its book value, including allocated 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. There was no impairment of goodwill or other intangible assets for the years ended December 31, 2009, 2008 and 2007.

Revenue Recognition

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

	Year Ended December 31,		
	2009	**2008**	**2007**
Gross product sales	$ 148,652	$ 82,547	$ 31,258
Sales allowances	(39,364)	(19,342)	(5,011)
Net product sales	109,288	63,205	26,247
Royalty agreement revenues	276	1,662	1,824
Net revenues	$ 109,564	$ 64,867	$ 28,071

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.

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, from six months prior to and up to twelve months subsequent to the expiration date of its product. The Company s products, except for

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

CUROSURF®, have a 24 to 36 month expiration period from the date of manufacture. CUROSURF has an 18-month expiration period. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

Rebates. The liability for commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial contract. The liability for Medicaid and Medicare rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state.

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 payors, 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 payors 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 three voucher programs for its promoted products whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on 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 or 60 days after the invoice date depending on the products purchased (see Accounts Receivable above).

Royalty Agreement Revenues

The Company receives royalties under a license agreement with a third party that sells products to which the Company has the rights. The license agreement provides for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period, which is based on interim data provided by the licensee and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. The Company maintains regular communication with its licensee to gauge the reasonableness of its estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following

quarter.

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

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 expenses, which include promotional expenses and the cost of samples, are generally expensed as incurred. Advertising expenses related to new products are expensed upon the first public showing of the product. Advertising expenses were $5.6 million, $3.8 million and $2.2 million for the years ended December 31, 2009, 2008 and 2007, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of income.

Shipping and Handling Costs

The Company includes shipping and handling costs within cost of product sales. Shipping and handling costs were $1.9 million, $967,000 and $352,000 for the years ended December 31, 2009, 2008 and 2007, 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 that 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.

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

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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 at the effective date to be recognized upon adoption of these principles and in subsequent periods.

Fair Value of Financial Instruments

The estimated fair values of the Company s financial instruments, including its cash and cash equivalents, receivables, accounts payable, line of credit 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: MERGER

As previously discussed in Note 1, on October 31, 2008, the Company completed the Merger whereby the Company, which was then known as Critical Therapeutics, merged (through a transitory subsidiary) with Cornerstone BioPharma. The Company s reasons for the Merger included, among other things, the following considerations: the opportunity to expand the Company s respiratory product portfolio, the potential for enhanced future growth and value and the ability to access additional capital. Because former Cornerstone BioPharma stockholders owned, immediately following the Merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with GAAP. Accordingly, Critical Therapeutics assets and liabilities were recorded as of the Merger closing date at their estimated fair values.

The fair value of the 4,347,919 outstanding shares of Critical Therapeutics common stock used in determining the purchase price was $23.5 million, or $5.40 per share, based on the average of the closing prices for a range of trading days (April 29, 2008 through May 6, 2008, inclusive) around and including the announcement date of the transaction.

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

Fair value of Critical Therapeutics shares outstanding	$ 23,479
Acquiring company transaction costs incurred	1,753
Purchase price	$ 25,232

Under the purchase method of accounting, the total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of Critical Therapeutics based on their estimated fair values as of the closing date of the Merger. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The allocation of the total purchase price, as shown above, to the acquired tangible and intangible assets and assumed liabilities of Critical Therapeutics based on their estimated fair values as of the closing date of the Merger is as follows (in thousands):

Cash and cash equivalents	$ 3,871
Accounts receivable	2,302
Inventory	6,300
Prepaid expenses and other current assets	701
Fixed assets	315
Other assets	40
Intangible assets:	
Product rights	11,500
Acquired in-process research and development	1,900
Goodwill	13,231
Assumed liabilities	(14,928)
Total	$ 25,232

The amount allocated to acquired inventory was attributed to the following categories (in thousands):

Raw materials	$ 5,314
Work in process	393
Finished goods	593
Total	$ 6,300

The estimated fair value of raw materials was determined based on their replacement cost. The estimated fair values of work in process and finished goods were determined by estimating the selling prices of those goods less the costs of disposal, a reasonable profit allowance and, with respect to work in process, the costs of completion.

The amount allocated to acquired identifiable intangible assets was attributed to the following categories (in thousands):

ZYFLO CR® product rights	$ 11,500
Alpha-7 program	1,900
Total	$ 13,400

The estimated fair value attributed to the ZYFLO CR product rights was determined based on a discounted forecast of the estimated net future cash flows to be generated from the ZYFLO CR product rights and was estimated to have a 7.2 year useful life from the closing date of the Merger.

The amount allocated to in-process research and development for the alpha-7 program represented an estimate of the fair value of purchased in-process technology for this research program that, as of the closing date of the Merger, had not reached technological feasibility and had no alternative future use. The alpha-7 program is the only Critical Therapeutics research program that had advanced to a stage of development where management believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed.

The estimated fair value of in-process research and development related to the alpha-7 program was determined based on a discounted forecast of the estimated net future royalties from the anticipated out-

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

licensing of this program considering the estimated probability of technical success and FDA approval. Following the closing of the Merger, the amount allocated to the alpha-7 program was immediately charged to research and development expenses.

Pro Forma Results of Operations (Unaudited)

The results of operations of Critical Therapeutics are included in the Company s consolidated financial statements from the closing date of the Merger on October 31, 2008. The following table presents pro forma results of operations and gives effect to the Merger transaction as if the Merger 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 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,	
	2008	2007
	(Unaudited)	
Net revenues	$ 78,972	$ 40,940
Net loss	$ (17,073)	$ (38,383)
Basic and diluted net loss per common share	$ (2.46)	$ (6.47)

NOTE 4: GOODWILL AND PRODUCT RIGHTS

Goodwill

The Company s goodwill balance as of December 31, 2009 and 2008 was $13.2 million and relates to the Merger. No amount of the goodwill balance at December 31, 2009 will be deductible for income tax purposes.

Product Rights

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

	2009	2008
Product rights	$ 141,949	$ 26,730
Less accumulated amortization	(15,143)	(9,028)

Product rights, net	$ 126,806	$ 17,702

On May 6, 2009, the Company entered into a series of agreements for a strategic transaction, subject to approval by the Company s stockholders, with Chiesi Farmaceutici S.p.A. (Chiesi), whereby the Company agreed to issue Chiesi approximately 12.2 million shares of common stock in exchange for $15.5 million in cash, an exclusive license for 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. On July 27, 2009, the Company s stockholders approved the Company s issuance of the shares at a special stockholders meeting, and the transaction closed on July 28, 2009. The Company s license agreement with Chiesi is for a ten-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. As part of this transaction, the Company s President and Chief Executive Officer and its Executive Vice President, Manufacturing and Trade agreed to sell to Chiesi an aggregate of 1.6 million shares of their common stock in the Company and enter into lockup,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

right of first refusal and option agreements with respect to approximately 80% of their remaining shares and vested and unvested options as of May 6, 2009.

The total purchase price of approximately $119.3 million was determined based on the fair value of the shares of common stock issued using the closing market price on July 28, 2009, or $9.30, and the difference between the fair value of the aggregate 1.6 million shares sold by the Company s President and Chief Executive Officer and its Executive Vice President, Manufacturing and Trade on the date of closing and the amount paid by Chiesi for those shares. The total purchase price was allocated to tangible and intangible assets based on relative fair value. The related product rights of $107.6 million are being amortized over a period of 10 years. Although CUROSURF no longer has patent protection, the Company believes 10 years is an appropriate amortization period based on established product history, a unique trade secret manufacturing process and management experience.

On September 9, 2009, the Company acquired the commercial rights to the antibiotic FACTIVE® in North America and certain countries in Europe, certain inventory and related assets and specific product-related liabilities from Oscient Pharmaceuticals Corporation for $8.1 million, which includes capitalized acquisition costs of $300,000. The purchase price was allocated to tangible and intangible assets and liabilities using a relative fair value basis.

The following table represents the allocation of the purchase price (in thousands):

Inventory, net	$ 2,906
Product rights	7,613
Accrued product returns	(2,455)
Total purchase price	$ 8,064

The Company is amortizing the product rights for FACTIVE of $7.6 million over a period of 58 months based on the future expiration of the patents associated with the product.

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of December 31, 2009, ranged from approximately five to ten years. As of December 31, 2009, the Company had $3.1 million of product rights related to products it expects to launch in the future. The Company expects to begin amortizing these rights upon the commercial launch, if any, of the first product using these rights over the estimated useful lives of the new products. The weighted-average amortization period for the Company s product rights related to its currently marketed products is approximately nine years.

Amortization expense for the years ended December 31, 2009, 2008 and 2007 was $6.1 million, $1.3 million and $3.2 million, respectively.

Future estimated amortization expense (excluding the rights related to products expected to be launched) subsequent to December 31, 2009 is as follows (in thousands):

2010	$ 14,378
2011	14,366
2012	14,360
2013	14,360
2014	13,612
Thereafter	52,630
	$ 123,706

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NOTE 5: LINE OF CREDIT

In April 2005, the Company obtained financing under a bank line of credit for up to $4.0 million. Interest was due monthly with all outstanding principal and interest due on maturity. The initial maturity of the line of credit was April 2006 and the line of credit thereafter was successively renewed on an annual basis on each maturity date. Amounts outstanding under the line of credit bore interest at a variable rate equal to the prime rate published by the Wall Street Journal.

Because the Company s borrowing base under the line of credit exceeded $4.0 million as of December 31, 2008, the full amount of the line of credit was available for borrowings and issuance of letters of credit on that date. As of December 31, 2008, the Company had no borrowings outstanding and had issued letters of credit totaling $68,000, resulting in $3.9 million of available borrowing capacity.

Effective May 4, 2009, the Company exercised its right to terminate its bank line of credit. There were no penalties associated with the early termination of the line of credit.

In January 2010, the Company obtained financing under a bank revolving line of credit. The Company may borrow up to $5.0 million under the line of credit subject to certain conditions.

NOTE 6: ACCRUED EXPENSES

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

	2009	2008
Accrued product returns	$ 10,962	$ 5,043
Accrued rebates	1,013	884
Accrued price adjustments and chargebacks	3,503	4,307
Accrued compensation and benefits	2,486	2,507
Accrued royalties	5,547	6,259
Accrued expenses, other	192	52
Total accrued expenses	$ 23,703	$ 19,052

NOTE 7: LICENSE AGREEMENT LIABILITY

Abbott

On December 18, 2003, the Company entered into a license agreement, as amended, with Abbott Laboratories (Abbott) granting the Company an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell certain controlled-release and injectable formulations of zileuton. This license

included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec AG (Jagotec). In March 2004, the Company 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. As partial consideration for the December 2003 license, the Company agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including specified minimum net sales of licensed products. In connection with an obligation that the Company assumed in connection with the Merger to make a $1.5 million milestone payment to Abbott on the second anniversary of FDA approval of the ZYFLO CR new drug application (NDA) in May 2009, the Company accrued the present value of the total $1.5 million owed, and the accretion of the discount was included in interest expense based upon imputed interest at 5% per annum. Except for certain termination rights provided for in the agreements, the terms of both agreements are perpetual. As of December 31, 2009, all milestone payments have been made.

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Jagotec

On December 3, 2003, the Company entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to the Company of rights to make, use and sell a controlled-released zileuton formulation covered by Jagotec s patent rights and know-how that the Company markets as ZYFLO CR. In addition to an upfront fee, the Company agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. In connection with an obligation that the Company assumed in connection with the Merger to make a $375,000 milestone payment to Jagotec on the second anniversary of FDA approval of the ZYFLO CR NDA in May 2009, the Company accrued the present value of the total $375,000 owed, and the accretion of the discount was included in interest expense based upon imputed interest at 5% per annum. 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. As of December 31, 2009, all milestone payments have been made.

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.

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):

	2009	2008
License agreement liability to Abbott; imputed interest at 5% per annum; principal and interest payable in May 2009	$	$ 1,471
License agreement liability to Jagotec; imputed interest at 5% per annum; principal and interest payable in May 2009		368
License agreement liability to Meiji; imputed interest at 12% per annum; principal and interest payable for the remaining three and four years, respectively	2,360	3,017
Less current portion	(1,019)	(2,543)
Long-term	$ 1,341	$ 2,313

Principal maturities of the license agreement liability subsequent to December 31, 2009 are as follows (in thousands):

2010	$ 1,019
2011	1,341
Total	$ 2,360

NOTE 8: STOCKHOLDERS EQUITY

Authorized Capital

As of December 31, 2009, 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 February 2006, the Company issued a warrant to purchase 3,571 shares of common stock at $0.43 per share in exchange for services. The warrant was valued at $2,000 and was exercisable for a ten-year period from the date of grant. The fair value of the warrant 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 157%, risk-free interest rate of 4.51% and expected life of ten years. The warrantholder exercised the warrant in October 2008 prior to the completion of the Merger.

In July 2004, Cornerstone Biopharma Holdings, Ltd., an entity affiliated with the Company, issued an option to purchase 5% of its common shares to a company owned by a former stockholder of an affiliated company in connection with a license agreement. The option had an exercise price of $100,000, had an exercise period that extended through December 31, 2009 and was exercisable for such number of shares that would give the optionholder a 5% ownership interest in Cornerstone Biopharma Holdings, Ltd. s issued and outstanding shares following the exercise. At issuance, the fair value of the option was approximately $48,000. In July 2006, in connection with the May 2005 corporate restructuring of the Company, the option was cancelled and replaced with a warrant exercisable on the same terms but for shares in the Company. The Company did not record any additional compensation expense in 2006 when it issued the warrant because the fair value of the warrant was the same as the fair value of the option that it replaced. In April 2007, the Company amended the warrant to, among other things, decrease its exercise price to $50,000 and extend its

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exercise period through December 31, 2010. In the year ended December 31, 2007, the Company recorded $508,000 of compensation expense due to the amendment of the warrant, which is included in general and administrative expenses in the accompanying consolidated statements of income. The warrant was exercised on October 30, 2008 prior to the Merger. In connection with the exercise, the Company issued the warrantholder 312,530 shares of 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 $41,600 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 are exercisable for up to 348,084 shares of the Company s common stock, have an exercise price of $65.80 per share, expire in June 2010 and contain a cashless exercise feature. The warrants issued in October 2006 are exercisable for up to 372,787 shares of the Company s common stock, have an exercise price of $26.20 per share and expire in October 2011. As of December 31, 2009, none of these warrants have been exercised.

NOTE 9: 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). As of December 31, 2009, there were 106,666 and 159,066 shares of common stock authorized under the 2000 Equity Plan and the 2003 Stock Incentive Plan, respectively. There were no shares of common stock available for award under either of these plans as of December 31, 2009.

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 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, 2009, there were 1,720,666 shares of common stock authorized, and 859,795 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

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effective date of the increase or 133,333 shares. The Company s board of directors did not authorize any annual increase to be effective as of January 1, 2010.

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, 2009, there were no shares available for award under the 2005 Plans.

Stock Options

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

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

	Year Ended December 31,		
	2009	2008	2007

Estimated dividend yield	0.0%	0.0%	0.0%
Expected stock price volatility	75%	75%	68%
Risk-free interest rate	2.31% - 2.85%	1.43% - 3.05%	3.52% - 4.79%
Expected life of option (in years)	4.84	6.00	6.04
Weighted-average grant date fair value per share	$4.85	$2.50	$1.15

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for stock option awards prior to the

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Merger was based on the historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. For awards granted on the date of and subsequent to the Merger, the expected stock price volatility was based on Critical Therapeutics (now the Company s) historical volatility from July 1, 2004 through the month of grant and on the historical volatility of a representative peer group of comparable companies selected using publicly available industry and market capitalization data. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of the stock options granted was estimated based on the historical exercise patterns over the option lives while considering employee exercise strategy and cancellation behavior.

Prior to the date of the Merger, Cornerstone BioPharma s board of directors determined the fair value at the time of issuance or grant of equity instruments to employees and non-employees based upon the consideration of factors that it deemed to be relevant at the time, including Cornerstone BioPharma s results of operations; its available cash, assets and financial condition; its prospects for growth; and positive or negative business developments since the board of directors last determination of fair value. With respect to equity issuances immediately prior to the completion of the Merger on October 31, 2008, Cornerstone BioPharma s board of directors based the fair value on the closing price of Critical Therapeutics common stock on October 30, 2008.

Following the completion of the Merger, the fair value per share of the underlying common stock is based on the market price of the Company s common stock.

The following table summarizes the Company s stock option activity during 2009 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, 2009	2,437,572	$ 5.45		
Granted	523,833	$ 7.94		
Exercised	(393,105)	$ 1.11		
Forfeited	(277,740)	$ 4.08		
Expired	(243,896)	$ 36.96		
Outstanding at December 31, 2009	2,046,664	$ 3.36	6.34	$ 6,779
Vested or expected to vest at December 31, 2009	2,007,917	$ 3.29	6.28	$ 6,764
Exercisable December 31, 2009	1,483,446	$ 2.11	5.33	$ 6,319

The total intrinsic value of options exercised during 2009 was $2.6 million. There were no options exercised during the years ended December 31, 2008 and 2007. As of December 31, 2009, there was approximately $1.9 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.94 years.

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The following table summarizes information about the Company s stock options outstanding as of December 31, 2009:

	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-$1.06	418,991	3.57	$ 0.47	418,991	$ 0.47
$1.77	828,997	5.67	$ 1.77	767,692	$ 1.77
$2.02-$3.90	324,668	8.15	$ 3.55	259,918	$ 3.66
$6.20-$9.30	458,716	8.83	$ 7.88	22,283	$ 8.33
$10.50-$26.00	10,372	4.59	$ 11.87	9,677	$ 11.43
$26.00-$70.50	4,920	5.34	$ 67.33	4,885	$ 67.53
	2,046,664	6.34	$ 3.36	1,483,446	$ 2.11

Restricted Stock

In 2005, the Company required certain employees to enter into employment agreements and stock purchase agreements, as subsequently amended, that would allow them to vest in their stock over time. The stock vested 25% annually. The Company had the right to repurchase the unvested portion of the restricted common stock on termination of employment for the original purchase price per share. The restricted stock under these agreements was fully vested as of December 31, 2008.

The Company also entered into restricted stock agreements with certain employees under the 2004 Stock Incentive Plan and the 2005 Stock Incentive plan during 2009 and 2008 and assumed restricted stock in connection with the Merger.

The following table summarizes the Company s restricted stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested January 1, 2009	475,355	$ 4.01
Granted	230,000	6.38

Vested			(433,367)	4.11
Forfeited			(59,488)	4.14
Unvested	December 31, 2009		212,500	$ 6.32

The fair value of restricted stock that vested during the year ended December 31, 2009 was $3.1 million. No restricted stock vested during the years ended December 31, 2008 and 2007. As of December 31, 2009, 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 3.62 years.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation Expense

The following table shows the approximate amount of total stock-based compensation expense recognized for employees and non-employees based on the total grant date fair value of shares vested (in thousands):

	For the Year Ended December 31,		
	2009	2008	2007
Employee	$ 3,227	$ 728	$ 290
Non-employee	64	21	3
Total	$ 3,291	$ 749	$ 293

The following table shows the amount of total stock-based compensation expense recognized by classification in the accompanying consolidated statements of income (in thousands):

	For the Year Ended December 31,		
	2009	2008	2007
General and administrative	$ 2,673	$ 614	$ 225
Sales and marketing	618	135	68
Total	$ 3,291	$ 749	$ 293

As a result of the strategic transaction with Chiesi (see Note 4), 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 tables above.

NOTE 10: EMPLOYEE BENEFIT PLANS

The Company established a qualified 401(k) plan (the Cornerstone Plan), effective January 1, 2005, covering all employees who are 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. As of December 31, 2009, the Company had not made any contributions to the 401(k) plan. Expenses related to the plan were insignificant during the years ended December 31, 2009, 2008 and 2007.

Prior to the Merger, Critical Therapeutics also offered a qualified 401(k) retirement plan (the Critical Therapeutics Plan), which included discretionary matching employer contributions for employees that participated in the plan. In connection with the Merger, the Company terminated discretionary matching contributions on elective deferrals made under the Critical Therapeutics Plan after October 31, 2008. Effective November 1, 2008, the assets of the Critical Therapeutics Plan were transferred into the Cornerstone Plan, and the Critical Therapeutics Plan was merged into the Cornerstone Plan.

NOTE 11: 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 $1.0 million, $719,000 and $466,000 for the years ended December 31, 2009, 2008 and 2007, respectively.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On October 2, 2009, the Company entered into a lease modification agreement for its corporate headquarters in Cary, North Carolina. The modification agreement increases leased space by 6,114 square feet to a total of approximately 21,000 square feet. The Company will not be obligated to pay rent for the additional space for the first seven months following the lease modification. The base rent for the additional space for the seven months following the abatement period will be approximately $11,800 per month. Subsequently, the aggregate rent for the entire leased space will be approximately $41,300 per month, or approximately $496,000 on an annual basis, subject to annual rent increases thereafter of approximately 2.5%. In addition to rent, the Company is obligated to pay certain operating expenses and taxes. The modification agreement also entitles the Company to a first offer right on available space located on the property s second floor during the remainder of the lease term.

Future minimum aggregate payments under non-cancelable lease obligations as of December 31, 2009 are as follows (in thousands):

Year Ending	Operating Leases
2010	$ 766
2011	521
2012	520
2013	536
2014	584
Thereafter	751
Total minimum lease payments	$ 3,678

Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $29.5 million as of December 31, 2009, 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, 2009, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $11.3 million.

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or licensors of certain product rights that have been acquired by or licensed to the Company, some of which are described above in Note 7. These royalties are typically based on a percentage of net sales of the particular licensed product. For the years ended December 31, 2009, 2008 and 2007, total royalty expenses were $18.8 million, $16.2 million and $3.4 million, respectively. Certain of these royalty agreements also require minimum annual payments, which have been included in royalty expense on

the consolidated statements of income. Pursuant to these agreements, the Company is obligated to pay future minimum royalties of $7.5 million.

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

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company may be required to make $42.2 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 consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

As of December 31, 2009, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $741,000.

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, and the Company is responsible for all 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 second agreement, the Company pays the third party fees based on a percentage of the net profits from sales of the product above a specified baseline within assigned sales territories. The second agreement is also subject to sunset fees that require the Company to pay additional fees for up to one year in the event of certain defined terminations of the agreement.

As of December 31, 2009, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.9 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, 2009 and 2008, the Company had approximately $401,000 and $0 recorded as accrued severance, respectively.

Settlements

Legal Proceedings

In 2008, the U.S. Patent and Trademark Office (USPTO) ordered a re-examination of a patent licensed to the Company that covers one or more of the Company s day-night products. In June 2009, the USPTO examiner issued an office action, rejecting claims of the patent as failing to satisfy the novelty and non-obviousness criteria for U.S. patent claims, in view of the patents and publications cited. In August 2009, the patent owner filed an amendment to the claims and request for reconsideration of the office action issued in June 2009. If the USPTO re-examination examiner maintains one or more of the USPTO rejections of the claims of the patent, the patent owner may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If the Board of Patent Appeals

thereafter affirms the examiner s rejections, the patent owner could take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the patent with narrowed claims. The further proceedings involving the patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the patent. The Company s intellectual property counsel believes that valid arguments exist for distinguishing the claims of the Company s patent over the references cited in the request for re-examination. In cooperation with the licensor of the patent, the Company intends to vigorously pursue its claims and to vigorously defend against any counterclaims that might be asserted.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 12: INCOME TAXES

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

	2009	2008	2007
Current:			
Federal	$ 8,400	$ 3,161	$ 62
State	779	563	68
Total	9,179	3,724	130
Deferred:			
Federal	(3,164)	(2,930)	
State	(468)	(380)	
Total	(3,632)	(3,310)	
Total tax provision	$ 5,547	$ 414	$ 130

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

	2009	2008
Current:		
Deferred tax assets:		
Accounts receivable, net	$ 144	$ 116
Inventories, net	1,171	400
Accrued expenses	3,173	2,542
Total current deferred tax assets	4,488	3,058
Deferred tax liabilities:		
Acquired intellectual property	(981)	(630)
Net current deferred tax assets	$ 3,507	$ 2,428
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	$ 61,610	$ 61,888

Tax credits	1,900	1,900
Stock-based compensation	935	293
Product license rights, net	1,557	315
Valuation allowance	(63,510)	(63,788)
Total noncurrent deferred tax assets	2,492	608
Deferred tax liabilities:		
Acquired intellectual property	(6,868)	(3,783)
Property and equipment, net	(188)	(155)
Total noncurrent deferred tax liabilities	(7,056)	(3,938)
Net deferred tax liability noncurrent	(4,564)	(3,330)
Total net deferred tax liability	$ (1,057)	$ (902)

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company s transaction with Chiesi resulted in a difference between the carrying amount of acquired product rights for financial reporting purposes and the amount used for income tax purposes. The Company established a deferred tax liability of approximately $3.8 million to account for this difference. The deferred tax liability was established by an addition to the carrying amount of the product rights for financial reporting purposes.

As of December 31, 2009 and 2008, 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. 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 decreased by approximately $278,000 and $4.2 million during the years ended December 31, 2009 and 2008, respectively. These decreases are due to utilization 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, 2009, the Company had federal NOLs of approximately $161.4 million that begin to expire in the year 2021, state NELs of approximately $154.0 million that begin to expire in 2010 and federal tax credits of approximately $1.9 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 any of these federal or state loss carryforwards or federal tax credit carryforwards. Accordingly, the Company has established a valuation allowance with respect to the entire amount of these loss carryforwards and tax credit carryforwards. The Company recognized approximately $809,000 in tax benefits in 2009 and 2008 related NOL carryforwards, of which $278,000 and $277,000 were recorded as a reduction of tax expense and goodwill, respectively. Separate from the impact of the Merger, the Company also recognized approximately $45,000 and $60,000 of tax benefits related to the utilization of contribution carryforwards and tax credits, respectively, in the year ended December 31, 2008.

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

	2009	2008	2007
Federal statutory taxes	35.0%	34.0%	34.0%
State income taxes, net of federal benefit	2.3	4.4	4.3
Permanent differences	2.6	4.3	33.9
Acquired in-process research and development		7.7	
Other	(2.9)	(1.0)	(4.6)
Change in valuation allowance	(1.8)	(45.0)	(49.0)
	35.2%	4.4%	18.6%

The 2006 through 2009 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 is 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, 2009 and 2008, the Company continues to have no unrecognized tax benefits. Additionally, there are no unrecognized tax benefits that would impact the effective tax rate. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next twelve months.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recognizes annual interest and penalties related to uncertain tax positions as general and administrative expenses in its statements of income. As of December 31, 2009 and 2008, the Company had no interest or penalties related to uncertain tax positions.

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, 2009 and 2008. The Company had approximately $0 and $48,000 in penalties related to the underpayment of required taxes included in the consolidated statements of income and accrued in the consolidated balance sheets as of December 31, 2009 and 2008, respectively.

NOTE 13: RELATED PARTY TRANSACTIONS

Stockholders

During the year ended December 31, 2008, the Company made advances of $19,000 to its President and Chief Executive Officer, who, prior to the closing of the Merger, was Cornerstone BioPharma s majority stockholder. The Company s President and Chief Executive Officer repaid all advances prior to the closing of the Merger on October 31, 2008.

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 $11.8 million for the year ended December 31, 2009. As of December 31, 2009, the Company had prepaid inventory of $268,000 due from Chiesi and accounts payable of $1.3 million due to Chiesi.

Other Related Parties

In April 2004, the Company executed a promissory note with Carolina Pharmaceuticals Ltd. (Carolina Pharmaceuticals), an entity under common control with the Company, to borrow up to $15.0 million for five years with an annual interest rate of 10% (Carolina Note). The Company borrowed $13.0 million under the Carolina Note in April 2004.

In connection with the Merger, the Company entered into a noteholder agreement, as amended (the Noteholder Agreement), with Carolina Pharmaceuticals. The Noteholder Agreement required Carolina Pharmaceuticals to surrender the Carolina Note to the Company prior to the effective time of the Merger and required the Company to, immediately prior to the effective time, cancel the Carolina Note and issue common stock of the Company in exchange for, at Carolina Pharmaceuticals option, all or a portion of the Carolina Note, but in an amount not less than the principal amount outstanding. The Noteholder Agreement provided that the number of shares to be issued to Carolina Pharmaceuticals would be based on a per share price of $6.20 (after adjustment for the 10-to-1 reverse stock split), which was the closing price of Critical Therapeutics common stock on April 30, 2008, the day before the signing of the merger agreement.

As required by the Noteholder Agreement, Carolina Pharmaceuticals surrendered the Carolina Note prior to the closing of the Merger with instructions that the principal amount outstanding be converted into common stock of the Company. Immediately prior to the effective time of the Merger, the Company issued Carolina Pharmaceuticals

1,443,913 shares of common stock in satisfaction of the principal amount outstanding under the Carolina Note and paid Carolina Pharmaceuticals $2.2 million in full satisfaction of the accrued interest outstanding thereunder. The fair value of the shares issued in extinguishment of the Carolina Note on the date of exchange was $3.90 per share, or $5.6 million, which was $3.3 million less than the Carolina Note s outstanding principal balance on the date of exchange. Under applicable accounting principles, the forgiveness of debt between related parties may, in essence, be capital transactions. The Company has concluded that Carolina Pharmaceuticals forgiveness of the $3.3 million of principal under the Carolina Note was, in essence, a capital contribution by Carolina Pharmaceuticals to the Company. Accordingly, the Company has

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

included the entire $9.0 million principal balance that was extinguished in common stock and additional paid-in capital in the accompanying consolidated financial statements.

During the year ending December 31, 2008, the Company paid $260,000 to Carolina Pharmaceuticals for royalties related to the sale of Humibid® and DECONSAL® in 2007. The Company did not pay any royalties to Carolina Pharmaceuticals in the years ended December 31, 2007 and 2009. The Company s President and Chief Executive Officer is the chief executive officer and chairman of the board of directors of Carolina Pharmaceuticals and the Company s Executive Vice President, Manufacturing and Trade is a director of Carolina Pharmaceuticals.

NOTE 14: NET INCOME PER SHARE

Basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding during each period. Diluted net income per share is computed by dividing net 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 income per share (in thousands, except share and per share data):

	Year Ended December 31,		
	2009	2008	2007
Numerator:			
Net income	$ 10,203	$ 8,993	$ 570
Denominator:			
Weighted-average common shares, basic	17,651,668	6,951,896	5,934,496
Dilutive effect of stock options, warrants and restricted stock	1,124,920	909,223	816,631
Weighted-average common shares, diluted	18,776,588	7,861,119	6,751,127
Net income per share, basic	$ 0.58	$ 1.29	$ 0.10
Net income per share, diluted	$ 0.54	$ 1.14	$ 0.08
Anti-dilutive weighted-average shares	1,136,792	94,244	

NOTE 15: SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2009 through March 4, 2010, the date the Company issued these consolidated financial statements. During this period, the Company did not have any material recognizable or nonrecognizable subsequent events.

NOTE 16: RECENT ACCOUNTING PRONOUNCEMENTS

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

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 17: 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, 2009 and 2008 (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2009					
Net revenues	$ 30,705	$ 24,993	$ 23,078	$ 30,788	$ 109,564
Gross profit	27,504	22,092	18,935	21,576	90,107
Income (loss) from operations	10,359	3,087	(1,042)	3,474	15,878
Net income (loss)	6,315	1,738	(538)	2,688	10,203
Net income (loss) per share, basic	0.53	0.14	(0.03)	0.11	0.58
Net income (loss) per share, diluted	0.48	0.13	(0.03)	0.10	0.54
2008					
Net revenues	$ 9,445	$ 14,067	$ 20,591	$ 20,764	$ 64,867
Gross profit	8,880	13,134	18,987	17,915	58,916
Income (loss) from operations	1,367	3,018	6,383	(140)	10,628
Net income	669	2,155	3,307	2,862	8,993
Net income per share, basic	0.11	0.36	0.56	0.29	1.29
Net income per share, diluted	0.10	0.31	0.48	0.26	1.14

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

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CORNERSTONE THERAPEUTICS INC.

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, 2009					
Reserves:					
Allowance for product returns	$ 5,043	$	$ 15,417(2)	$ 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(6)	583	1,802
Year Ended December 31, 2008					
Reserves:					
Allowance for product returns	$ 4,913	$	$ 7,277(3)	$ 7,147	$ 5,043
Allowance for rebates	303		1,661(4)	1,080	884
Allowance for price adjustments and chargebacks	828		9,054(5)	5,575	4,307
Deducted from asset accounts:					
Allowance for prompt payment discounts	81		1,887	1,666	302
Inventory allowance	201	599		123	677
Year Ended December 31, 2007					
Reserves:					
Allowance for product returns	$ 5,781	$	$ 2,879	$ 3,747	$ 4,913
Allowance for rebates	140		228	65	303
Allowance for price adjustments and chargebacks	687		1,259	1,118	828
Deducted from asset accounts:					
Allowance for prompt payment discounts	43		645	607	81
Inventory allowance	100	169		68	201

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

(2) Includes a provision of $4,231 relating to sales made in prior periods and $2,455 which was recorded in connection with the acquisition of FACTIVE product rights.

(3) Includes a provision of $1,401 relating to sales made in prior periods and a provision of $353 that was acquired in the Merger.

(4) Includes a provision of $51 that was acquired in the Merger.

(5) Includes a provision of $133 that was acquired in the Merger.

(6) 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, 2009, 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, 2009, our disclosure controls and procedures were effective in ensuring that material 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 material 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

As discussed in our annual report on Form 10-K for the year ended December 31, 2008, our management initiated a comprehensive assessment of our internal control over financial reporting. As a result of this assessment, management identified a material weakness related to our lack of a sufficient number of personnel in our accounting and finance department with appropriate accounting knowledge and experience to record our financial results in conformity with GAAP, which prevented us from being able to timely and effectively close our books at the end of each interim and annual period. During the quarter ended June 30, 2009, we expanded our accounting and finance department and remediated the related disclosure controls. During the quarter ended December 31, 2009, management completed its testing of the design and operating effectiveness of the remediated controls and concluded that the material weakness has been remediated as of December 31, 2009.

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, 2009 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, 2009. 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, 2009, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their report which appears below.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cornerstone Therapeutics Inc.

We have audited Cornerstone Therapeutics Inc. s (a Delaware Corporation) internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Fram*ework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cornerstone Therapeutics Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on Cornerstone Therapeutics Inc. s internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Cornerstone Therapeutics Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cornerstone Therapeutics Inc. as of December 31, 2009 and 2008, and the related consolidated statements of income, stockholders equity (deficit) and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2009, and our report dated March 4, 2010, expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina
March 4, 2010

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ITEM 9A(T). ***CONTROLS AND PROCEDURES***

Not applicable.

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 2010 Annual Meeting of Stockholders. Information regarding our executive officers may be found under the caption Executive Officers of the Registrant 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 2010 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 2010 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 may be found under the captions Corporate Governance Board Committees Audit Committee and Corporate Governance Audit Committee Report in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee Financial Expert

Our board of directors has determined that Christopher Codeanne is an audit committee financial expert as defined by Item 407(d)(5) of Regulation S-K and is independent as defined by the applicable listing standards of The NASDAQ Stock Market LLC.

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 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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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 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Corporate Governance Transactions with Related Persons and Corporate Governance Board Determination of Independence in the Proxy Statement for our 2010 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 Corporate Governance Independent Registered Public Accounting Firm s Fees and Corporate Governance Pre-Approval Policy and Procedures in the Proxy Statement for our 2010 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 87 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
President and Chief Executive Officer
March 4, 2010

Date: March 4, 2010

We, the undersigned officers and directors of Cornerstone Therapeutics Inc., hereby severally constitute and appoint Craig A. Collard and David Price, 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 Craig A. Collard	President, Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2010
/s/ DAVID PRICE David Price	Executive Vice President, Finance, and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 4, 2010
/s/ ALESSANDRO CHIESI Alessandro Chiesi	Director	March 4, 2010
/s/ MARIA PAOLA CHIESI Maria Paola Chiesi	Director	March 4, 2010
/s/ CHRISTOPHER CODEANNE	Director	March 4, 2010

Christopher Codeanne		
/s/ MICHAEL ENRIGHT	Director	March 4, 2010
Michael Enright		
/s/ ANTON GIORGIO FAILLA	Director	March 4, 2010
Anton Giorgio Failla		
/s/ MICHAEL HEFFERNAN	Director	March 4, 2010
Michael Heffernan		
/s/ ROBERT STEPHAN	Director	March 4, 2010
Robert Stephan		

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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	Form of Merger Partner Stockholder Agreement among the Registrant, Cornerstone BioPharma Holdings, Inc. and certain stockholders of Cornerstone BioPharma Holdings, Inc. (included in Exhibit 2.1 hereto).
2.4	Merger Partner Noteholder Agreement among the Registrant, Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals Ltd. dated May 1, 2008 (incorporated by reference to Exhibit 2.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
2.5	Amendment No. 1, dated August 7, 2008, to Merger Partner Noteholder Agreement among the Registrant, Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals Ltd. dated May 1, 2008 (incorporated by reference to Exhibit 2.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
2.6	Form of Public Company Stockholder Agreement among Cornerstone BioPharma Holdings, Inc., the Registrant and certain stockholders of the Registrant (included in Exhibit 2.1 hereto).
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).

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Exhibit No	Description
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+	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).
10.7+	Formulation Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated January 11, 2008 (incorporated by reference to Exhibit 10.9 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+	Joint Development Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated February 11, 2008 (incorporated by reference to Exhibit 10.11 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.10+	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).
10.11+	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).
10.12+	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).
10.13+	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).
10.14+	Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant dated May 9, 2007 (incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007).
10.15+	First Amendment, dated November 5, 2007, to Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant dated May 9, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007).
10.16+	Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated August 8, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.17+	Change of Scope Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated November 20, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.18+	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)).
10.19	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).
10.20+	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)).
10.21	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).

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Exhibit No	Description
10.22+	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)).
10.23+	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)).
10.24+	Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective August 31, 2006 (incorporated by reference to Exhibit 10.12 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.25+	Amendment No. 1, dated August 10, 2007, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective August 31, 2006 (incorporated by reference to Exhibit 10.13 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.26	Amendment No. 2, dated February 15, 2008, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective August 31, 2006 (incorporated by reference to Exhibit 10.14 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.27+	Development, License and Services Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated March 19, 2008 (incorporated by reference to Exhibit 10.15 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.28+	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).
10.29+	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).
10.30+	Amended and Restated Products Development Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated August 27, 2008 (incorporated by reference to Exhibit 10.17 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.31+	Supply and Marketing Agreement between Sovereign Pharmaceuticals, Ltd. and Aristos Pharmaceuticals, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 10.18 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.32+	Amendment No. 1, dated December 18, 2009, to Supply and Marketing Agreement between Sovereign Pharmaceuticals, Ltd. and Aristos Pharmaceuticals, Inc. dated May 1, 2008.
10.33+	License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) dated July 1, 2001, as amended by the First Amendment Agreement dated May 15, 2003 (incorporated by reference to Exhibit 10.5 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.34+	Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) dated July 1, 2001, as amended by the First Amendment Agreement dated July 1, 2003 (incorporated by reference to Exhibit 10.6 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.35+	Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) effective January 1, 2003 (incorporated by reference to Exhibit 10.7 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).

10.36+	Amendment No. 2, dated January 8, 2007, to Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) effective January 1, 2003 (incorporated by reference to Exhibit 10.8 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006).

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Exhibit No	Description
10.37+	Amendment No. 3, dated June 29, 2007, to Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) effective January 1, 2003. (incorporated by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007).
10.38+	Exclusive License and Collaboration Agreement between the Registrant and MedImmune, Inc. dated July 30, 2003 (incorporated by reference to Exhibit 10.8 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.39	Amendment No. 1, dated December 7, 2005, to Exclusive License and Collaboration Agreement between the Registrant and MedImmune, Inc. dated July 30, 2003 (incorporated by reference to Exhibit 10.50 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2005).
10.40+	License Agreement between the Registrant and Beckman Coulter, Inc. dated January 10, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2005).
10.41+	Exclusive License Agreement between the Registrant and SetPoint Medical Corp. (formerly known as Innovative Metabolics, Inc.) dated January 29, 2007 (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated January 29, 2007).
10.42+	First Amendment, dated June 29, 2007, to Exclusive License Agreement between the Registrant and SetPoint Medical Corp. (formerly known as Innovative Metabolics, Inc.) dated January 29, 2007 (incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007).
10.43	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).
10.44+	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).
10.45	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).
10.46	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).
10.47	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).
10.48	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).
10.49	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).
10.50	Voting Agreement between the Registrant and Chiesi Farmaceutici S.p.A. dated May 6, 2009 (incorporated by reference to Exhibit 10.7 to the Registrant s Current Report on Form 8-K dated May 6, 2009).

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Exhibit No	Description
10.51	Voting Agreement among Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd., Lutz Family Limited Partnership, Brian Dickson, Joshua B. Franklin, David Price, Alan Roberts and, solely with respect to Section 2(b) thereof, the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.8 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.52	Asset Purchase Agreement between Oscient Pharmaceuticals Corporation and Cornerstone BioPharma, Inc. dated July 13, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated July 13, 2009).
10.53+	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).
10.54	Commercial Note issued by Cornerstone BioPharma Holdings, Inc. to Paragon Commercial Bank dated April 21, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.55	Security Agreement by Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated April 21, 2005 (incorporated by reference to Exhibit 10.42 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.56	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated April 10, 2006 (incorporated by reference to Exhibit 10.43 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.57	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated July 31, 2007 (incorporated by reference to Exhibit 10.44 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.58	Letter Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 23, 2008 (incorporated by reference to Exhibit 10.45 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.59	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., John S. Towles (as trustee), Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 25, 2008 (incorporated by reference to Exhibit 10.46 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.60	Unconditional Guaranty by Cornerstone BioPharma, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.47 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.61	Security Agreement by Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.48 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.62	Unconditional Guaranty by Aristos Pharmaceuticals, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.49 to the Registrant s Current Report on Form 8-K dated October 30, 2008).

10.63	Security Agreement by Aristos Pharmaceuticals, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.50 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.64	Letter from Paragon Commercial Bank to Cornerstone BioPharma Holdings, Inc. dated October 29, 2008 (incorporated by reference to Exhibit 10.51 to the Registrant s Current Report on Form 8-K dated October 30, 2008).

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Exhibit No	Description
10.65	Warrant Agreement between the Registrant and Mellon Investor Services LLC as Warrant Agent, dated June 20, 2005 (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated June 20, 2005).
10.66	Form of Warrant (Included in Exhibit 10.60 hereto).
10.67	Warrant Agreement between the Registrant and Mellon Investor Services LLC dated October 31, 2006 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the period ended September 30, 2006).
10.68	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).
10.69	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).
10.70	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).
10.71#	2004 Stock Incentive Plan of the Registrant (as Amended and Restated May 28, 2009) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 28, 2009).
10.72#	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).
10.73#	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).
10.74#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.72 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.75#	Form of Restricted Stock Agreement granted under 2004 Stock Incentive Plan.
10.76#	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).
10.77#	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).
10.78#	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).
10.79#	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).
10.80#	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).
10.81#	

	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated March 1, 2006 (incorporated by reference to Exhibit 10.27 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.82#	Executive Retention Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated February 8, 2006 (incorporated by reference to Exhibit 10.28 to the Registrant s Current Report on Form 8-K dated October 30, 2008).

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Exhibit No	Description
10.83#	First Amendment, dated June 18, 2009, to Executive Retention Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated February 8, 2006 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.84#	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).
10.85#	Severance Agreement and General Release between the Registrant and Chenyqua Baldwin dated May 7, 2009 (incorporated by reference to Exhibit 10.16 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009).
10.86#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Brian Dickson dated March 1, 2006 (incorporated by reference to Exhibit 10.30 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.87#	First Amendment, dated June 12, 2009, to Executive Employment Agreement between Cornerstone BioPharma, Inc. and Brian Dickson dated March 1, 2006 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.88#	Amended and Restated Executive Employment Agreement between the Registrant and Brian Dickson dated May 6, 2009 (incorporated by reference to Exhibit 10.12 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.89#	Separation Letter Agreement and General Release between the Registrant and Brian Dickson dated October 16, 2009.
10.90#	Letter Agreement between Cornerstone BioPharma, Inc. and Joshua B. Franklin dated September 12, 2008 (incorporated by reference to Exhibit 10.87 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.91#	Agreement Regarding Employment, Employee Duties, Ownership of Employee Developments, and Confidentiality between Cornerstone BioPharma, Inc. and Joshua B. Franklin dated September 29, 2008 (incorporated by reference to Exhibit 10.81 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.92#	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).
10.93#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Steven M. Lutz dated March 1, 2006 (incorporated by reference to Exhibit 10.32 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.94#	First Amendment, dated June 12, 2009, to Executive Employment Agreement between Cornerstone BioPharma, Inc. and Steven M. Lutz dated March 1, 2006 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.95#	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).
10.96#	Executive Employment Agreement between the Registrant and Andrew K. W. Powell dated October 30, 2009.
10.97#	Executive Employment Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated August 20, 2008 (incorporated by reference to Exhibit 10.33 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.98#	Amended and Restated Executive Employment Agreement between the Registrant and David Price dated May 6, 2009 (incorporated by reference to Exhibit 10.11 to the Registrant s Current Report on

	Form 8-K dated May 6, 2009).
10.99#	Amendment No. 1, dated June 26, 2009, to Amended and Restated Executive Employment Agreement, between the Registrant and David Price dated May 6, 2009 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated June 26, 2009).
10.100#	Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008 (incorporated by reference to Exhibit 10.34 to the Registrant s Current Report on Form 8-K dated October 30, 2008).

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Exhibit No	Description
10.101#	First Amendment, dated June 12, 2009, to Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.102#	Second Amendment, dated July 27, 2009, to Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008 (incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.103#	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).
10.104#	Amended and Restated Employment Agreement between the Registrant and Scott B. Townsend dated November 6, 2007 (incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007).
10.105#	First Amendment, dated September 16, 2008, to Amended and Restated Employment Agreement between the Registrant and Scott B. Townsend dated November 6, 2007 (incorporated by reference to Exhibit 10.55 to the Registrant s Registration Statement on Form S-4/A dated September 18, 2008 (SEC File No. 333-152442)).
10.106#	Restricted Stock Agreement between the Registrant and Scott B. Townsend dated September 16, 2008 (incorporated by reference to Exhibit 10.93 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.107#	Separation Letter Agreement and General Release between the Registrant and Scott B. Townsend dated June 5, 2009 (incorporated by reference to Exhibit 10.25 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009).
10.108#	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.

* Pursuant to Regulation S-K, Item 601(b)(2), certain schedules to the Agreement and Plan of Merger have not been filed herewith. The Registrant agrees to furnish supplementally a copy of any such schedule to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

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.